PD ISO/TR 14639-2:2014

BSI Standards Publication

Health informatics — Capacity-based eHealth architecture roadmap

Part 2: Architectural components and maturity model

bsi.

...making excellence a habit.™

National foreword

This Published Document is the UK implementation of ISO/TR 14639-2:2014.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Published by BSI Standards Limited 2014

ISBN 978 0 580 84642 7
ICS 35.240.80

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 October 2014.

Amendments issued since publication

Date	Text affected

PD ISO/TR 14639-2:2014

TECHNICAL REPORT

ISO/TR 14639-2

First edition
2014-10-01

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

Reference number
ISO/TR 14639-2:2014(E)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword ... **iv**
Introduction ... **v**
1 Scope ... **1**
2 Terms and definitions ... **2**
3 Abbreviations ... **12**
4 Overview of business requirements ... **13**
5 Development and application of eHealth enterprise architectures ... **13**
5.1 eHealth enterprise architectures ... 13
5.2 Development of an eHealth architecture ... 13
5.3 Building up the architecture: A methodology ... 14
6 Health architecture components and requirements ... **20**
6.1 Governance and national ownership ... 22
6.2 Health process domain components ... 44
6.3 Foundation Components — eHealth infostructure ... 85
6.4 Foundation components — ICT infrastructure ... 100
7 Profiling countries with the eHAM ... **111**
8 Future Considerations ... **115**
Annex A (informative) **World Economic Forum — Global Health Data Charter** ... **117**
Annex B (informative) **Generic component model** ... **121**
Annex C (informative) **Health informatics — Service architecture (HISA)** ... **122**
Annex D (informative) **Candidate standards supporting eHealth Architecture Model and Maturity Models** ... **125**
Annex E (informative) **WHO Indicator and Measurement Registry (IMR)** ... **128**
Annex F (informative) **Statistical Data and Metadata Exchange for the Health Domain (SDMX-HD)** ... **129**
Annex G (informative) **List of figures and tables in this part of ISO 14639** ... **132**
Bibliography ... **133**

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

TECHNICAL REPORT **ISO/TR 14639-2:2014(E)**

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 [7], Figure 14, with kind permission of the World Health Organization (WHO).

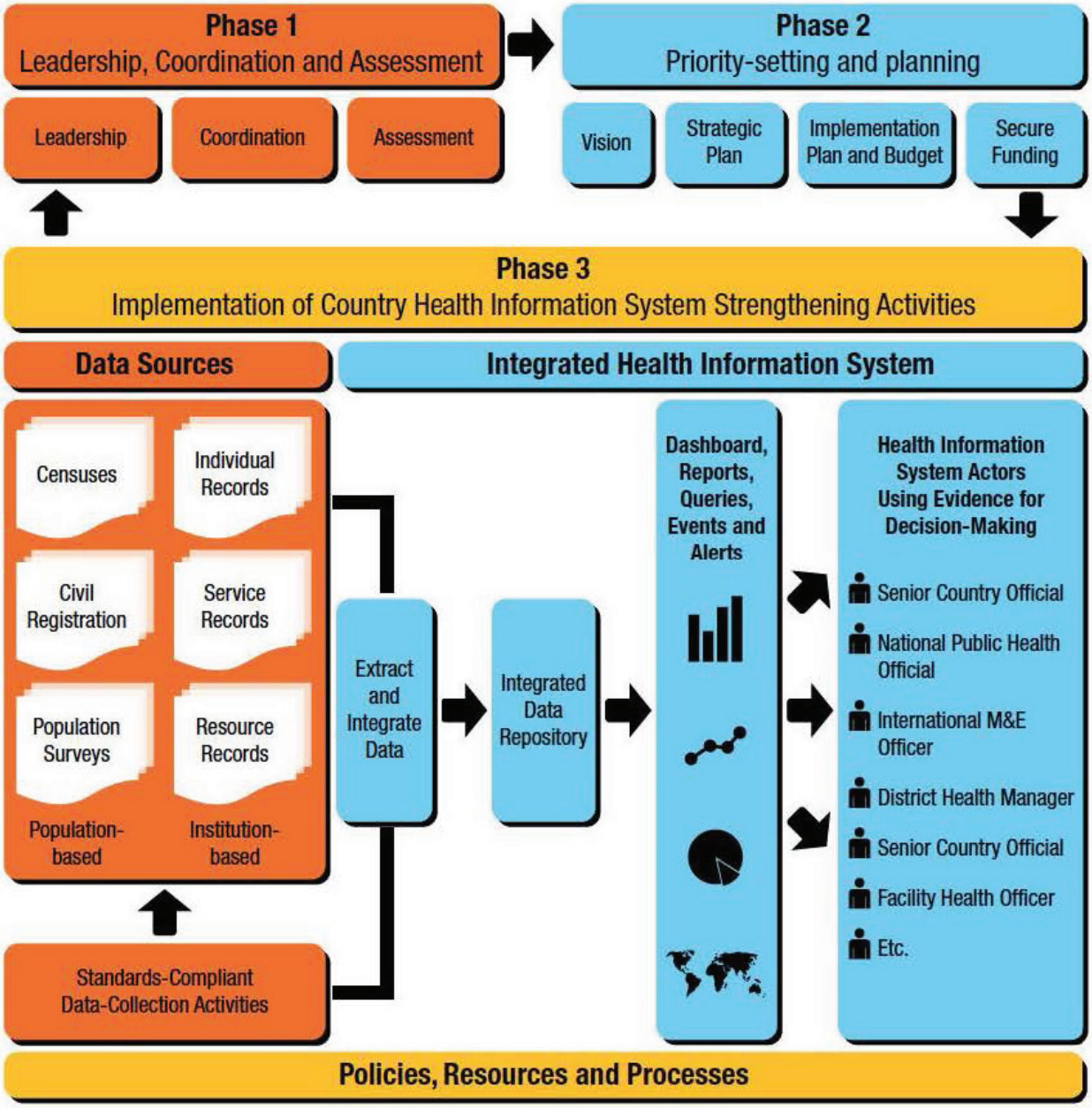

Figure 1 — Health metrics network framework

In the following, the ISO 12967 HISA standard, described briefly in Annex C, shall be used to help in identifying

a) the basic characteristics of the IDR component,

b) the relationship between the IDR and the data-handling eHealth services, and

c) 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.

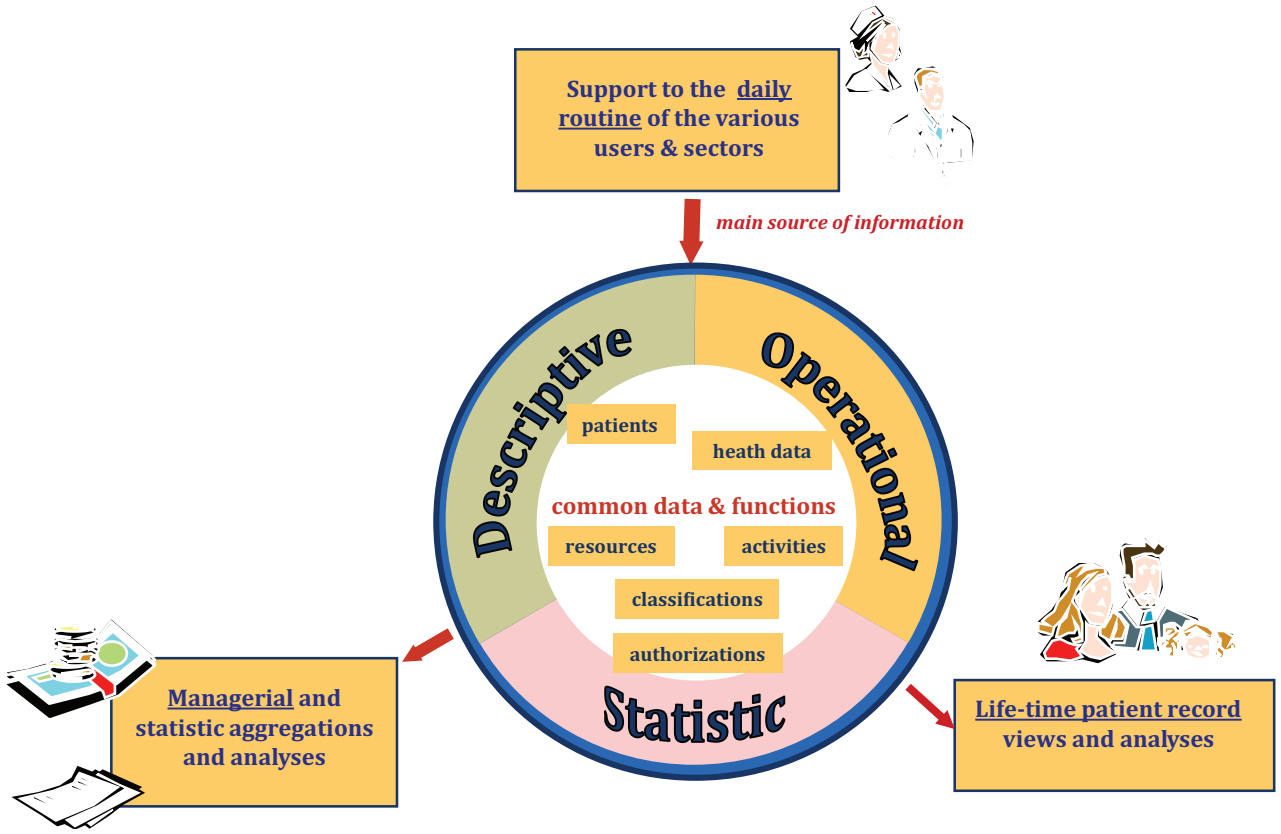

Figure 2 — Real-time gathering of information

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 service

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.

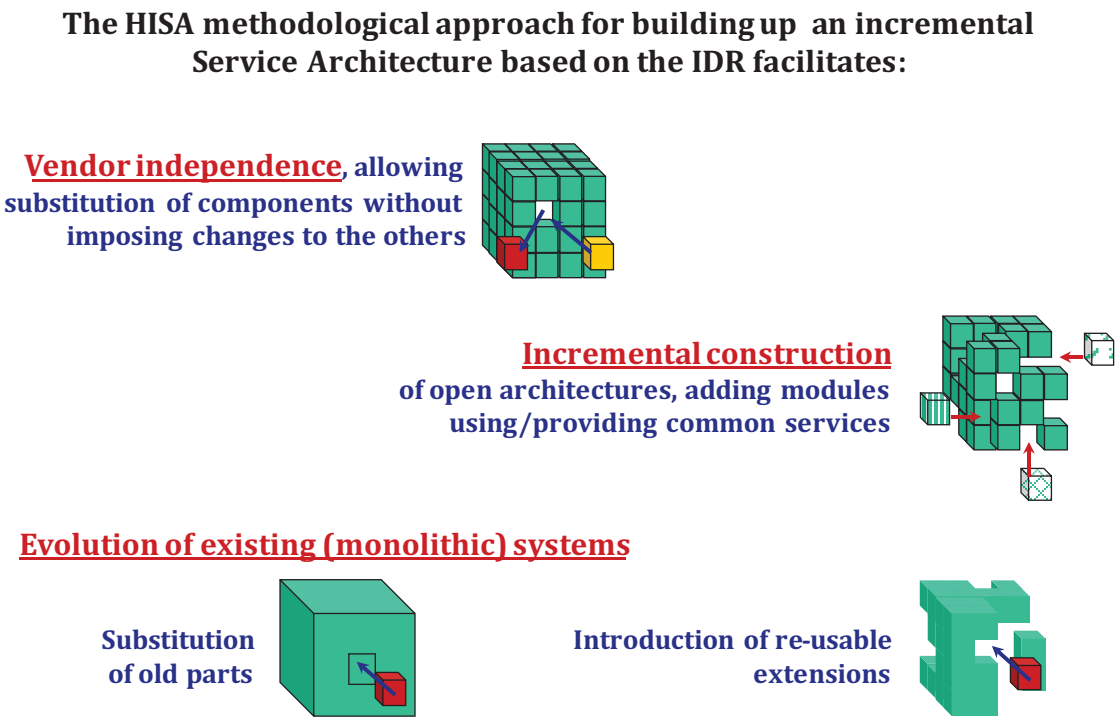

Figure 3 — Benefits of HISA approach

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.

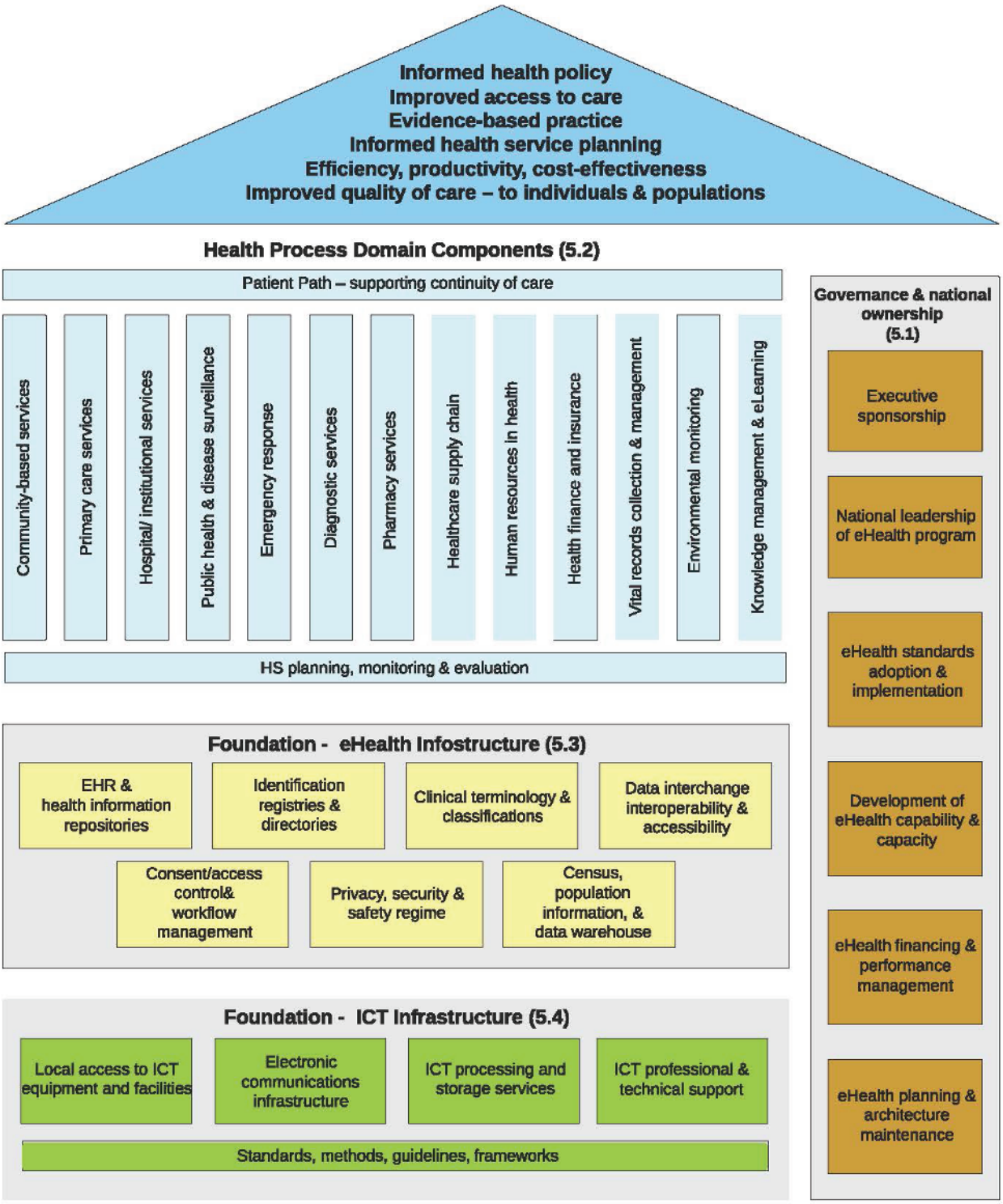

Figure 4 — eHealth architecture model

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

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

a) **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.[78]

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 though 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 heath 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 infostructure 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

the population; often the most dramatic improvements in health and wellbeing of a population can be achieved from the simplest but most effective interventions.

6.1.7.1.2 Planning and developing an eHealth strategy

The ITU National eHealth Strategy Toolkit home page[195] states that "Experience has shown that harnessing ICT for health requires strategic and integrated action at the national level, to make the best use of existing capacity while providing a solid foundation for investment and innovation. Establishing the main directions as well as planning the detailed steps needed is key to achieving longer-term goals such as health sector efficiency, reform or more fundamental transformation. Collaboration between the health and ICT sectors, both public and private, is central to this effort."

Further, ITU notes[195] that "Ministries of health play a pivotal role, not only in meeting people's needs for care and protecting public health, but in preserving health systems through uncertain times. Ministries of information technology and telecommunications are key to development in all spheres, and can make a vital contribution to the health sector. Common goals and a predictable ICT environment enable coordinated action: building consensus on policy, facilitating better use of shared resources and involvement of the private sector, and investment in skills and infrastructure to improve health outcomes."

In developing plans for eHealth, it is necessary to determine the planning window, based on the scope and the duration of the plan. Short-term plans with limited scope are needed when dealing with urgent tactical situations; for example a national pandemic emergency would require a rapid approach, focused on the disease. Longer term plans with wide scope emerge out of major national initiatives with strong government support. In any economy, there is likely to be a need for a mixture of short-term and longer term plans driven by pragmatic short-term needs and the long term broader needs and goals of the community.

Maintenance of the eHealth architecture is a core part of planning. All plans should be baselined in the current architecture, and targeted towards a new architecture. Within the ICT industry the majority of enhancement comes under the maintenance phase as incremental extensions. Therefore maintenance must be considered a key part of strategy and planning. Whole lifecycle costs must be core to planning, considering the maintenance and support of solutions.

eHealth architecture can be realized in a variety of ways. A blueprint approach adopted by some larger nations sets an aspirational configuration at a national level, coupled with standards and incentives for adoption. A more vigorous approach involves the provision of national infrastructure, such as a national VPN for health that requires health delivery organizations to exchange information using the national network. Other strategies are bottom-up, based on a more market-centred approach to development and integration, with the architecture being emergent. There is no absolutely right way to define an eHealth architecture, and the choice of strategy depends on the social, commercial, and political context within which it is to be applied.

Core to any architecture are the standards for interoperability, from basic coding and recording standards through to information exchange standards. Without clear standards, any investment strategy can at best achieve islands of success. Consistency and compatibility of standards are necessary; it is not necessary to be uniform in all standards areas if there can be some translation between information represented using different standards. A balance needs to be struck between pragmatic interchange of information in poorly structured form through to the ideal of fully coded and structured electronic health records. Creating barriers to entry through overly ambitious standards strategies can be almost as limiting as having no standards strategy.

Large, "big bang" implementation and replacement strategies have a poor track record in the ICT industry, and the risks of such approaches are exacerbated by the complex demands of the health industry. Even if complete replacement of an existing architecture is envisaged, an incremental replacement strategy is usually the best approach. Evolution rather than revolution should be the maxim. The interim costs of dual running and phased replacement can be more than offset by the reduction in risk. A feasible evolution strategy has previously been outlined in 5.3.2. See 5.2 and 5.3 for details on development of an eHealth architecture (5.2) and the methodology for building up the architecture (5.3).

Finally, planning and maintenance needs to include a risk management strategy. Identification of risks up front, with regular review and response to the risks is critical. The biggest failures are usually a consequence of not recognizing and responding to risks early enough. This is often confounded by the complex politics around health, where aspirations can be high and unrealistic while the public expression of concern around potential failure can be difficult to manage.

In 2012, the WHO in collaboration with the ITU developed a National eHealth Strategy Toolkit as a resource for developing or revitalizing a country's eHealth strategy, addressing a range of countries, from those just setting out to those that have already invested significantly in eHealth.[196] The toolkit is an expert, practical guide that provides governments, their ministries and stakeholders with a solid foundation and method for the development and implementation of a national eHealth vision, action plan, and monitoring framework.[196] All countries, whatever their level of development, can adapt the Toolkit to suit their own circumstances.

The Toolkit identifies three major areas of activity for planning and developing an eHealth Strategy as shown in Figure 6.

NOTE Figure 6 was reproduced from Reference [197], eHealth brochure, p. 2, with kind permission of the World Health Organization (WHO).

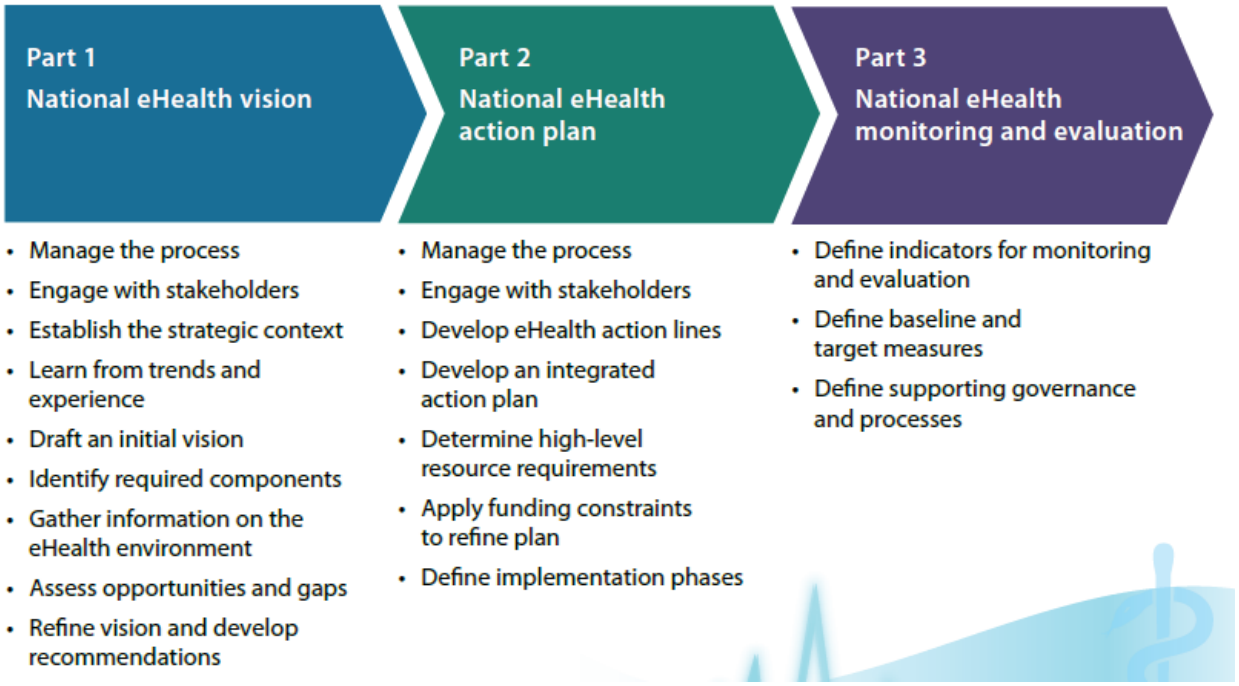

Figure 6 — WHO/ITU Toolkit — Planning and development of eHealth strategy

6.1.7.1.3 Factors impacting maturity models

The maturity of eHealth planning and architecture maintenance is dependent on a number of factors.

6.1.7.1.3.1 Political factors

The political stability of a nation radically affects health outcomes and the potential for eHealth. Frequent political changes can make it difficult for long-term investment in and maintenance of eHealth architectures. Conflict in a geographic area e.g. political, civil, religious, etc. will further limit the ability to plan and provide stable, effective investment. Where there is instability, planning, and maintenance of architecture is more problematic. Pragmatic decisions need to be made in light of the planning window that is feasible.

Another political factor to consider is the role of central government and its willingness to intervene. Central investment makes it feasible to plan at a national level, but can be an inhibitor to local initiatives and investment. Without some government support, it is difficult to have a national strategy.

The coupling of health to government spending affects investments significantly. Even in mature economies, national eHealth investment strategies and the focus of national eHealth ICT priorities can be quite divergent. The public/private split of healthcare delivery has a significant impact on eHealth. Public investment more often than not focuses on deliverable infrastructure that is widely shared. In a mainly privately funded eHealth economy, the role of standards and incentives is more important.

Government structures and policies have a significant impact on delivery. Heavily devolved government can provide more robust delivery but inhibit national integration. Centralist government can provide more integration but have greater issues with local delivery and innovation. Planning and maintenance needs to be cognisant of the approach to national governance.

6.1.7.1.3.2 Economic factors

Economic factors have a major role to play in health outcomes; there is a strong correlation between the wealth of a nation and the health of its population. This is driven by a number of underlying factors, including the ability to invest in eHealth. Income distribution is also important; the size of disadvantaged groups even in relatively wealthy nations can significantly impact overall health outcomes and access to eHealth functions.

Economic stability is important for large scale investment in eHealth architectures. Private and public investors will only invest where there is a likelihood of long term value. High local inflation and weak currencies are risks which impact any major investment program even in relatively wealthy nations. Substantial inward investment is often needed to encourage third party organizations to engage with confidence. Economic downturns have a massive effect globally as well as locally, and in all economies.

The funding model for health can impact the funding model for eHealth. State funded health initiatives are likely to have money for eHealth. In an insurance model, privately or publicly funded, the flows of money can be very different, and require the providers of health services to source investment funding independently of the state; this can influence national strategies with respect to incentives programs and policies.

Strong markets and mature financial management are conducive to stability and long term investment. Plans and investments therefore need to be very sensitive to this. Expecting an immature market to deliver complex solutions is unrealistic. On the other hand, not taking advantage of mature markets and creating eHealth solutions independent of the wider ICT infrastructure can be wasteful and sometimes counter-productive.

6.1.7.1.3.3 Social factors

Social factors strongly influence the needs and delivery mechanisms for health, and hence, the eHealth requirements. Good social support networks can radically influence health outcomes, and impact the need for and utility of eHealth solutions and eHealth enabled services. Mobility and change, such as increasing urbanization will have similar impacts. Education level and literacy can have similar impacts. A highly educated population will have higher expectations and higher ability to utilize eHealth initiatives from both a patient and a provider perspective. The stability of healthcare services depends on a strong, educated, and eHealth savvy health professional group.

Population density will also affect the utility of eHealth. Dense, well developed population centres will be conducive to good eHealth architectures. Dense, poorly developed population centres will be problematic. Dispersed populations will create different problems.

The age and mobility of populations strongly influence health outcomes and the utility of eHealth. A young, mobile population will put particular strains on eHealth, requiring more adaptability in the architecture to meet changing needs. An aging, static population will impose different strains, with a higher proportion requiring chronic disease management.

6.1.7.1.3.4 Technology factors

Base technologies, supporting the wider community, radically influence the ability to plan and maintain. If eHealth has to include basic commodity costs for national ICT infrastructure, then this will impact the time, cost, and quality of delivery. Core communications are a minimum requirement, but this can be delivered in a variety of ways, from high bandwidth land-based wide area networks through to low bandwidth mobile telephony networks.

Standards are core to technology adoption and integration. A mature standards-based approach is important for success. The ideal market has full engagement of all parties in the development and adoption of standards. National initiatives on standards can range up to full legislative requirements around the adoption of standards. However, the best incentive for standards adoption is a commitment from the user base to adopt the standards; in particular, endorsement of standards from healthcare professional organizations is key to overall success.

6.1.7.1.3.5 Geographic factors

Geography will influence eHealth planning. The costs of connecting dispersed populations over a wide area or difficult terrain can be significant. Distances to care delivery can impact the effectiveness of eHealth solutions. In large densely populated areas, there is often the option of providing choice, and choice is a driver for quality and innovation in many mature economies. However, choice becomes more difficult to provide when there are large distances between population centres.

6.1.7.1.3.6 Endemic disease factors

Endemic diseases including infectious diseases, malnutrition, and obesity have significant impact on the demand for health services. Where there is an endemic disease, greatest benefit is usually achieved by focusing on treating that disease. eHealth planning should focus on addressing dominant health needs in a community.

6.1.7.2 Maturity model

The maturity of the environment for effective planning and maintenance is indicated by the characteristics outlined below.

6.1.7.2.1 Low

a) A politically unstable environment, with conflict or frequent changes of government, making it difficult to provide robust plans and stable infrastructure.

b) Little or no central government planning and investment make it difficult to fund and sustain plans and infrastructure.

c) Policy on health focused on short term issues reduces the options for long term planning and investment.

d) Poor health outcomes and weak measurement of health outcomes order the priorities towards tactical rather than strategic interventions on health.

e) Low gross national product (GNP) limits the investment possibilities and the ability of the market to provide ICT.

f) Significant changes in population, such as rapid urbanization, migration or high birth rate, place high strains on infrastructure.

g) Geographically dispersed populations, with large rural areas and significant amounts of subsistence living, make deployment of ICT problematic.

h) Early stage urbanization with rapid growth and migration towards urban centres place pressure on the urban areas.

i) High level of endemic diseases, with low life expectancy, places the priorities firmly on immediate problems rather than longer term investments to address the wider health issues.

j) Unorganized professional groupings, driven by the health demands of the population, make the system more reactive rather than strategic in its response to health issues.

k) Poor ICT infrastructure generally means that eHealth must either make do with established infrastructure or bear some general investment costs.

6.1.7.2.2 Medium

a) A politically stable environment with little or no conflict, and stability in governments, encourages medium term planning, and inward investment.

b) Modest central government budgets allow for some national investments on priority areas.

c) Health outcome priorities known, and focused on key issues.

d) National measures of health outcomes developing or in place.

e) Well-defined policy on health, seeking to address priority areas in the short to medium term, leads to direction of national funds to eHealth.

f) Moderate GNP drives inward investment and available national funds for investment in eHealth.

g) Strong urban centres, with a move towards greater urbanization, create stable islands of infrastructure.

h) Endemic diseases being dealt with in most areas, creating opportunities for focus on broader health issues.

i) Good ICT infrastructure in urban centres, with some national infrastructure, allows for investment in eHealth to exploit general infrastructure.

j) Developing professional groupings with a recognition for the need for eHealth in key areas and the importance of information exchange through standards-based solutions.

k) Growing educated class, with increasing expectations regarding health services.

l) Mobile telephony and some wired telephony out to non-urban centres provides connectivity. Some wide area networks provide higher bandwidth within urban areas. These enable eHealth initiatives.

6.1.7.2.3 High

a) Long term political stability allows for significant long term investment at a national level and encourages inward investment and a strong market.

b) Good balance between national and local government investment creates options and diversity.

c) Road map for health outcomes well developed.

d) Well-defined policy on health, with a long term strategic view, encourages planning and investment in eHealth architectures.

e) Good monitoring of health outcomes at a national level.

f) High GNP creates funding for investment, creates an environment where choice and diversity are possible and drives up quality.

g) Education level high, and demand for quality and choice in health are high.

h) Endemic diseases are more lifestyle driven (e.g. obesity, diabetes, cardiac), than poverty driven, moving the emphasis towards public health and management of chronic and acute diseases.

i) Aging demographic moves the emphasis towards chronic disease management.

j) High urbanization and well developed rural infrastructure means that eHealth can exploit a rich national infrastructure.

k) Strong professional groups are established, with regular professional accreditation and a strong commitment to standardizing information use.

l) Good ICT infrastructure nationally creates a wide array of options for eHealth investment.

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

There are a number of tools that are useful for planning, but very few standards that provide guidance for national eHealth planning. The primary reference standard is the ISO 12967- series:

— ISO 12967-1:2009;

— ISO 12967-2:2009;

— ISO 12967-3:2009.

For those embarking on an eHealth strategy, knowledge and understanding of similar initiatives is very important. Most major economies have eHealth strategies. Prime examples are the following:

a) the English information strategy, "The Power of Information", published by the Department of Health, England, in May 2012;[101]

b) the second eHealth Strategy for NHS Scotland, September 2011;[102]

c) the "Meaningful Use" Strategy by The Office of the National Coordinator for Health IT in the USA;[103]

d) the Personal Health Management Strategy for Singapore;[104]

e) the Personal eHealth Record Strategy in Australia;[105]

f) the Strategic Investor initiatives managed by Canada Health Infoway.[106]

The tools suitable for maintenance are those that are used for development of architectures. (See Clause 5). Quality standards, such as ISO 9001, are very appropriate for any organization developing and maintaining eHealth architectures. (See Clause 5.)

6.2 Health process domain components

6.2.1 Description

This component of the eHAM addresses the various health process domains that comprise the set of services and processes delivered across the healthcare continuum. These processes generally involve both patients seeking and accessing healthcare services and providers offering these services. The health domains encompass a broad range of services intended to address clinical (provider) assessment of health problems coupled with diagnostic (test) assessments, therapeutics and related components such as payment for services and evaluation of services, provider and patient education and knowledge management, essentially the spectrum of patient-provider experiences that span the continuum of care.

A process of care is a healthcare related activity performed for, on behalf of, or by a provider, a patient (or client), or another caregiver.

6.2.2 Community-based services

In many developing countries, community-based services serve to either augment or extend primary care services. The range of skills and training for community health workers varies widely, and their general scope of care varies as well.

Community-based services typically are delivered in two ways:

a) primary care outreach activities (community visits and interventions performed by healthcare providers based in a clinic or community/district hospital);

b) community health workers based in the community.

Community-based services delivered as outreach activities are primarily healthcare focused, including immunizations, screening programs, family planning, sexual health, and health education, disease prevention, and wellness promotion programs.

Health information related to outreach activities is typically recorded and managed at the facility level, although community based health workers will often keep duplicate records as well. Outreach activities are considered extensions of primary care, simply delivered in another setting. They often use standardized forms for data collection and data entry identical to those used when delivering the same services in the facility e.g. community health workers will bring the same immunization registers or books on outreach.

Services delivered by community health workers based in the communities pose greater challenges and tend to be less integrated with the overall health services. While the responsibilities of the community health worker vary widely by country, they are typically responsible for activities such as

a) health promotion,

b) health education,

c) basic screening,

d) referrals to primary health clinics,

e) very basic treatments or interventions (in some areas), and

f) registration of vital events.

Most of the health promotion and health education activities are rarely recorded. When they are recorded, the reasons tend to be linked to financial incentives rather than improved data collection. This is because if community health workers are paid at all, it is almost always based on performing specific activities e.g. conducting health promotion activities; sending a pregnant woman to the clinic for ante-natal care.

The actual flow of information and information-sharing will depend largely on the actual setup of community services in the country and the scope of responsibilities assigned to the community health workers.[80][81]

6.2.2.1 Maturity model

6.2.2.1.1 Low

a) Care encounters might not be recorded at all especially if they do not include the provision of medication, or a referral to a health centre.

b) Information might be recorded by the community health worker in a non-standardized way, such as a note book they keep themselves.

c) Information is rarely shared with the primary care facility, and if it is, not in any regular or standardized fashion.

6.2.2.1.2 Medium

a) Person-specific health data is recorded on a standardized form (such as a ledger or register) and summary data is routinely shared with primary care services, e.g. via monthly reports.

b) Referrals to primary care are recorded in a standardized manner (a referral form). Mechanisms to follow up and ensure the referral happened are typically absent or inconsistent.

c) Follow-up on referrals (the sharing of information from the primary care centre to the community health worker) does not exist.

d) While processes do exist, and can be somewhat standardized, all collection and aggregation of data is done manually, with pen and paper.

6.2.2.1.3 High

a) Community members are uniquely identified in a standardized way, and that identifier is used to share information between health centers and providers.

b) There can be some use of technology to improve data collection and reporting, typically a mobile phone.

c) Messaging and health information exchange is standardized and codified.

d) There is strong bi-directional data sharing between the community and the health centers.

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

Relevant data standards include the following:

— HL7 CDA CCD;[107]

— green CDA (and other clones of this concept,[179][189] with simplified schemas that can be transformed directly to and from normative CDA);

— ISO 18308;

— ISO 10781;

— code sets such as SNOMED[62] and ICD.[63]

Relevant broad-based data and communications standards might include the following:

— ISO 13606 EHR Communications

  — ISO 13606-1 — Reference model

  — ISO 13606-2 — Archetype interchange specification

  — ISO 13606-3 — Reference archetypes and term lists

  — ISO 13606-4 — Security

  — ISO 13606-5 — Interface specification

Relevant architectural International Standards and frameworks for reference include the following:

— ISO 12967 (all parts), Health Informatics Service Architecture (HISA);

— World Economic Forum (WEF) Global Health Data Charter[4] (see Annex A);

— Health Enterprise Architecture Framework (HEAF);[5]

— General Component Model (GCM)[6] (see Annex B);[6]

— WHO Health Metrics Network (HMN) Framework;[7]

— The Open Group Architecture Framework (TOGAF);[8]

— Zachman framework.[9]

The move to electronic records for community-based services is essential for progression from low or medium to high maturity levels and for integration with primary care services.

Other health process domains may depend on the continuum of community-based care and primary care to support and drive their overall clinical usefulness and activities, and look to these services as the main data source for their domains.

A highly developed eHealth architecture can be 100 % client centric, designed to facilitate the actual delivery of healthcare and able to feedback on its own processes to assist in that task.

6.2.3 Primary care services

6.2.3.1 Description

Primary care is the usual entry point for a client/patient's first contact and engagement with the healthcare system.

This type of care is characterized by

a) longitudinality, i.e. recurring visits over time to the same care provider or provider team for ongoing management of health and health conditions including medication prescribing; health screening, immunizations and other types of prevention programs; wellness promotion, health education and empowerment in support of self-care; family planning and sexual health,

b) comprehensiveness, i.e. holistic approach to assessing and managing the overall health needs of the client, and

c) coordination of access to appropriate services across the care continuum on behalf of, and in collaboration with the client.

Primary care can also include other services such as family counselling and culturally relevant care.

Some of these services can also be provided through community-based services rather than a formal primary care practice/clinic or there can be a mixed model of community and primary care service providers.

Given the rural or remote locations of and great distances between populations in many developing countries, publicly funded primary care is usually provided in a "tiered" fashion.

Small primary care clinics (PCCs) staffed by minimally trained health workers, with/without the support of a nurse or midwife, act as the first point of contact at the most local level, serving hundreds or a few thousand people in surrounding villages. These clinics handle women's health issues (pre and postpartum care, family planning, gynaecological problems), childhood illnesses, and minor adult infections and major prevalent adult diseases e.g. TB, malaria, diabetes, and hypertension.

Larger primary healthcare (PHC) clinics serve larger populations (20-30,000, similar to sub-urban areas in developed countries) and act as referral sites for the small "feeder" PCCs. The PHC clinics will usually have a medical officer (physician) trained in primary care or possibly a nurse practitioner (advanced practice nurse) along with other trained providers, e.g. physiotherapists. Such sites can have a small number of beds onsite to manage patients who require observation and treatment for a few days. In addition to the types of problems served at PCCs, these sites provide some or all of the following services:

a) medical consultation and treatment via telemedicine;

b) normal deliveries;

c) immunization of infants and children;

d) ophthalmic services (refraction testing);

e) treatment of minor injuries, wounds, animal bites;

f) minor procedures e.g. incision and drainage;

g) public health programs.

Comprehensive primary healthcare (CPHC) centers may be the next level up acting as referral sites for the larger PHCs. These are really district hospitals of the equivalent of district hospitals and cover much more than primary care. These sites refer to provincial or state level secondary and tertiary level hospitals. District sites offer core specialist physician services e.g. internal medicine; general surgery; ob/gyne and paediatrics, and supporting services e.g. X-ray, lab, OR and may offer 20-30 inpatient beds. Additional services offered (including those offered PCCs and PHCs) may include

a) high-risk pregnancies; emergency Caesarean sections,

b) neonatal care,

c) more severe cases of childhood and adult diseases e.g. meningitis; cancer, neurological disorders,

d) trauma and poisonings, and

e) major and minor surgeries.

Despite this type of tiered approach, many clients travel long distances to obtain care, often on foot. Communications and information sharing between local clinics and higher level primary care centers and comprehensive/district sites may be limited and most data is collected on paper.

Information gathered from primary care visits can serve as the main source of client health information for other health domains if the data is captured in a readily shareable format, preferably electronically.

Adoption and implementation of technology based healthcare delivery systems is essential to enhance primary care reach and accessibility for rural populations and improve data-sharing across care providers.

Requirements for ICT and other advanced technologies in primary healthcare include the following:

a) necessary infrastructure, networks and connectivity e.g. fibre (wired), wireless, satellite;

b) telemedicine and telehealth services;

c) healthcare information systems (patient/client record data collection, sharing);

d) healthcare data management systems (data analysis and use);

e) appropriate data collection devices and analysis tools;

f) video and multi-modal conferencing and other forms of e-connectivity;

g) inventory management systems;

h) adherence to national/international standards as applicable, while designing and developing equipment, products and systems; standardization of data, should occur where possible, through modification of existing formats (to improve user acceptance) but may require new systems and methods of data collection if interoperability is to be achieved.

In addition to publicly funded primary care, there can be large and diverse private and non-governmental organization (NGO) supported primary care and related health services that need to be part of overall considerations for ICT and information sharing eHealth initiatives. Networks, connectivity, and telemedicine capabilities will foster public-private partnerships to improve effectiveness of healthcare delivery and improve access to resources.

Mobile clinics and mobile hospitals with/without telemedicine capabilities can also be part of primary care delivery in developing countries. These mobile care services are a very effective way of offering

primary and other types of healthcare, e.g. eye screening to rural and remote populations on a time shared basis, and can also provide emergency medical services during disaster management and relief. When connectivity is available through satellites or wireless, it is also possible to provide linkages to other care providers at established district and higher level sites.

NOTE Description adapted and extended from ICT for Primary Healthcare.[82]

6.2.3.2 Maturity model

6.2.3.2.1 Low

a) Paper records, or no records at all afford little or no interoperability or continuity of care across different healthcare settings, except that evident from the diseased organs themselves.

b) There is little or no opportunity for aggregation of patient data for public health collections, or for use of information from the accumulated wisdom of other clinicians for decision support.

c) If connectivity with minimally acceptable bandwidth exists to support data storage and transfer, web-enabled hand-held devices e.g. smart phones, android tablets, can be used to collect client healthcare data to replace manual processes, and to collect other types of data e.g. disease surveillance; births/deaths; immunizations; communicable diseases; these devices should also support phone and email communications as well as staff education online

d) Telephone landline or smart phone for communications with large PHCs or other provider organizations, e.g. NGOs.

e) Core digital devices, e.g. weight scale.

6.2.3.2.2 Medium

a) Paper or electronic silos of information are available through mobile and/or onsite [personal computer (PC) or laptop] systems at primary care clinics. Data captured using hand-held devices can be uploaded to large PHC centre databases and further uploaded to comprehensive centers/district hospitals, real-time if possible, where supported by the infrastructure and connectivity.

b) A PC or laptop with printer and web-enabled digital camera at all PHC sites for maintenance of local databases and patient histories especially for high risk groups, which can be readily accessed by health workers.

c) PHCs have additional digital biomedical devices are e.g. glucometer, stethoscope, sphygmomanometer, ECG, X-ray, ultrasound.

d) Connectivity with sufficient bandwidth to support video-conferencing and video monitors to support telehealth e.g. tele-consultations; tele-prescribing; telehealth systems should be web-enabled.

e) Some level of electronic administrative and management capabilities e.g. patient registration and assignment of patient Ids; record maintenance; budget and inventory management, via PCs and/or mobile.

f) Connectivity from PHCs to comprehensive PHCs (CPHCs)/district hospitals.

g) There can be some continuity of care provided the records are accessible at points of care.

h) There can be some information retrieval and availability of information for reporting and public health data accumulation, also cross referencing of data from different points of care and clinical contexts.

i) There may be interoperability across some electronic health information systems where provision for it has been made as part of adoption and implementation strategies.

j) There may be rudimentary alignment of local activities with enterprise-level strategies and programs if they exist.

6.2.3.2.3 High

a) Enhanced telemedicine and video conferencing capabilities at comprehensive PHCs/district hospitals, as well as communications capabilities via email, SMS, other e-routes.

b) Broad interoperability across electronic health information systems.

c) Unique patient identifiers used across the enterprise; in some jurisdictions there need be no new investment in paper-based health information, but paper-based collection can still occur at local clinics as an adjunct to electronic recording in specific circumstances.

d) High level of continuity of care based on achievement of connected, interoperable systems across public and private primary care provider organizations.

e) There can be two-way data flow from local to enterprise and enterprise to local (management information).

f) There can be strong alignment between local activities and enterprise objectives and strategies.

6.2.3.3 Examples of applicable standards cross-references and dependencies

Relevant data standards include:

— HL7 CDA CCD;[107]

— green CDA (and other clones of this concept,[179][189] with simplified schemas that can be transformed directly to and from normative CDA);

— ISO 18308;

— ISO 10781;

— code sets such as SNOMED[62] and ICD.[63]

Relevant broad-based data and communications standards might include:

— ISO 13606 EHR Communications

  — ISO 13606-1 — Reference model

  — ISO 13606-2 — Archetype interchange specification

  — ISO 13606-3 — Reference archetypes and term lists

  — ISO 13606-4 — Security

  — ISO 13606-5 — Interface specification

Relevant architectural standards and frameworks for reference include:

— ISO 12967 (all parts), Health Informatics Service Architecture (HISA);

— World Economic Forum (WEF) Global Health Data Charter[4] (see Annex A);

— Health Enterprise Architecture Framework (HEAF);[5]

— General Component Model (GCM)[6] (see Annex B);

— WHO Health Metrics Network (HMN) Framework;[7]

— The Open Group Architecture Framework (TOGAF);[8]

— Zachman framework.[9]

The move to electronic records spanning primary, secondary, and tertiary care is essential for progression from low or medium to high maturity levels.

Other health process domains may depend on primary care to support and drive their overall clinical usefulness and activities, and look to primary care as the main data source for their domains. A highly developed eHealth architecture can be 100 % client centric, designed to facilitate the actual delivery of healthcare, and able to feedback on its own processes to assist in that task.

Primary care depends on other components of the eHAM for such resources as client, HC Worker and facilities registries, terminologies, privacy and security processes, interoperability paradigms, eHealth policies, financial, and accounting support, etc.

6.2.4 Hospital/institutional services

6.2.4.1 Description

In both developed and developing countries, a minimum of three levels of hospitals commonly exist. Each level is progressively more comprehensive and sophisticated with respect to the type, scope, capability, and availability of healthcare services and related health human resources provided to the populations served.

Primary level hospitals are typically local and are the equivalent of comprehensive primary healthcare centers in terms of core speciality services provided.

Secondary level hospitals are regional and offer additional specialist care services and ambulatory (outpatient) clinics.

Tertiary level hospitals are major service hospitals, typically run by or affiliated with universities and offer the highest level of specialist expertise and care for both inpatient and outpatient services. A fourth level, the quaternary hospital, is available in many developed countries and offers highly specialized services such as burn units or hyperbaric chambers (for treatment of diving injuries) coupled with academic, education, and research focused activities.

In primary level hospitals, information systems and their requirements are close to those offered at primary healthcare centers. There may be a hospital information system installed or the system in use may be in common with systems available at primary healthcare centers. Information collected can be used for local clinical decision-making, sent to higher level hospitals and be shared with patients and the primary healthcare centers that patients attend for regular care.

At the secondary level, there is usually a main hospital information system (HIS) but this system comprises several clinical sub-systems and separate clinical systems may be in use outside of the main HIS that do not share data with the main system. Systems are more complex than those found in primary level sites There may be vertical information flows in addition to the usual horizontal information flows. Information from secondary level hospitals is usually collected for regional and national level decision-making in addition to local decision-making and clinical decision support.

At the tertiary level, the basic structure of hospital information systems is similar to the secondary level but the number and types of clinics increases and there is more sub-specialist expertise which means additional, separate specialized IT systems and more fine-grained data collection requirements. In addition to reasons for secondary level data collection, information is gathered for scientific and educational purposes.

Independent of hospital level, hospitals must deal with several major issues involving integration, of services and programs across the organization including multiple physical sites (where they exist), of common data and of common functionality. The main challenge to tackling and providing solutions to these issues is the fact that a significant number of hospitals and related healthcare enterprises continue to operate in a fragmented environment. They consist of networks of operational units characterized by a high degree of heterogeneity and diversity, from organizational, logistic, clinical, technological, and

cultural perspectives. The structure of such individual centers, whether they are hospitals, outpatient clinics, or other clinical practice environments (e.g. primary care clinics) is evolving from a vertical enterprise towards the aggregation of a set of specialized functional areas/domains spread over the territory served. These need to share common information and to operate according to organizationally integrated workflows within the frame of the larger healthcare service enterprise (municipal, regional, or national).

Supporting the specific requirements of each operational unit (or user) in the most appropriate and cost-effective way needs to be done while at the same time the overall consistency and integration of the whole organization must be secured, at local and territorial levels. Such integration requirements are not only needed to improve clinical treatment but also demanded by the necessity of controlling, containing, and optimizing the overall expenditures for healthcare.

Regrettably, today's hospitals and related healthcare enterprises comprise a large number of different database systems and applications, and information systems are frequently fragmented across a number of domains, applications, and functionalities, isolated and scarcely consistent with each other.

A primary need, and an indicator of maturity level, is to integrate the organization itself through integration of the organizational processes and the existing information assets, thereby, enabling interoperability of applications and systems and protecting the investments that have been made.

6.2.4.2 Maturity model

While the specific low, medium, and high maturity models for hospitals are described herein, a methodology that can be used by enterprises for evolving their systems from lower to higher levels is described in Clause 5.

6.2.4.2.1 Low

a) The healthcare service or enterprise is not integrated. Units or departments are islands loosely interconnected or not connected at all.

b) Paper records or no records at all come with a patient nor are they available to be retrieved from the healthcare service. All information is related to acute care and little or no historical information is available. There is no continuity of care across different hospital levels or specialists.

c) Paper records or no records are sent out with a patient at discharge from inpatient care or an ambulatory clinic visit, or delivered to another hospital healthcare service where the patient may be seen in follow-up. The records may not be located and available the next time the patient comes to the hospital or to the follow-up service.

d) There is no opportunity to collect information for decision-making, statistics, or scientific purposes.

6.2.4.2.2 Medium

a) The healthcare service or enterprise is loosely integrated. Integration is mainly focused on administrative requirements rather than on clinical, patient-centred requirements.

b) Most patient information is collected electronically and available. There are separate systems for specific purposes which are not integrated or integrated solely for administrative purposes. The clinical staff must look after patient information.

c) Information can be sent and received electronically from other institutes as long as agreements are in place beforehand related to information sharing, including agreed ad hoc interfaces and IT capability is available to support these exchanges. Data from hospitals outside of these sharing arrangements will not be available should a patient attend one of these facilities. This means that some part of the patient's health record information is missing and staff cannot fully trust the information received.

d) Systems to collect information for decision-making, statistics, and research purposes use different classification criteria and are not an integrated part of normal processes. They require extra work.

6.2.4.2.3 High

a) Healthcare enterprises and institutes are integrated as an organization, as are their information and functional assets. Also at the territorial level, the overall healthcare service that groups the institutes and enterprises acts and is structured itself as an integrated organization.

b) The patient-centred information flow is designed to fit processes in such a way that the personnel involved in the activities automatically use and feed the common information needed in each step of the process. Information is always available to help the staff and decisions are supported by the system. This means that all common information is managed in an integrated manner in the enterprise's integrated data repository and made available through service architecture in every location it is required. The patient also has direct or indirect access to their own information and can possibly determine how it will be used by granting or denying consent to use the information for specified purposes beyond those of the entity that recorded it.

c) Information is not restricted by organizations. Rather, the enterprises have become effectively part of the integrated healthcare service guaranteeing continuity of care. The information is made available through the healthcare service architecture in any part of the organization where a patient is treated. The integrated information asset permits building a lifelong archive to store all patient information (i.e. the Patient Record), which is available anytime and anywhere the patient requires treatment.

d) All information needed for decision makers, statistics, or research is collected automatically without any extra work in the enterprise's data repository and made available through technology-independent service architecture for all required uses whether they be clinical, research, statistical, managerial, administrative, or other.

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

Listing examples of applicable standards when spanning the whole enterprise-wide healthcare service is not a trivial task and requires a detailed analysis. There are many standards to take into consideration when building up a service architecture for healthcare enterprises and hospitals in general. Those deemed of most relevance are noted here, while acknowledging that work is ongoing in the standardization world to provide roadmaps and guidelines for the correct understanding and adoption of the most appropriate standards for each of the relevant areas of an enterprise (service architecture, messaging, etc.).

In brief, healthcare information systems, while necessarily being conformant to local, regional, or national regulations and laws regarding security of data and privacy, must also be based on an open and documented architecture comprising a series of components and modules, the most fundamental of which are listed here, together with the basic characteristics and reference standards.

a) The system includes an integrated information repository capable of handling all of the enterprise's common live and historical data regarding clinical and organizational activities and processes.

   — The reference standard detailing the characteristics and the conformance criteria of this component is ISO 12967. (Also, see Clause 5 and Annex C.) User front-end functionality (user interfaces) and integration engines supporting the clinical and administrative processes should be based on a service architecture that supports retrieval of common data from the repository and capture of new data that is considered common to the organization (e.g. results of activities, etc.).

b) To ensure continuity of treatment processes with message based devices or systems, the system should be able to handle messages conformant to HL7 standards.[18][190]

c) In order to manage and display diagnostic images stored in a Picture Archival Communications System (PACS) and provide continuity with radiology equipment and departments, the system should be able to communicate via DICOM standard interfaces.[109]

d) Clinical documents (reports, discharge letters, etc.) can be structured according to the Clinical Document Architecture (CDA)[110][179][189] or as EHR extracts according to the ISO 13606 model with archetypes.[19]

e) Classifications and taxonomies are required to classify data and models accordingly. The enterprise's information asset comprises huge amounts of data. Each single piece of information needs to be described from various viewpoints: what it means, how it should be interpreted, its terms of reference, links to other terms, etc. Without this set of descriptors it is impossible to interpret and understand, register and retrieve the data from the information system, analyse and compare it with other data of the same family coming from different systems, etc. Thus, the coding schemes provide a unified language that allows sharing of the data amongst professionals of the healthcare enterprise.

   — There are many coding schemes and classifications in use in the various domains of healthcare and there is still ongoing work in this area. It is fundamental that standard classifications and taxonomies need to be adopted within the healthcare information system (e.g. the ICD family, SNOMED CT, etc.)[62][63] and the information system itself must be able to cope with multiple concurrent classifications used.

A useful cross-reference for this overall Clause is the Health Information Management Systems Society (HIMSS) (US) EMR Adoption (Maturity) model,[83] an eight-step process that allows a hospital to analyse its level of information systems adoption, chart accomplishments, and track progress against other hospitals across the country. The UK is moving to adopt this model and other countries have also adopted/adapted it or are planning to in the near future.

6.2.5 Public health and disease surveillance

6.2.5.1 Description

NOTE The description of public health included here has been extracted with small adaptations from the UCLA book (Ch. 1.1) on Public Health (August 2012).[84]

Public health is the art and science of preventing disease, prolonging life, and promoting health through the organized efforts of society. The goal of public health is the biologic, physical, and mental well-being of all people. While medical care focuses on the health of the individual, public health focuses on the health of the public in the aggregate. To achieve this broad, challenging goal, public health professionals engage in a wide range of functions involving biological sciences, technology, social sciences, and politics. Public health professionals utilize these functions to anticipate and prevent future problems, identify current problems, identify appropriate strategies to resolve these problems, implement the strategies, and evaluate their effectiveness.

Public health is concerned with the process of mobilizing local, state/provincial, national and international resources to ensure that conditions exist in which all people can be healthy. To successfully implement this process and to make health for all achievable, public health must perform the following functions:

a) prevent disease and its progression, and injuries;

b) promote healthy lifestyles and good health habits;

c) identify, measure, monitor, and anticipate community health needs;

d) formulate, promote, and enforce essential health policies;

e) organize and ensure high-quality, cost-effective public health and health-care services;

f) reduce health disparities and ensure access to healthcare for all;

g) promote and protect a healthy environment;

h) disseminate health information and mobilize communities to take appropriate action;

i) plan and prepare for natural and man-made disasters;

j) reduce interpersonal violence and aggressive war;

k) conduct research and evaluate health-promoting/disease-preventing strategies;

l) develop new methodologies for research and evaluation;

m) train and ensure a competent public health workforce.

Public health is a global issue, and will become even more so in the 21st century, as the interconnectedness of nations increases through modern communication, resulting in the need to deal with epidemics of communicable and non-communicable diseases and environmental issues that require transnational solutions. Public health must address the challenge of confronting health problems and political, social, and economic factors affecting health, not only at the community, state, and national levels, but at the global level as well.

Disease surveillance, depending on capacity and reporting requirements, can consist of individual or summary data reporting. Summary data reporting is often the first step towards development of a surveillance system and migration towards an EHR and IDR. For individual data, sentinel surveillance at specific sites can be used to estimate incidence of disease with results adjusted appropriately for any biases introduced from site selection.

According to the World Health Organization (WHO), disease surveillance is the routine ongoing collection, analysis, and dissemination of health data. An effective surveillance system has the following functions:

a) detection and notification of health events;

b) collection and consolidation of pertinent data;

c) investigation and confirmation (epidemiological, clinical and/or laboratory) of cases or outbreaks;

d) routine analysis and creation of reports;

e) feedback of information to those providing data;

f) feed-forward (i.e. the forwarding of data to more central levels).

The rationale for the surveillance of a specific health event should be established and based on clear national priorities, disease control objectives and strategies. Otherwise, the data collected may be irrelevant. What data to collect depends on the analyses that are needed to guide decision-making on matters of public health. In the case of outbreaks, especially in cases of new or unknown diseases, or where the vector is not known, data collection needs to be dynamic so that the appropriate data can be collected depending on the circumstances.

At the national level, clear surveillance standards should be established to achieve maximum efficiency and ensure that data are comparable throughout the country concerned. These standards cover:

a) case definitions;

b) the type of surveillance to be conducted;

c) the data elements to be collected;

d) the minimum analyses and routine reports to be produced;

e) the use of the data in decision-making.

To achieve operational surveillance, it is necessary to carefully define

a) the process of surveillance,

b) the tasks at each level,

c) the data/specimen flow,

d) the most effective way to capture the data (e.g. as a by-product of routine data collection for patient care, or through registries, surveys, etc.,

e) the logistics, including,

f) staff issues e.g. designations of staff; staff training, and

g) appropriate tool distribution (e.g. means of communication, transportation, specimen kits).

Standard performance indicators should be monitored as a part of supervision to identify weaknesses in the system so that corrective action can be taken.[60]

Figure 7 shows where surveillance-related activities fit into the Health Metrics Network Framework and eHealth architectural model (eHAM) and how advances in IT can streamline the flow of information from secondary sources to an IDR using an IMR and the SDMX-HD indicator exchange format.

The use of these models can assist with strategy development by identifying gaps and prioritizing activities.

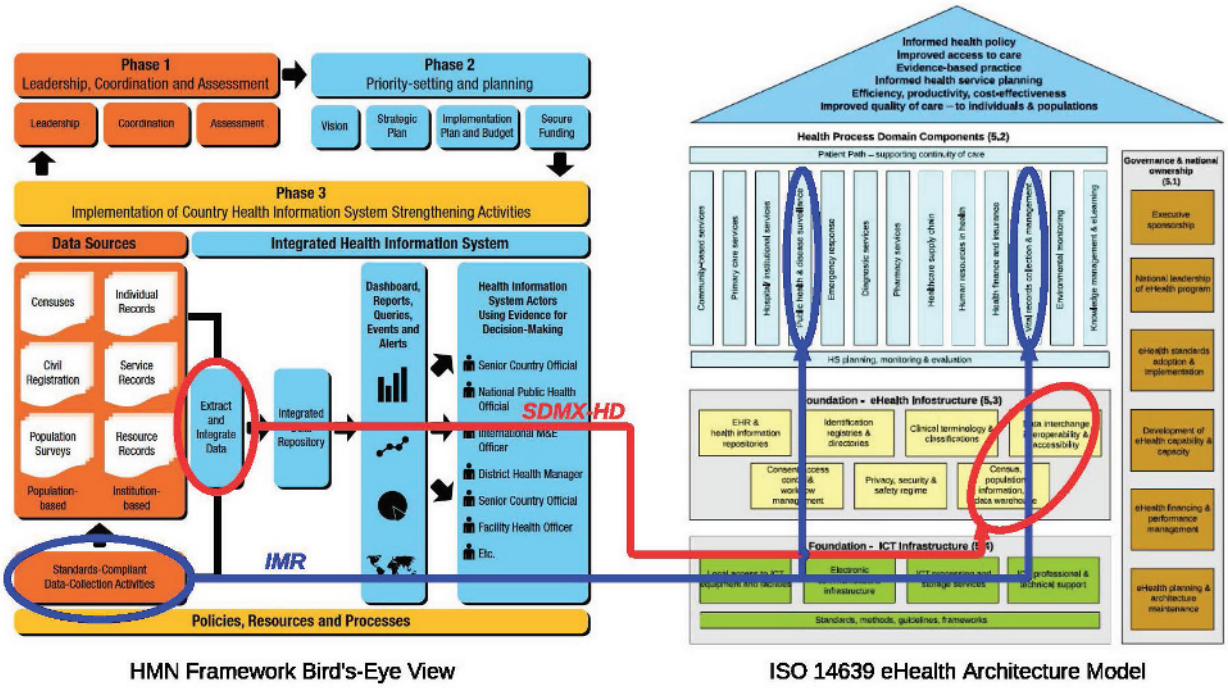

Figure 7 — Relationship of indicator and measurement registry (IMR) and statistical data and metadata exchange (health domain) (SDMX-HD) to public health and disease surveillance[61]

Monitoring and evaluation of public health programs has been a core component of traditional public health work. Public health monitoring systems have historically depended on tools like spreadsheets, vertical systems, and geographic mapping applications to store and manage data. A need for more robust data repositories emerged to support monitoring and evaluation (M & E) analyses as disaggregation, indicator management, and other weaknesses in design and scalability of applications became apparent.

A larger perspective on monitoring and evaluation as it applies to health system performance is provided in 6.2.15.

Central to the development of this framework are contributions from the informatics community in data standards. The statistical data and metadata exchange (SDMX) standard, an ISO standard for describing

statistical data, in particular, has been useful. The WHO implementation of SDMX, SDMX-HD (Health Doman), is configured to support the requirements of public health, including custom code lists which are necessary in an environment where perfect harmonization is not possible.

Other aspects include increasing maturity of organizational work processes, the UNAIDS Monitoring and Evaluation Reference Group (MERG) being a notable example, and development of a variety of monitoring applications like Country Response Information System (CRIS) (UNAIDS), District Health Information System (DHIS) and DevInfo, a database system developed under the auspices of the United Nations and endorsed by the United Nations Development Group for monitoring human development. DevInfo's specific purpose is monitoring the Millennium Development Goals (MDGs),[2] which is a set of human development indicators. DevInfo is a tool for organizing, storing, and presenting data in a uniform way to facilitate data sharing at the country level across government departments, UN agencies and development partners. It is distributed royalty-free to all UN member states. It is a further development of the earlier UN Children's Fund (UNICEF) database system ChildInfo.

In low-income countries, a strategy that balances development of systems for patient-care and international reporting can meet both near and long-term needs. Results-based monitoring and evaluation, which requires documented performance measures, drives target-setting, and reporting of facility-level data. This presents an opportunity to develop a global monitoring infrastructure to support flow of data between the facility, sub-national, national, and international levels.

A public health monitoring system framework could be based on an infrastructure consisting of three parts:

— indicator vetting and harmonization processes;

— indicator registries;

— individual and summary country reporting systems.

The system is based on a system of interoperable computer applications using a common data exchange format (SDMX-HD) for summary data.

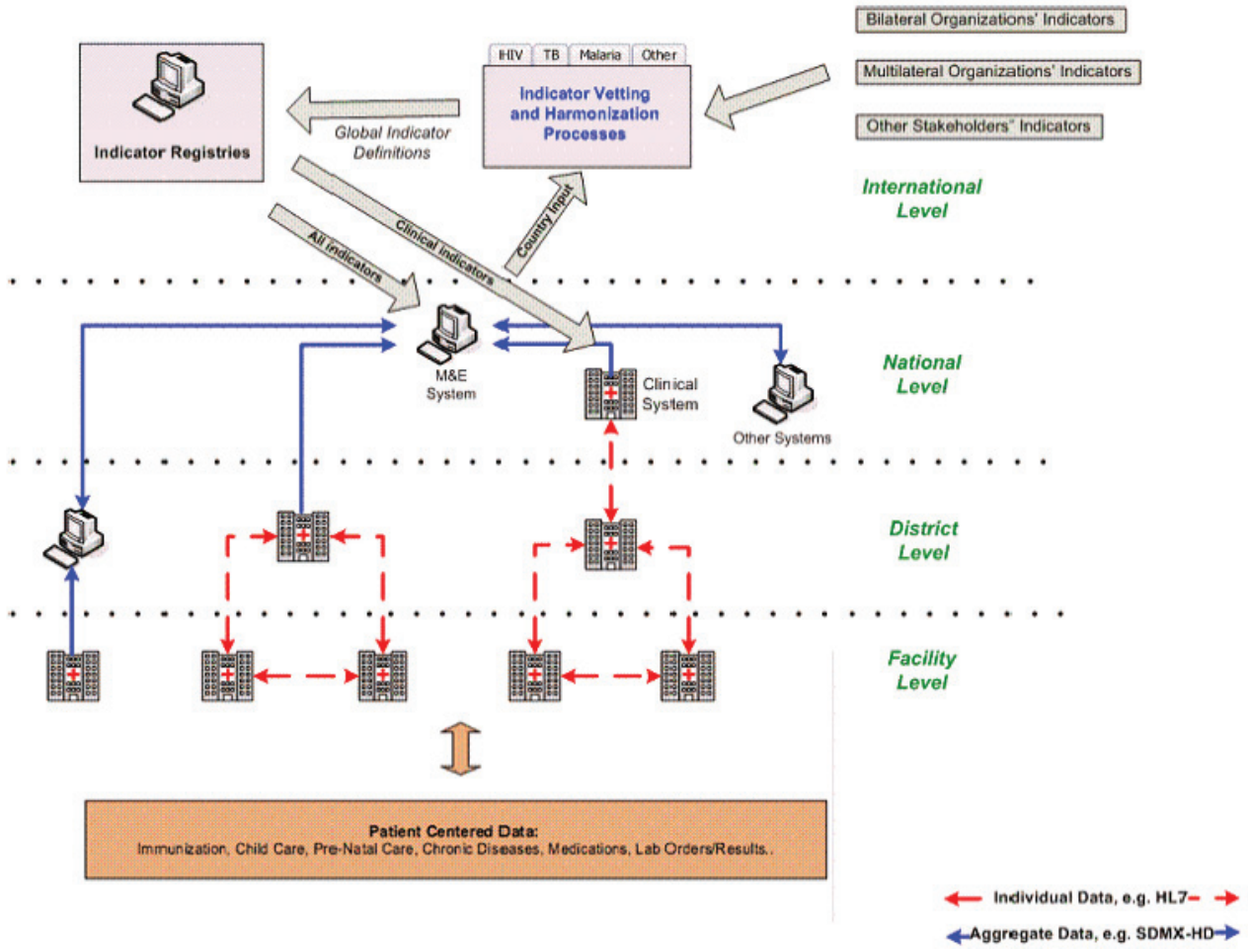

Figure 8 — Public health monitoring infrastructure[61]

Figure 8 shows the use of Health Level Seven (HL7) and Statistical Data and Metadata Exchange — Health Domain (SDMX-HD) to exchange data. Logically, similar to the use of transmission formats like HL7 to link hospital systems containing patient data, the SDMX-HD is used to link systems producing or consuming aggregate data. A format for sharing aggregate data makes data available in low-connectivity environments, facilitating development of monitoring infrastructure.

Global organizations typically develop guidelines for local program management and reporting. Going forward indicator definitions will shift from being organizational to global intellectual property. See Annexes E and F for more information on the IMR and SDMX-HD.

6.2.5.2 Maturity model

6.2.5.2.1 Low

a) No regular reporting of disease surveillance data from facilities to the national level.

b) Surveys and epidemiologic studies provide estimates of disease incidence.

c) Little or no process for harmonizing indicators nationally or with international standards.

d) No electronic reporting of programmatic or surveillance data to national level.

6.2.5.2.2 Medium

a) Sentinel surveillance using established facilities is used to estimate disease incidence.

b) Paper reporting of summary data from facilities to the national level.

c) Population-based electronic summary reporting initiated.

d) Basic documentation on national indicators is available. May lack complete metadata on disaggregation or methodology.

e) Some data use at local level of reported data.

6.2.5.2.3 High

a) Individual and summary data reporting from facilities established.

b) Two-way communication between national and local level, e.g. outbreak alerts.

c) Reporting of programmatic indicators used for management and allocation of resources.

d) Trends in indicators analysed longitudinally.

e) Indicators are sufficiently disaggregated to permit evaluation of national issues.

f) As capacity increases, case-based reporting can be implemented and clinical data warehouses (CDW) developed as needed, the latter being an important tool for facilitating the systematic extraction, linkage, and analysis of surveillance data.

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

See 6.2.15.

An additional applicable standard is ISO/TR 22221:2006.

6.2.6 Emergency response

6.2.6.1 Description

Emergency response scenarios include all non-hospital and non-facility based healthcare management and care provision functions for patients, as follows:

a) first responder care e.g. fire fighters trained in life support procedures;

b) emergency ambulance care;

c) emergency response functions pertaining to actual or potential mass casualty events e.g. motor vehicle, train and plane crashes; actual or threatened acts of terror;

d) healthcare rendered following a disaster or humanitarian crisis.

Excluded are:

a) transport and low care only functions of an ambulance service e.g. for planned inter-facility transfers, and

b) emergency care within the Emergency Department of a hospital or healthcare facility.

These are important distinctions to be made to ensure that the IT and informatics capabilities subsequently described relate to a relatively homogeneous group of business use cases, albeit these use cases may extend across a range of systems and geographies with the patient at their centre.

In some environments, there are minimal electronic systems in support of emergency response functions. During the initial stages of managing a natural or humanitarian disaster electronic communications, are unlikely to be available to healthcare workers unless response teams are pre-equipped with portable

satellite terminals and computers. Ambulance services in some countries may be forced to rely on limited coverage from public terrestrial radio networks.

In all scenarios, emergency response is the first stage in the healthcare continuum. Clinical information on the treatment provided to a patient during the emergency phase can be of value to healthcare provided at a later time in a hospital or clinic. For this reason, the information systems used during the emergency response phases need to be capable of transferring clinical records to regional and national medical record systems.

Responses to humanitarian disasters may transition to a maintenance phase during which preventative healthcare becomes a priority. Information on care of this type such as vaccination campaigns should also be accessible to all concerned regional and national health organizations.

In some environments e.g. Australia, ambulance services, and the emergency management arm of such services, have access to point of care clinical information systems that are networked, deployed on "in the field devices", and also allow warehousing of all clinically collected data for subsequent outcomes assessment and service planning. Such data allows, for instance, measurement of the effectiveness of pain relief in the emergency setting, or of the impact of particular cardiac support drugs in the event of cardiac arrest.

Other highly specialized, clinically focused systems in this domain allow the electronic transmission of key biomedical information (for example, ECG waveforms) to hospital emergency departments for early specialist advice regarding diagnosis and treatment, in advance of the patient arriving at the healthcare facility.

More logistically focused systems are also critical to effective emergency system management and the prompt delivery of healthcare. Such systems include computer aided dispatch (CAD) systems and specialized data network systems that track and disseminate data such as patient and emergency vehicle GPS coordinates.

6.2.6.2 Maturity model

6.2.6.2.1 Low

a) Low level of emergency response services.

b) Low level of preparedness of emergency response services.

c) Limited telecommunications to support emergency services, including dedicated data and voice networks (usually radio) and/or mobile phones.

d) Standards for data collection, storage, sharing and transmission of clinical information do not exist.

e) Paper based records.

f) No use of electronic systems to capture clinical information.

6.2.6.2.2 Medium

a) Some emergency response services have been planned and are available.

b) Public telecommunications services (satellite, mobile, point-to-point radio, and fixed terrestrial networks) can support emergency response services, including dedicated data and voice networks.

c) Procedures and mechanisms exist for the collection, storage, sharing, and transmission of clinical information.

d) Limited use of dedicated, isolated electronic clinical systems.

e) Clinical information can be shared with other organizations by special arrangement.

6.2.6.2.3 High

a) Emergency response services have been planned and are widely available across the healthcare system.

b) Dedicated private and public telecommunications services (satellite, mobile, point to point radio, and fixed terrestrial networks) can support emergency response services, including dedicated data and voice networks.

c) Procedures, mechanisms, and standards for the collection, storage, sharing, and transmission of clinical information are clearly defined and implemented electronically.

d) Fully electronic clinical systems are used, capable of transferring clinically relevant data and information across organizational boundaries.

e) Clinical and operational data in support of service evaluation and outcomes measurement can be archived in a data warehouse.

f) Some paper records continue to persist for specific purposes e.g. not yet scanned and electronically archived; some emergency response services slow to convert to electronic systems due to resource restrictions.

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

Standards for the management of clinical information collected during an emergency response are usually defined in the implementation of regional or national electronic health record systems. These may be based on ICD-10 (International Statistical Classification of Diseases and Related Health Problems), a medical classification list by the World Health Organization (WHO).[63] It codes for diseases, signs and symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or diseases. Other standards required to ensure the safe transmission and storage of information are discussion in other clauses of this part of ISO/TR 14639. In the humanitarian sector, best practice management guides such as SPHERE (76)[111] propose minimum health data sets to be collected, but do not directly address healthcare record maintenance.

It is important to note that in the emergency response space, the positive impact of excellent clinical systems (be they paper-based or electronic) can be completely undermined if the core logistical support systems are absent or inadequate. There is no point in humanitarian workers, vaccination teams, paramedics, or other emergency service workers e.g. fire fighters, having a highly functional clinical system that supports good clinical decision-making, the recording of care, and the automatic transmission of relevant information to downstream services, if the core logistical systems are lacking or absent, resulting in delayed response to an emergency situation, by which time it is too late to utilize their advanced tool set in the clinical context.

6.2.7 Diagnostic services

6.2.7.1 Description

Diagnostic services are procedures that are used to provide healthcare practitioners with information about the presence, severity, and cause of illness and health problems.

At the most basic level, diagnostic procedures can involve the observation of symptoms or the use of a simple microscope. At the intermediate level, diagnostic services use equipment such as X-rays or facilities to grow and observe cultures. At the most sophisticated level, diagnostic services require complex equipment such as CT scanners or MRI machines.

In resource poor settings, diagnostic tools may be used to focus on diseases that impose a high burden on the population, e.g. rapid HIV testing or TB sputum testing.

Diagnostic services include the ordering of and scheduling of diagnostic procedures, the collection and identification of samples, recording results in the supporting information systems such as laboratory information systems (LIS) or radiology information systems (RIS) and reporting these results.

6.2.7.2 Maturity model

6.2.7.2.1 Low

a) There is limited access to sophisticated diagnostic services.

b) Orders for diagnostic tests and procedures are recorded on paper.

c) Results are recorded on paper and delivered telephonically, by post or by fax.

d) There is little or no integration of orders placed with results received. It is difficult to track orders and results.

e) There is no integration of data for public health and disease specific care programs.

6.2.7.2.2 Medium

a) Patient record systems and diagnostic information systems are maintained but, although some are electronic, most still operate in silos.

b) Well-defined workflows mean that results can be reliably linked to orders. However due to lack of integration, these usually have to be manually entered or recorded.

c) Laboratory results are always recorded for disease specific programs, e.g. management of TB.

d) Some facilities may have sophisticated digital imaging systems such as PACS with a related RIS. In some instances the RIS may have an interface with local electronic medical records (EMRs).

e) There is some use of telemedicine for diagnosis, e.g. tele-dermatology.

6.2.7.2.3 High

a) Widespread implementation of EMRs, laboratory information systems and digital diagnostic modalities such as PACS/RIS coupled with a high degree of interoperability.

b) Diagnostic results are seamlessly linked with orders across the enterprise. This enables clinical decision support and evidence-based care protocols at all levels of care.

c) Diagnostic information is fully integrated with public health and disease specific care programs.

d) There is widespread use of telemedicine for diagnosis, e.g. teleradiology.

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

Standards pertinent to diagnostic services include the following:

a) DICOM;[109]

b) ISO/IEEE 11073-10406:2012;

c) ISO/TS 11073-92001:2007;

d) ISO 18812:2003.

Diagnostic services range across all levels of care and all levels of maturity.

Dependencies:

a) Policies: health technology policy, national e-health policy, telemedicine policy, privacy policy, national guidelines for treatment of specific diseases, national diagnostic protocol guidelines, and standard operating procedures (SOPs).

b) Human resource capacity.

c) Infrastructure: physical infrastructure, electricity, ICT foundational capabilities.

d) All foundational eHealth infostructure elements.

6.2.8 Pharmacy services

6.2.8.1 Description

Pharmacy services include preparation and dispensing of medical products and related consultative services that may be provided by licensed pharmacists or by other pharmacy workers. Additional services may include drug compounding, tracking patient compliance, evidence-based care protocols, management reporting, population care, and public health program integration.

6.2.8.2 Maturity model

6.2.8.2.1 Low

a) Local paper or electronic records in the pharmacy are incomplete.

b) Incomplete tracking of patient medication histories.

c) Ability to monitor patient compliance is limited to manual processes in the pharmacy.

d) Pharmacy supply chain management is a manual process with little or no integration of dispensing data.

e) Inconsistent or no integration of data for management reporting and public health reporting.

6.2.8.2.2 Medium

a) Good local information, usually electronic but may be paper.

b) Complete or reasonably complete patient medication histories may be available.

c) Some ability to track patient compliance through linkage of orders to dispensing records.

d) Possibility of interoperability where provider EMRs exist.

e) Local supply chain management may incorporate dispensing data with ability to plan and manage drug stock levels within each pharmacy.

f) Ability to aggregate data for manual or automated management reporting and public health reporting.

6.2.8.2.3 High

a) Local information is comprehensive, reliable, primarily electronic, and consistently available.

b) Patient medication histories are reliable and consistently available.

c) Patient compliance is monitored routinely with automated processes reporting discrepancies to pharmacy and/or prescriber.

d) Electronic linking of pharmacy information with orders and prescriber information systems enables clinical decision support and evidence-based care protocols.

e) Integration of dispensing data with supply chain management enabling local and regional medication stock management.

f) Comprehensive, automated management reporting, and public health reporting.

g) Broad interoperability is the norm.

h) Local pharmacy systems include advanced clinical support functions where patient specific information is integrated with information from trusted sources (e.g. drug knowledge vendors, manufacturers, and other health information systems).

i) Unique patient identifiers used in the pharmacy are shared across the health system enterprise.

j) National program for electronic pharmacy systems and pharmacy interoperability as a part of EHR programs includes standards for terminology, messaging and records systems.

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

Some pharmacy services are required at all levels of health system maturity.

Examples of applicable standards:

a) HL7 v3;[18]

b) HL7v 2.5 – an application protocol for electronic data exchange in healthcare environments;[190] [115]

c) IHE (Integrating the Healthcare Enterprise);[116]

d) National Council for Prescription Drug Programs (NCPDP) Standards (US-centric standard, however some countries have inquired regarding using NCPDP standards as a basis for e-prescribing in their countries. NCPDP should be recognized as a potential standard for eRx.).[117]

Dependencies on other blocks:

a) policies: medication-related policies; privacy policies; national e-health policy;

b) human resources capability and capacity;

c) infrastructure: drug distribution; logistical capability; ICT foundational capabilities;

d) all foundational eHealth infostructure elements.

6.2.9 Healthcare supply chain

6.2.9.1 Description

The healthcare supply chain deals with the physical flow of products, materials and the related flow of information from pharmaceutical and medical device manufacturers through wholesalers, distributors, group purchasing organizations to healthcare providers and patients. Several tasks (purchasing, production, delivery, distribution, dispensing and administration of goods) have to be optimized to improve the efficiency, traceability and patient safety along the entire supply chain.

6.2.9.1.1 Stakeholders in the healthcare supply chain

6.2.9.1.1.1 Pharmaceutical and medical device manufacturers

Manufacturers receive and store raw materials which are used for their manufacturing process. The finished products and the related information are then transferred to other healthcare stakeholders.

6.2.9.1.1.2 Wholesalers, distributors, group purchasing organizations (GPO)

This group of organizations is the link between manufacturers and healthcare providers. The main activities of such organizations are the correct receipt, storage, transport and delivery of goods and data about the goods.

6.2.9.1.1.3 Healthcare providers

Healthcare providers include hospitals, pharmacies and practitioners which receive products from wholesalers, distributors, GPOs or directly from the manufacturers. They have to manage the flow of goods and information from their receipt till the dispensation and/or administration at the point of dispense or point of care.

6.2.9.1.1.4 Subjects of care

The subject of care is at the end of the healthcare supply chain. Pharmaceuticals and other medical products are applied or provided to the patient and the related information is processed in the IT system.

6.2.9.2 Maturity model

6.2.9.2.1 Low

a) Information between the stakeholders is transferred via paper or rarely with electronic lists, e.g. spreadsheets; text documents.

b) There is no electronic correlation between the order and the delivered goods.

c) Product master data are incomplete or split over several IT systems.

d) Traceability from manufacturer to patient and vice versa is not possible with the existing IT systems.

e) IT systems of involved organizations are incompatible. No standardized interface between IT systems.

f) Health information related to a patient is stored in a paper record, seldom electronically.

6.2.9.2.2 Medium

a) Information interchange is based on IT systems using electronic lists (excel, word ...), e-mail, or fax. Electronic Data Interchange (EDI) standards are possible but rarely used.

b) Several interfaces between IT systems do exist, but not along the entire supply chain.

c) The manufacturer stores the whole product master data in his system, but there is no (easy) standardized way to share this information with other stakeholders.

d) Traceability is partially possible, e.g. between manufacturer and wholesaler.

e) Storage of product information in a patient's electronic medical record but there is no or little potential to transfer this data to other IT systems.

6.2.9.2.3 High

a) Transfer of supply chain information (product information, traceability information ...) between the involved IT systems with standardized messages such as GS1 Despatch Advice.

b) Comprehensive interoperability between the different enterprise resource planning (ERP) systems of the involved stakeholders.

c) Comprehensive interoperability between the ERP system and the hospital information system (HIS) and/or pharmacy information system.

d) Involved organizations have access to standardized product master data provided by the manufacturer.

e) End-to-end traceability of all information electronically from manufacturer to the subject of care's electronic health record.

f) Linking of supply chain information with order information enables an accurate correlation between the ordered and the received goods.

g) Integration of product information into the subject of care's electronic medical record and where such exists, the patient's integrated (shared) electronic health record e.g. which pharmaceutical was prescribed/dispensed/administered.

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

Supply chain standards support in a scalable way the move from low to high maturity levels. The GS1 System of standards[118] is the most commonly used solution, which has been endorsed by a number of countries and users, including LMIC.

The healthcare supply chain embraces all movement of goods from suppliers to end users. Usually, the healthcare supply chain is not limited to a particular jurisdiction, but regional or global. The maturity level is strongly influenced by local circumstances, which can be summarized as follows:

a) power supply, which impacts local capacities regarding cold chain storage as well as use of electronic means (including use of computers and scanners for data capture);

b) transport facilities, which impacts cold chain as well as product availability at the right place;

c) network availability and performance, which impacts information exchange possibilities, such as despatch advices, delivery report, etc, all contributing to product traceability;

d) electronic repositories and catalogues, which allow common references about product characteristics, locations and actors identifications, etc;

e) electronic capacities to store and access supply chain data, authentication data, etc.

6.2.10 Human resources in health

6.2.10.1 Description

The proper management of human resources in health, especially its allocation in places where resources are scarce, is a key factor for the health system. Most low- and middle-income (LMIC) countries have a limited number of physicians and nurses; therefore the allocation of this specialized workforce is critical. The need for specific workforce management and strategic development tools is often overlooked. The specialized nature of the health informatics component of the healthcare workforce is not well recognized. It is therefore necessary to include this component whenever an eHealth architecture is being considered.

6.2.10.2 Maturity model

6.2.10.2.1 Low

a) A national Human Resources Information System (HRIS) is not available.

b) Information on the healthcare (HC) workforce is on paper and does not show the allocation to the specific HC facility.

c) There is no national facility register. There might be some information in electronic format in isolated spreadsheets.

d) There is no comprehensive national HC workforce plan and consequently no data management and related Management Information Systems (MIS) support for management of information (including projections) relating to HC worker training or needs.

e) Capacity building requirements and strategies for HC workforce are not in place.

f) The professional nature of HI workers in the HC workforce is undefined and expectations of qualifications are unregulated.

6.2.10.2.2 Medium

a) A national Human Resources Information Systems (HRIS) is available, and supports management and tracking of all mainstream HC workers (but not necessarily the broader HC service delivery community); however, the information is not reliable since is based on aggregated data, updated at the most every quarter without consistent allocation to the specific HC facility.

b) A national facility register exists but is not integrated with the HRIS.

c) A national workforce plan exists and associated data and MIS support components are in use, but may not be comprehensively and consistently applied.

d) Capacity building programs are underway but these may be fractioned and specifically targeted.

e) Health informatics (HI) is recognized as a specific area of HC workforce need.

f) The appropriate qualifications of HI workers are identified, but HI workers tend to be distributed trough disparate sections of the health system and not seen as a unified group.

6.2.10.2.3 High

a) A national Human Resources Information Systems (HRIS) is available. The entire HC workforce is in the system including the broader HC service delivery workforce including civil servants and collaborators (i.e. HR provided by other funds such as NGOs, projects and other donations).

b) The system encompasses an integrated national HC facility database, allowing for all HC workers to have their allocation to the specific HC facility informed.

c) Online reports are available, with a list of indicators to manage HR also available.

d) A comprehensive national workforce plan is implemented and subject to regular reviews, and draws from the HRIS/facility data as well as workforce projections and health system development strategic and operational plans.

e) Capacity building programs are established and there is meaningful engagement with educational service providers to align with the national workforce plan.

f) The HI component of the HC workforce is well established as a professional and specifically qualified group which takes responsibility for major projects and strategic direction setting.

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

a) ISO 21091.

b) ISO/TS 27527.

c) ISO/TS 22220.

d) WHO country assessment tool on the uses and sources for human resources for health (HRH) data. [122]

e) WHO template on classifying health workers.[123]

f) International standard classification on occupations.[124]

6.2.11 Health finance and insurance

Health finance in this context represents fees and payments, whether in cash or other forms, from patients, other users of healthcare services, citizens or third party entities that are transferred to healthcare providers to pay for the provision of healthcare and public health. There are many variations and combinations in the cash transfer chain. The third parties can include insurance companies, state organizations and charities. Healthcare providers can be individual healthcare professionals, usually doctors, or healthcare provider organizations, such as GP practices and hospitals. Most of the money transferred finances the operating costs of healthcare providers. Most capital finance, especially for large scale projects, is from separate sources and addressed elsewhere in this report (see 6.1.6). The data at the core of healthcare finance is the invoice or an equivalent document requesting payment or reimbursement.

Health insurance is an arrangement where citizens or employers transfer some or all of the risks of healthcare charges to third parties such as health insurance companies, mutual societies and the state. Insurance can be voluntary or compulsory, depending on each country's health system. There are several types of cash flow models for health insurance. Some reimburse healthcare providers directly, some reimburse patients who have paid their healthcare invoices. Where patients are not reimbursed in full by their health insurer, patients' contributions are referred to as co-payments.

The precise arrangements for health finance and insurance can differ between countries, but most have core information requirements and regulations. Where state agencies provide lump sum grants from taxation to healthcare providers, the information requirements may be less demanding than for health insurance models, especially in regard to reliance on patient information.

6.2.11.1 Description

With an invoice, or an equivalent, at the core of health finance and insurance, the health informatics requirements are specific to the invoicing sources and the related processes. There are differences between primary care provided by healthcare professionals such as GPs, and secondary care provided by hospitals and clinics.

Invoices for hospital services need information about some of the following:

a) Patients name, address, health insurer and health insurance coverage.

b) Health insurers' codes and references that authorize the treatment.

c) Specialities and facilities that patients attended, the doctors responsible for their care and the dates and times that patients attended and were discharged, transferred or died.

d) Treatments and clinical services provided, often using codes such as the World Health Organization's (WHO) International Classification of Diseases (ICD).

e) General, approved prices for the clinical services provided and additional items, such as drugs and tests where these are not included in the general prices.

f) Price lists may rely on ICD groupings such as diagnosis related groups (DRG). Some new, expensive treatments, especially those provided by tertiary hospitals, may not be included effectively in DRGs, so have their own classifications agreed with health insurers and state agencies.

Invoices for primary care services are usually specified, standard, general payments for attending a GP practice or clinic, plus any additional items, such as drugs and medicines. Some GP practices dispense drugs and some rely on community pharmacies where patients pay either in full or in part. States' national or regional healthcare agencies or health insurers may set the prices for attending a GP or community clinic, consumables and dispensed drugs.

6.2.11.2 Maturity model

6.2.11.2.1 Low

a) Information transferred between the stakeholders is transferred using telephones for authorizations and paper documents, records and invoices.

b) No or limited electronic money transfers.

c) Data sources for invoicing and insured registers are paper documents and records.

d) Paper documents used for accounting records.

e) Standards, cross-references, dependencies, and regulations are difficult to apply and manage efficiently or effectively.

6.2.11.2.2 Medium

a) Some electronic information interchange between some healthcare providers and some health insurers for some authorization and invoicing.

b) Some use of credit and debit cards for patients' payments to healthcare providers.

c) Electronic transfer of money between some health insurers and some healthcare providers.

d) Authorized access by healthcare providers' invoicing staff to data from electronic patient administration systems with a patient master index and coding system for information needed for invoicing.

e) Some health insurers have electronic insured registers.

f) Use of electronic general ledger packages and spreadsheets for high-level reporting and debt management.

g) Some eHealth regulation, above 30 % and up to 60 % of all regulation requirements mainly from telecommunications and data protection legislation.

6.2.11.2.3 High

a) Electronic information interchange between all healthcare providers and all their main health insurers for authorization and invoicing, with some exceptions such as for patients and healthcare providers from other countries.

b) Use of credit, debit cards and mobile phones for patients' payments to healthcare providers.

c) Electronic transfer of money between all main health insurers and all main healthcare providers, with other systems for cases such as overseas links.

d) Authorized access by healthcare providers' invoicing staff to electronic patient records systems with a patient master index and clinical information needed for invoicing.

e) All health insurers have electronic insured registers.

f) Use of electronic general ledger packages and spreadsheets for all aspect of reporting and debt management.

g) High, effective, and specific eHealth regulation, above 60 % of all regulation requirements.

h) High and effective financial regulation.

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

6.2.11.3.1 Standards

a) International and national accounting and reporting standards.

b) National healthcare costing standards and methodologies.

c) ICD codes, depending on the series adopted by each country.[63]

d) Healthcare providers standing financial instructions, reimbursement and authorization requirements and procedures.

e) Health insurers' standing financial instructions, reimbursement and authorization requirements and procedures.

6.2.11.3.2 Cross-references

a) eHealth legislation and regulations for health data, especially privacy and security (confidentiality, integrity and availability)

b) Health finance and insurance legislation and regulations.

c) Healthcare providers' patients' attendance records.

d) Health insurers' registers of insured citizens.

e) Authorized payment and reimbursement records.

f) Audit reports, findings and actions needed

6.2.11.3.3 Dependencies

a) Authorized access to appropriate data from patient administration systems.

b) Authorized access to data from electronic patient records.

c) Authorized access to appropriate test request and results records.

d) Authorized access to appropriate pharmacists' drug dispensing records.

e) Requirements and benefits of the country's health finance and insurance model(s).

f) Links between invoicing services and cashiers' functions.

g) Accounting, invoicing and cash flow recording, management and reporting requirements.

h) Cash flow management and slow and bad debt management.

i) Skills capacity and capabilities.

6.2.12 Vital records collection and management

6.2.12.1 Description

Civil registration systems record information on vital events including live births, deaths, and fetal deaths, among others. These systems are established primarily for the value of the legal documents produced, as provided by law. However, information collected through the registration process also

provides useful and important statistics about vital events and is an important component of a health information system.

The United Nations defines civil registration as "the continuous, permanent, compulsory recording of the occurrence and characteristics of vital events…provided through decree or regulation in accordance with the legal requirements in each country".

Administrative records produced by a civil registration system usually provide the basis for a vital statistics system, although surveys or other sources of information also may serve as the source of vital statistics.

Records management is an important part of both civil registration and vital statistics systems: administrative records of vital events must be carefully maintained and properly stored to permit retrieval and timely production of certified copies; vital statistics data also must be carefully managed to ensure the best quality information is produced in a timely manner and made available to users.

6.2.12.2 Maturity model

6.2.12.2.1 Low

a) Paper records are completed for vital events, but only in major cities.

b) There is no national vital registration law identifying the organization responsible for the system, nor standard definitions to ensure interoperability.

c) Records are not well preserved and are not stored in a manner permitting rapid retrieval.

d) No information is extracted from existing records and published or otherwise made publicly available.

6.2.12.2.2 Medium

a) National registration law is established with one organization responsible for the system; standard definitions are prepared to ensure interoperability.

b) Vital registration on paper forms includes all urban and rural areas, with 50 % or more of births and deaths registered.

c) Paper records are bound for storage/preservation; retrieval and certificate production are still time-consuming.

d) Some vital statistics are produced but are unreliable due to incomplete coverage of events; little information is collected on cause of death.

6.2.12.2.3 High

a) Electronic registration system captures 90 % or more of births and deaths.

b) Central database created for storage and rapid retrieval of records.

c) Good-quality vital statistics are produced, including cause of death information.

d) Vital statistics data including small area data is made available to selected users, including government agencies; detailed annual vital statistics reports are produced on a timely basis.

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

The move to electronic records for registration of vital events will improve the quality (due to built-in edit checks) and timeliness of vital event registration. Equally important in terms of interoperability will be standard definitions and registration procedures. This is particularly important in federal

registration systems, in which individual states or provinces operate their own registration systems and report results to a national authority. Federal systems call for national coordination, including the development of model vital registration laws, registration forms, and definitions for use by the individual components of the federal system.

The most important data standard for vital statistics data is the most recent ICD revision, used for coding causes of death.[63]

6.2.13 Environmental monitoring

6.2.13.1 Description

This assessment of national capacities and building of environmental health tracking systems examines mature, already existing systems for tracking environmental hazards, environmental health, and their potential integration into the eHealth architecture.

For the purpose of environmental attribution to human health, "Environment" is defined by the World Health Organization (WHO) as "all the physical, chemical and biological factors external to the human host, and all related behaviours, but excluding those natural environments that cannot reasonably be modified".[85]

The US Center for Disease Control (CDC) defines an Environmental Hazard as a substance or situation in the environment that might adversely affect human health.[86] In 2000, WHO released a categorization of environmental hazards[87] that provides guidance to minimize health risks and includes development of a framework for technical capabilities for tracking systems and examples of applicable standards (Table 1).

NOTE Table 1 was reproduced from Reference [87], with kind permission of the World Health Organization (WHO).

Table 1 — Classification of environmental hazards

Category	Examples of hazards	Health risks
Natural hazards	Volcanic activity	Includes effects of direct injury by volcanic debris, lava, etc., inhalation of gas/dust and indirect effects of famine etc.
	Avalanches	Primarily direct injuries from avalanches; includes rock and snow avalanches
	Earthquakes	Includes direct injury from effects of earth tremors (e.g. building collapse), and indirect effects (e.g. of flooding, tsunamis, epidemics and famine)
	Flooding/storms	Includes direct effects of drowning and injury by floods/storms, and infirect effects of water contamination, famine and epidemics
	Drought	Primarily health effects due to lack of potable water and famine
	Hurricanes/wind	Primarily direct effects of injurt (e.g. by collapsing buildings), but may also include longer-term effects of famine and contamination/loss of water supplies
	Lightning strikes	Direct injury
	Soil erosion	Primarily famine and poor diet due to effects on desertification food supply
	UV radiation	Skin cancer
Atmospheric hazards	Outdoor air pollution	Wide range of respiratory, pulmonary and cardio-vascular illnesses and cancers
Water-related hazards	Surface water	Primarily diarrhoeal and gastro-intestinal diseases, but may also include chemical poisoning
	Drinking water contamination	Gastro-intestinal and urinary diseases; rarely checmical poisoning
Food-borne hazards	Biological contamination	Wide range of diseases of the digestive system
	Chemical contamination	Diseases of the digestive and urinary systems; rarely chemical poisoning
Vector-borne hazards	Water-related vectors Animal-related vectors	Infectious and parasitic diseases Infectious and parasitic diseases

Table 1 *(continued)*

Category	Examples of hazards	Health risks
Domestic hazards	Indoor air pollution	Wide range of respiratory, pulmonary, and cardi-vascular illnesses and cancers
	Domestic accidents Suicide	Physical unjury and poisonings Suicide through use of household chemicals, drugs, instruments
	Sanitation	Infectious and parasitic diseases; diseases of the digestive and urinary system
	Waste handling	Infectious and parasitic diseases; diseases of the digestive and urinary system
Occupational hazzards	Industrial pollutants	Wide range of respiratory, pulmonary, and cardi-vascular illnsesses and cancers; chemical poisoning
	Occupational accidents	Acute physical injury (e.g. by fire, explosions, accidents with equipment) and chronic injuries (e.g. reperirive strain injury, back-pain)
Infrastructural hazards	Traffic accidents	Physical injury (to vehicle occupants and pedestrians/cyclists)
	Industrial accidents	Primarily acute physical injury (e.g. by fire, explosions), chemical poisoning and respiratory effects
	Contaminated land	Mainly diseases of digestive and urninary system
Social conflicts	War	Almost all forms of health effect
	Domestic violence	Physical injury, stress-related illnesses

Also, the same WHO publication[87] divides environmental hazards into categories, such as acute and chronic. Acute environmental hazards may appear episodically and result in more-or-less immediate health effects. Examples of these hazards are epidemic spread of infectious diseases, and short-duration, high intensity pollution events. Chronic environmental hazards affect populations repeatedly or continuously, sometimes as a low-level exposure of individuals to the hazard.

Environmental monitoring is defined as a measurement of a material in the environment at regular time intervals.[86] Examples of environmental monitoring are collecting an environmental sample, such as stream water, preparation of the sample in the laboratory, and analysis of the prepared sample. These examples demonstrate that environmental monitoring tasks may not be necessarily organized and managed from a perspective of health monitoring. As a result, in analysing an architectural design of eHealth systems, it should be expected that environmental monitoring systems may or may not be integrated with health monitoring systems.

Environmental health is the branch of public health that is concerned with understanding how the environment affects human health.[86] In 1999, WHO proposed a framework and methodology for establishing environmental health indicators,[88] which became a guiding principle for development of population-specific health indicators (e.g. children's environmental indicators[89]) and disease-specific health indicators (e.g. environment-related cancer[90]).

There is an assumption that a system architecture that supports environmental health should provide integration of both, environmental and health monitoring. As a result, the Electronic Environmental Health Tracking System is an electronic enterprise system that integrates ongoing monitoring of environmental hazards, health risk factors, and health indicators. Guiding principles for high-level

design of such a system were described within the European project, Integrated Environmental Health Impact Assessment (IEHIA) System[91] as shown in Figure 9.

NOTE Figure 9 was reproduced from Reference [91], with kind permission of the Integrated Assessment Toolbox Consortium.

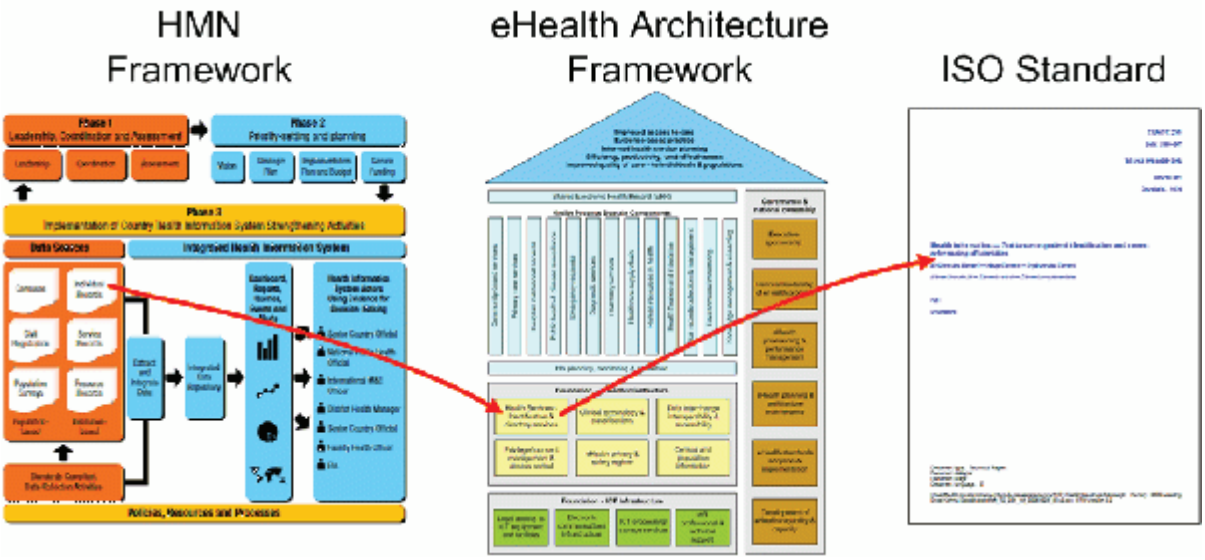

Figure 9 — Guiding principles for design of an integrated environmental impact assessment system

One example of a practical national approach that was modelled after the integrated environmental health system and managed by CDC is the National Environmental Public Health Tracking Network.[92] This Network was designed on premises of integrating health, exposure, and hazard information and data from a variety of national, state, and local sources.

6.2.13.2 Maturity model

6.2.13.2.1 Low

a) Status of electronic environmental monitoring

   1) Only fragments of a national electronic environmental monitoring system exist (e.g. only a few environmental hazards systematically tested, testing is established only in a few national regions).

b) Status of assessment of environmental health indicators

   1) Only methods for assessment of some health risk indicators are adopted at a national level (e.g. only infectious and parasitic diseases mortality and morbidly is collected on ongoing basis).

   2) There is no framework for ongoing assessment of environmental health risks for specific populations (e.g. children) or diseases (e.g. cancer, infectious and parasitic diseases).

c) Status of environmental health tracking

   1) Electronic environmental health tracking is deployed only for cases of acute environmental risk situations (e.g. during a cholera epidemic).

   2) There are no national electronic systems that integrate environmental monitoring, assessment of risk factors, and health indicators.

6.2.13.2.2 Medium

a) Status of electronic environmental monitoring

   1) There are well-established regional environmental monitoring practices (a broad spectrum of environmental hazards is tested on an ongoing basis).

   2) National electronic system(s) for collection and analysis of environmental test results is partially established (e.g. some types of test results are shared through paper-based forms; there is no national ongoing electronic gathering of environmental status).

b) Status of assessment of environmental health indicators

   1) A national list of environmental health indicators is established.

   2) An ongoing assessment of environmental health indicators exists partially for both acute and chronic environmental health risk factors (e.g. there is no electronic collection of children's morbidity that is associated with a specific environmental hazard).

c) Status of environmental health tracking

   1) Electronic environmental health tracking system is deployed for acute and some chronic environmental health risk factors.

   2) There is a national electronic system(s) that partially integrates environmental monitoring, assessment of risk factors, and health indicators (e.g. there is a national system for collection of paper-based environmental test results; however, there is a web portal that provides mapping of environmental hazards and health status).

6.2.13.2.3 High

a) Status of electronic environmental monitoring

   1) There is a well-established national electronic environmental monitoring system(s) that operates on best international practices, including an architectural system design, a spectrum of monitoring environmental hazards, and test methods.

b) Status of assessment of environmental health indicators

   1) There is a well-established national electronic system(s) for the collection and assessment of environmental health status that operates on best international practices, including an architectural system design, for different population, and disease categories.

c) Status of environmental health tracking

   1) There is a well-established national electronic integrated system(s) for the collection, analysis, and gathering of results of environmental health tracking that operates on premises of the best international practices, including an architectural system design, capabilities for utilization on population and patient levels, and supporting tasks of clinical decision support and establishing national health policies and practices.

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

6.2.13.3.1 Standards

a) Standards for laboratory testing for environmental hazards.

b) National environmental health indicators.

c) Semantic and structural interoperability of environmental health tracking information.[62][63][65]

6.2.13.3.2 Dependencies

Further progress on development and implementation of robust environmental health tracking systems depends on existing national policies (e.g. in areas of health technology, eHealth, privacy, and security), and national guidelines for assessment and monitoring of environmental health.

6.2.14 Knowledge management and eLearning

6.2.14.1 Description

Many difficulties in health informatics implementations can be linked to lack of attention to ensuring that the different parties involved are skilled and able to undertake the required activities for implementation.

Knowledge management refers to the access to relevant knowledge that can be well understood taking into account that persons involved can have different expertise and experience. Furthermore, knowledge management includes learning and the opportunity to critique that knowledge and how it is applied.

Knowledge resources need to be maintained and updated. The Internet offers ever-expanding opportunities to access updated and timely knowledge, including eLearning programs and to enable collaborative work and user groups. However, the Internet may not make it clear whether those materials, programs, and knowledge are up-to-date. Mobile-based communications might complement access to knowledge for a particular context and support communications within project management.

6.2.14.2 Maturity model

6.2.14.2.1 Low

a) Mainly paper; no electronic information.

b) Need to ensure that a given project plan is clear to project management at all levels and that implementers of the plan have been informed and have the opportunity and are encouraged to ask questions to clarify any areas of knowledge deficit.

c) Need to ensure regular and adequate reporting of progress in project implementation also identify summary data that is useful in follow-up of project functioning and impact.

6.2.14.2.2 Medium

a) Mixed environment – paper and electronic communications, either by design or in transition.

b) As well as meeting the needs identified in the low maturity model, use electronic communication to inform concisely on the progress of a given project, whether predefined milestones are being achieved or not and also regularly report pre-specified data for follow-up of project impact.

c) Signal issues that involve follow-up using manual methods of management (paper) and electronic communications to resolve issues.

d) Training and education can be delivered in part electronically.

6.2.14.2.3 High

a) Reliable electronic communications exist to support project management, communications, education, and training.

b) As well as meeting the needs defined in the low- and medium-level maturity models, Internet tools are in use for all components of training, project management, and follow-up.

c) Coherent communication structures are enabled so that problems can be identified early and resolved.

d) Different e-learning opportunities are available, as well as e-continuing education exploiting existing including mobile technology and in relation to universities, colleges, and other educational providers.

e) Competency assessments are enabled and tailored to different needs, based on a set of standard competencies that cover particular applications and roles.

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

ISO/TR 13054.

6.2.15 Health system planning, monitoring, and evaluation

6.2.15.1 Description

6.2.15.1.1 Introduction

Health system planning is the systematic, orderly process of defining health problems, identifying unmet needs and surveying the resources to meet them, establishing priority goals that are realistic and feasible, and projecting administrative action. Health system planning is concerned not only with the adequacy, efficacy, efficiency, and effectiveness of health services, but also with those factors of ecology and of social and individual behaviour that affect the health of the individual and the community.

In order to discuss health system planning, it is important to also consider the meaning of the term "health system". In its most generic form, a health system can be defined as set forth in the WHO Health Systems Strengthening Glossary[100] as the combination of components, activities, processes, and policies intended to promote, restore, and maintain health. This includes the people, institutions, and resources organized to work together, in accordance with established dictums, to improve the health of the population they serve, while responding to people's needs and expectations and protecting them against the effects of ill-health through a variety of coordinated activities and actions.

The various aspects of health system planning can be organized into four core functions:

a) providing services;

b) generating the human and physical resources that make service delivery possible;

c) raising and pooling the financial resources needed and used to pay for healthcare;

d) providing stewardship – setting and enforcing the rules and providing strategic direction for all of the different entities involved.

These core functions are performed in the pursuit of three goals: health, responsiveness, and fair financing.

6.2.15.1.2 Components of a well-functioning health system

A well-functioning health system responds in a balanced way to a community's needs and expectations by

a) improving the health status of individuals, families, and communities,

b) defending the population against what threatens its health,

c) protecting people against the financial consequences of ill-health,

d) providing equitable access to people-centred care, and

e) making it possible for people to participate in decisions affecting their health and their health system.

In order to perform well, country health systems must address the following key areas:

a) Leadership and governance: Ensuring that health authorities take responsibility for steering the entire health sector (not merely public sector service delivery) and dealing with future challenges (including unanticipated events or disasters), as well as with current problems.

b) Human resources for health: The health workforce is central to achieving health. A well-performing workforce is one that is responsive to the needs and expectations of people, is fair, and is efficient in achieving the best outcomes possible given available resources and circumstances. Countries are at different stages of development of their health workforce but common concerns include improving recruitment, education, training and distribution, enhancing productivity and performance, and improving retention.

c) Service delivery: Health systems are only as effective as the services they provide. These critically depend on networks of close-to-client primary care with the back-up of specialized and hospital services responsible for defined populations; provision of a package of benefits with a comprehensive and integrated range of clinical and public health interventions, that respond to the full range of health problems of their populations, including those targeted by the Millennium Development Goals; standards, norms, and guidance to ensure access and essential dimensions of quality: safety, effectiveness, integration, continuity, and people-centeredness; mechanisms to hold providers accountable for access and quality and to ensure consumer voice.

d) Essential medical products and technologies: Universal access to healthcare is heavily dependent on access to affordable essential medicines, vaccines, diagnostics, and health technologies of assured quality, which are used in a scientifically sound and cost-effective way. Medical products are the second largest component of most health budgets (after salaries) and the largest component of private health expenditures in low- and middle-income countries.

e) Health financing: Health financing can be a key policy instrument to improve health and reduce health inequalities if its primary objective is to facilitate universal coverage by removing financial barriers to access and preventing financial hardship and catastrophic expenditure.

f) Health information systems: Good governance is only possible with good information - on health challenges, on the broader environment in which the health system operates, and on the performance of the health system.

6.2.15.1.3 Types of health planning

Reference[126] describes three different types of planning in the healthcare system.

a) Dispersed health planning: Many decisions made by all individuals and organizations in the healthcare system as they attempt to provide, finance, and use healthcare services.

b) Focused health planning: The voluntary association of persons and organizations in an attempt to solve problems which they have in common or to attain goals which they cannot achieve on an individual basis.

c) Centralized health planning: The planned use of power controlled by an individual or organization to force other individuals and organizations to use their own resources in accordance with its plans.

Since then, many different new terms, definitions, approaches, scope, and areas of attention have been identified and defined. They can be structured into the following categorization:

Table 2 — Types of planning in the healthcare system

	Strategic planning	Operational planning
Health system planning	✓	✓
Health services planning	✓	✓
Health resource planning	✓	✓
Health goals planning	✓	✓
Population health planning	✓	✓

Health system or systems planning is the most complex type of health planning. It requires a clear and politically supported vision for the delivery model and the support of service providers to make it happen.

There are two essential phases of health systems planning:

a) the design and system development phase;

b) the implementation of the system management and operations components.

Health system planning has the most potential for payoff in improved health because it can include both health services and population health within its strategic directions.

Health services planning relates to the analysis, structure, and organization of health services. It can encompass multiple health services across an environment (a country, a community) or a single service or sector, for example, mental health service delivery. This type of planning can be undertaken by a government or devolved to providers.

Health resource planning encompasses the evaluation of all physical, technical, human, and environmental resources needed to allow a health system to satisfy the needs of the individuals and communities it serves.

Health goals planning is a critical strategy for overall national, regional, local, or community health direction over time. Many countries undertake national health goals planning in order to set major milestones to be achieved in various areas by the country's healthcare system. A good example of such a planning approach is the Healthy People 2000, 2010, and, more recently, 2020 efforts[127] established by the US Department of Health and Human Services, which provides science-based, 10-year national objectives for improving the health of all Americans.

Population health planning focuses on macro issues identification and related prioritized and targeted strategies and interventions. It is usually performed by national, regional, or local public health agencies and encompasses efforts to create healthy environments (such as healthy schools, workplaces, community centers, etc.) based on an analysis of determinants of health in a community.

Strategic planning involves framework setting and defining the principles of the health system and its general thrust and is most frequently undertaken by authorities at the highest level of health-system governance or the respective regional or local tier in decentralized systems. The degree of involvement of lower-level administrations in strategic planning is largely determined by their levels of autonomy and their decision-making powers.

Operational planning refers to the translation of the strategic plan into activities, which might cover the whole range of operations involved in healthcare provision, including the allocation of budgets and resources, the organization of services, and the provision of staff, facilities, and equipment. This function is most often carried out by regional authorities but can also involve local authorities. In some countries, regional/local planning is directly informed by national health plans, and regional authorities are required to integrate national directives with regional health plans ("vertical integration").

6.2.15.1.4 Scope and levels of health system planning

Many countries around the world are experimenting with major transformative changes in their healthcare systems. Care delivery reforms, payment and cost reforms, insurance and benefit reforms, health information technology transformation, and the explosion of 'big' health data and data analytics are reconfiguring the way health and healthcare is thought about, perceived, approached, demanded, used, planned, monitored, and evaluated.

In this context of change, health system planning is gaining renewed interest and attention globally. In most countries, health system planning takes place at national, regional, or local levels, reflecting the various tiers of government, but the distinction between these levels is not always clear cut. For example, regional and local authorities may oversee entities that differ greatly in terms of population size, legal and political mandates, and organizational structures.

The scope of health system planning also varies, depending on the purpose and goals of the planning exercise and the entity or organization conducting the planning. Still, there are at least four common foundational components that cut across most planning efforts:

a) community health assessment (the community and individual needs);

b) health capacity and resource planning (the resources of health and healthcare);

c) financial planning (the economic dimension);

d) health system monitoring and evaluation.

The outcome of an effective health planning process should be an actionable link between needs and resources. The health planning process itself can be a deliverable. A good planning process reflects necessary perspectives and engages key stakeholders in the development of strategies. Through that process, some of the initial marketing of the changes required will be accomplished.

6.2.15.1.4.1 Community health assessment

A community health assessment is a process that uses quantitative and qualitative methods to systematically collect and analyse data to understand health within a specific community. An ideal assessment includes information on risk factors, quality of life, mortality, morbidity, community assets, forces of change, social determinants of health and health inequity, and information on how well the public health system provides essential services. Community health assessment data inform community decision-making, the prioritization of health problems, and the development, implementation, and evaluation of community health improvement plans.

6.2.15.1.4.2 Health capacity and resource planning

Capacity refers to the ability to make a decision about a particular issue at the time the decision needs to be made. Health capacity and resource planning is a key component of the overall health system planning and encompasses evaluation of the capacity of the health resources available in a community to meet the individual/community needs.

6.2.15.1.4.3 Financial planning

Financial planning is aimed at determining the cost associated with organizing and delivering health and healthcare services in a community and the sources of revenue to cover those costs.

6.2.15.1.4.4 Health system monitoring and evaluation

A critical step in ensuring a health system is continuously performing effectively and efficiently in fulfilling its mission, purpose, and objectives is to develop and implement a comprehensive monitoring and evaluation (M & E) program.

Monitoring can be defined as the routine tracking and reporting of priority information about a program or intervention and its intended outputs and outcomes. Evaluation is the rigorous, science-based analysis of information about program activities, characteristics, outcomes, and impacts that determines the merit or worth of a specific program or intervention.

Monitoring and evaluation is performed at various levels (national, regional, local) and by various entities or organizations (government, NGOs, non-profit entities, private organizations). The focus of M & E efforts can vary from large health system programs to individual, specific interventions or initiatives. There are also many different dimensions of a program or intervention that are monitored or evaluated. Lastly, there are multiple methods and approaches to achieving monitoring and evaluation.

To guide and assist countries organize and strengthen their programs for monitoring and evaluating national health plans and strategies, the World Health Organization and the International Health Partnership (IHP+)[128] developed a programmatic platform that outlines the key attributes and characteristics of a sound monitoring and evaluation program and review of health sector progress and performance, as the basis for information accountability.

Sound M & E systems are built on inclusive policy dialogue and regular evidence-based assessments that inform progress and performance reviews and that result in remedial action and mutual accountability among all stakeholders. The ongoing results of M & E should be the basis for periodic updating, modification, adjustment, remediation, and correction of existing programs and interventions, as well as resource allocation, policy-making, and overall effective management of programs.

The following table, extracted from the WHO/IHP+ report, summarizes the key attributes and characteristics of a monitoring and evaluation program for review of national health strategies.

NOTE Table 3 was reproduced from Reference [128], with kind permission of the World Health Organization (WHO).

Table 3 — Approach to monitoring, evaluation, and review of national health strategies

Table 1. A monitoring, evaluation and review platform for national health strategies

KEY ATTRIBUTES	CHARACTERISTICS
I. The national health strategy as the basis for information and accountability	
1. The national health strategy specifies a sound monitoring, evaluation and review component.	1.1 Monitoring, evaluation and review addresses the goals and objectives of the national health strategy and is based on a sound situation analysis.
	1.2 Disease- and programme-specific monitoring, evaluation and review are aligned with that of the national health strategy.
	1.3 The monitoring, evaluation and review plan is costed and funded with full partner alignment and support.
	1.4 Monitoring, evaluation and review is regularly assessed.
II. Institutional capacity	
2. Roles, responsibilities and coordination mechanisms for monitoring, evaluation and review are clearly defined.	2.1 There is an effective country-led coordination mechanism for monitoring, evaluation and review.
	2.2 Key institutions and stakeholders have clear roles and responsibilities.
3. Capacity strengthening in monitoring, evaluation and review is addressed.	3.1 Capacity strengthening requirements are identified and addressed.
III. Monitoring and evaluation	
4. There is a comprehensive framework that guides the monitoring, evaluation and review work, including core indicators and targets.	4.1 There is a balanced and parsimonious set of core indicators with well-defined baselines and targets.
	4.2 Disease- and programme-specific indicators are aligned.
	4.3 Integrated with the national health information system strategy.
5. The monitoring, evaluation and review component specifies data sources, identifies and addresses data gaps, and defines responsibilities for data collection and information flow.	5.1 Data sources are specified in a comprehensive and integrated manner.
	5.2 Critical data gaps are identified and addressed.
	5.3 Responsibilities for data collection and management are specified.
6. Data analysis and synthesis work is specified, and data quality issues are anticipated and addressed.	6.1 Data analysis and synthesis work is specified.
	6.2 There are regular assessments of progress and performance, including systematic analyses of contextual and qualitative information.
	6.3 Specific processes for data quality assessment and adjustment are in place and are transparent.
7. Data dissemination and communication are effective and regular.	7.1 Analytical outputs as the basis for national and global reporting are defined and produced.
	7.2 Appropriate decision-support tools and approaches are used.
	7.3 Data, methods and analyses are publicly available.
8. Prospective evaluation is planned and implemented.	8.1 Prospective evaluation is planned and linked to monitoring, evaluation and review of national health strategies.
IV. Country mechanisms for review and action	
9. There is a system of joint periodic progress and performance reviews.	9.1 A regular and transparent system of reviews with broad involvement of key stakeholders is in place.
	9.2 There are systematic linkages between health sector reviews, disease- and programme-specific reviews, and global reporting.
10. There are processes by which related corrective measures can be taken and translated into action.	10.1 Results from reviews are incorporated into decision-making, including resource allocation and financial disbursement.
	10.2 Multi-stakeholder mechanisms are specified to provide routine feedback to subnational stakeholders.

6.2.15.2 Maturity model

6.2.15.2.1 Low

a) No national, regional, or local planning activities in the areas of health goals, systems, services, resources, or population health.

b) No M & E plans developed.

c) Some system performance indicators being collected.

d) No electronic reporting or use of national or international standards for data collection.

e) Limited resources for M & E data analysis.

6.2.15.2.2 Medium

a) Some national, regional, or local planning efforts being implemented, mainly in the areas of services, resources, or population health.

b) Limited M & E plans developed and being implemented.

c) A basic set of system performance indicators is being collected.

d) Some electronic data collection and reporting being implemented using limited national or international standards.

e) Health system planning governance and leadership in place.

f) Basic resources available for M & E data analysis.

6.2.15.2.3 High

a) National, regional, and local planning activities are being implemented in most or all areas of health goals, systems, services, resources, or population health.

b) Defined national health goals exist.

c) M & E plans are in place and periodically revisited.

d) A comprehensive set of system performance indicators is being collected.

e) Electronic data collection and reporting is the preferred method, with use of harmonized national or international electronic standards.

f) Indicators are sufficiently granular to permit M & E at various levels (national, regional, local) and for multiple initiatives and purposes.

g) Active health system planning governance and leadership operates and directs activities.

h) Advanced, trained resources available for M & E data analysis.

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

There is no single set of national or international health system planning standards available. Many organizations have developed templates, guides, resources, and methodologies to perform health system planning.[129][130] Generally accepted parameters and steps for classifying and conducting health system planning exist, and some of them have been referenced above.

Similarly, monitoring and evaluation standards vary and are usually specific to the focus of the M & E effort.

National and international guidelines and resources exist, and as the evaluation becomes more granular (i.e. a specific program such as AIDS), national and international standards for program evaluation indicators exist and are available for use.

CIHI (Canada) published a new Health System Performance Measurement Framework in mid-2013, which is depicted in Figure 10. The proposed health system performance measurement framework is composed of four interrelated quadrants: Health System Outcomes, Social Determinants of Health, Health System Outputs, and Health System Inputs and Characteristics. Each quadrant is composed of different performance dimensions linked through expected causal relationships. These four quadrants sit within a demographic, political, economic and cultural context. The contextual environment influences the relationships among the dimensions of each quadrant and also the way they interact with each other.

NOTE Figure 10 was reproduced from Reference [193], with kind permission of the Canadian Institute for Health Information (CIHI).

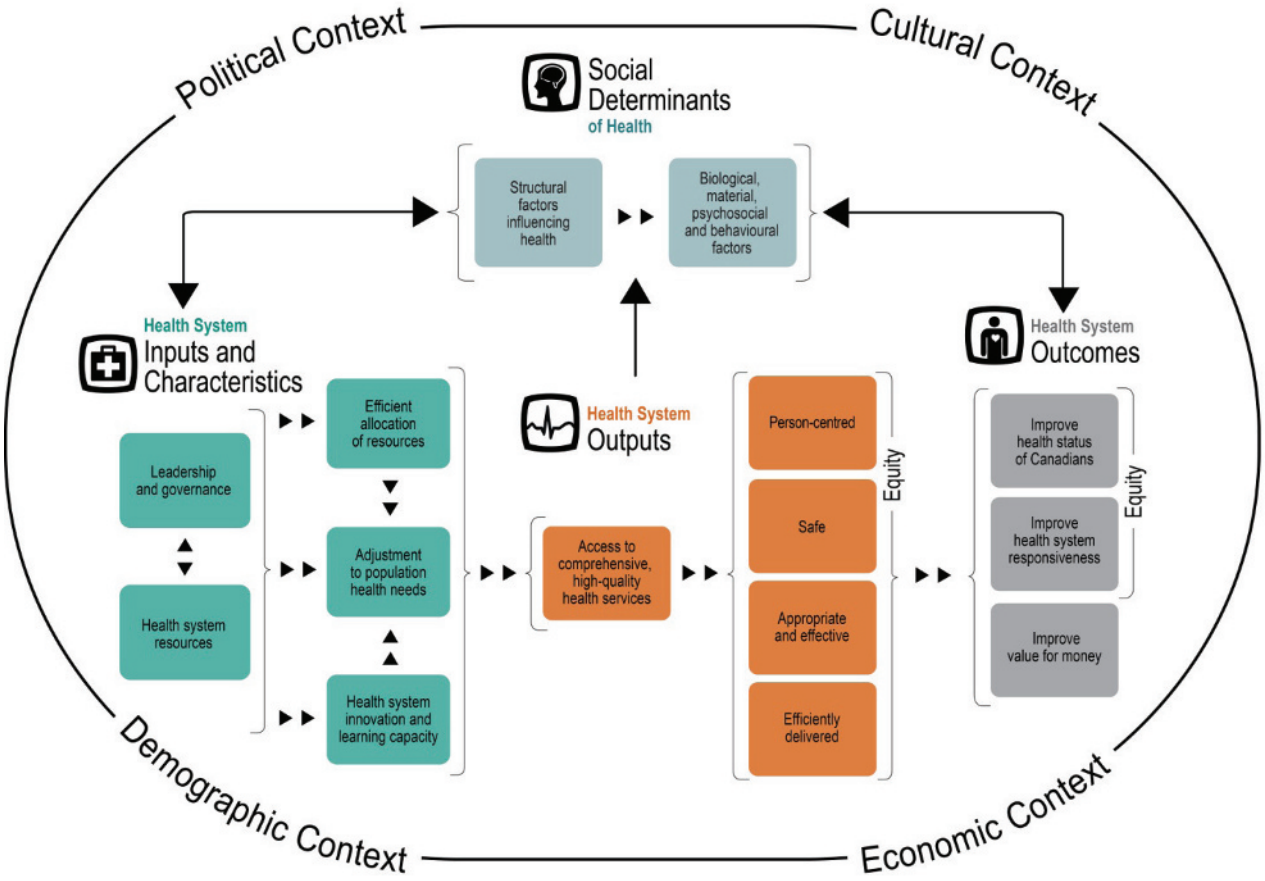

Figure 10 — Health system performance measurement framework 2013

6.3 Foundation Components — eHealth infostructure

6.3.1 Description

The eHealth infostructure includes those foundation components that exist at the national level or in some instances, the state/province level or both, acting as "cornerstone" resources that provide interoperability, both functional and semantic, plus related consent, privacy, and security controls for the transmission and broad sharing of data from various point-of-service systems, including repositories of domain data. These components also provide data processing and analytic capability supporting the secondary use of aggregate data. Infostructure resources/solutions include EHR repositories, registries, data interchange interoperability and accessibility, consent, access control, and workflow management within this context, as well as privacy, security and patient safety, 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. The proper utilization of standards will define how robust and scalable the final application or the eHealth platform will be.

The remainder of 6.3 discusses details of each of the identified infostructure components and their related maturity models.

6.3.2 EHR and health information repositories

6.3.2.1 Description

EHR and health information repositories are used to store health information created by and for health professionals during their daily activities of providing care in the various healthcare institutions. Health data is about the patient, and too often, this data resides solely in the healthcare provider's system. The goal is to make this health data available, on a territorial basis, to all other clinical stakeholders who require updated information for treatment purposes. Thus, new generation repositories have been emerging to support the healthcare enterprises and systems in the storage, retrieval, management, and interchange with other institutions and systems capturing and holding detailed healthcare information. It is important to highlight that there are privacy and security requirements (laws and/or regulations) in each country that require compliance and which support access to viewing and using a subject of care's healthcare data based on his/her consent.

To fulfil their scope of making clinical data available to all clinical operators in the territory, it is necessary that health repositories be able to interoperate with each other through well-defined interfaces. Interoperability is achievable if the different institutions adopt common component-based architectural paradigms, fixing the informational and functional characteristics. This approach should be promoted (enforced) by national healthcare and eHealth authorities. In other words, an EHR repository should be seen at the highest level (regional, national) as a unique infostructure component, able to interact with similar components in other countries.

In terms of data, the classes of information managed by the repositories must include the description and the classification of the various types of EHR items, as well as the actual value sets for such data for individual subjects of care. The classification criteria for all clinical data managed may conform and refer to taxonomies and coding criteria defined for individual specialities, according to examples of applicable standards and national/local regulations.

EHR repositories are operated by healthcare institutions where the clinical data is identified, observed, and/or generated. This contrast with Personal Health Records (PHRs) where the patient manages the record, available online, containing their clinical history. While PHRs have not been as successful as initially expected in terms of consumer uptake and adoption, there are a few important features which make the data in PHRS relevant to clinical data repositories. The first is that these records are managed by the subject of care, not their providers. The patient is also involved in the process of generating and/or creating the clinical data in the record. For example, a PHR might include patient-reported outcome data, laboratory results, and data from medical devices or data collected passively from a tablet or smart phone. This data should be considered for inclusion in EHR repositories.

6.3.2.2 Maturity model

6.3.2.2.1 Low

a) No national policy for interoperable sharing of health data through an EHR repository has been defined.

b) No standardized informational or functional paradigm is applied at the national level.

c) Clinical data repositories do not exist or if available on a local, limited basis, do not interoperate with each other and hold only a silo of locally generated data, mainly clinical documents e.g. discharge summaries, other types of clinical reports, fed in by a single or a few institutions. This data can be

informative about the health condition of a subject of care, but cannot be integrated into the records at other enterprises or institutions, in terms of elementary data elements.

6.3.2.2.2 Medium

a) A national policy for interoperable sharing of health data contained in an EHR repository has been defined.

b) Overall organization of the health data and the properties of each piece of information contained in the EHR repository must conform to applicable ICT standards, e.g. ISO 13606, HL7 Clinical Document Architecture (CDA), ISO 12967, etc.

c) The description of the various types of data in the EHR repository includes both the syntactic description (types of data, domains of values, critical values, etc.) and the semantic description (information that allows machines to understand the meaning of the data, e.g. technologies and methods that convey the meaning of the information such as data interchange formats[177] and notations, concepts, terms, and relationships).

d) Clinical data repositories conformant to these criteria are implemented to a certain extent in healthcare enterprises and institutions where the clinical data is collected.

e) Interfaces are either already available or being developed to network them to other EHR repositories.

6.3.2.2.3 High

a) EHR repositories are interoperable according to the enforced national policy, itself compliant to applicable international standards.

b) All clinical data managed in the repository is available for integration into recent records of other institutions, allowing, for example, the charting of clinical values over time and over different encounters and therapies.

c) EHR repositories do not solely contain data generated within institutions, but are integrated with data generated and/or collected (observations, considerations, adverse reactions, etc.) by subjects of care, their caregivers, medical devices, and others collaborating in the subject of care's lifetime treatment.

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

This service is a foundational component for almost all health process domain components but cannot exist at any level without a patient (or person) identification registry component.[41][120][121] Low-maturity systems cannot guarantee complete or up-to-date information regarding subjects of care, making EHR repositories difficult to accept as fundamental for accessing comprehensive health data.

6.3.3 Identification registries and directories

6.3.3.1 Description

Identification registries and services facilitate and support the identification of persons, facilities, procedures, and products. Each person, facility, procedure, or product is assigned an identifier – a string of characters and numbers - for unique identification within the jurisdiction where healthcare services are being provided. These identifiers are used to document who has done what to whom at which facility and by what means. With directory services, additional (demographic) information on persons and facilities can be documented and retrieved, mainly for obtaining access to the person or facility (addresses, phone numbers, email, etc.). More advanced directory services will include geographic information on where the person is living (and working) or on the location of the facility. Additional information on procedures and products are normally found in knowledge management environments (see 6.2.14).

Identification services for persons can exist for patients and for healthcare providers. Identification services for facilities can be for healthcare facilities and/or for other facilities that are relevant for health and healthcare.

Identification and directory services are used for a large variety of health process domain components and form one of the core eHealth Infostructure components.

6.3.3.2 Maturity model

6.3.3.2.1 Low

a) Patient identification services are limited to registering patients by name, on paper, with collection of rudimentary information captured for the client's health record. This may lead to mix-ups or irretrievable records due to spelling errors and duplicate or multiple records with the same names.

b) Providers may be registered by name, on paper along with other basic information.

c) There is no use of identification services for products and procedures.

6.3.3.2.2 Medium

a) Local patient identification services are in place, but services are implemented that allow linkage of patient identifiers from different organizations. Such patient identification service allows linking of patient records, but there is still the risk of mixing patients with similar names and initials.

b) Registries of healthcare providers may exist in medium capacity implementations.

c) There are some directory services implemented for parts of the health system but not for all components (e.g. only for healthcare providers but not for healthcare facilities).

d) Within facilities, identification services may be used to document procedures and identification services may exist for certain products that are used in healthcare (e.g. drugs).

6.3.3.2.3 High

a) There is universal use of unique identifiers across the whole health system for persons, facilities, procedures, and products, as well as directory services for all components of the health system.

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

This service is a foundational component for almost all health process domain components. In low-maturity level implementations, the quality of the service may be less than optimal and certain services may even not be possible because there is no way to make sure that every person is accounted for in the proper way.[41][120][121]

Medium maturity level implementations will implement most of the services at a satisfactory level of quality. High maturity level implementations will allow for broad integration of the health process domain components.

6.3.4 Clinical terminology and classifications

6.3.4.1 Description

Clinical terminology and classifications are both required to deliver eHealth. They form a significant part of the clinical ontology domain but as fundamentals can be addressed individually. It is assumed that the need for both (terminology and classifications) is understood and also that Natural Language Processing (deriving accurate meaning from free text, speech or handwriting) at this juncture and at current levels of sophistication and capability is generally not suitable to meet primary and secondary

uses for clinical data. (Note that there is software available which in context-specific EHRs is proving highly accurate and better than drop down lists.)

A clinical terminology is a "structured, human and machine-readable representation of concepts used in the clinical context". The concepts can represent a subject of care but do not need to. This includes the relationship of the terminology to the specifications for organizing, communicating and interpreting such a set of concepts.

The use of the term terminology in healthcare implies a terminology that is designed for use in computer systems. The term vocabulary or health or medical language is used to indicate the broader idea of linguistic representation without the specification of computability.

A terminology should cover enough areas of clinical information (diseases, findings, procedures, microorganisms, pharmaceuticals, etc.) to allow the consistent recording, retrieval and aggregation of clinical data across specialities and sites of care. It also helps to reduce the variability in the way data is captured, encoded and used for clinical care of patients, clinical audit and research. There is much evidence to suggest that a single terminology is the preferred route for an enterprise to take. Given the complexity and the investment cost to develop and maintain, it is not recommended at this point that an enterprise author its own terminology. There will, however, be a requirement for organizations to be able to extend and localize the content of terminologies to meet local need. This requires local authoring capability for terms and concepts which are truly unique to that environment.

A classification is an exhaustive set of mutually exclusive categories to aggregate data at a pre-prescribed level of specialization for a specific purpose. Though often used for secondary purposes, classifications are also used for administration, and that data is often primary in collection.

For example, asthma has specificities of brittle, allergic, seasonal, and intrinsic. Classifications may group all of these together and offer an option for asthma "not otherwise specified". Classifications are complete - in that they offer catch-all representations such as "Other" and "NEC (not elsewhere classified)". Typically, classifications are less 'granular' than terminologies and although some are in use in clinical care they do not allow richness of expression. Major classifications used in healthcare are typically developed and maintained on an international basis and used for statistical and fiscal purposes, but others may be developed for local purposes.

In order for an enterprise to be able to coordinate and deliver care across health, wellness, and social care, it is essential that systems seeking to deliver in this space use the chosen terminology and classifications in a native fashion. Allowing mapping between terminologies inevitably increases workload in achieving the map, potentially introduces error and creates an ongoing maintenance burden. An enterprise must, however, set up and maintain local capability to deliver a terminology and classifications. Stipulations may also exist around local license conditions.

6.3.4.2 Maturity model

6.3.4.2.1 Low

Data collection exists solely on paper or primarily on paper with some electronic data capture within the same healthcare organization. Both summary data and individual data are captured for reporting but few data standards exist.

a) No coordination of the use of clinical terminology; some classification systems in use, even on paper, e.g. classification of country of birth, sex, etc.

b) Standards-based and/or proprietary-based terminologies and classifications may be in use.

c) Duplication of content exists for different purposes.

d) Translation from one representation to another is needed to meet often different reporting requirements.

e) No local capability with respect to the implementation, use and management of clinical terminology or classifications. IT departments may have data managers for classifications but do not have clear competencies identified.

f) Where vendors are present there is no buy-in to the use of common, organization-wide standards-based clinical terminology or classifications; vendors often see their proprietary approaches as a way of marketing the uniqueness and strengths of their products.

g) Ad hoc and uncontrolled local coding systems are in use.

h) Multiple and/or uncontrolled mappings are developed in order to attempt secondary use of data with limited governance or oversight to manage these efforts.

i) No use of, or link to, professional record-keeping standards.

6.3.4.2.2 Medium

A mixture of paper and electronic data collection exists but the majority of data are captured by electronic means, with a deprecation of paper. Individual data collection and summary reporting data are supported by some level of data standards.

a) A standardised metadata directory is in place and used by vendors and healthcare organizations with appropriate governance.

b) A local enterprise terminology facility is in place with a clear roadmap towards large-scale rollout.

c) Vendors are cooperating in implementing and supporting chosen solution(s).

d) Local modifications are supported but controlled through the local enterprise terminology facility.

e) There is facilitation of work to deliver the use of definitions and first steps taken towards knowledge linkage.

f) Organized clinical engagement is underway.

g) Governance of standards and systems is being established.

h) Reproducible audit and research and other legitimate secondary uses of common data are underway.

6.3.4.2.3 High

There is a pre-dominance of electronic data capture (summary and individual) using the chosen terminology with appropriate use of classifications for secondary clinical use and primary non-clinical use e.g. administrative.

a) Local capacity exists to govern and manage terminological, information model and classification representation and use.

b) Use of non-electronic systems at “end of life” is tightly controlled and deprecated.

c) Vendors are delivering systems that are fully compliant with chosen solutions and rolling out to replace non-compliant solutions;

d) Definitions are integrated into systems as well as educational processes.

e) There is full clinical and citizen buy-in to record-keeping standards in use in implemented systems.

f) Knowledge is linked and able to drive care plans and pathways, supported and facilitated by appropriate clinical governance.

g) Research, public health clinical and audit are all driven by the same data.

h) Research outcomes are integrated and fed back into vendor systems, facilitating vendor behaviour change.

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

Controlled clinical terminologies and classifications are essential to allow eHealth to be implemented at scale in any enterprise. Simple implementation with rigor can deliver benefits early, even at low maturity levels. Decisions made early will determine the ability or lack of ability to progress.

a) As a foundation element, it is not possible to deliver eHealth at scale without these terminologies and classifications.

b) This element can be developed in a surprising amount of isolation. However, large-scale implementation requires appropriate software, infrastructure, vendor, clinician, organizational IT, administrative and citizen engagement, as well as program and policy support.

Relevant standards: ISO/TR 12309:2009

An incomplete list of applicable terminologies is maintained at http://en.wikipedia.org/wiki/Medical_classification which divides the items available into subsets as follows:

a) Diagnostic codes

b) Procedural codes

c) Pharmaceutical codes

d) Topographical codes

6.3.4.3.1 Terminology

SNOMED CT[62]

6.3.4.3.2 Classifications - Choose as many as budget allows to maintain maps for (examples)

a) ICD[63]

b) ICPC[64]

c) LOINC[65]

d) ICNP[131]

e) ICF[132]

6.3.4.3.3 Interventional Classifications

a) OPCS[66]

b) CPT4[67]

6.3.4.3.4 Drugs (choose one which is fit for purpose)

a) Dm+d (NHS Dictionary of Medicines)[68]

b) ATC (WHO)[69]

c) SNOMED CT (international) (IHTSDO)[60]

d) RxNorm (US)[133]

e) Australian Medical Terminology[70]

6.3.5 Data interchange interoperability and accessibility

6.3.5.1 Description

The components of the eHealth system that are providing data interchange interoperability and accessibility consist of the following:

a) Directory(s) of healthcare organizational units and possibly health professionals in an organizational structure as entities of communications (senders and receivers);

b) Message handling system components;

c) Transaction buses based on a Web service architecture;

d) Security infrastructure with public key infrastructures to allow communicating entities to be authenticated in real-time interactions, to be accountable through digital signatures on relevant health data, and to be able to exchange data with appropriate confidentiality protection using encryption;

e) Rules for exchange managing legal and ethical compliance to good practice for accountability, as well as privacy protection but also business rules regarding possible service fees for the use of the infrastructure components described above and for the healthcare services implied by the exchange of health related data.

NOTE 1 The necessity for a regional or national program for identifying the subjects of care is not dealt with in this clause but it is of course necessary for safe interchange in most situations.

NOTE 2 The technical components for data interchange are dealt with in 6.4.3.

6.3.5.2 Maturity model

6.3.5.2.1 Low

Low level of data interchange interoperability and accessibility services.

a) No electronic directory service for healthcare communicating parties but local lists with names and electronic addresses of communicating parties. Addresses may be telephone numbers, IP addresses, or Uniform Resource Descriptors (URIs).

b) No health-specific message handling systems but general purpose components, particularly the Internet as Simple Mail Transfer Protocol (SMTP) based emails may be present. Standard services of the telecom network such as Short Message Service (SMS) and Multi-Media Messaging Service (MMS) are also present.

c) No transaction buses based on Web services.

d) No national security infrastructure components. Authentication and protection of communication may depend on local in-person exchange of credentials including possible hidden addresses and encryption keys.

e) No general rules adopted for exchange of different classes of health information but local agreements may be present between communicating parties, ensuring business protection and compliance to national legislation.

6.3.5.2.2 Medium

Some data interchange interoperability and accessibility services included as part of the system.

a) Local and/or regional electronic directories of communicating entities available. They may use various structures including the standard X.500 type of directory.

b) Some health-specific message handling system exists to enhance basic connectivity with agreed structures for intra-organizational addressing and security packaging using point-to-point channels or encrypted and signed packages. This also includes reliable systems for acknowledging receipt of communication and resending where failure occurs.

c) Transaction buses based on Web services exist in a local and/or regional context for some health applications.

d) Local and/or regional security infrastructure components exist, allowing the use of Public Key based security.

e) Business rules for health communication exist in a local and/or regional setting and are enforced by some data security enforcement policy and services. The rule set also includes message specifications for different purposes which may be derived from some of the internationally available series in different generations or often may be based on regional specifications in different syntaxes, often XML.

6.3.5.2.3 High

Highly developed data interchange interoperability and accessibility services included as part of the system.

a) A national directory service of all healthcare entities, organizational units, as well as legally authorized health professionals exists. This is often based on a federated approach where local and/or regional governing bodies manage local directories that are interconnected and accessible through a national infostructure. This is usually achieved using an X.500-based system with health specific directions from the ISO/TC 215 standard ISO 21091.

b) Health-specific message handling infrastructure exists on a national scale which may be based on federated regional infrastructures. Some countries use message handling systems based on the ITU-ISO X.400 standards; others have adopted other approaches often related to health extensions of SMTP or transaction bus - see below.

c) A national specification exists for a transaction bus, most often realized on top of a special network protected against non-healthcare intrusion. This protects communicating components from some attacks. It is often realized as a virtual private network (VPN) where encrypted channels and perhaps guaranteed bandwidth is ensured of by a telecom provider allocating parts of the general communication backbone to health-specific purposes. Such networks may be land-based, wireless, mobile telephony-based (especially 3G and 4G systems), or in some situations, satellite-based.

d) A national public key infrastructure (PKI) exists for communicating health entities that may also be a part of a wider collaboration including several countries.

e) Business rules exist for at least some national healthcare exchanges, including compliance to legislation, ethical rules, and service provider responsibilities. Specifications exist for structured data components allowing semantic interoperability of core health information (but possibly not for all). This may be based on message specifications with nationally agreed profiles and/or archetypes and templates of a general purpose structure for an EHR.

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

Examples of applicable standards include the following:

a) Directory services - ISO 21091. This is based on the inter-sector directory services standard series developed jointly by ITU-T and ISO X.500.[119]

b) Message handling systems - may use ISO/ITU X.400 Message Handling systems or SMTPs.[134]

c) Transaction interactions via health-specific bus - may use the Web Services Protocol and health-specific service architecture based on ISO 12967-1, ISO 12967-2, and ISO 12967-3.

d) Harmonized data types for information interchange – ISO 21090

e) National Public Key Infrastructure (PKI) for health - can be based on ISO 17090-1, ISO 17090-2, and ISO 17090-3 which in turn depend on many ISO/IEC ITU standards such as X.509 for certificates. [136]

f) Message specifications for different purposes - can be based on different generations of structuring paradigms and no one coherent system exists for all aspects of messaging.

Important providers of message specifications for international use (that often require national profiling) are: HL7 version 2 and 3,[18][115][190] CEN/TC 251,[137] UN/CEFACT with Edifact syntax specifications,[138] ISO/IEEE 11073 series, and DICOM[109] series of standards related to image communication.

6.3.6 Consent, access control, and workflow management

6.3.6.1 Description

This architectural component relates to processes and functions of the IT supporting systems that are targeting the capture, storage, and communication of different types of consents by the patient/subject of care or their authorized proxy. One important use of ICT-based consent mechanisms is that the preference of the subject of care can, with a consent statement, steer the collection, use (for a specified purpose), or the disclosure to various health professionals of their personal health data that corresponds to agreed workflows of healthcare organizations. Such consent often pertains to accessing the data in a local system or transfer of the data from its origin to various secondary organizations. Purposes of information transfer may be for the direct care of the subject or for secondary uses such as public health surveillance, research, or quality management. Direct patient care includes various units within a healthcare organization or between individual providers that may have legitimate requirements to access part or all of the health-related information about a subject of care.

Different possible workflows include the following:

a) Provider 1 refers a patient to provider 2 for a specific service and EHR extracts may preferably accompany the referral. Alternatively, provider 2 is granted access to the same information in the EHR system of provider 1. In both cases, the subject of care is often requested to provide express consent. This flow can be nested, i.e. provider 2 invokes provider 3, etc., in which case a renewed consent may be required dependent on jurisdiction.

b) Change of provider - The patient is permanently transferred from provider 1 to the care of provider 2, e.g. provider 1 retires or moves to a different geographic location.

c) Ad hoc workflow - A patient is seen in the emergency department (ED), perhaps in a location outside of their home territory. Provider 2 in the ED may request information from provider 1 who normally treats the patient, i.e. is their attending physician. The patient needs to provide consent for this information transfer and also for sharing the ED discharge summary with provider 1 after ED treatment is completed.

d) A clinical process is established where two or more providers agree to work together for the benefit of the patient who needs to provide consent for the required information exchanges, perhaps to be given for repeated exchanges.

Consent to information management relates to the requirements outlined in 6.3.7.

Consent may also be captured by IT systems which do not deal with the information regarding the subject of care but about some other aspect of the intended care of the individual. Examples of issues for which consents may be recorded are the following:

a) Approval or rejection of a certain therapeutic procedure, e.g. surgery;

b) Approval of being considered as an organ donor after death.

Consent and access control needs to be coupled with workflow concepts in a mature implementation. Consent-related processes include the following workflow:

a) Informing the subject of care about the issue where consent or the opposite is requested.

b) Capturing the expression from the subject of care by an IT application, typically a Web- based solution but mobile telephony based solutions are also very important and may use different techniques, from simple short message service (SMS) to special smart phone apps.

c) Special attention required for those persons that because of disease or other reasons, e.g. literacy, cannot use the IT system directly; a proxy person in the form of next-of-kin or a health professional may assist the subject to capture the expression.

d) Storage of the consent.

e) Provision of the consent expression to appropriate parties which may reside within an organization or possibly in a federated national infrastructure to other organizations where relevant.

f) Attention to the life cycle and possible requirements for repeated expression of consent.

6.3.6.2 Maturity model

6.3.6.2.1 Low

a) Health professionals record consent in an EHR or other relevant system.

b) There is no connectivity between systems.

c) Consent may be used for access control to patient data.

6.3.6.2.2 Medium

a) Some capture of consent exists where the subjects of care are directly using an IT solution to record their preference as relevant for information disclosure/sharing.

b) There is limited authentication sophistication, e.g. passwords locally or a similar solution.

6.3.6.2.3 High

a) Provision for a national patient summary record.

b) Subjects can access their consent records by different methods.

c) Consent management does not only include information sharing but also other aspects of care.

d) A solution for access via proxy exists.

e) The identity and authentication of the consent expression is secured using public key cryptographic methods.

6.3.6.3 Examples of applicable standards cross-references and dependencies

Examples of applicable standards include the following:

a) ISO 13606 is highly relevant;

b) ISO 22600 is also an important guidance related to access control use of consent;

c) ISO 17090-1, ISO 17090-2, ISO 17090-3, and ISO 17090-4 are also relevant to ensure authenticated use of the system;

d) ISO/PD/TS 17975;

e) ISO/TS 14265:2011.

For cross-references and dependencies, see 6.3.7.

6.3.7 Privacy, security, and safety regime

6.3.7.1 Description

Health services are highly sensitive due to the personal and social impact of health information, as well as the strong legislation and regulations ruling them. Therefore, security and privacy services are fundamental for designing, implementing, and deploying health information systems.

The concept of security can be specialized (separated) into communication security and application security. Communication security in the context of connectivity between principals (persons, organizations, systems, devices, applications, components) covers the following security services:

a) identification/authentication of principals;

b) accountability of actors;

c) traceability of actions;

d) integrity, availability, and confidentiality of information communicated.

Communication security is quite similar in different domains such as healthcare, banking, business transactions, commerce, and government services. This allows communication security solutions to be borrowed from advanced domains, if available there.

Application security in the context of collecting, storing, processing, and sharing information covers the following services:

a) identification/authentication;

b) authorization of actors;

c) access control in the context of actions;

d) accountability of actors;

e) traceability of actions;

f) integrity, availability, and confidentiality of information collected, stored, processed, and shared.

Those services include audit and certain notaries' functions. Application security services are domain specific, e.g. ruled by a domain specific set of policies.

Identification/authentication management starts with the assignment of an identifier to an entity, which should be verified in an authentication process. The authentication can be based on knowledge just the individual has (e.g. passwords), on a certified token the principal has been given by an authority (e.g. smartcard, cryptographic key, etc.), or on properties characterizing the individual (e.g. biometrics,

speech, handwriting, etc.). The granted capacities and rights in the context of authorization and access control, including the permitted actions, can be based on privileges and roles assigned to an entity by an authority according to the entity's attribute or a set of competencies and/or performances that are associated with a task, respectively.

Authorization and access control can also be based not only on policies reflecting legislation and regulations including consents established by the subject of care or its representative, but also environmental or contextual conditions. Therefore, the following security and privacy management services have to be implemented:

a) ID management;

b) password management;

c) token management;

d) certificate management;

e) privilege management;

f) role management;

g) policy management;

h) de-identification services (anonymization, pseudonymization).

6.3.7.2 Maturity model

The maturity level of solutions can be characterized by the number of services in place, the maturity of a single service, the integration of different services, the maturity of this integrative environment, and the domain covered by the services such as a local place, an organizational unit, an organization, an enterprise covering several organizations, a regional network covering several enterprises, a national network covering several regions, or an international network. The opportunity for pre-definition, as well as the possible details of policies, becomes more limited the larger the domain.

6.3.7.2.1 Low

a) No interoperability: A few inevitable services have to be in place such as integrity and local availability of information. Missing services are not required or partially compensated by natural trustworthy relationships.

b) Interoperability in organizational units: ID management including simple privilege/role assignment, as well as local patient identifiers and simple policy management including consent management, are required. Missing services are compensated for by policies.

c) Interoperability in organizations: ID management, authentication services and master patient identifiers, privilege and role management, policy management are required.

6.3.7.2.2 Medium

a) Interoperability in the enterprise: ID management, authentication services based on certificates, Master Person Index (MPI), policy management, signatures are required.

b) Interoperability at regional level: Certified ID management (ID services) and authentication services, policy management including policy bridging, certified signature are required.

6.3.7.2.3 High

a) Interoperability at national level: Certified ID cervices including EID services, policy management/bridging including dedicated services such as Policy Location Point (PLP), Policy

Decision Point (PDP), and Policy Enforcement Point (PEP) are required. Policies cannot be completely defined anymore. The solution should be semantically rich, policy driven.

b) Interoperability at international level: Mobile, pervasive, and autonomous solutions are required.

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

For examples of applicable standards, see 6.3.6.3 and the following:

a) ISO/TS 21298:2008;

b) ISO 27799:2008;

c) ISO/TR 13054:2012;

d) ISO/TS 22600-2:2006;

e) ISO/TS 22600-3:2009;

f) ISO/TS 25237:2008;

g) ISO/TS 21547:2010;

h) ISO/TR 21548:2010.

As security and privacy services provide the basis for acceptance and legitimization for health services and consume a large part of the budgets allocated to national eHealth programs and projects, they practically define the overall maturity achievable.

Other blocks that depend on this block include foundational elements (such as terminologies, privacy and security, interoperability, and the client, provider, and location registries). These elements are prerequisites for developing a domain component as an enabler for eHealth environments. Security and privacy services directly and indirectly impact all health process domain components, as well as administrative processes. They are interrelated to most components of the addressed architecture, especially the Process Management, Health Services Identification and Directory Services, Data Interchange Interoperability and Accessibility, Census and Population Information and Data Warehouse, Safety and ICT Infrastructure Foundation services.

Security and privacy services depend on infrastructural services such as Terminology Services[62] and Directory Services.[119]

6.3.8 Census information, population information, and data warehouse

6.3.8.1 Description

Census and population data, the latter including population health data, are critical to understanding the needs of individuals, populations, and sub-populations within a country and the planning, design, implementation, and monitoring of health systems and the health services those systems deliver at all levels (local, regional, national).

The United Nations (UN) defines the essential features of population and housing censuses as "individual enumeration, universality within a defined territory, simultaneity, and defined periodicity".[152] Data includes population counts with details of age, sex, occupation, housing, etc. The UN also provides information and recommendations on census topics to be collected, official definitions, classifications, and other useful information to coordinate international practice.[153]

Population data takes a deeper look at various types of observables for a target population for purposes of statistical analysis.

The establishment of national health quality indicators,[154] e.g. adherence to evidence-based preventative health screening guidelines and disease monitoring recommendations within the context

of a national framework, e.g. CIHI (Canada) Health Indicators Framework,[155][156] provides direction and focus for the collection and use of census and population/population health data. Such a framework should consider determinants of health such as income, education, culture, and other factors impacting on life circumstances. It will support provincial/state improvement priorities by demonstrating how indicators interconnect and relate to one another and how they contribute to overall performance goals, such as improved health status and better value for money. The framework could also support viewing population data through an 'equity' lens which implies the need to disaggregate health and health system indicators by key population groups to see where large population differences exist in health system inputs, services, and outcomes.

The ability to effectively collect, aggregate, pseudonymize/anonymize the data, and generate useful analysis and reporting (both standardized and customized) through data warehouse services confers value on the data collected and reaps benefits for all key stakeholders – clients/patients, health workers, healthcare providers, purveyors of health products and services, health planners, and health policy-makers.

A data warehouse is a managed database that can receive diverse sources of information that are relevant to a particular organization. The data collected is intended for analytical purposes and in some cases, the data may need some prior treatment (such as change of measurement units). Also, the relationships between the data are selected by the data warehouse architecture based on user analytical requirements in order to optimize different queries based on these relationships. The value of the data warehouse is to enable an integral view to help decision-making within the organization and at all levels. An example would be a query to show disease prevalence associated with a particular drug use with respect to a defined population, thence to enquire in more detail (drill down) to see the characteristics for a sub-group of that population, such as the elderly.

Business intelligence and interactive Web tools can further enhance the value of data warehouse capabilities by enabling performance tracking, comparison across similar groups, and identification of specific areas for health system improvements.

Building these types of services and capabilities can allow countries to clearly identify health disparities and prevent or ameliorate the known consequences – avoidable death, disease, disability, distress, and discomfort and their associated costs to the healthcare system and society.

6.3.8.2 Maturity model

6.3.8.2.1 Low

a) Minimal census and population data collected (baseline or below) national and/or international recommendations, largely paper-based.

b) Health quality indicators not established.

c) Minimal level of data transfer to central location for analysis and reporting by regional- or state-level government systems or other funded third-party systems.

d) No integration of health-related data into a single warehouse repository.

e) No data warehouse services as part of the system.

6.3.8.2.2 Medium

a) Baseline or above baseline census and population data collected aligned with international recommendations; mainly electronic capture with some paper-based.

b) Baseline national level health indicators developed and aligned with international standards; some health system indicators established.

c) Some data warehouse services included as part of the system.

d) Some integration of data into a single repository with data warehouse analytical capacity and reporting for local organizations or communities.

e) Limited tracking or comparison of performance over time against indicators; limited collaboration at regional, provincial/state, national levels.

f) Local research on quality of care, health system efficiency, patient safety.

6.3.8.2.3 High

a) Highly-developed census and population information; well-established set of national level, comparable health indicators aligned with or serving as a model for international standards operating within a national health indicators framework.

b) Regional or national integration of data from different local sources with comprehensive data warehouse analytical capacity and reporting used for decision making at local, regional, and national levels.

c) Structured and coordinated national-level reporting on health system performance that is tailored to the information needs of different audiences, including the general public, health ministries, regional health authorities, and health care facilities.

d) Nationally developed analytical tools and products that support and enable provincial/state-level health system improvement priorities accompanied by capacity-building for using and understanding performance measurements and tools.

e) Business intelligence and interactive Web tools that allow health system managers to track performance over time, view peer group comparisons, and identify areas for improvement through drill-down capabilities.

f) Collaborative partnerships (regional, provincial/state, national) to identify which health indicators are most important, how they relate to each other, and how they can best support improvements to health care and the health of the country's population.

g) Research at national and state/provincial levels in priority themes related to health system performance, such as quality of care, patient safety, and health system efficiency.

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

Examples of applicable standards are the following:

a) ISO 21667:2010

b) ISO/TR 22221:2006

c) ISO/TS 29585:2010

For cross-references and dependencies, see 6.2.5, 6.2.12, and 6.2.15.

6.4 Foundation components — ICT infrastructure

6.4.1 General

ICT infrastructure is most evident in the form of devices such as desktop computers, personal digital assistants, laptops, tablets, smart phones, biomedical monitors, diagnostic imaging equipment, and printers.

ICT devices are connected using electronic communications that enable voice, video, paging, messaging, data transmission, and connection to the Internet. Electronic processing and storage services are provided by computer servers that access data stored on solid state, magnetic discs, or magnetic tape.

Staff supporting ICT infrastructure include computer technicians, application specialists, network engineers, database designers, and many other specialists.

Standards provide the framework to maximize the safe, reliable, and efficient operation of devices, servers, and networks which in turn, depends on the quality, compatibility, interoperability, and durability of the physical devices and software.

The development of a mature ICT infrastructure is constrained by a number of economic and social factors. The same factors may also limit the development of other types of infrastructure such as water supply, housing, agriculture, etc.

In all infrastructure sectors, the definition of suitable benchmarks to measure development progress and levels of maturity is very dependent on social and economic perspectives. The notion that a house should be built with a kitchen, bathroom, living room, and two bedrooms is just as questionable as the notion that the most efficient way to store data may be in a cloud computer service. Infrastructure development may also be extremely uneven across sectors as demonstrated by communities in Kenya that can access mobile phone services but have no access to clean drinking water.

The use of ICT technology originating in high-income countries may provide challenges to national economies. For instance, the high price of ICT devices manufactured outside the boundaries of most low-income countries (LIC) presents a balance of payments challenge. The use of cloud computing services provides a similar fiscal challenge and raises issues of national sovereignty over health information and services.

Notwithstanding the problems of measuring ICT development, the following cross cutting factors influence the development of foundational ICT infrastructure for the health sector.

6.4.1.1 Affordability

The affordability of devices, Internet and private network bandwidth, international bandwidth software, systems, services, and ICT staff are key constraints for the development of the infrastructure needed to support eHealth services.

For most countries, the cost of ICT devices manufactured outside their boundaries presents a budgetary and balance of payments challenge. Even health jurisdictions in high-income countries may be reluctant to invest in large numbers of computing devices when the cost of ownership of these devices has to be compared with the salary of a nurse or doctor.

Ultimately, investment in ICT devices and systems is only justifiable on the basis that deployment of ICT devices will provide a real saving of clinical time and improvements in health outcomes.

NOTE There is little information on the relative affordability of ICT devices. The ITU reports on the affordability of fixed line, mobile, and broadband services and a price basket of these services.[158] Experience in high-income countries has been that an expenditure of between 3 % and 5 % of the total health budget should be allocated to ICT functions.

6.4.1.2 National ICT development

ICT products and services support the infrastructure required by eHealth services. The extent to which these services are widely available throughout a country will limit the deployment of eHealth service. The ITU has a developed a national metric to compare the extent of national ICT capability.

NOTE Overall, national ICT development, as measured by the ITU, is based on indicators for fixed-telephone connections per 100 inhabitants, mobile-cellular telephone subscriptions per 100 inhabitants, international Internet bandwidth (bit/s) per Internet user, percentage of households with a computer, percentage of households with Internet access, percentage of individuals using the Internet, fixed (wired)-broadband Internet subscriptions per 100 inhabitants, active mobile-broadband subscriptions per 100 inhabitants, adult literacy rate, secondary gross enrollment ratio, and tertiary gross enrollment ratio.[159]

6.4.1.3 Educational attainment

ICT products and services require an educated population to consume services and provide sales, implementation, and support services.

NOTE Educational attainment as measured by the UNDP as part of a Human Development Index. The Education Index is measured by the adult literacy rate (with two-thirds weighting) and the combined primary, secondary, and tertiary gross enrollment ratio (with one-third weighting).[160]

6.4.1.4 Digital literacy

This refers to both the health workforce and the general population. In part, digital literacy is an outcome of educational attainment, but significant portions of a population may become very proficient in the use of ICT devices such as mobile phones or Internet applications, without attaining a high level of education.

Digital literacy has many forms and definitions. For instance, the ability to send a Short Message Service (SMS) message on a mobile phone, operate a security alarm, produce an electronic document using a word processing program, use a Web browser program, or take an X-ray are all forms of digital literacy.

NOTE Digital literacy can be measured using composite indicators such as communicating with others (by e-mail and other online methods), obtaining (or downloading) and installing software on a computer, questioning the source of information on the Internet, and searching for the required information using search engines. Other methods exist.[161]

6.4.1.5 ICT Service industry capacity

The capacity of a national ICT service industry to support the use of ICT in the health sector is very important. In most countries, it makes little sense to build extensive sector-specific ICT service capability, so the health sector will rely heavily on the commercial ICT sector to install, maintain, and provide helpdesk services for eHealth systems.

6.4.1.6 Supportive ICT policy environment

A supportive ICT policy environment can enable a business environment where ICT and broadband deployment and adoption can grow rapidly. The ITU recommends that governments ensure a fair and dynamic market where barriers to entry are low, competition is healthy and private sector investment is encouraged. For a wide-ranging discussion of markets and standards issues in telecommunications, see Reference [162].

By implementing demand-driven programs such as e-government platforms, digital literacy initiatives, and connected public institutions, governments can enable the broadband environment by both stimulating investment and spurring Internet adoption.

6.4.1.7 Electric power availability

Electric power availability, especially for health facilities throughout a country, is key to supporting ICT devices and communications in the health sector.

NOTE There is no single internationally accepted definition for electricity access. The definition used by the International Energy Agency[163] covers electricity access at the household level, that is, the number of people who have electricity in their home. It comprises electricity sold commercially, both on-grid and off-grid. It also includes self-generated electricity for those countries where access to electricity has been assessed through surveys by government or government agencies.

6.4.2 Local access to ICT equipment and facilities

6.4.2.1 Description

Healthcare providers and consumers rely on information provided at the point-of-care in clinically useful timeframes across a range of healthcare settings. Healthcare providers have an expectation that

they can access electronic health information from within a healthcare facility and when on the move. A range of ICT equipment and devices are required in healthcare for the following:

a) multi-purpose information processing such as desktop computers, personal digital assistants, laptops, tablets, smart phones;

b) voice communications such as telephones, mobile phones, two-way radios;

c) video communications, video conferencing systems;

d) notification and messaging, pagers, mobile phones;

e) biomedical monitoring of vital signs;

f) diagnostic imaging, e.g. X-rays, ultrasound, magnetic resonance imaging;

g) security and monitoring devices, duress alarms, man-down devices;

h) printing, print servers;

i) data storage, magnetic (hard discs), USB memory, solid-state memory, CD, DVD, storage arrays, storage area networks.

An increasing body of evidence is available that shows that health outcomes can be improved when consumers of healthcare

a) manage and improve their own health by accessing a network of health resources through a variety of communications and channels operating over reliable networks, systems, and applications,

b) interact with health providers at a distance to obtain advice and provide information while minimizing patient and clinician travelling, and

c) benefit from effective planning of patient care and management of referrals, scheduling, and waitlists across the health system (especially for rural and regional communities).

The ability to use one portable device such as a smart phone for many types of personal and work-related actions presents an opportunity to provide health information at the right time in the right place on one device for healthcare providers and consumers.

6.4.2.2 Maturity model

6.4.2.2.1 Low

a) Health workers in urban areas can access health information systems in a timely fashion using fixed computing devices.

b) There is limited access to printers, bio-medical devices, diagnostic imaging, and data storage devices.

c) Support for mobile healthcare in targeted disease areas is available via mobile phone technologies.

6.4.2.2.2 Medium

a) Health workers in urban and regional facilities can access key local and regional health information systems in a timely fashion using fixed computing devices.

b) There is access where clinically required to printers, bio-medical devices, and diagnostic imaging devices in most health facilities.

c) A minority of mobile health workers can access the information and systems they need to support their work in communities and patient homes using mobile devices.

d) Patients and the community can access a basic set of information that is needed to manage their health using computers at home and mobile devices.

e) Patients in some locations can report changes in their clinical condition using simple computer or mobile phone applications such as email or SMS.

f) Access to data storage devices enables regular online file access and data backup.

6.4.2.2.3 High

a) Health workers in all facilities are able to access most national health information systems in a timely fashion using fixed and mobile computing devices.

b) There is access where clinically and administratively required to printers, bio-medical devices, and diagnostic imaging devices in all health facilities.

c) All mobile health workers can access the information and systems they need to support their work in communities and patients' homes using mobile devices.

d) Any patient and the community at large can access advice and information that is needed to manage their health from computers at home and mobile devices.

e) Patients at home or in care can be monitored in near real-time for changes to their clinical condition.

f) Access to data storage devices enables use of electronic document retrieval and management systems in all health facilities.

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

Examples of applicable standards are addressed in subsequent sub-sections relevant to specific systems and services.

Effective access to electronic-based health information depends on the following:

a) Availability of devices, such as computers, personal digital assistants (PDAs), tablets, mobile phones, and smart phones for both health workers and patients or clients.

b) Connection to appropriate, cost-effective electronic communications systems.

c) The ability to use electronic processing and storage systems that may be located many kilometers away to search for, retrieve, store, and manipulate data.

d) Use of safe, secure, clean, climate-controlled physical environments to locate sensitive electronic equipment such as servers, data storage, or special-purpose medical devices such as medical image scanners.

e) Access to professional technical support to train users in the operation of software, resolve faults, and undertake regular maintenance tasks.

6.4.3 Electronic communications infrastructure

6.4.3.1 Description

Electronic communications enable voice, video, paging, messaging, data transmission (mobile or fixed) services, and connection to the Internet. Often these services can be purchased from a national telecommunication carrier(s) that provides the required infrastructure. Some health jurisdictions may also install their own infrastructure such as microwave radio and fibre optic links. In other cases, the health sector will use services provided for all government departments.

Most telecommunications carriers offer a tiered set of services. Consumer services are offered at a low price with no guarantee of rapid repair when faulty. These services usually include access to the Internet

through the international bandwidth that the carrier has access to. Business grade services are priced at higher levels, offer some level of repair guarantee, may be more symmetrical in bandwidth availability (up/down), and may or may not include access to the national and international Internet.

A health jurisdiction has the option of requesting the telecommunications carrier to distribute the service connections (usually fixed voice and data services only) to each of its facilities, and within each facility. Alternatively, a health jurisdiction can choose to do this itself. In the latter case, cabling in facilities, network devices such as firewalls, routers, switches, voice switches (PABXs), etc. will need to be purchased, installed, and maintained.

6.4.3.2 Maturity model

6.4.3.2.1 Low

a) Health facilities in urban areas have network access to centralized computing resources and connection to the Internet.

b) Healthcare workers and patients can obtain mobile phone coverage in urban and regional centers.

6.4.3.2.2 Medium

a) Health facilities in urban and regional areas have network access to centralized computing resources and connection to the Internet.

b) Healthcare workers and patients can obtain mobile phone coverage in urban and regional and rural centers.

c) Patients and the community in general can obtain affordable connection to the Internet in urban, regional, and rural areas.

6.4.3.2.3 High

a) Health facilities in urban, regional, and remote areas have network access to centralized computing resources and connection to the Internet.

b) Healthcare workers and patients can obtain 3G or 4G mobile phone data coverage in urban and regional and rural centers.

c) Patients and the community in general can obtain affordable connection to high-speed broadband Internet services of 12 Mbps or more in urban, regional, and rural areas.

6.4.3.3 Dependencies

Industry standards, national and international standards from organizations such as the International Telecommunications Union (ITU),[164] Internet Engineering Taskforce (IETF),[165] and Telecommunications Industry Association (TIA)[166] provide a large number of standards relevant to electronic communications.

Electronic communications costs are governed by geography, population density, the capability of the national ICT sector, and government policy.

a) The delivery costs of healthcare using electronic communications are strongly influenced by geography, in particular the size of a country and its population density, the degree of competition in the market, and the costs of international connections via satellite (most expensive) or optical fibre (cheapest).

b) A national health jurisdiction will rely on the small business ICT sector to install, maintain cabling, network devices, servers, PABXs, etc. in its health facilities and provide training in ICT management.

c) Government policy that aggregates the ICT needs and communications bandwidth required by schools, health facilities, and government departments can stimulate investment in infrastructure and drive Internet adoption.

6.4.4 Electronic processing and storage services

6.4.4.1 Description

Electronic processing and storage services are provided by computer servers, the system software that runs on the servers, and data storage using solid-state, magnetic discs, or magnetic tape. These systems are often housed in purpose-built equipment rooms connected via structured cabling systems to users throughout a building. High-end computers or servers provide the networked application processing and storage services required by multiple simultaneous users. A server will host the system software and several virtual operating systems within which system software, application environments, management, and control systems can be built.

System software provides the underlying services used by most applications including operating systems, storage, telephony, notification, file and print, virtualization, and collaboration services.

Application environments support business, clinical, health record, and patient administration applications, including portals, web servers, application and messaging integration engines, messaging, clustering of web servers, user directories and databases.

Management and control software helps maintain user devices, software licensing, servers configuration, manage storage systems, file and print services, user identity, call desk services, configuration databases, and track assets.

ICT processing, storage and communications systems require an appropriate physical environment to operate reliably. Electric power of a sufficient quality and reliability is the first requirement. Climate control of the environment housing equipment is also very important.

Dedicated equipment rooms will be needed in most health facilities, which have reliable power, air conditioning, and protection against rain, wind, or flood. Larger health facilities may require data centers that are located on- or off-site and built according to industry standards to meet Tier 1 to 4 specifications as appropriate. Systems such as diagnostic imaging may have specialized accommodation needs.

Larger facilities use distribution cabinets to house cabling and network equipment on each floor or building section. All facilities will need network cabling installed to strict standards to connect user desktop equipment or wireless access points to a central network core for the facility. Small health facilities may be able to be serviced by commercial 3G or 4G mobile data services if they exist or through a single wireless access point connected to a consumer grade Internet connection.

6.4.4.2 Maturity model

6.4.4.2.1 Low

a) There are little or no centralized electronic application processing and storage services housed in dedicated accommodation outside of urban area.

b) Most electronic processing and storage is undertaken on isolated user specific computers, housed in individual facilities.

6.4.4.2.2 Medium

a) A centralized core of electronic application processing and storage services exists in a data centre with some limited backup, fail over, and load sharing features. The data centre is rated at least Tier 2.

b) Regional electronic application processing and storage services may exist that are linked to the centralized core to obtain common information e.g. patient identity, access to the Internet, etc.

c) Cabling installation in urban and regional area facilities meets minimum standards.

d) Accommodation for biomedical vital signs monitoring and diagnostic imaging is designed to the required standards.

6.4.4.2.3 High

a) A centralized core of electronic application processing and storage services exists across two or more data centers with full backup, fail over, and load sharing features. The data centers are rated at least Tier 3.

b) Extensive use of virtual machine operating systems enables efficient capacity management.

c) Regional electronic application processing and storage services exist that are linked to the centralized core to obtain common information, e.g. patient identity, access to the Internet, etc).

d) Health facilities in urban, regional, and remote areas have access to dedicated accommodation for ICT equipment.

e) Cabling installation in urban, regional, and remote area facilities meets minimum standards.

f) Accommodation for biomedical vital signs monitoring and diagnostic imaging is designed to the required standards.

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

Industry standards, national and international standards from organizations such as the International Telecommunications Union (ITU),[164] Internet Engineering Taskforce (IETF),[165] and Telecommunications Industry Association (TIA)[166] provide a large number of standards relevant to electronic storage and processing. The TIA also provides standards for data centre design.

Effective use of electronic devices to support healthcare requires that electronic processing and storage is affordable and supported with training and maintenance by the local ICT service industry:

a) The cost of high-end computers, storage, and software designed for use by many (1000 +) users is significant. Additional cost is incurred in the licensing, configuration, and maintenance of these systems.

b) The skills required to maintain servers, storage, and software are often very specific and tied to proprietary products such as Microsoft servers, Oracle databases, etc. A reasonable educational base and basic ICT skills are needed before undertaking training courses on these products. In some cases, the costs of these courses can be negotiated with the original product purchase. These skills are usually in high demand and difficult to retain within the government sector.

c) Access to professional technical support is necessary in order to train health sector ICT staff in the operation of software, resolve faults, and undertake regular maintenance tasks.

d) Partnership with the local ICT service industry may be required to build the skills needed to support systems used in healthcare.

6.4.5 ICT professional and technical support

6.4.5.1 Description

Each health jurisdiction should find a balance between developing in-house ICT staff and working with small and medium businesses to develop the services that are needed to support health ICT systems.

Staff are needed with the skills to maintain, install, and develop computers, applications, networks databases, health messaging, security, operational processes, enterprise architecture, and ICT strategy. Some of these skills can be acquired through on-the-job experience, others require specific training, and many can be acquired in college or university courses.

Detailed degree curricula for ICT professionals have been produced by the Joint IEEE/ACM Computing Curriculum Task Force in five computing subject areas: computer science, computer engineering, information systems, information technology, and software engineering (Computer Science Curricula 2013, ACM/IEEE-CS Joint Task Force).[167]

The formation of specialist ICT associations and health informatics associations can also contribute to the management of health applications by promoting best practice, standards, and skills.

Health workers can benefit from courses such as the International Computer Driving License, (ECDL Foundation, http://www.ecdl.org/programmes/ecdl_icdl).[168] The syllabus has seven units including concepts of IT, computer use and managing files, word processing, spreadsheets, databases, presentations, and information and communication (Internet use).

No health jurisdiction can operate ICT systems successfully without adopting some elements of an ICT service management framework. The Information Technology Infrastructure Library (ITIL) (The APM Group Limited, http://www.itil-officialsite.com/)[169] is one framework for IT service management (ITSM) that focuses on aligning IT services with the needs of business.

ITIL describes procedures, tasks and checklists that are not organization-specific and used by an organization for establishing a minimum level of competency. It allows the organization to establish a baseline from which it can plan, implement, and measure. It is used to demonstrate compliance and to measure improvement.

ITIL v3 has five focus areas: Service Strategy, Service Design, Service Transition, Service Operation, and Continual Service Improvement. Few organizations achieve a complete implementation of all ITIL processes, preferring instead to customize the methodology to suit their particular needs.

6.4.5.2 Maturity model

6.4.5.2.1 Low

a) Health facilities in urban areas are able to employ or contract experienced ICT technicians to service most systems.

b) In urban areas, management of ICT services is planned to ensure key services keep on operating.

c) In regional and remote areas, management of ICT services is ad hoc and depends on the efforts of individuals.

6.4.5.2.2 Medium

a) Health facilities in urban areas are able to employ or contract experienced ICT technicians and providers to service most systems. Regional areas are serviced by technicians travelling from urban areas.

b) In urban areas, management of ICT services is planned to ensure key services keep on operating. Most IT service processes are documented, standardized, and integrated into standard service processes.

c) In regional and remote areas, management of ICT services is planned to ensure key services keep on operating.

6.4.5.2.3 High

a) Health facilities in urban and regional areas are able to employ or contract experienced ICT technicians and providers to service most systems.

b) In urban areas, management of ICT services is planned to ensure key services keep on operating. Most IT service processes are documented, standardized, and integrated into standard service processes. Quantitative objectives exist for quality and process performance and are used as criteria in managing processes. Quantitative objectives are based on needs of the customer, end users, organization, and process implementers.

c) In regional and remote areas management of ICT services is planned to ensure key services keep on operating. Most IT service processes are documented, standardized, and integrated into standard service processes.

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

ITILv3[170] underpins ISO/IEC 20000 (previously BS 15000), the International Service Management Standard for IT service management, although differences between the two frameworks do exist. The ISO provides standards in a wide range of disciplines related to professional and technical support, education, and training.

The provision of adequate professional and technical support for ICT systems in the health sector depends on the following:

a) The general education level of ICT staff (whether working for a healthcare employer or for an ICT service provider), the specific training that staff have been given, and the range of ICT specific courses that are available.

b) A supportive policy environment that encourages healthcare organizations to cooperate with the ICT service sector, universities, and colleges in providing staff training and education.

c) Development of common ICT skills across all national economic sectors and need to be encouraged through appropriate government initiatives. The Skills Framework for the Information Age SFIA Foundation[192] provides a detailed taxonomy of 86 specialist ICT practitioner skill areas and 290 tasks.

6.4.6 Standards, methods, guidelines, and frameworks (component of ICT infrastructure foundation)

6.4.6.1 Description

Access to electronic health information is provided through ICT infrastructure comprising the electronic devices and electronic networks. The safe, reliable, and efficient operation of these devices and networks depends on the quality, compatibility, interoperability, and durability of the hardware and software.

For this reason, a number of national, international, and domain-specific collaborative organizations exist to coordinate and standardize the design and construction of ICT devices and networks. Some of these organizations are focused on the manufacturing processes, others on the device communications protocols and the implementation practices used to deploy ICT infrastructure.

When implementing an eHealth project, an organization has limited control over the design and manufacturing stage but is very concerned that equipment and networks are compatible in many ways, will interoperate, and are installed to function safely for the required amount of time.

National ICT staff will need to refer to, follow, and enforce standards, methods, guidelines, and frameworks that are locally acceptable and approved through local governance processes. The availability of proven standards from international organizations enables the efficient design and implementation and interoperability of ICT infrastructure.

The internationally adopted standards most relevant to eHealth foundation ICT infrastructure are produced by a number of organizations including the following:

a) Integrating the Healthcare Enterprise (IHE)[116] provides a common health sector technical framework for harmonizing and implementing multiple standards in health systems, devices, and ICT infrastructure, e.g. ICT Infrastructure Integration Profiles.

b) "Health Level 7" (HL7)[18] has developed a common "language" that allows healthcare applications to share clinical data with each another. HL7 creates international standards for inter-system and inter-organization messaging, for decision support, clinical text document mark-up and user interface integration, as well as a health data model and a message development methodology.

c) Digital Imaging and Communications in Medicine (DICOM)[109] is a cooperative standards effort to create and maintain international standards for communication of biomedical diagnostic and therapeutic information in disciplines that use digital images and associated data.

d) International Standards Organization (ISO)[171] provides standards in health informatics, devices, health system communications, safety, security, ICT architecture, and related areas.

e) International Telecommunications Union (ITU)[164] provides standards in all areas of telecommunications and wired and wireless networks.

f) European Committee for Standardization (CEN)[137] brings together the National Standardization Bodies of 33 European countries. CEN, along with CENELEC and ETSI, has been officially recognized by the EU and by the European Free Trade Association (EFTA) as being responsible for developing and defining voluntary standards at the European level in a wide range of sectors including health and safety, healthcare, and ICT.

g) Internet Engineering Taskforce (IETF)[165] provides guidance through Request for Comments (RFCs) on the use, design, and development of the Internet. Many health systems, protocols (e.g. DICOM), and standards rely on the use of IETF recommendations.

h) Telecommunications Industry Association (TIA)[166] is a USA-based trade association that provides standards in wireless equipment, cabling systems, and mobile devices. The TIA also provides standards for data centre design.

i) National Electrical Manufacturers Association (NEMA)[172] is a USA-based association of electrical equipment manufacturers that provides standards for many types of electrical products. NEMA helped develop the DICOM standard for radiology imaging.

j) Institute of Electrical and Electronics Engineers (IEEE)[173] provides technology standards, across a wide range of technologies.

k) International Electrotechnical Commission (IEC)[174] provides a wide range of standards for electrical equipment. The IEC works jointly with ISO on many standards.

l) World Wide Web Consortium (W3C)[175] develops protocols and guidelines that ensure the long-term growth of the Web. Many healthcare communications standards rely on W3C protocol standards.

6.4.6.2 Maturity model

6.4.6.2.1 Low

a) Access to national or international standards for ICT infrastructure is difficult and costly.

b) ICT infrastructure is implemented without reference to standards and guidelines.

c) Little or no recognition and support is provided for the use and development of ICT infrastructure standards.

6.4.6.2.2 Medium

a) National or international standards for ICT infrastructure are available.

b) ICT infrastructure is implemented with limited reference to standards and guidelines.

c) International standards are adopted, but not widely promoted.

d) Limited encouragement and support if offered for participation in the adoption and development of ICT infrastructure standards.

6.4.6.2.3 High

a) National or international standards for ICT infrastructure are widely accessible.

b) ICT infrastructure is implemented with extensive reference to standards and guidelines.

c) International standards are adopted and are widely promoted.

d) Extensive encouragement and support exists for participation in the adoption and development of ICT infrastructure standards.

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

The effective use of international standards requires affordable access to standards, an educated health ICT workforce, and recognition of the importance of standards by business and government:

a) The affordability of access to international standards, in printed and electronic form determines the extent to which these standards are referenced in the design and implementation of ICT foundation infrastructure.

b) Digital literacy skills are required to interpret and apply standards and frameworks which depend on the digital literacy and educational attainment of the health ICT workforce. A reasonable educational base and basic ICT skills are needed before international standards can effectively be applied to the local context.

c) A national health jurisdiction will rely on a well-developed small business ICT sector to understand and use appropriate standards in the design, installation, and operation of eHealth systems.

The national recognition of the importance of standards for ICT infrastructure can be driven by a supportive policy environment. Government policy that provides the resources for national participation and use in formulation of international standards will stimulate the development of local understanding and use of standards and the formulation of national standards to meet local needs.

7 Profiling countries with the eHAM

ISO Technical Committee - Health Informatics (TC 215) has developed a maturity model for eHealth Architecture, which can be used by LMIC to assist with development of a health system strengthening (HSS) strategy. Often absent in the definition of health informatics standards, the concepts of maturity and capacity enable granular and appropriate perspectives on HSS in information technology environments with varying levels of development.

The eHealth architecture model (eHAM) described herein fits within the context of the WHO/HMN Framework for National Health Information Systems, which provides a high-level perspective on HSS and data sources, as illustrated in Figure 11. Figure 11 shows how the HMN Framework and eHAM complement each other to guide standards development, in this example, for patient identifier.

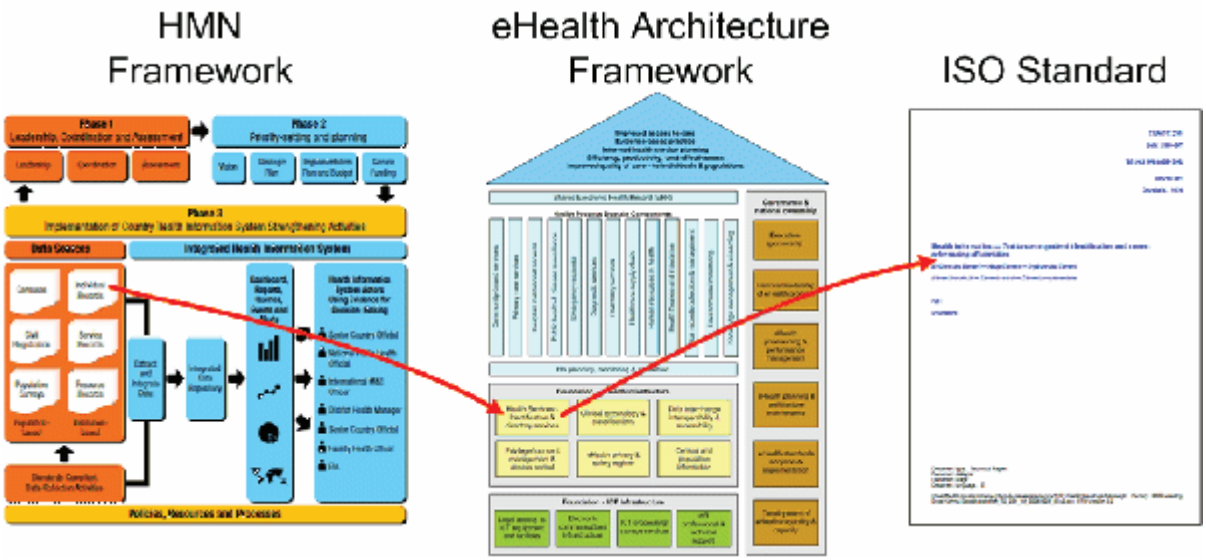

Figure 11 — Relationship of frameworks to standards

The model shows a high-level view of the components of an eHealth architecture. These are described further in this document with general descriptions of levels of maturity. The levels of maturity are guidance only since environments can vary from country to country.

International standards are an important part of developing robust and interoperable health information systems. However, international standards have historically described mature or highly evolved systems, making implementation challenging for those seeking an entry-point into standards for strengthening their eHealth architectures.

There is a need for systematic analyses of eHealth architectures within and across countries to facilitate strategic planning and program management. The model described herein can be used for analysis in countries with less developed systems. By defining indicators against this framework, HSS efforts can be monitored over time and priorities and gaps addressed. The countries described would show different profiles, which would be consistent with their level of maturity and strategic direction.

Figure 12 below shows this model of eHealth architecture and the relationship of the components that impact healthcare delivery. In this part of ISO/TR 14639, each of the elements contained in the governance, infrastructure, infostructure, and functional domains are defined with levels of maturity to describe HIS at different levels of development.

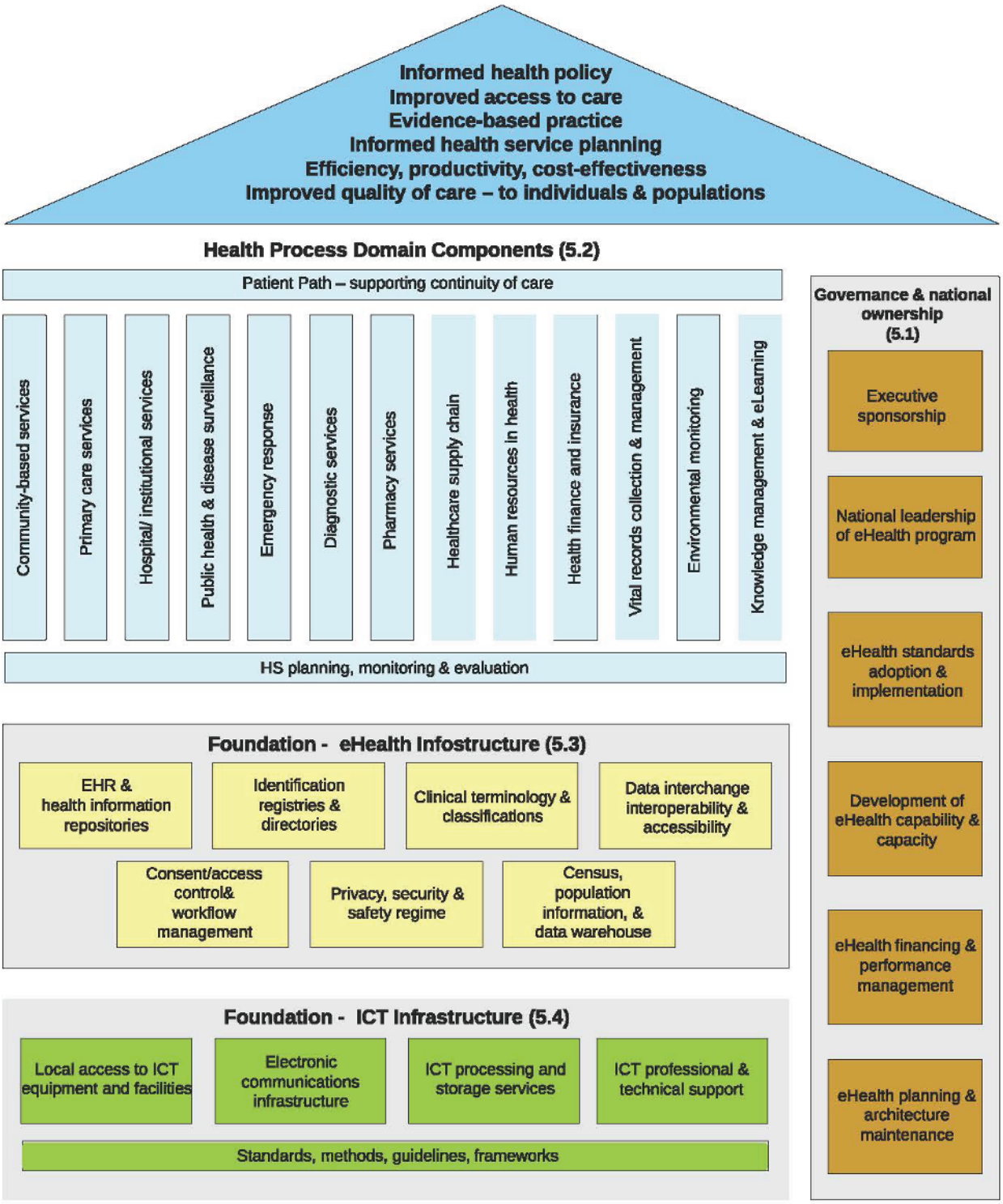

Figure 12 — Model of an eHealth architecture[200]

The methodology introduced in this part of ISO/TR 14639 will be useful at the international level to assist with strategy development, resource mobilization, and alignment with initiatives like the Millennium Development Goals (MDGs), which are the eight goals that all 191 UN member states have agreed to try to achieve by the year 2015.[72] The United Nations Millennium Declaration, signed in September 2000, commits world leaders to combat poverty, hunger, disease, illiteracy, environmental degradation, and discrimination against women. The MDGs are derived from this Declaration, and all have specific targets and indicators.

Figure 13 illustrates the state of the health process domain components in a low-income country. This country might be well-positioned, having initiated electronic vital statistics and disease surveillance reporting and pharmacy services to address the MDG. Other areas of the eHAM can be similarly analysed and compared to other countries to assist with strategic planning. A worksheet is provided below to assist with this effort.

NOTE Figure 13 was created using Reference [71] software and reprinted with the kind permission of Dr. Andrew Grant, CRED, Université de Sherbrooke, Quebec, Canada.

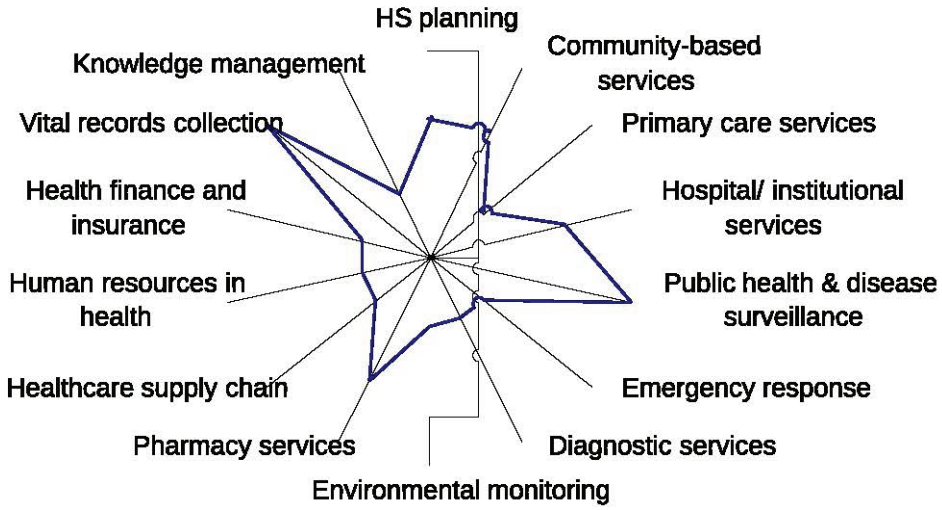

Figure 13 — Health process domain components in low-income countries

While the goals of eHealth architecture and HIS are to support patient-care and population-based programmatic interventions, high- and low-income countries may have different entry-points due to differences in capacity. For example, initial priority may be on disease surveillance and vital statistics reporting in a low-income country for summary reporting while other areas in the model are developed. The framework will help these countries transition to a more developed eHealth architecture and HIS supporting patient-centred healthcare.

This worksheet can be used to summarize the state of a country's eHealth architecture according to the eHAM. While subject to interpretation, it provides a framework for analysis of country needs. Eventually, the methodology and scoring the list could facilitate regional strategy and resource allocation.

Table 4 — Summary worksheet - eHAM components and maturity levels

	Low	Med	High
Governance and national ownership			
Executive Sponsorship			
National leadership of eHealth program			
eHealth standards adoption and implementation			
Development of eHealth capability and capacity			
eHealth financing and performance management			
eHealth planning and architecture maintenance			
Health process domain components			
Community-based services			
Primary care services			

Table 4 *(continued)*

	Low	Med	High
Hospital/institutional services			
Public health and disease surveillance			
Emergency response			
Diagnostic services			
Pharmacy services			
Healthcare supply chain			
Human resources in health			
Health finance and insurance			
Vital records collection and management			
Environmental monitoring			
Knowledge management and eLearning			
HS planning, monitoring, and evaluation			
Foundation Components — eHealth infostructure			
EHR and health information repositories			
Identification registries and directories			
Clinical terminology and classifications			
Data interchange interoperability and accessibility			
Consent/access control and workflow management			
Privacy, security, and safety regime			
Census information, population information, and data warehouse			
Foundation Components — ICT infrastructure			
Local access to ICT equipment and facilities			
Electronic communications infrastructure			
ICT processing and storage services			
ICT professional and technical support			
Standards, methods, guidelines, frameworks			

8 Future Considerations

The eHAM is a milestone in global standardization with its proposed HIS evolution methodology.

It is clear that this model will continue to grow and evolve with implementation and use and ongoing input from various experts who have reason to review and utilize the model when developing, designing, implementing, evaluating, and maintaining their eHealth initiatives.

While the core components of the model are not expected to change, there may be a need to explicitly identify and drive out additional sub-components within the existing main categories, e.g. infostructure and health process domains, and to more clearly articulate the role of standards as being both integral to and a benefit of the model.

To help further evolve the model and achieve the goal of truly interoperable systems, additional international standards efforts should focus on the following:

— individual data and summary data exchange formats;

— development of indicators associated with the components of the architecture, as well as development and use of indicator registries;

— standardizing clinical concepts;

— resource allocation and capacity-building based on standard country profiles.

This part of ISO/TR 14639 is intended to spur action at both local and international levels by providing a roadmap that supports these undertakings.

Annex A
(informative)

World Economic Forum — Global Health Data Charter

A.1 Background

At its annual meeting held in Davos-Klosters, Switzerland in January 2011, the World Economic Forum (WEF) released its Global Health Data Charter (charter),[4] which was developed with support from a major international consulting firm and a broad group of stakeholders, including many leaders in the delivery of healthcare services.

The charter recognizes that accurate health data are essential for effective and efficient health management and aims to enable individuals and patients, health professionals, and policy-makers to make more informed decisions through secure access to comprehensive, quality data. Despite overwhelming demand, in both developed and developing countries, there are critical challenges to the collection, analysis, and application of high-quality health data; accurate health data are often simply not available.

The charter has been designed to provide direction and help those seeking to improve health data management by encouraging better data management practices. It is designed as a foundation document capable of being applied at different levels within a country, health system, or individual health facility and identifies components that need to be addressed in concert to ensure success in managing health data.

The charter is available for download from http://www3.weforum.org/docs/WEF_HE_GlobalHealthData_Charter_2011.pdf.[4]

A.2 Vision

The charter notes that better health for all is a "universal vision" but it cannot be realized without major transformation of the health system at all levels. The success of efforts to transform the health system will greatly depend on the ability of health planners and funding bodies, clinical service providers, and the communities and individuals that they serve to obtain and apply high-quality health data to make informed decisions.

For these reasons, the charter's vision is "Better Health Data for Better Health".

A.3 Principles

The WEF review found that there are currently two broad areas that represent gaps needing to be addressed in order to be able to obtain and use higher quality data for the planning and improvement of care processes. They are the following:

a) Access – the inability to effectively and efficiently access and use health data – the right data in the right format, where, and when they are needed.

b) Privacy – the lack of clear global policies, standards, regulations, and health data stewardship protocols to address the challenges associated with access to health data and its use, while maintaining an individual's privacy rights and minimising the risks of misuse.

The charter identified eight key principles that are essential to closing the gaps in access and privacy, in order to realize the vision. They are the following:

1) Availability - Comprehensive health data should be made available for authorized use.

2) Accessibility - Individuals and other authorized users of health data should have access to health data, plus know what data exist and how to access them.

3) Data Quality - Data quality and integrity must be maintained throughout the life of health data.

4) Standardization - Common health data standards must be adopted to facilitate comparability and interoperability.

5) Technology - Digital records, interoperable networks, and technical toolsets must be in place for optimal management and dissemination of health data.

6) Rights and Protection - Clear policies and procedures should be implemented to ensure the privacy, confidentialty, and security of health data.

7) Secondary Use - Appropriately de-identified health data should be used to advance research, public health, quality improvement, and other efforts.

8) Stewardship - Clear accountabilities for managing, using, and protecting health data should be established at all levels to build confidence and promote data sharing.

Those voluntarily adopting the WEF charter commit to apply all of the above eight principles within their environments.

A.4 Enablers

Seven fundamental enablers have been identified as being pre-requisites for ensuring that the principles are addressed and that progress is made on the journey toward successful implementation of the charter.

a) Leadership - Appropriate leadership must be put in place and nurtured at all levels to advocate for the charter's implementation and create the necessary cultural change.

b) Collaboration - Collaboration and cooperation must be mobilized throughout the health landscape to realize the mutual benefits of effective health data management.

c) Capacity - Targeted efforts to build capacity must be implemented to ensure that the requisite knowledge, skills, infrastructure, processes, and technology are in place.

d) Knowledge - Stakeholders must actively disseminate best practices, lessons learned, case studies, etc. to demonstrate the value that can be realized from improved health data management.

e) Investment - Sufficient financial and other resources must be mobilized to support the necessary effort to both launch and sustain implementation.

f) Incentives - Appropriate incentives must be put in place to expedite adoption and adherence to the charter's principles.

g) Evaluation - A systematic, standardized approach to measuring adoption of the charter's principles must be implemented to assess progress and accelerate improvement.

Those voluntarily adopting the WEF charter commit to apply all of the above enablers within their environments.

A.5 Proposed outcomes

Figure A.1 summarizes the principles and enablers contributing to achievement of the charter's vision to realize outcomes in the following four key result areas:

a) Improve health outcomes - Individual health data and population-based data are valuable assets towards optimizing decision-making, which in turn can lead to more effective health management and improved health outcomes.

b) Address disparities - Disadvantaged populations have the most to gain from improved health data management, if workforce capacity, technology, and investment deficiencies are adequately addressed.

c) Enable innovation - Health data can significantly influence transformation by enabling creative thinking and the development of innovative solutions to address our current challenges.

d) Drive efficiencies - Use of health data can deliver increased time and cost-efficiency, resulting in improved productivity and optimized resources.

NOTE Figure A.1 was reproduced from Reference [4], with kind permission of the World Economic Forum, Geneva, Switzerland.

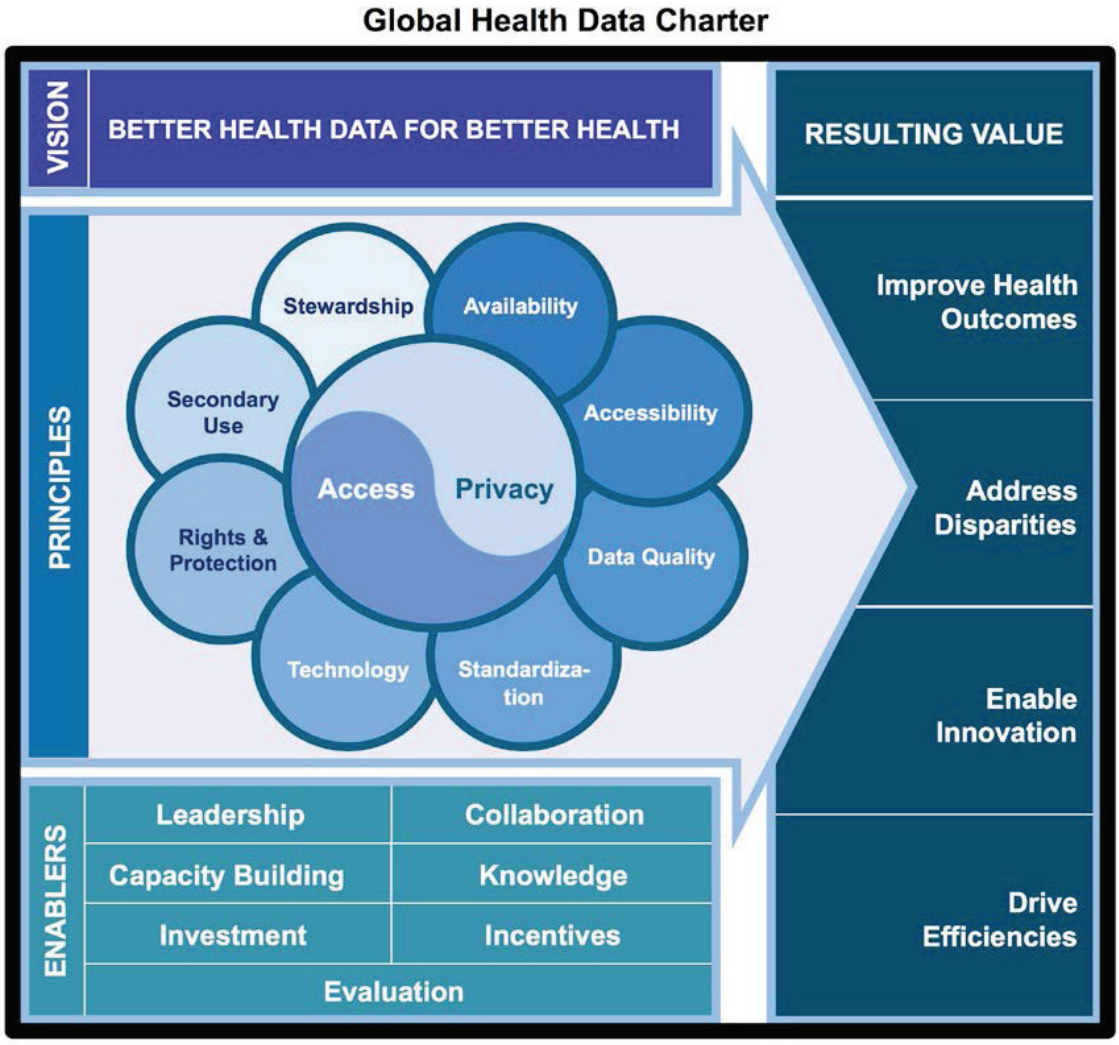

Figure A.1 — Global Health Data Charter, World Economic Forum 2011

Commentary on progress and the most current list of organizations that have endorsed the charter are available from the World Economic Forum's website.[4]

Annex B
(informative)

Generic component model

The architectural approach to optimally interoperable and sustainable eHealth systems must start by considering the business processes for achieving intended business objectives, reflected by different domains such as medical (with specializations), technical, legal, and financial.

For meeting these requirements mentioned in the previous section, the system consists of components realizing certain functionalities. The components aggregation (composition) enables a higher complexity of the system's structure and behaviour. The aforementioned different aspects can be separately modelled by specializing the system model into domain models. Those domain models, which have to follow the architectural approach of composition/decomposition (generalization/specialization), are interrelated and constrain each other. Finally, the architecturally and domain-specifically described eHealth system must be formally specified and implemented as an ICT solution. This process is defined, e.g. in ISO/IEC 10746, and implemented by a Unified Process and appropriate tooling. The architectural framework of any system has been comprehensively summarized in the Generic Component Model (GCM).[6] In the GCM context, the eHealth architecture TR 14639 deals with can be depicted as shown in Figure B.1.

NOTE Figure B.1 has been adapted from Reference [6], with kind permission of Dr. Bernd Blobel, eHealth Competence Center, University Hospital Regensburg, Regensburg, Germany.

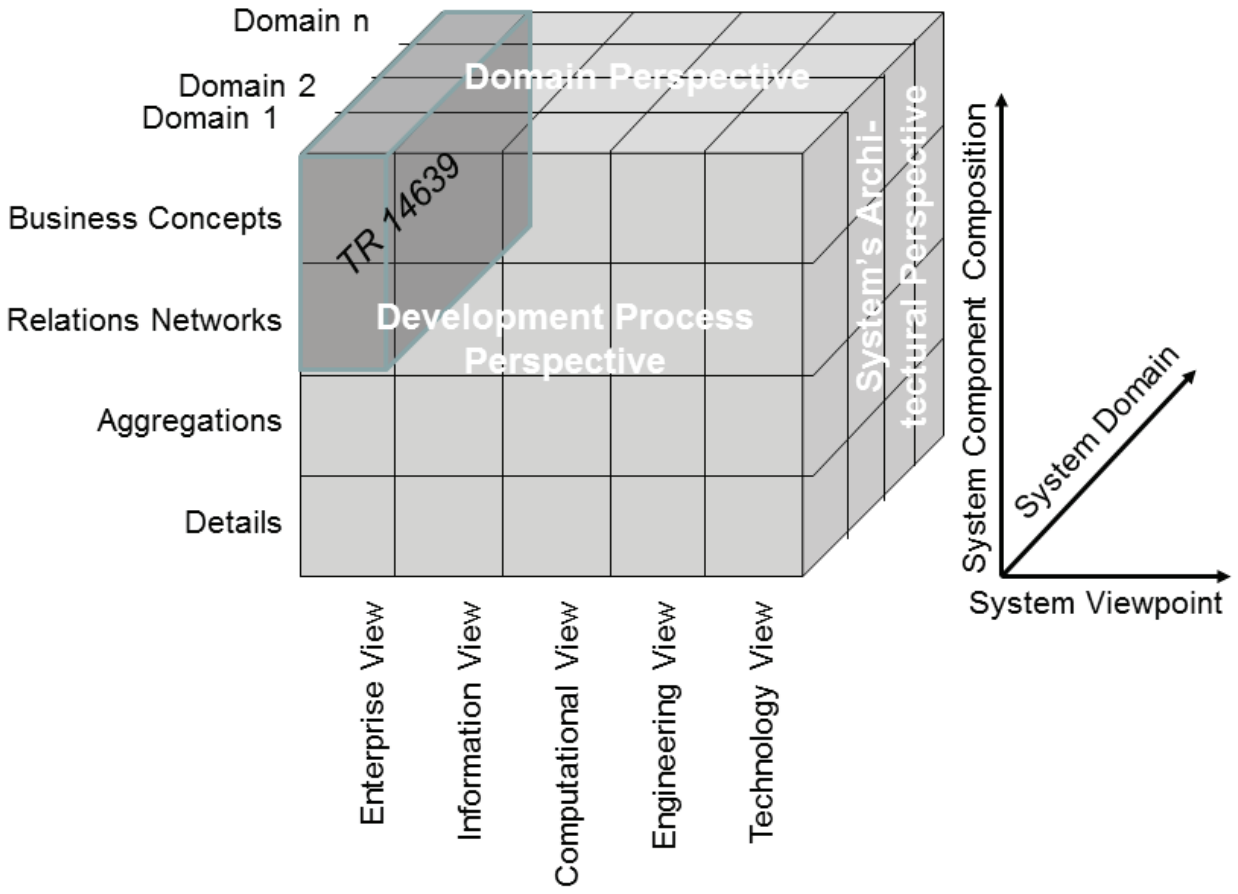

Figure B.1 — eHAM within the GCM framework

Annex C
(informative)

Health informatics — Service architecture (HISA)

C.1 HISA in short

ISO 12967 is a standard having the scope of defining, on one side, an architecture enabling openness, integration, and interoperability amongst healthcare enterprise information systems and, on the other side, a methodology to describe healthcare systems through a language, notation, and paradigm suitable to facilitate the planning, design, and comparison of systems.

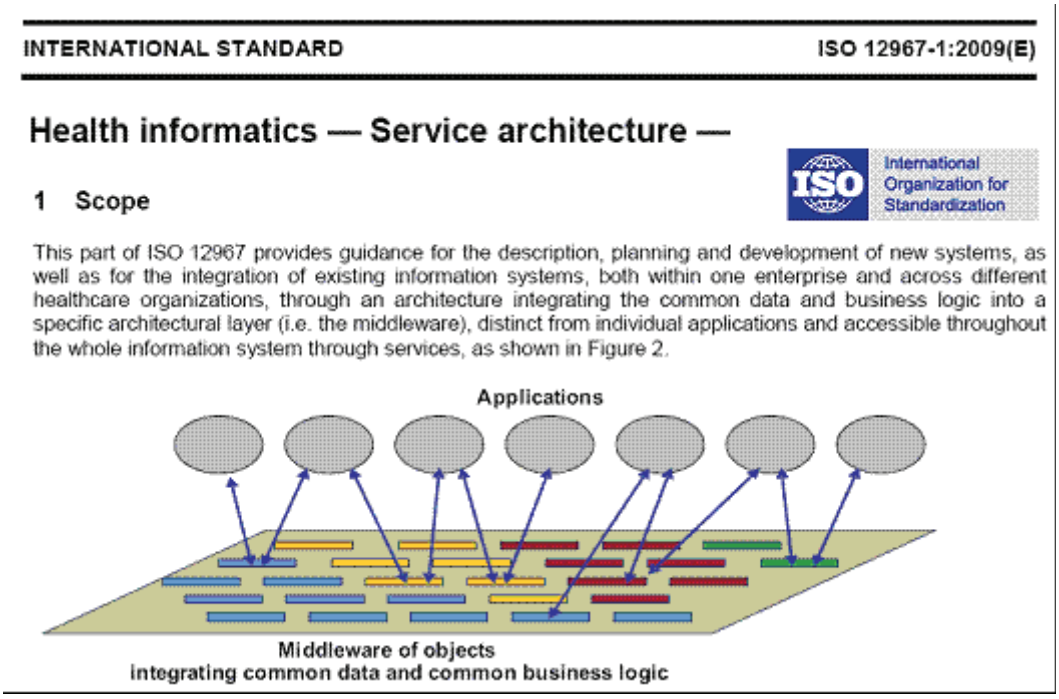

Figure C.1 — Health informatics — Service architecture (HISA)[1][2][3]

The goal is achieved through a unified, open service architecture based on a middleware layer, also referred to in the report as the Integrated Data Repository (IDR) which is independent not only from technological specifications but also from specific applications. It is capable of handling the integrated common information asset and basic business logic of the healthcare enterprise. The middleware makes such common data and business logic available to diverse, multi-vendor applications through a service architecture than can be based on many types of deployment interfaces (e.g. Web-services, etc.).

According to the integration objectives at the enterprise level, all aspects (i.e. clinical, organizational, and managerial) of the healthcare centre are supported by the architecture, which is able to include all relevant information and all business workflows, structuring them according to criteria and paradigms independent from aspects related to specific sectors, temporary requirements, or technological solutions. The architecture is intended as a basis both for working with existing systems, as well as for the planning and construction of new systems or evolving existing architectures towards a higher capacity level.

HISA provides guidance for the enterprise to develop and describe its architecture by identifying its own specific requirements as regards business, existing legacy, information, and external dependencies. The three parts of HISA are structured as follows:

a) **Enterprise Viewpoint** - Overall methodological and architectural framework, conformance criteria, fundamental organizational processes of the healthcare organizations.

b) **Information Viewpoint** - Specification of the information model supporting the service architecture to integrate the common information and make them available in the system.

c) **Computational Viewpoint -** Specification of the (fundamental) services in terms of the interfaces and the behavioural aspects to be provided by the service architecture to allow manipulation of elementary data and to execute common business logic.

C.2 Cooperation of new and legacy systems

The healthcare-specific middleware service architecture approach represents a step forward in interoperability between parts of the healthcare enterprises. A limit that has hindered interoperability is that real integration is not actually guaranteed, like in systems having only interaction of separated modules through messages. As a consequence, without real integration there is no contribution to the information integrity of the healthcare process (and of the whole enterprise), which is instead a fundamental role played by the IDR. In sole message-based systems, data still remains under the property and control of specific application modules, in case even proprietary. Furthermore, since several modules of the system might manage the same information, the whole architecture may end up with copies of the same data which are scattered across the applications and managed through algorithms, timing phases, and business rules which are quite different from each other and not synchronised with each other.

The IDR solves this problem by automatically implementing the 'corporate repository, where all information are organized in a consistent and homogeneous way. The corporate repository may be both physically integrated or logically distributed depending on the configuration and on the requirements/organization of the enterprise; nevertheless, it provides a unique, common model of the enterprise's information asset, as well as becoming the basis for a unique common set of services for managing them.

It must be pointed out that the middleware paradigm does not however impede at all the synergic utilization of message-based mechanisms and protocols that instead may be effectively used to allow existing applications to interact with the service architecture, as a possible physical implementation of the feeding and retrieving of the common data.

C.3 Describing the Enterprise's eHealth service and information models

HISA methodology can be used to describe the Enterprise's eHealth Service Architecture, analysing the healthcare processes while taking into account also the patient or assisted citizen as the central player in the scenario. HISA standard addresses the development of service architecture for the information systems providing guidance for the development and description of the architecture by identifying the Enterprise's own specific requirements as regards business, existing legacy, and external dependencies, according to the three-part structure used by HISA itself.

The LIC healthcare enterprise identifies its central processes relating them to the HISA ones (i.e. Subject of Care Workflow, Activities Management Workflow, Clinical Information Workflow, etc.) in its own Enterprise Viewpoint of the services architecture. The Information Viewpoint is the prepared and used to detail the information structures using UML class diagrams. The information model must be specified without any explicit or implicit assumption on the physical technologies, tools, or solutions to be adopted for its physical implementation in the various target scenarios.

Finally, a computational Viewpoint shall be required to specify the interfaces and the behavioural patterns of the healthcare services for supporting the workflows and activities identified in the Enterprise View. This is done by identifying computational objects associated to the information objects seen in the Information Viewpoint. In other words, for each healthcare service cluster, there will be a set

of computational objects providing interfaces allowing the management of the common information and business logic relevant to the enterprise.

Annex D
(informative)

Candidate standards supporting eHealth Architecture Model and Maturity Models

The candidate standards have been provided in two groups – Candidate Group 1 and Candidate Group 2. This division is based on expert opinion but does not reflect a full consensus agreement. Individuals may see the need to choose standards from either group to meet their specific implementation needs.

Candidate Group 1 are those deemed of high importance and relevance with respect to facilitating the development, design, and implementation of national-level health information system (HIS) initiatives, particularly in LMICs. The list includes standards pertaining to core areas such as data, messaging, architecture, and security.

Candidate Group 2 are those deemed useful and may be of high value relevant to a particular country's national HIS initiative but may not be deemed essential (core) to moving forward with implementation in LMICs.

The majority of the standards listed are ISO standards but other key standards of importance, e.g. HL7, SNOMED CT, are also included.

Table D.1 — Candidate Standards — Group 1

Recommended			
#	**Standard**	**Reference**	**Available at:**
1	Business requirements for health summary records — Part 1: Requirements	TR 12773–1	ISO/TR 12773-1:2009
2	Business requirements for health summary records — Part 2: Environmental scan	TR 12773–2	ISO/TR 12773-2:2009
3	Capacity-based eHealth architecture roadmap — Part 1: Overview of national eHealth initiatives	TR 14639–1	ISO/TR 14639-1:2012
4	Classification of purposes for processing personal health information	TS 14265	ISO/ TS 14265:2011
5	Deployment of a clinical data warehouse	TS 29585	ISO/ TS 29585:2010
6	Directory services for healthcare providers, subjects of care and other entities (renamed 2007 - Brisbane)	ISO 21091	ISO 21091:2013
7	EHR communication — Part 1: Reference model	ISO 13606-1	ISO 13606-1:2009
8	EHR communication — Part 2: Archetype interchange specifications	ISO 13606-2	ISO 13606-2:2008
9	EHR communication Part 3 — Archetypes and term list interchange specifications	ISO 13606-3	ISO 13606-3:2008
10	EHR communication — Part 4: Security	ISO 13606-4	ISO/TS 13606-4:2009
11	EHR communication — Part 5: Interface specification	ISO 13606-5	ISO 13606-5:2010
12	EHR definition, scope and context	TR 20514	ISO/ TR 20514:2005
13	EHR system functional model	ISO 10781	ISO/ HL7 10781:2009
14	Functional and structural roles	TS 21298	ISO/ TS 21298:2008

Table D.1 *(continued)*

Recommended			
15	Good principles and practices for a clinical data warehouse	TR 22221	ISO/ TR 22221:2006
16	Guidelines for terminology development organizations	TR 12309	ISO/ TR 12309:2009
17	Harmonized data types for information interchange (name change 2007)	ISO 21090	ISO 21090:2011
18	Health indicators conceptual framework	ISO 21667	ISO 21667:2010
19	Health Informatics — Service architecture — Enterprise viewpoint	ISO 12967-1	ISO 12967-1:2009
20	Health Informatics — Service architecture — Information viewpoint	ISO 12967-2	ISO 12967-2:2009
21	Health Informatics — Service architecture — Computational viewpoint	ISO 12967-3	ISO 12967-3:2009
22	Clinical document architecture (Release 2)	ISO 27932	ISO/ HL7 27932:2009
23	HL7v 2.5 — An application protocol for electronic data exchange in health-care environments	ISO 27931	ISO/ HL7 27931:2009
24	HL7 v3 — Reference information model	ISO 21731	ISO/ HL7 21731:2006
25	Identification of subjects of healthcare	TS 22220	ISO/ TS 22220:2011
26	IHE Integrating the Healthcare Enterprise		www.ihe.net
27	Information security management in health using ISO/IEC 27002	ISO 27799	ISO 27799:2008
28	Interoperability of telehealth systems and networks — Part 1: Introduction and definitions	TR 16056	ISO/TR 16056-1:2004
29	Knowledge management of health information standards	TR 13054	ISO/ TR 13054:2012
30	Logical Observation Identifiers Names and Codes (LOINC)		http://loinc.org
31	Personal health records: definition, scope and context	TR 14292	ISO/ TR 14292:2012
32	Privilege management and access control — Part 1: Overview and policy management	TS 22600–1	ISO/TS 22600-1:2006
33	Privilege management and access control — Part 2: Formal models	TS 22600–2	ISO/TS 22600-2:2006
34	Privilege management and access control — Part 3: Implementations	TS 22600–3	ISO/TS 22600-3:2009
35	Pseudonymization	TS 25237	ISO/ TS 25237:2008
36	Requirements for an electronic health record architecture	TS 18308	ISO 18308:2011
37	Secure archiving of electronic health records — Part1: Principles and requirements	TS 21547	ISO/ TS 21547:2010
38	Secure archiving of electronic health records — Part 2: Guidelines	TR 21548	ISO/ TR 21548:2010
39	System of concepts to support continuity of care	ISO 13940	ISO/IS 13940
40	SDMX-HD		http://www.sdmx-hd.org/
41	SNOMED-CT		http://www.ihtsdo.org/
42	WHO ICD-10		http://www.who.int/classifications/icd/en/

Table D.2 — Candidate Standards — Group 2

Optional			
#	**Standard**	**Number**	**Source**
1	Classification of safety risks from health software	TS 25238	ISO/ TS 25238:2007
2	Clinical analyser interfaces to laboratory information systems — Use profiles	ISO 18812	ISO 18812:2003
3	Controlled health terminology — Structure and high-level indicators	TS 17117	ISO/ TS 17117:2002
4	Format of length limited globally unique string identifiers	ISO 18232	ISO 18232:2006
5	Health Cards — General characteristics	ISO 20301	ISO 20301:2006
6	Health cards — Numbering system and registration procedure for issuer identifiers	ISO 20302	ISO 20302:2006
7	Health informatics profiling framework	TR 17119	ISO/ TR 17119:2005
8	Integration of a reference term model for nursing	ISO 18104	ISO 18104:2003
9	Medical waveform format — Part 92001: Encoding rules	TS 11073–92001	ISO/TS 11073-92001:2007
10	National Council for Prescription Drug Programs (NCPDP) Standards		www.ncpdp.org
11	Patient healthcard data — Part 1: General structure	ISO 21549-1	ISO 21549-1:2004
12	Patient healthcard data — Part 2: Common objects	ISO 21549-2	ISO 21549-2:2004
13	Patient healthcard data — Part 3: Limited clinical data	ISO 21549-3	ISO 21549-3:2004
14	Patient healthcard data — Part 4: Extended clinical data	ISO 21549-4	ISO 21549-4:2006
15	Patient healthcard data — Part 5: Identification data	ISO 21549-6	ISO 21549-5:2008
16	Patient healthcard data — Part 5: Administrative data	ISO 21549-5	ISO 21549-6:2008
17	Patient healthcard data — Part 7: Medication data	ISO 21549-7	ISO 21549-7:2007
18	Patient healthcard data — Part 8: Links	ISO 21549-8	ISO 21549-8:2010
19	Personal health device communication — Part 10406: Device specialization — Basic electrocardiograph (ECG) (1- to 3-lead ECG)	ISO/ IEEE 11073-10406	ISO/IEEE 11073-10406:2012
20	Public key infrastructure — Part 1: Overview of digital certificate services	TS 17090–1	ISO 17090-1:2008
21	Public Key Infrastructure — Part 2: Certificate profile	TS 17090–2	ISO 17090-2:2008
22	Public key infrastructure — Part 3: Policy management of certification authority	TS 17090–3	ISO 17090-3:2008
23	Vocabulary for terminological systems	ISO 17115	ISO 17115:2007

Annex E
(informative)

WHO Indicator and Measurement Registry (IMR)

Multiple sources of indicator definitions containing discrepancies or incomplete metadata limit our ability to collect comparable data. Efforts to rationalize and streamline computer and human processes associated with indicator management are needed.

Guidelines documents produced by reference groups may not contain sufficient information to create a computer application, i.e. calculation or disaggregation information may not be present. Further, when multiple groups define the same indicators, differences occur, including differences in metadata and representation, making exchange of data difficult.

The IMR[73] is a utility to facilitate harmonization of indicator definitions across organizations. Analysts can create, manage, harmonize, and publish summary indicator definitions, which can be implemented in computer applications. Multi-organizational views of metadata provide support for similar indicator definitions while harmonization efforts proceed.

A process for distribution of global indicator definitions, implementing standard data exchange formats, and developing technical capacity will accelerate the development of global monitoring and disease surveillance.

Complete indicator specifications, i.e. concept and metadata, provide guidance on data collection methodology, metadata required, and disaggregation and give clear direction to both analysts and system developers. Electronic indicator definitions help to promote standard data-collection methodology and international standards with the documentation and structure built into indicator definitions.

A standard transmission format alone, however, is not sufficient to permit data exchange. The SDMX-HD[75] is the health domain's implementation of the ISO SDMX standard[74] for aggregate data exchange. The IMR addresses the harmonization of semantic content while the SDMX-HD addresses the syntax for the information.

An indicator management infrastructure can improve our ability to define, collect, and analyse indicator data. The accuracy and timeliness of analyses will improve as variant definitions converge and data moves in a more streamlined manner via more automated international reporting.

To address this need, IMR leverages the strengths of knowledge in data exchange and Monitoring and Evaluation (M & E) to build an infrastructure for managing indicator definitions. The IMR includes functionality to support development, harmonization, vetting, and sharing of programmatic indicator definitions.

Annex F
(informative)

Statistical Data and Metadata Exchange for the Health Domain (SDMX-HD)

F.1 General considerations

The adoption of ISO/TS 17369:2005 for summary data exchange will contribute to efforts to promote computer system interoperability and data use. The SDMX-HD (Health Domain)[75] is the WHO implementation of the SDMX standard which is implemented in the WHO Indicator and Measurement Registry (IMR),[73] a facility for harmonizing, managing, and publishing computer-readable indicator definitions.

An interoperability-based strategy for health information system (HIS) strengthening is appropriate for countries beginning development of summary data based monitoring and disease surveillance systems. As capacity is developed, movement toward case-based reporting and development of clinical data warehouses (CDW) can occur if needed.

The SDMX-HD is intended to become part of countries' initial HIS and M & E infrastructure strengthening strategy, facilitating flow of information from facility to district, national, and international levels in the absence of well-developed Internet connectivity.

F.2 Uses

F.2.1 Capacity-building, monitoring and evaluation (M & E), and international reporting

An NGO unaware of international indicator harmonization efforts imports an SDMX-HD indicator definition file into an existing application. It is now clear what data are required by national and international groups for reporting, including information on methodology for providing collection guidance. Prior to import, the existing application was modified to accept the SDMX-HD, including addition of a dimension required by donors not existing in the database. The data are combined and analysed for all districts at the national level. In turn, data aggregated across countries at WHO, received via SDMX-HD, enables timely creation of a global report.

F.2.2 Patient care and development of monitoring infrastructure

Indicator definitions are imported into a clinical system that supports the SDMX-HD. Another clinic in a different location imports the same indicator definitions which include clinical concepts. A patient transferred to the other clinic will encounter a system that has clinical data defined in the same manner, enabling both patient data exchange and standard summary reporting, horizontally in the clinical system and vertically up through the M & E system.

F.2.3 Application interoperability

SDMX-HD enables specialized functionality of systems supporting the standard to be leveraged, making application development more cost-effective. For example, for geographic mapping, data can be imported into GIS applications supporting the format, eliminating the need to replicate the mapping functionality in multiple applications.

F.3 Data exchange requirements

Data exchange has historically occurred through negotiation of file formats between partners with documentation consisting of a file format and dictionary. The further data are removed from its source, the more important metadata, or data about data, becomes to unambiguously describe data. The SDMX-HD defines the attributes of a data item, which reduces the negotiation required to exchange data, providing more complete context and meaning of data.

The SDMX-HD incorporates both M & E and informatics requirements for content, providing a guide for computer applications and data to conform to international standards. It will be a useful benchmark for countries to evaluate applications being considered for M & E systems. In some cases, applications may need to be revised to support the standard, with support for dimensional data for performance-based M & E being a prominent example.

F.4 SDMX structure

The SDMX standard describes statistical data and metadata through a data structure definition (DSD), which sets out concepts that define dimensions, attributes, code lists, and other artefacts necessary to describe the structure and meaning of data. A parallel metadata structure definition (MSD) describes metadata associated with data at observation, series, group, and data set levels.

With the SDMX-HD, these structures define metadata concepts recommended in international standards and programs, creating a message that will satisfy a majority of PHI requirements with common and program-specific needs.

Harmonization of globally-reported indicators and metadata are a priority, which the IMR intends to address. However, enhancements to SDMX-HD were needed to accommodate all reporting requirements in the absence of harmonized and centrally managed indicator definitions and metadata. Examples of these PHI requirements included the following:

a) deconstruction of indicators into clinical concepts and synchronization with clinical systems;

b) unharmonized concepts and code lists across organizations and programs;

c) organization and program-specific metadata views and code lists.

F.5 SDMX individual and summary country reporting systems

An added benefit of implementing data interchange standards in applications has been to promote differentiation of software. A combination of clinical, monitoring, analytic, and geographic mapping software which can exchange data can provide a cost-effective comprehensive solution for countries.

Note that both individual and summary data are part of a population-based monitoring system. With a lag between the rollout of electronic medical record systems and an immediate need for national and international reporting, both individual and summary systems may be needed to obtain population-based data. Within this context, the requirements for a monitoring system need to be prioritized and phased to guide project progress.

Use of the standards permits horizontal integration of clinical systems and vertical interoperability in the M & E system, helping to break down ‘silos’ of data, providing a seamless flow of data from the facility to district, national, and international levels. An opportunity exists to strengthen monitoring systems in addition to the improvement of patient care with international reporting requirements for UNGASS (UN General Assembly Special Session), the Global Fund, and PEPFAR (President’s Emergency Plan for AIDS Relief) driving demand for facility-level data. This does not preclude the development of national clinical data warehouses as a longer-term goal, when required.

The global monitoring system schematic includes multiple domains in addition to different implementation scenarios. These scenarios vary depending on country circumstances such as existence

of clinical systems, administration, connectivity, the location of aggregation of individual data, and other factors.

The mix of aggregate and individual-data systems and their location in the country reporting system will vary. Development of Maturity models can be useful to describe individual and summary data systems in countries. Being able to accommodate both types of systems, data can move seamlessly from the facility or from the district to the international level, establishing the processes upon which future systems can evolve.

F.6 SDMX Data exchange standards

The data exchange standards are the heart of the monitoring architecture. The data exchange formats enable legacy, vertical, and local systems to be integrated into 'one' national Monitoring and Evaluation (M & E) system, which includes clinical, population-based, geographic, financial, and programmatic data.

Data use can create feedback loops that can lead to improved data quality and more effective programs. Indicators will give decision makers the information they need to make adjustments to personnel, resources, activities, and supervision to fine tune program performance. As the stakeholders guide the roll out of activities and programs, M & E tools and approaches will be used to measure impact.

Annex G
(informative)

List of figures and tables in this part of ISO 14639

Figure 1 — Health metrics network framework

Figure 2 — Real-time gathering of information

Figure 3 — Benefits of HISA approach

Figure 4 — eHealth architecture model

Figure 5 — Health informatics scope of practice

Figure 6 — WHO/ITU Toolkit — Planning and development of eHealth strategy

Figure 7 — Relationship of indicator and measurement registry (IMR) and statistical data and metadata exchange (health domain) (SDMX-HD) to public health and disease surveillance

Figure 8 — Public health monitoring infrastructure

Figure 9—Guiding principles for design of an integrated environmental impact assessment system

Figure 10 — Health system performance measurement framework (2013)

Figure 11 — Relationship of frameworks to standards

Figure 12 — Model of an eHealth architecture

Figure 13 — Health process domain components in low-income countries

Figure A.1 — Global Health Data Charter, World Economic Forum 2011

Figure B.1 — eHAM within the GCM framework

Figure C.1 — Health Informatics — Service architecture (HISA)

Table 1 — Classification of environmental health hazards

Table 2 — Types of planning in the healthcare system

Table 3 — Approach to monitoring, evaluation, and review of national health strategies (WHO/IHP+)

Table 4 — Summary worksheet — eHAM components and maturity levels

Table D.1 — Candidate Standards — Group 1

Table D.2 — Candidate Standards — Group 2

Bibliography

[1] EN ISO 12967-1:2009, *Health informatics — Service architecture — Part 1: Enterprise viewpoint* [Internet]. [cited 2011 May 12]; Available from: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=50500

[2] EN ISO 12967-2:2009, *Health informatics — Service architecture — Part 2: Information viewpoint* [Internet]. [cited 2011 May 12]; Available from: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=51121

[3] EN ISO 12967-3:2009, *Health informatics — Service architecture — Part 3: Computational viewpoint* [Internet]. [cited 2011 May 12]; Available from: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=51122

[4] Global Health Charter. January 2011. World Economic Forum [Internet] [cited 2012 July 10]; Available from: http://www3.weforum.org/docs/WEF_HE_GlobalHealthData_Charter_2011.pdf.

[5] Health Enterprise Architecture Framework (HEAF). JEMBI [Internet] [cited 2011 January 10]; Available from: http://heaf.jembi.org/index.php?title=HEAF

[6] Blobel B. Application of the Component Paradigm for Analysis and Design of Advanced Health System Architectures. *Int. J. Med. Inform.* 2000, **60** (3) pp. 281–301

[7] Health Metrics Network Framework. World Health Organization [Internet]. [cited 2011 May 12]; Available from: http://www.who.int/healthmetrics/documents/hmn_framework200803.pdf

[8] The Open Group Architecture Framework Version 8.1.1 [Internet]. [cited 2011 May 12]; Available from: http://pubs.opengroup.org/architecture/togaf8-doc/arch/

[9] Zachman J.A. A framework for information systems architecture. *IBM Syst. J.* 1987, **26** (3) p. 276

[10] Bridging the Digital Divide - Aligning ISO, eHealth Architecture, and Open Access Activities to Facilitate Standards Implementation in Low-income Countries. Personal communication - minutes of international meeting of experts, March 30th - April 3rd, 2010, Bellagio, Italy. http://www.rockefellerfoundation.org/bellagio-center/conferences-and-residencies/18676

[11] WHO Health Services Coverage Statistics - Antenatal care coverage (percentage) [Internet]. [cited 2011 Jul 20]; Available from: http://www.who.int/healthinfo/statistics/indantenatal/en/index.html

[12] U.S. Centers for Disease Control and Prevention Biosurveillance [Internet]. [cited 2011 May 12]; Available from: http://www.cdc.gov/osels/pdf/Concept_Plan_V1+5+final+for+print+KMD.PDF

[13] Wikipedia. the free encyclopedia – definition of reference architecture [Internet]. [cited 2011 Jul 20];Available from: http://en.wikipedia.org/wiki/reference_architecture

[14] BS EN 13940-1:2007*Health informatics. System of concepts to support continuity of care. Basic concepts – BSI British Standards* [Internet]. [cited 2011 May 12];Available from: http://shop.bsigroup.com/ProductDetail/?pid=000000000030132247

[15] U.S. Centers for Disease Control and Prevention (CDC) National Center for Health Statistics [Internet]. [cited 2011 May 12]; definition of chronic disease; Available from: http://www.cdc.gov/nchs/

[16] ISO/TS 17117:2002, Health informatics — Controlled health terminology — Structure and high-level indicators [Internet]. [cited 2011 May 17]; Available from: http://www.iso.org/iso/catalogue_detail.htm?csnumber=32883

[17] ISO/TR 22221:2006, Health informatics — Good principles and practices for a clinical data warehouse [Internet]. [cited 2011 May 12];Available from: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=40783

[18] Health Level Seven International [Internet]. Available from: http://www.hl7.org/

[19] EN ISO 13606-1:2008, *Health informatics -- Electronic health record communication -- Part 1: Reference model* [Internet]. [cited 2011 May 12];Available from: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=40784

[20] ISO/TS 22789:2010, Health informatics — Conceptual framework for patient findings and problems in terminologies [Internet]. [cited 2011 May 12];Available from:http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=41141

[21] WHO. 2004 A Glossary of Terms for Community Healthcare and Services for Older Persons http://www.who.int/kobe_centre/ageing/ahp_vol5_glossary.pdf

[22] ISO 18308:2011, *Health informatics — Requirements for an electronic health record architecture* http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=52823

[23] World Bank Country Classification [Internet]. [cited 2011 May 12];Available from: http://data.worldbank.org/about/country-classifications

[24] SKMT Glossary Tool [Internet]. [cited 2011 May 12];Available from: http://www.skmtglossary.org

[25] eHealth Strategies Report – European countries on their way towards national eHealth Infrastructures, European Commission, January 2011 http://www.ehealth-strategies.eu/report/eHealth_Strategies_Final_Report_Web.pdf

[26] World Health Organization (WHO) 58th World Health Assembly, May 2005, Resolutions and Decisions, Resolution #58.28 eHealth [Internet]. [cited 2011 May 12]; Available from: http://apps.who.int/iris/bitstream/10665/20378/1/WHA58_28-en.pdf?ua=1

[27] ISO/TS 18308: 2004[1)] - Health informatics -- Requirements for an electronic health record architecture [Internet]. [cited 2011 May 12];Available from: http://www.iso.org/iso/catalogue_detail.htm?csnumber=33397

[28] ISO/CD 13940-1 - Health informatics -- System of concepts to support continuity of care -- Part 1: Basic concepts [Internet]. [cited 2011 May 12];Available from:http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=52389

[29] Wikipedia. the free encyclopedia [Internet]. [cited 2011 Jul 20];Available from: http://en.wikipedia.org/wiki/Enterprise_Architecture

[30] Blobel B. Architectural approach to eHealth for enabling paradigm changes in health. *Methods Inf. Med.* 2010, **49** (2) pp. 123–134

[31] WHO World Health Assembly May 2005 Resolutions and Decisions; resolution #58 | eHealth [Internet].[cited2011Jul20];Availablefrom:http://apps.who.int/iris/bitstream/10665/20378/1/WHA58_28-en.pdf?ua=1

[32] World Health Organization (WHO) Health Definition [Internet]. [cited 2011 May 12];Available from: http://www.who.int/suggestions/faq/en/index.html

[33] Info for Solution Providers - Canada Health Infoway [Internet]. [cited 2011 May 12];Available from: https://www.infoway-inforoute.ca/working-with-ehr/solution-providers

1) Replaced by ISO 18308: 2011

[34] ISO/TR 12773-2:2009, Business requirements for health summary records — Part 2: Environmental scan [Internet]. [cited 2011 May 12];Available from: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=53599

[35] ISO/TR 18307:2001, Health informatics — Interoperability and compatibility in messaging and communication standards — Key characteristics [Internet]. [cited 2011 May 12];Available from:http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=33396

[36] Canada's Health Infostructure [Internet]. [cited 2011 Jul 20];Available from: http://www.hc-sc.gc.ca/hcs-sss/eHealth-esante/infostructure/index-eng.php

[37] Integrated Disease Surveillance - WHO Regional Office for Africa [Internet]. [cited 2011 May 12];Available from: http://www.afro.who.int/en/clusters-a-programs/dpc/integrated-disease-surveillance.html

[38] Wikipedia. the free encyclopedia [Internet]. [cited 2011 Jul 20];Available from: http://en.wikipedia.org/wiki/Capability_Maturity_Model

[39] Global Fund for AIDS, Tuberculosis, and Malaria (GFATM) Monitoring and Evaluation Concepts [Internet]. [cited 2011 May 12];Available from: http://www.theglobalfund.org/documents/me/ME_Concepts.pdf

[40] World Health Organization (WHO) International Health Regulations. (IHR) [Internet]. [cited 2011 May 12]; Available from: http://www.who.int/ihr/en/; http://whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf

[41] ISO/IEC 6523-1:1998, *Information technology — Structure for the identification of organizations and organization parts — Part 1: Identification of organization identification schemes*

[42] ISO/TR 21089:2004, Health informatics — Trusted end-to-end information flows [Internet]. [cited 2011 May 12];Available from: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=35645

[43] ISO/IEC 2382-8:1998, Information technology — Vocabulary — Part 8: Security [Internet]. [cited 2011 May 12];Available from: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=7243

[44] Standard in development. BS ISO TR 14292 Health informatics: Personal health record - Definition, scope and context [Internet]. [cited 2011 May 12];Available from:http://standardsdevelopment.bsigroup.com/Home/Project/201003542

[45] ISO/TR 20514:2005, Health Informatics — EHR Definition, scope and context http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=39525

[46] ISO/TS 22600-1:2006, Health informatics — Privilege management and access control — Part 1: Overview and policy management [Internet]. [cited 2011 May 17];Available from:http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=36337

[47] Primary care : concept, evaluation, and policy / Barbara Starfield | National Library of Australia [Internet]. [cited 2011 May 17];Available from: http://catalogue.nla.gov.au/Record/331833

[48] ISO/IEC 10036:1996, Information technology — Font information interchange — Procedures for registration of font-related identifiers [Internet]. [cited 2011 May 12];Available from: http://www.iso.org/iso/catalogue_detail?csnumber=24744

[49] ISO/TS 16058: 2004 - Health informatics -- Interoperability of telelearning systems [Internet]. [cited 2011 May 12];Available from: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=37353

[50] ISO. IEC 10036: 1996 - Information technology -- Font information interchange -- Procedures for registration of font-related identifiers [Internet]. [cited 2011 May 17];Available from: http://www.iso.org/iso/catalogue_detail?csnumber=24744

[51] ISO/IEC Guide 2: 2004 - Standardization and related activities -- General vocabulary [Internet]. [cited 2011 May 12];Available from: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=39976

[52] ISO/CD 13940-1 - Health informatics -- System of concepts to support continuity of care -- Part 1: Basic concepts [Internet]. [cited 2011 May 12];Available from:http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=52389

[53] Wikipedia. the free encyclopedia [Internet]. [cited 2011 Jul 20];Available from: http://en.wikipedia.org/wiki/Systems_architecture

[54] ISO/TR 16056-1: 2004 - Health informatics -- Interoperability of telehealth systems and networks -- Part 1: Introduction and definitions [Internet]. [cited 2011 May 17];Available from: http://www.iso.org/iso/catalogue_detail?csnumber=37351

[55] ISO 1087-1:2000, *Terminology work — Vocabulary — Part 1: Theory and application* http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=20057

[56] ISO 19011:2011, *Guidelines for auditing management systems* http://sqt.ie/wordpress/?p=2007

[57] CMMI for Development, version 1.3. November 2010. Software Engineering Institute. CMU/SEI-2010-TR-033. ESC-TR-2010-033

[58] Official Mexicana NORMA NOM-024-SSA3-2010

[59] Personal communication. M Pardave, head of Mexican Delegation to ISO TC215

[60] World Health Organization (WHO) Immunization surveillance, assessment and monitoring [Internet]. [cited 2011 May 18];Available from: http://www.who.int/immunization_monitoring/en/

[61] SDMX-HD. (Statistical Data and Metadata Exchange http://www.sdmx-hd.org/ [Internet]. http://sdmx.org/

[62] IHTSDO. International Health Terminology Standards Development Organization [Internet]. [cited 2011 Jul 20];Available from: http://www.ihtsdo.org/

[63] WHO | International Classification of Diseases (ICD) [Internet]. [cited 2011 Jul 20];Available from: http://www.who.int/classifications/icd/en/

[64] WHO | International Classification of Primary Care, Second edition (ICPC-2) [Internet]. [cited 2011 Jul 20];Available from: http://www.who.int/classifications/icd/adaptations/icpc2/en/index.html

[65] Logical Observation Identifiers Names and Codes (LOINC®) — LOINC [Internet]. [cited 2011 Jul 20];Available from: http://loinc.org/

[66] OPCS-4 Classification — NHS Connecting for Health [Internet]. [cited 2011 Jul 20];Available from: http://www.connectingforhealth.nhs.uk/systemsandservices/data/clinicalcoding/codingstandards/opcs4/index_html

[67] Current Procedural Terminology - Wikipedia, the free encyclopedia [Internet]. [cited 2011 Jul 20];Available from: http://en.wikipedia.org/wiki/Current_Procedural_Terminology

[68] dm+d — The NHS Dictionary of Medicines and Devices [Internet]. [cited 2011 Jul 20];Available from: http://www.dmd.nhs.uk/

[69] ATC/DDD Index [Internet]. [cited 2011 Jul 20];Available from: http://www.whocc.no/atc_ddd_index/

[70] Australian Medicines Terminology (AMT) - nehta.gov.au [Internet]. [cited 2011 Jul 20];Available from: http://www.nehta.gov.au/connecting-australia/terminology-and-information/clinical-terminology/australian-medicines-terminology

[71] Health Information Standards Knowledge Resource (HISKR). 2011, developed by Collaborative Research for Effective Diagnostics (CRED) Research Group, Université de Sherbrooke, Quebec, Canada; http://www.hiwiki.org/hiskr

[72] United Nations Statistics Division (UNStats) Millennium Development Goals. (MDG) Indicators [Internet]. [cited 2011 May 17];Available from: http://mdgs.un.org/unsd/mdg/Default.aspx

[73] World Health Organization (WHO) Indicator and Measurement Registry. (IMR) [Internet]. [cited 2011 May 12];Available from: http://apps.who.int/gho/indicatorregistry/App_Main/browse_indicators.aspx

[74] SDMX – Statistical Data and Metadata Exchange [Internet]. [cited 2011 Jul 21];Available from: http://sdmx.org/

[75] SDMX-HD (Health Domain) [Internet]. [cited 2011 Jul 21]. Available from: http://sdmx-hd.org/

[76] Health Information Systems in Developing Countries. Vital Wave Consulting, 2009. Available from http://vitalwaveconsulting.com/Insights/articles/2011/his.htm

[77] Interoperable eHealth is Worth it – Securing Benefits from Electronic Health Records and ePrescribing; EU Commission Study Report 2010. Available at: http://www.ifap.ru/library/book476.pdf

[78] Canada Health Infoway – A pan-Canadian Approach, M. Catz and J. Bayne. AMIA Annual Symposium Proceedings Archive, 2003. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1480340/

[79] COACH Health Informatics Professionals Role Profiles https://ams.coachorg.com/inventory/PurchaseDetails.aspx?Id=529927ef-0e5d-4f0e-81e2-5b2968501fd9

[80]. Information needs of healthcare workers in developing countries: a literature review with a focus on Africa. N. Pakenham-Walsh and F. Bukachi. *Hum. Resour. Health*. 2009, **7** p. 30. Available at: http://www.human-resources-health.com/content/7/1/30 and http://www.human-resources-health.com/content/7/1/30

[81] Strengthening Health Development at the Community Level in Thailand: What Events Should Be Managed? V. Tanvatanakul et al. World Health & Population, 9(1) January 2007: 65-73.doi:. Available at: www.longwoods.com/content/18690 doi:10.12927.whp.2007.18690

[82] ICT for Primary Healthcare. Media Lab Asia. July 2005 Available at: http://www.medialabasia.in/downloads/mlasia-ict-hc-rep-excerpts.pdf

[83] HIMSS EMR Adoption (Maturity) Model. 2013 http://www.himssanalytics.org/emram/emram.aspx

[84] University of California. Los Angeles book on Public Health Ch. 1.1 Available at: http://www.ph.ucla.edu/epi/faculty/detels/PH150/OTBPH_Chap1_Aug2012.pdf

[85] Preventing diseases through healthy environments. Towards an estimate of the environmental burden of the disease. WHO, 2006, http://www.who.int/quantifying_ehimpacts/publications/preventingdisease.pdf

[86] CDC public Health Tracking Glossary. [Internet]. [cited 2011 May 12]CDC, http://ephtracking.cdc.gov/showGlossaryByTermName.action. [Internet]. [cited 2013, April 10]

[87] Environmental health hazard mapping for Africa. Commissioned by WHO-AFRO, Harare, Zimbabwe, February 2000. http://www.who.int/hac/techguidance/tools/healthhazard.pdf

[88] Environmental health indicators: Framework and methodologies. WHO, 1999, http://www.who.int/ceh/publications/cehframework/en/index.html [Internet]. [cited 2013, April 10]

[89] Children's environmental health indicators. WHO, http://www.who.int/ceh/indicators/en/. [Internet].

[90] Environmental and occupation cancers. WHO, http://www.who.int/mediacentre/factsheets/fs350/en/[Internet]

[91] Integrated Environmental Health Impact Assessment (IEHIA) System. http://www.integrated-assessment.eu/guidebook/steps_iehia. [Internet]

[92] The CDC National Environmental Public Health Tracking Network. CDC, http://ephtracking.cdc.gov/showHome.action. [Internet]. [cited 2013, April 10]

[93] WHO/ITU National eHealth strategy toolkit. http://www.itu.int/dms_pub/itu-d/opb/str/D-STR-E_HEALTH.05-2012-PDF-E.pdf. [Internet] [cited 2013, April 10]

[94] Tivoli Reference Architectures I.B.M. March 14, 2012. IBM Developer Works https://www.ibm.com/developerworks/community/blogs/tivoli-ra/entry/welcome_to_the_tivoli_reference_architecture_blog12?lang=en

[95] Canadian Approved Standard Pharmacy Messaging https://infocentral.infoway-inforoute.ca/2_Standards/1_pan-Canadian_Standards/Messaging/1_HL7_v3_R02.04.xx_(MR2009)/nVolume_8_-_Pharmacy

[96] WHO Public Health Surveillance http://www.who.int/topics/public_health_surveillance/en/

[97] Canada Health Infoway pan-Canadian Registry Messaging Standards (HL7v3) https://infocentral.infoway-inforoute.ca/2_Standards/1_pan-Canadian_Standards/Messaging/1_HL7_v3_R02.04.xx_(MR2009)/lVolume_6_-_Location_Registry; https://infocentral.infoway-inforoute.ca/2_Standards/1_pan-Canadian_Standards/Messaging/1_HL7_v3_R02.04.xx_(MR2009)/kVolume_5_-_Provider_Registry; https://infocentral.infoway-inforoute.ca/2_Standards/1_pan-Canadian_Standards/Messaging/1_HL7_v3_R02.04.xx_(MR2009)/jVolume_4_-_Client_Registry

[98] Merriam-Webster Dictionary http://www.merriam-webster.com/dictionary/road%20map

[99] Centers for Medicare and Medicaid Services. US http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/Stage2_EPCore_17_UseSecureElectronicMessaging.pdf

[100] WHO Health System Strengthening Glossary http://www.who.int/healthsystems/hss_glossary/en/index5.html

[101] The Power of Information, Department of Health, May. 2012 http://informationstrategy.dh.gov.uk/

[102] eHealth Strategy 2011-2017 Scotland, September 2011 http://kinwahlin.wordpress.com/2011/09/23/ehealth-strategy-2011-2017-scotland-12-september-2011/

[103] Meaningful Use Strategy, Office of the National Coordinator for Health IT, US. http://www.healthit.gov/policy-researchers-implementers/meaningful-use

[104] Personal Health Management Strategy. Singapore, 2011 http://www.ijic.org/index.php/ijic/article/view/907/1635

[105] Personal eHealth Record Strategy, Australia, 2010 http://www.health.gov.au/internet/budget/publishing.nsf/Content/budget2010-hmedia09.htm

[106] Canada Health Infoway Infocentral https://infocentral.infoway-inforoute.ca/

[107] HL7/ASTM Implementation Guide for CDA R2 – Continuity of Care Document (CCD) Release 1 http://www.hl7.org/implement/standards/product_brief.cfm?product_id=6

[108] ISO/HL7 10781: 2009 R1.1 http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=46087

[109] Standard D.I.C.O.M. (Digital Imaging and Communications in Medicine) http://medical.nema.org/standard.html

[110] HL7 CDA Release 2 http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

[111] Project SPHERE http://www.sphere.com/

[112] ISO. IEEE 11073-10406: 2012: Personal health device communication – Part 10406: Device specialization – Basic electrocardiograph (ECG) (1- to 3-lead ECG http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=61876

[113] ISO/TS 11073-92001: 2007: Medical waveform format – Part 92001: Encoding rules http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=41602

[114] ISO 18812:2003, *Health informatics — Clinical analyser interfaces to laboratory information systems — Use profiles* http://www.iso.org/iso/catalogue_detail?csnumber=33668

[115] Templates for using HL7 v2.5 messages http://www.hcup-us.ahrq.gov/datainnovations/clinicaldata/TemplatesforusingHL7v2.jsp

[116] IHE (Integrating the Healthcare Enterprise) http://www.ihe.net/

[117] National Council for Prescription Drug Programs (NCPDP) http://www.ncpdp.org/

[118] GS 1 (Global Standards 1) http://www.gs1.org/

[119] ISO 21091:2013, *Health informatics — Directory services for healthcare providers, subjects of care and other entities* http://www.iso.org/iso/catalogue_detail.htm?csnumber=51432

[120] ISO/TS 27527, Health informatics — Provider Identification http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=44216

[121] ISO/TS 22220, Health informatics — Identification of subjects of health care http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=59755

[122] WHO country assessment tool on the uses and sources for human resources for health (HRH) data - http://www.who.int/hrh/statistics/survey_use_source/en/index.html

[123] WHO template on classifying health workers - http://www.who.int/entity/hrh/statistics/Health_workers_classification.pdf

[124] International Standard Classification on Occupations - http://www.ilo.org/public/english/bureau/stat/isco/index.htm

[125] ISO/TR 13054, Health Informatics — Knowledge management of health informatics standards - http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=52465

[126] Types of Planning in the Health Care System. Darwin Palmiere, AJPH; Aug. 1972 Vol. 62, Issue 8, p. 1112 http://connection.ebscohost.com/c/articles/24294240/types-planning-health-care-system

[127] Healthy People 2020, US Department of Health & Social Services http://www.healthypeople.gov/2020/default.aspx

[128] Monitoring, Evaluation and Review of National Health Strategies IHP+ and WHO, Nov 2011 http://www.internationalhealthpartnership.net/fileadmin/

uploads/ihp/Documents/Upcoming_events/Session4MonitoringEvaluationReview_of_NationalHealthStrategies2011.pdf

[129] The Health Planner's Toolkit http://www.health.gov.on.ca/transformation/providers/information/im_resources.html#health

[130] European Observatory on Health Systems and Policy, Capacity Planning in Healthcare: A Review of the International Experience. WHO, 2008 http://www.euro.who.int/__data/assets/pdf_file/0003/108966/E91193.pdf

[131] ICNP. (International Classification for Nursing Practice) http://www.icn.ch/pillarsprograms/international-classification-for-nursing-practice-icnpr/

[132] ICF. (International Classification of Functioning, Disability and Health WHO http://www.who.int/classifications/icf/en/

[133] RxNorm http://www.nlm.nih.gov/research/umls/rxnorm/

[134] X.400 Message Handling protocols - http://en.wikipedia.org/wiki/X.400

[135] ISO 17090 (all parts), Health informatics — Public key infrastructure http://www.iso.org/iso/home/news_index/news_archive/news.htm?refid=Ref1115

[136] ITU X.509 Standard http://www.itu.int/rec/T-REC-X.509

[137] CEN/TC 251 Published Standards http://www.cen.eu/CEN/Sectors/TechnicalCommitteesWorkshops/CEN/TechnicalCommittees/Pages/Standards.aspx?param=6232&title=CEN/TC+251

[138] UN/EDIFACT - The International EDI Standard http://www.disa.org/international/edif.htm

[139] ISO. IEEE 11073-20101: 2004 Health informatics – Point-of-care medical device communication – Part 20101: Application profiles – base standard http://www.iso.org/iso/catalogue_detail.htm?csnumber=36347

[140] ISO/PDTS 17975 Health informatics – Principles and data requirements for consent in the collection, use or disclosure of personal health information http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=61186

[141] ISO. IEC 27007: 2011 Information technology — Security techniques — Guidelines for information security management systems auditing http://www.iso27001security.com/html/27007.html

[142] ISO. IEC 17021: 2006 Conformity assessment -- Requirements for bodies providing audit and certification of management systems http://www.iso.org/iso/catalogue_detail?csnumber=29343

[143] ISO. IEC 27006: 2011 Information technology — Security techniques — Requirements for bodies providing audit and certification of information security management systems http://www.iso27001security.com/html/27006.html

[144] ISO. IEC 38500: 2008 Corporate governance of information technology http://www.iso.org/iso/catalogue_detail?csnumber=51639

[145] ISO. IEC 20000-1: 2011 Information technology – Service management – Part 1: Service management system requirements http://www.iso.org/iso/catalogue_detail?csnumber=51986

[146] AS8000 Corporate Governance http://www.ncsi.com.au/AS-8000.html#nogo

[147] AS8001 Fraud and Corruption Control http://www.cufa.com.au/downloads/library/csr/Australian_Standard.pdf

[148] AS8002-2003 Corporate governance – organizational codes of conduct http://infostore.saiglobal.com/store2/details.aspx?ProductID=323765

[149] AS8003-2003 Corporate governance – corporate social responsibility http://infostore.saiglobal.com/store/Details.aspx?ProductID=323784&utm_source=PDF&utm_medium=Website_Infostore&utm_campaign=IS-PreviewPDF

[150] AS8004-2003 Corporate governance - Whistleblower protection programs for entities http://infostore.saiglobal.com/store/Details.aspx?ProductID=323803

[151] AS8015-2005 corporate governance of information and communication technology http://www.bartier.com.au/publications/publicationDetail.aspx?PublicationID=83

[152] United Nations. 2008). Principles and Recommendations for Population and Housing Censuses. Statistical Papers: Series M No. 67/Rev.2. p8. ISBN 978-92-1-161505-0.

[153] UNECE. Measurement of emerging forms of families and households". http://www.unece.org/fileadmin/DAM/stats/publications/CES_2010_Census_Recommendations_English.pdf Retrieved 2012-12-12.

[154] Indictors of Health Inequalities – A report from the Population Health Promotion Expert Group and the Healthy Living Issue Group for the Pan-Canadian Public Health network, August, 21, 2009. http://www.phn-rsp.ca/pubs/ihi-idps/pdf/Indicators-of-Health-Inequalities-Report-PHPEG-Feb-2010-EN.pdf

[155] CIHI – Enhancing Pan-Canadian Health System Reporting at CIHI. Nov. 2012 http://www.cihi.ca/CIHI-ext-portal/pdf/internet/HSP_INITIATIVE_BACKGROUNDER_EN

[156] The population health record: concepts, definition, design and implementation. JAMIA J Am Med Inform Assoc 2010;17:359-366 doi: http://jamia.bmj.com/content/17/4/359.full doi:10.1136/jamia.2009.001578

[157] ISO/TS 29585: 2010 – Health informatics - Deployment of a clinical data warehouse http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=45582

[158] ITU Measuring the Information Society 2012 http://www.itu.int/en/ITU-D/Statistics/Documents/publications/mis2012/MIS2012_without_Annex_4.pdf

[159] ITU World Telecommunication/ICT Development Report 2010: Monitoring the WSIS targets, International Telecommunications Union, Geneva http://www.uis.unesco.org/Communication/Documents/WTDR2010_e.pdf

[160] Human Development Report, United Nations Development Program, 2013 http://hdr.undp.org/en/mediacentre/humandevelopmentreportpresskits/2013report/

[161] A Review of Digital Literacy Assessment Instruments, Stephen Covello, Syracuse University, School of Education/IDD & E, IDE-712: Analysis for Human Performance Technology Decisions, May, 2010. PDF available for download.

[162] Conformity Assessment and Interoperability. Arab Region Perspectives, Sherif Guinena, ITU, Geneva, 13 January 2012. PDF available for download.

[163] The 2010 Energy and Development Index, International Energy Agency http://www.iea.org/publications/worldenergyoutlook/resources/energydevelopment/

[164] ITU (International Telecommunications Union) http://www.itu.int/en/Pages/default.aspx

[165] IETF. (Internet Engineering Task Force) http://www.ietf.org/

[166] TIA (Telecommunications Industry Association) http://www.tiaonline.org/

[167] Computer Science Curricula 2013, ACM/IEEE-CS Joint Task Force http://ai.stanford.edu/users/sahami/CS2013/

[168] International Computer Driving License. (ECDL Foundation, http://www.ecdl.org/programmes/ecdl_icdl

[169] Information Technology Infrastructure Library (ITIL) The APM Group Limited. http://www.itil-officialsite.com/

[170] ITIL v3 http://www.best-management-practice.com/gempdf/itsmf_an_introductory_overview_of_itil_v3.pdf

[171] ISO http://www.iso.org/iso/home.html

[172] NEMA. (National Electrical Manufacturers Association) http://www.nema.org/pages/default.aspx

[173] IEEE Institute of Electrical and Electronics Engineers http://www.ieee.org/index.html

[174] IEE. (International Electrotechnical Commission) http://www.iec.ch/

[175] W3C — World Wide Web Consortium http://www.w3.org/

[176] ISO. IEC 10746 Information technology – Open distributed processing – Reference model (ODP-RM) http://www.enterprise-architecture.info/Images/Documents/RM-ODP.pdf

[177] ISO 21090:2011, *Health informatics — Harmonized data types for information interchange* http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=35646

[178] ISO/TR 12309: 2009 Health informatics – Guidelines for terminology development organizations http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=51345

[179] ISO/TR 12773-1: 2009 Health informatics - Business requirements for health summary records – Part 1: Requirements http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=51683

[180] ISO/TS14265. 2011 Health informatics - Classification of purposes for processing personal health information http://www.iso.org/iso/catalogue_detail?csnumber=54547

[181] ISO/TS 21298: 2008 Health informatics - Functional and structural roles http://www.iso.org/iso/catalogue_detail.htm?csnumber=40133

[182] ISO 27799:2008, *Health informatics — Information security management in health using ISO/IEC 27002* http://www.iso.org/iso/catalogue_detail?csnumber=41298

[183] ISO/TR 13054: 2012 Health informatics – Knowledge management of health information standards http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=52465

[184] ISO/TS 22600-2: 2006 Health informatics – Privilege management and access control – Part 2: Formal Models http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=40930

[185] ISO/TS 22600-3: 2009 Health informatics - Privilege management and access control – Part 3: Implementations http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=45376

[186] ISO/TS 25237: 2008 Pseudonymization http://www.iso.org/iso/catalogue_detail?csnumber=42807

[187] ISO/TS 21547: 2010 Health informatics – Secure archiving of electronic health records – Part 1: Principles and requirements http://www.iso.org/iso/catalogue_detail?csnumber=44479

[188] ISO/TR 21548: 2010 Health informatics – Secure archiving of electronic health records – Part 2: Guidelines http://www.iso.org/iso/catalogue_detail?csnumber=44480

[189] ISO/HL7 27932: 2009 Data Exchange Standards -- HL7 Clinical Document Architecture, Release 2 http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=44429

[190] ISO/HL7 27931: 2009 Data Exchange Standards – HL7v2.5 – An application protocol for electronic data exchange in healthcare environments http://www.iso.org/iso/catalogue_detail.htm?csnumber=44428

[191] ISO/HL7 21731: 2006 Health informatics – HL7 v3 Reference information model Release 1 http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=40399

[192] Skills Framework for the Information Age SFIA Foundation http://www.sfia-online.org/

[193] CIHI A Performance Measurement Framework for the Canadian Healthcare System. Updated November 2013 https://secure.cihi.ca/free_products/HSP-Framework-ENweb.pdf

[194] WHO Global Observatory for eHealth http://www.who.int/goe/en/

[195] ITU ICT applications – National eHealth Strategy Toolkit http://www.itu.int/ITU-D/cyb/app/e-health/NeHSToolkit/intro.phtml

[196] WHO-ITU ehealth Strategy toolkit 2012 http://www.itu.int/ITU-D/cyb/events/2012/e-health/Nat_eH_Dev/Session%201/ITU-WHO%20National%20eHealth%20Strategy%20toolkit%20March%202012.pdf

[197] National eHealth Strategy Toolkit – WHO Brochure. http://www.who.int/ehealth/brochure.pdf

[198] WHO World Health Report, Chapter 1, January 2006. http://www.who.int/whr/2006/chapter1/en/index.html

[199] Health Informatics Professional Core Competencies v 3.0. 2012 COACH: Canada's Health Informatics Association http://coachorg.com/en/resourcecentre/resources/Health-Informatics-Core-Competencies.pdf

[200] ISO/TR 14639-1: 2012 Health informatics- Capacity-based eHealth architecture roadmap - Part 1: Overview of national eHealth initiatives http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=54902

This page deliberately left blank

British Standards Institution (BSI)

BSI is the national body responsible for preparing British Standards and other standards-related publications, information and services.

BSI is incorporated by Royal Charter. British Standards and other standardization products are published by BSI Standards Limited.

About us

We bring together business, industry, government, consumers, innovators and others to shape their combined experience and expertise into standards -based solutions.

The knowledge embodied in our standards has been carefully assembled in a dependable format and refined through our open consultation process. Organizations of all sizes and across all sectors choose standards to help them achieve their goals.

Information on standards

We can provide you with the knowledge that your organization needs to succeed. Find out more about British Standards by visiting our website at bsigroup.com/standards or contacting our Customer Services team or Knowledge Centre.

Buying standards

You can buy and download PDF versions of BSI publications, including British and adopted European and international standards, through our website at bsigroup.com/shop, where hard copies can also be purchased.

If you need international and foreign standards from other Standards Development Organizations, hard copies can be ordered from our Customer Services team.

Subscriptions

Our range of subscription services are designed to make using standards easier for you. For further information on our subscription products go to bsigroup.com/subscriptions.

With **British Standards Online (BSOL)** you'll have instant access to over 55,000 British and adopted European and international standards from your desktop. It's available 24/7 and is refreshed daily so you'll always be up to date.

You can keep in touch with standards developments and receive substantial discounts on the purchase price of standards, both in single copy and subscription format, by becoming a **BSI Subscribing Member**.

PLUS is an updating service exclusive to BSI Subscribing Members. You will automatically receive the latest hard copy of your standards when they're revised or replaced.

To find out more about becoming a BSI Subscribing Member and the benefits of membership, please visit bsigroup.com/shop.

With a **Multi-User Network Licence (MUNL)** you are able to host standards publications on your intranet. Licences can cover as few or as many users as you wish. With updates supplied as soon as they're available, you can be sure your documentation is current. For further information, email bsmusales@bsigroup.com.

BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK

Revisions

Our British Standards and other publications are updated by amendment or revision.

We continually improve the quality of our products and services to benefit your business. If you find an inaccuracy or ambiguity within a British Standard or other BSI publication please inform the Knowledge Centre.

Copyright

Useful Contacts:

Customer Services
Tel: +44 845 086 9001
Email (orders): orders@bsigroup.com
Email (enquiries): cservices@bsigroup.com

Subscriptions
Tel: +44 845 086 9001
Email: subscriptions@bsigroup.com

Knowledge Centre
Tel: +44 20 8996 7004
Email: knowledgecentre@bsigroup.com

Copyright & Licensing
Tel: +44 20 8996 7070
Email: copyright@bsigroup.com

bsi.

...making excellence a habit.™