PD ISO/TR 14639-1:2012



BSI Standards Publication

Health informatics — Capacity-based eHealth architecture roadmap

Part 1: Overview of national eHealth initiatives

NO COPYING WITHOUT BSI PERMISSION EXCEPT AS PERMITTED BY COPYRIGHT LAW



National foreword

This Published Document is the UK implementation of ISO/TR 14639-1:2012.

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.

© The British Standards Institution 2012. Published by BSI Standards Limited 2012

ISBN 978 0 580 76330 4

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 30 September 2012.

Amendments issued since publication

Date Text affected

PD ISO/TR 14639-1:2012

INTERNATIONAL STANDARD

ISO 14639-1

First edition 2012-08-15

Health informatics — Capacity-based eHealth architecture roadmap —

Part 1:

Overview of national eHealth initiatives

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

Partie 1: Aperçu des initiatives de santé électronique nationale





COPYRIGHT PROTECTED DOCUMENT

© ISO 2012

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

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

Forewordv			
Introduction		v	
1	Scope	1	
2	Terms and definitions	1	
3	Abbreviations	6	
4	Initiatives reviewed		
4.1	Health Metrics Network		
4.2	Australia	7	
4.2.1	National health system		
4.2.2	Focus of national health system		
4.2.3	Components of the national health information system		
4.2.4	National eHealth policies		
4.2.5 4.2.6	National eHealth architecture stage of development		
4.2.7	Standards in use		
4.2.8	Standards Development Organizations (SDOs) and Health Informatics Associations		
4.2.9	National reporting infrastructure for individual and/or summary data	20	
4.2.10	Households with Internet access	20	
4.3	Brazil		
4.3.1	National health system		
4.3.2	Focus of national health system		
4.3.3	Components of the national health information system		
4.3.4	National eHealth policies		
4.3.5	National eHealth architecture stage of development		
4.3.6 4.3.7	National data warehouse		
4.3. <i>1</i> 4.3.8	Standards In use		
4.3.9	National reporting infrastructure for individual and/or summary data data	26	
4.3.10	Households with Internet access	26	
4.4	Canada		
4.4.1	National health system		
4.4.2	Focus of national health system		
4.4.3	Components of the national health information system		
4.4.4	National eHealth policies		
4.4.5	National eHealth architecture stage of development		
4.4.6	National data warehouse		
4.4.7	Standards in use		
4.4.8 4.4.9	Standards Development Organizations (SDOs) and Health Informatics Associations		
4.4.9 4.4.10	Households with Internet access		
4.5	India		
4.5.1	National health system		
4.5.2	Focus of national health system		
4.5.3	Components of the national health information system		
4.5.4	National eHealth policies	37	
4.5.5	National eHealth architecture stage of development		
4.5.6	National data warehouse and national reporting infrastructure for individual and/or	_	
4 = -	summary data		
4.5.7	Standards in use		
4.5.8	Standards Development Organizations (SDOS) and Health Informatics Associations	პბ	

4.5.9	Households with Internet access	38
4.6	Kenya	38
4.6.1	National health system; focus of national health system	38
4.6.2	Components of the national health information system	
4.6.3	National eHealth policies	
4.6.4	National eHealth architecture stage of development	43
4.6.5	Standards in use	
4.6.6	Standards Development Organizations (SDO) and Health Informatics Associations	
4.6.7	National reporting infrastructure for individual and/or summary datadata	44
4.6.8	Households with Internet access	44
5	International Monitoring and Evaluation frameworks	44
5.1	Overview	
5.2	Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM)	44
5.3	Joint United Nations Program on HIV/AIDS (UNAIDS)	4 4
5.4	Pan American Health Organization (PAHO) Framework	45
5.5	Brazilian Health Indicators Framework	
5.6	Canadian Health Indicators Framework	
5.7	United States Health Indicators Frameworks	45
6	Key findings	46
7	Need for an eHealth Architecture Maturity Model (eHAMM)	49
Rihlio	graphy	52

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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.

ISO/TR 14639-1 was prepared by Technical Committee 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

The following parts are under preparation:

— Part 2: Architectural components and maturity model

This part of ISO/TR 14639 complements and supports the general requirements for the use of information in health services which are to be set out in the proposed technical specification, ISO/TS 16555, *Health informatics — Framework for national health information systems*. ISO/TS 16555 will provide specifications defining data sources and business processes supporting the more general use of information within the delivery, operation, management and planning of health services within a country.

Introduction

This part of ISO/TR 14639 arises from the recognition that currently there is considerable diversity internationally in the approach and scope of development and implementation of national health information systems (HIS). Growing interest in health system strengthening in low-income countries (LIC) in the international community has led to increasing interest in and support of this activity^[3].

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, for whom there are potential lessons to be learned as they examine the way in which information is used, produced and managed 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 this part of ISO/TR 14639, and was largely inspired by the Health Metrics Network (HMN) activities sponsored by the World Health Organization (WHO)^{[1][2]}.

This work has been motivated in part by a recognition that countries vary in terms of readiness and resources for health system strengthening, with the expectation that it will help to provide the tools needed for policy-making, strategic planning and eHealth architecture development for robust and appropriate country HIS.

The particular focus of this part of ISO/TR 14639 is the potential for Information and Communications Technology (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.

This part of ISO/TR 14639 presents a description of contemporary national enterprise-wide HIS. The resulting landscape identifies key high-level categories for different aspects of such systems which should be considered in any national architecture design endeavour. While not an exhaustive inventory of systems or necessarily a description of best practices, it is roughly representative of all income levels and strives to illustrate the diversity of HIS in different information technology environments with varying levels of capacity.

Supported by the findings from this review, this part of ISO/TR 14639 also proposes development of an eHealth architecture maturity model (eHAMM) for expressing the extent of development of HIS and eHealth architecture. The model can be used to direct planning and assess progress of national HIS towards maturity.

The maturity model will be elaborated upon in ISO/TR 14639-2 and includes a methodology for classifying HIS according to descriptions of architectural components.

Health informatics — Capacity-based eHealth architecture roadmap —

Part 1:

Overview of national eHealth initiatives

1 Scope

This part of ISO/TR 14639 aims to identify the business requirements of an eHealth architecture as well as providing a generic and comprehensive context description to inform architectural structuring of Health Information Systems (HIS).

This part of ISO/TR 14639 reviews international experiences in the construction of national eHealth architectures and introduces a methodology for strategic development of HIS^[4], which will be elaborated upon in ISO/TR 14639-2.

This part of ISO/TR 14639 is intended to assist nations which are in the early or mid stages of developing such systems.

2 Terms and definitions

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

2.1

architecture system

structure of components, their functions and their inter-relationships, and the principles and guidelines governing their design and evolution over time, or a description of the structure and behaviour of a system, a system's components, its functions and inter-relationships

NOTE 1 Adapted from Open Group Architecture Framework (TOGAF), 2009^[14] and Blobel, B., Application of the Component Paradigm for Analysis and Design of Advanced Health System Architectures, 2000^[86].

NOTE 2 This term also includes architecture and system architecture.

22

biosurveillance

process of active data-gathering with appropriate analysis and interpretation of biosphere data that might relate to disease activity and threats to human or animal health (whether infectious, toxic, metabolic, or otherwise, and regardless or intentional or natural origin) in order to achieve early warning of health threats, early detection of health events and overall situational awareness of disease activity

[CDC Concept Plan for the Implementation of the National Biosurveillance Strategy for Human Health [88]

2.3

clinical information

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

[ISO 13606-1:2008, definition 3.13]

2.4

chronic disease

health condition of 3 months' duration or longer

[US National Center for Health Statistics]

2.5

data warehouse

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

NOTE 1 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.

NOTE 2 Adapted from ISO/TR 22221:2006.

2.6

eHealth

the combined use of electronic communication and information technology in the health sector to enable better health and healthcare

[World Health Organization]

2.7

eHealth architecture

structure of a system of eHealth components and services

2.8

electronic health record

EHR

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

NOTE Adapted from ISO 18308:2011 and the European 2011 eHealth Strategies Final Report, January 2011.

2.9

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

[European 2011 eHealth Strategies Final Report, January 2011]

2.10

electronic patient record

EPR

electronic record of an individual in a hospital or health care facility, which is typically in one organisation and is facility-centric

[European 2011 eHealth Strategies Final Report, January 2011]

2.11

health

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

[World Health Organization 1948]

2.12

health condition

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

NOTE These interventions could be anticipatory or prospective, such as enhancing wellness, wellness promotion or illness prevention (e.g. immunization).

[Canada Health Infoway EHRS Blueprint v1.0: 2003]

2.13

health information

information about a person relevant to his or her health

[ISO 18308:2011, definition 3.28]

2.14

health information system

HIS

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

NOTE Adapted from Canada Health Infoway, Canadian Electronic Drug Messaging (CeRx) Standards 1-2010/03/29.

2.15

health worker

person engaged in actions that are primarily intended to enhance health

NOTE 1 This term also includes healthcare worker.

NOTE 2 Adapted from World Health Report, January 01, 2006.

2.16

healthcare

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

[EN 13940-1:2007]

2.17

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

[EN 13940-1:2007]

2.18

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

NOTE Adapted from EN 13940-1:2007.

2.19

healthcare provider

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

[EN 13940-1:2007]

2.20

interoperability

see semantic interoperability (2.34) and syntactic interoperability (2.36)

2.21

low income country

LIC

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

NOTE 1 An LIC 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 - \$3,945; upper middle income, \$3,946 - \$12,195; and high income, \$12,196 or more.

NOTE 2 Adapted from World Bank Country Classifications.

2.22

monitoring and evaluation

M & E

routine tracking of the key elements of programme/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 programme or project/project intervention

NOTE Evaluation attempts to link a particular output or outcome directly to an intervention after a period of time has passed.

[Global Fund]

2.23

notifiable diseases

list of diseases determined by the International Health Regulations used as a decision instrument for the assessment and notification of events that may constitute a public health emergency of international concern

[World Health Organization, International Health Regulations]

2.24

organization

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

NOTE Adapted from ISO/IEC 6523-1:1998, definition 3.1.

2.25

patient

individual who is a subject of care

NOTE Adapted from ISO/TR 20514:2005, definition 2.30.

2.26

personal health information

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

NOTE Adapted from ISO/TR 18307:2001, definition 3.112.

2.27

policy

set of rules such as legal, political or organizational which can be expressed as obligations, permissions or prohibitions

NOTE Adapted from ISO/TS 22600-1:2006, definition 2.13.

2.28

primary care

first level of care (access to first contact), characterized mainly by longitudinality, comprehensive care and coordination of care within the health system itself

NOTE It may have additional features such as family counselling and community and cultural competence.

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

2.29

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

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

2.30

register

formal or official recording of items, names or actions

[ISO/IEC 10036:1996, definition 3.3]

2.31

registry

server capable of holding data for the systematic and continuous follow-up of information objects maintained in accordance with specific rules

[ISO/TR 21089:2004, definition 3.79]

2.32

roadmap

detailed plan to guide progress towards a goal

[Merriam-Webster Dictionary]

2.33

secure messaging

set of means for cryptographic protection of [parts of] command-response pairs

[ISO/IEC 7816-4:2005, definition 3.39]

2.34

semantic interoperability

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

[ISO/TS 18308:2011, definition 3.45]

2.35

subject of care

person seeking to receive, receiving, or having received healthcare

[EN 13940-1:2007]

2.36

syntactic interoperability

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

[ISO 18308:2011, definition 3.48]

2.37

teleconsultation

provision of healthcare via a telehealth service, generally for the purpose of diagnosis or treatment of a subject of care at a site remote from the patient or their primary care provider

NOTE Adapted from the Medical Conditions Dictionary.

2.38

telehealth

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

[ISO/TS 16058:2004, definition 3.13]

2.39

vocabulary

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

NOTE Adapted from ISO 1087-1:2000, definition 3.7.2.

3 Abbreviations

AIDS Acquired Immunodeficiency Syndrome

CDA Clinical Document Architecture

eHAMM eHealth architecture maturity model

EHR Electronic Health Record

EMR Electronic Medical Record

HIC Health Information Custodian

HIS Health Information System

HIV Human Immunodeficiency Virus

HL7 Health Level Seven

ICD International Statistical Classification of Diseases and Related Health Problems

ICT Information and Communications Technology

IHE Integrating the Healthcare Enterprise

IHTSDO International Health Terminology Standards Development Organization

ISO International Organization for Standardization

ISO/TC 215 ISO Technical Committee 215 (Health Informatics)

IT Information Technology

LIC Low Income Country

M & E Monitoring & Evaluation

MoH Ministry of Health

NGO Non-governmental organization

PHR Personal Health Record

SNOMED CT Systematized Nomenclature of Medicine Clinical Terms

TB Tuberculosis

4 Initiatives reviewed

4.1 Health Metrics Network

The Health Metrics Network (HMN), under the auspices of the World Health Organization (WHO)^{[1][2]}, is the first global health partnership that focuses on two core requirements necessary to strengthen the health system that delivers care and services in countries. It focuses on the need to enhance entire health information and statistical systems, rather than focusing only upon specific diseases. It also concentrates country efforts on strengthening country leadership for health information production and use. This Framework has been devised to coordinate and align partners to focus investments and technical assistance on standardizing health information system development.

The HMN Framework is expected to permit access to and better use of improved health information at country and global levels. The 2007 60th World Health Assembly and its nearly 200 member states passed Resolution 60.27 in which it urged stakeholders ranging from international bodies, the public and private sectors and health information and statistical communities to use the standardized norms and guiding principles of the HMN Framework in the strengthening of health information systems. All of these constituencies are expected to directly benefit from the use of the Framework by countries. To date, over 80 countries in all six continents have commenced using the Framework.

Formal vetting and publishing by ISO would help make this framework a keystone in strengthening these country health information systems. In the fall of 2010, the HMN brought a new work item (NWI) to ISO/TC 215 which passed balloting and is moving forward to become an ISO standard: ISO TS 16555 *Health informatics - Framework for national health information systems*. The aspects of standardization to be covered in the NWI include the preservation of the framework as a whole and delineation of the specifications of the framework into standardized formats. A timely follow-on work item to produce these formats could serve as a powerful catalyst to maintain the global momentum of enterprise architects and designers and users around this work, and crystallize global consensus. As the NWI specifications will be technology-neutral, present and future forms of technology will remain equally relevant. The urgency of the NWI is further exemplified by the growing global movement around the use of mobile technology (m-health) as a driver of country health information systems. It is necessary for this work to include the mHealth activities given their expected impact. The framework will also be updated to include other emerging topics such as human resources (HR), for example that may not be represented in the current landscaping.

4.2 Australia

4.2.1 National health system

Australia has a federal system of government with the Australian Government operating at the national level alongside six state governments and two territory governments. The Australian Government collects most of the tax revenue and distributes a proportion of it back to the states and territories, which have constitutional responsibility for delivering a range of health and welfare services within their jurisdictions - including acute-care public hospitals, mental health, public health and some community-based social care and preventative programs.

Most primary care and many specialist medical and allied health services are delivered by independent private practitioners on a fee-for-service basis. A significant proportion of the cost to consumers of medical and some

© ISO 2012 – All rights reserved

allied health services is covered by a universal health insurance program operated by the Australian Government (Medicare).

There are also networks of Aboriginal Medical Services and Aboriginal-Controlled Community Health Services serving indigenous (Aboriginal and Torres Strait Islander) communities. These are mainly funded by the Australian Government but managed through the states and territories.

Although there is no single national authority with responsibility for delivery of healthcare services across the country, the Australian Government uses its powers over health insurance, reimbursement of private practitioners (Medical Benefits Scheme), payment for prescription medications (Pharmaceutical Benefits Scheme), aged care, indigenous health, veterans care, special-purpose programs and particularly the funding it contributes to the states and territories under the Medicare Agreement, to maintain a reasonably uniform healthcare regime across the country.

Under this regime, all Australians (including non-citizen residents) are entitled to free care in public hospitals and public contributions toward the cost of care received from private practitioners and the amount they pay for prescription drugs - with an additional safety net that limits the cost for those on low incomes and those facing higher healthcare costs.

In March 2010, the Australian Government released a report entitled "A national health and hospitals network for Australia's future" (NHHN) which, among other things, proposed more direct involvement of the Australian Government in the funding of healthcare and hospitals and a reduced role for the states and territories in management of these services. While most Australians favour some level of reform to get more efficient and better integrated management of healthcare delivery, the proposed NHHN reforms faced significant constitutional, political and financial barriers.

Under the Australian federal system, the leaders of the Australian, State and Territory Governments regularly meet at the Council of Australian Government (COAG) to debate and, where possible, agree on common policy positions. Within the health sector, collaborative programs are also progressed through the Australian Health Ministers Council (AHMC) which is advised by AHMAC (the Australian Health Ministers Advisory Committee, made up of relevant heads of agencies responsible for health in each of the Australian, state and territory jurisdictions).

At the COAG meeting in May 2010 most, but not all, states/territories accepted the proposed NHHN reforms in principle but full agreement on the details could not be finalised before a series of elections changed the political landscape.

At a further COAG meeting in February 2011, some elements of the reform package were dropped in favour of a further heads of agreement [6] that provides the framework for a revised National Health Reform Agreement for execution in 2011. The heads of agreement reaffirms the state/territory role as managers of public hospital and public health systems within their jurisdictions but with increased funding and oversight from the Australian Government and better coordination of primary care service delivery.

Central to the reforms being proposed under the new National Health Reform Agreement are: a new national hospital funding authority, which will allocate funds directly to local hospital networks from a single consolidated pool of federal and state/territory funds, an Independent Hospital Pricing Authority (IHPA), a Health Performance Authority (HPA) and a permanent, increased role for the Australian Commission on Safety and Quality in Healthcare, which develops, monitors and implements national standards for improving clinical safety and quality to improve patient outcomes.

Australia also has a well-developed private hospital and aged care sector, which is an integral part of the national healthcare regime. There are tax incentives to encourage Australians to take out private health insurance which provides cover for private hospital and ambulance costs and, optionally, dental, optical and some other allied health services. Private practitioners are free to set their own fees and privately insured patients may choose to be treated by an approved private practitioner in a public hospital (in which case the public hospital also charges an accommodation fee set by each state/territory).

While Australians may insure against hospital costs, they must meet any additional amounts (gaps) charged by private practitioners above the public rebate out of their own pockets and are not allowed to insure for

these gaps. This measure is aimed at ensuring that there is some price competition moderating the fees charged for clinical services.

In summary, Australia has a national health funding regime (with healthcare costs shared between the Australian Government, state/territory governments, private insurance and the health consumer) but not a unified national healthcare delivery program. Health has recently become a major political issue with significant changes in responsibilities and greater central control having been proposed but it is too early to predict the outcomes.

4.2.2 Focus of national health system

The national healthcare funding regime is generally broad in coverage; however, there is less public funding available for dentistry and some allied health areas, but this is under discussion.

In terms of healthcare service delivery, Australia has high levels of public health, disease control and life expectancy with world-class clinical care facilities distributed across the country and readily available to much of the population; however, the ageing of both the population and the clinical workforce and the associated rising costs of health as a proportion of GDP (9,0 % in 2008-09) are putting traditional modes of care delivery under pressure. In particular:

- 1. Chronic Disease. A significant and rapidly growing proportion of healthcare costs in Australia are driven by chronic disease, particularly later in a person's life. The Australian, state and territory governments all have programs aimed at improving the treatment and management of chronic disease, reducing its burden on patients and its cost to society, with a particular focus on:
 - arthritis and musculoskeletal conditions
 - asthma, chronic obstructive pulmonary disorder (COPD) and other respiratory diseases
 - cancer control through research, early detection and prevention and continual improvement and targeting of treatment regimes
 - cardiovascular health through research, monitoring, reducing risk factors and improved treatment. Cardiovascular disease is the leading cause of death accounting for over one-sixth of all deaths in both males and females[7].
 - diabetes mellitus and the many co-morbidities that flow from it
 - injury prevention and control
 - mental health, and
 - reducing common risk factors smoking, alcohol, substance abuse, obesity, diet, inactivity, hypertension
- 2. Indigenous health. Indigenous Australians have significantly lower life expectancy and health outcomes compared with the rest of the Australian population. This is a matter of long-standing national concern across all jurisdictions. Some years ago, the Australian Government took a strong lead in seeking to address the problem but there are many issues and interacting social factors that need to be managed before it is likely to be solved.
- 3. Rural and regional healthcare. Australia is a very big country with most of its population concentrated along a narrow strip along the southern and eastern seaboards and a couple of other major centres. As in many countries, there has been a drift away from rural areas to the big cities. Clinical practices and health services in many small rural towns are no longer economically viable or able to provide or access the range of services now expected for modern care delivery. It is also difficult to attract and hold clinical staff in these areas. Programs aimed at addressing these problems include greater use of Information and Communications Technologies (ICT) to support both practitioners and patients in remote areas by leveraging policies aimed at getting effective broadband services to 98% of the Australian population.

- 4. Clinical workforce. The clinical workforce is ageing with the population and is under ever increasing workload. For many years, much of the shortfall has been made up by use of overseas-trained clinical personnel in both a temporary and permanent capacity; however, this is an issue that Australia is addressing in several ways including:
 - Greatly increasing the number of clinical training positions not only in medicine, but also in clinical nursing and allied health professions
 - Moving to shorter, postgraduate clinical training programs more strongly focused on clinical practice
 - Developing new models of team-based care, in which clinical nurse specialists, physician assistants, pharmacists and other clinical support personnel take on a wider range of responsibilities and there is greater collaboration between medical specialties in care delivery. To be effective these new models of care anticipate improved sharing of clinical information.

The NHHN health reforms put forward by the Australian Government in 2010 seek to address the above needs by a targeted program of activities in the following areas (see [8] for more details):

- Governance and funding of healthcare
- Hospitals
- GP and primary healthcare
- Aged care
- Mental health

- National standards and performance
- Workforce
- Prevention
- eHealth
- Stakeholder engagement

In 2010/11, for the first time, the Australian Government budget separately recognised eHealth as an enabler of health reform and allocated significant project funding to eHealth as part of its commitment to the overall NHHN reform package.

4.2.3 Components of the national health information system

There are nationally agreed and widely adopted specifications for classification of clinical information and statistical reporting of healthcare status and activities. These are applied at the level of individual healthcare facilities, state/territory and on an Australia-wide basis and are used to support statistical reporting, performance evaluation, health service planning and activity based funding - predominantly for institutional care. Under the proposed National Health Reform Agreement, most public hospital reimbursement is planned to be based on activity.

National health and welfare statistics are compiled in accordance with agreed national standards through the Australian Institute of Health and Welfare (AIHW) based on information sourced from the state and territory health authorities. These statistics include activities carried out in both public and private sectors. [For more information, see: http://www.aihw.gov.au/].

While the national health and welfare statistics contain comprehensive information on hospital activity, long-term care and some community care, there is much less information available on the health conditions addressed and the nature of care delivered in ambulatory settings including general practice, hospital outpatients, specialist consultations and allied health clinics. Obtaining better information on these activities without impeding clinical activities is one of the challenges facing health reform in Australia.

The Australian Bureau of Statistics (ABS) holds a comprehensive census every five years and has detailed information on the demographics of the Australian population and uses this to provide annual reports and population projections that are widely used for health service planning.

Well developed ICT solutions are deployed in most areas to support the use of information in health service operations and planning. This usage may be characterised as follows.

- In each of the major areas of health activity hospitals, primary care, retail pharmacy, laboratory, diagnostics, aged and long-term care, indigenous health and other application environments, the majority of the health information systems (HIS) market is covered by only a few dominant vendors that specialize in that market segment.
- There is only limited support for generalized electronic interoperation or sharing of patient clinical information between different hospital groups, general practitioner (GP) organizations, retail pharmacists etc.; however, there is considerable use of point-to-point messaging for reporting of laboratory/ diagnostic results and, increasingly, for specialist referrals, discharge summaries and pharmacy prescriptions.
- At the level of operational systems, there is almost no national coordination and consistency for ICT system structures and tools. Nevertheless, each state/territory has an eHealth program with their own enterprise architectures and various products selected for deployment in public hospitals and community health services across their jurisdiction including systems for PAS/ADT (patient administration system/ admissions, discharge, transfer), hospital electronic medical record (EMR), community health clinics, billing, HR/payroll, general accounting, asset management, statistical reporting, emergency department, operating rooms, facility scheduling, staff rosters, pharmacy, pathology laboratory, RIS/PACS (Radiology Information System/Picture Archiving and Communications System) and some clinical specialties (such as cancer care, renal, ophthalmology).
- Some cross-jurisdictional joint development and implementation projects have been attempted but usually result in higher costs, longer lead times and limited acceptance. The more populous states have a legacy of semi-autonomous regional health services with local HIS strategies. Most jurisdictions have adopted centralized or regionalized approaches to supply-chain management, purchasing, Human Resources (HR)/Payroll, accounting and laboratory.
- The private acute-care hospital sector includes a mix of stock-exchange-listed public companies and charitable institutions. Each of these organisations has its own HIS strategies and solutions similar to those found in the public sector, but with a greater emphasis on revenue management and interoperability with independently-run support services (e.g. labs, diagnostic imaging, pharmacy).
- Typically the aged and long-term care sector has lacked funds and is lagging in its use of eHealth systems; however, improving the flow of information between various providers involved with aged care and chronic care is seen as a major area of need – particularly as the population ages.
- Privacy and security issues have occupied a much higher priority on Australian Health IT agendas compared with countries that have made more rapid progress in the application of eHealth for the sharing of clinical information.

4.2.4 National eHealth policies

4.2.4.1 HealthConnect

The need for a national approach to eHealth was recognized over ten years ago and was progressed by the former Health Connect program - a joint initiative of the Australian, state and territory governments which researched the needs, systems architecture, business architecture, business case and implementation plan for sharing of health information - with a focus on better medication management and the potential for shared electronic health records (EHR). For more information on HealthConnect associated MediConnect program, refer to the Health Connect http://www.health.gov.au/internet/hconnect/publishing.nsf/Content/home, from which relevant website: documents may be downloaded, including References [9], [10] and [11]. Under Health Connect (and MediConnect), a range of pilot programs were carried out and evaluated including:

 Shared EHR for support of healthcare for across remote indigenous communities in the Northern Territory and remote North West of Western Australia (updated version provides increasingly valuable support for indigenous health in the communities).

- Sharing of clinical information to support diabetes separate trials using different approaches and technologies for shared EHR in Queensland (openEHR) and Tasmania (vendor product).
- Healthlink information sharing between primary care, child health, specialists and hospital services supporting child/adolescent health in Western Sydney and chronic disease management among older people in the Hunter Region — still operating and continuing to grow with over 100 000 registered participants.
- Trials of regional sharing of prescription, dispense and medication management information in rural Victoria and Northern Tasmania.
- Remote work-up and pre-admission for patients attending for orthopaedic surgery over long distances (>1 500 km) in Far North Queensland.
- Satellite-based broadband for health in the remote Eastern Goldfields of Western Australia.

In 2005, work under the Health*Connect* banner was discontinued and, following a review, the National e-Health Transition Authority (NEHTA) was formed in 2006 (initially for 3 years) as an independent joint enterprise of the Australian, state and territory governments to plan progression of a national eHealth agenda and to make recommendations on relevant policies for implementation by the health agencies at state, territory and Australian government level. Information on NEHTA's role and activities is available from the NEHTA website; see: http://www.nehta.gov.au/about-us.

In 2008, NEHTA's charter was renewed and strengthened to establish pre-requisites for effective interchange of personal health information. Several foundation components for eHealth building blocks progressed by NEHTA since this time include:

- Establishment of a national clinical terminology service managing national distribution of SNOMED CT, maintaining the Australian Medicines Terminology (AMT) and representing Australia at IHTSDO.
- A secure individual healthcare identifier (IHI) service, providing a unique healthcare identifier for every Australian citizen or permanent resident and, when required, for visitors needing care in Australian healthcare facilities.

Australia does not have and is most unlikely to ever adopt a unique multi-purpose national personal identifier (as in some other countries). However, every Australian is entitled to receive Medicare benefits – for which they are issued a Medicare card (issued to either an individual adult or to a family). There are now many more people identified on these cards than in the country; however, Medicare Australia has largely resolved this issue by using its database of internal identifiers to link the various appearances of an individual on the various cards (and to use this information to regulate safety net benefits). Legislation was passed allowing the Medicare identifiers to be used as a cross-check when issuing an IHI – greatly reducing the likelihood of duplicates and mismatches.

- A national health identifier service for healthcare providers a universal token-based healthcare provider identifier (HPI-I) for all clinical staff and a unique identifier (HPI O) for each healthcare provider organisation (i.e. hospital, practice, clinic etc.).
- Identifier services (for HPI-I, HPI-O and IHI) have been developed for NEHTA and the Australian Government by contractors working through Medicare Australia and were put into initial production in 2010, with some improvements being considered for incorporation as a result of initial stakeholder feedback. Use of healthcare identifiers is protected by amendments to national privacy legislation.
- A national eHealth privacy framework backed by laws to protect individuals from mis-use of their identities and personal health information.
- Specification and demonstration/test of secure message delivery (SMD) service based on unique identification, authorisation and message security to provide the safest and optimally secure method of exchanging healthcare information.

- Development of programs to specify information content and interchange protocols for key requirement areas - eDischarge Summary, eReferral, ePathology and eMedication Management.
- Supply chain management seeking significant efficiency gains and cost savings, particularly in procurement through a National Product Catalogue (NPC) information system
- Designing and contracting for delivery of a National Authentication Service for Health (NASH) for implementation in 2011 to provide token-based and certificate-based authentication of healthcare providers (individuals and organisations) to complement their use of healthcare identifiers and ensure more secure and accountable access to emerging national eHealth capability.
- Working toward a Compliance and Conformance Assessment (CCA) Scheme and conformance test specifications to support the secure messaging service and other NEHTA building blocks.
- New generation of eHealth interoperability based on development and profiling of eHealth standards, working closely with the Standards Australia IT 014 health informatics committee, HL7 Australia, HL7 International and IHE Australia.

In 2010, NEHTA's charter was again renewed as part of the activities being jointly supported by the Australian, state and territory governments under the NHHN reforms and was endorsed with priority being given to: continuing the development of eHealth foundations; coordination of national eHealth solutions and processes; and accelerated adoption of eHealth in Australia.

Under the eHealth component of the 2010 NHHN reforms, delivering the foundations for a personally-controlled electronic health record (PCEHR) has become a new national eHealth priority. The Australian Government is investing a total of AUD 66,7 million in the 2010/11 and 2011/12 financial years toward this end (with the expectation that states/territories will complement this by continuing their current investments in eHealth).

Some of these investments are being channelled into lead sites for PCEHR implementation building on different eHealth components, working in different geographic areas and addressing functional parts of the Australian health sector, with the purpose of:

- deploying and testing national eHealth infrastructure and standards in real world healthcare settings;
- demonstrating tangible outcomes and benefits from funded eHealth projects;
- building stakeholder support and momentum behind the national PCEHR system work program; and
- providing a meaningful foundation for further enhancement and roll-out of the national PCEHR system.

The Australian Government is also investing over AUD 400 million in telehealth services by introducing Medicare rebates for online consultations, incentives for GPs and specialists to participate and take part in online training; and extensions to upgrade the GP After Hours Helpline to include videoconferencing.

4.2.4.2 Electronic Health Record

As outlined above, funding put forward by the Australian Government in support of the 2010 National Health and Hospitals Reform (NHHR) package included AUD 466,7 million toward initial implementation of shared personally–controlled PCEHR capability as a national eHealth priority.

Prior to this initiative, there had been no funded policy aimed at delivery of a national system of electronic health records, although trials were conducted and proposals put forward under the former Health Connect program. Nevertheless, the subject remained under review as a desirable policy outcome with the concepts continuing to be developed within the Australian Government Department of Health and Ageing (DoHA) and NEHTA.

© ISO 2012 – All rights reserved

The stated purpose of Australian Government NHHR investment in PCEHR is as follows (see page 46 of Reference [8]): "To provide better access to health information enabling better health outcomes through more integrated care centred around the needs of patients." Specific objectives to be realised in achieving this purpose include:

- Providing every Australian with a PCEHR that is controlled by them.
- Ensuring individuals' privacy.
- Improving efficiency in the healthcare system through streamlining access to patient information thereby reducing duplication and improving use of scarce resources.
- Providing continuity of care by enabling access to patient information at the point of care.
- Improving safety and quality in healthcare

The Australian Government's current PCEHR investment is aimed at getting initial capability available. The cost, impact and methodology of extending the initial capability to encompass additional PCEHR repositories and the longer-term relationship to the eHealth programs of states, territories and private-sector providers continue to be major policy issues yet to be resolved.

4.2.4.3 Vertical systems (disease centred systems)

- Cancer/tumour registries. There is a comprehensive national system of cancer/tumour registries backed with a legal requirement for medical practitioners and laboratories to report summary data on incidences, treatment and progress of malignancies identified by individual for the purpose of longitudinal studies. This information is used for cancer research into cancer therapy and for epidemiological studies.
- All information used for patient treatment is held in a patient-centric EMR record available at or near the point-of care. Registry systems are not used to support direct care delivery.
- Infectious diseases, biosurveillance and public health. There are vertical systems for collecting and reporting summary data from medical practitioners, laboratories and public health workers on diseases that they are required to report by law ("notifiable diseases"), some biological agents and environmental health hazards. These systems typically operate at the state/territory level with significant events and potential outbreaks being the basis of alerts to relevant Australian government agencies.
- Malaria, TB, HIV/AIDS and common sexually-transmitted diseases are typically notifiable diseases
 and in some cases identification may be required for contact tracing and follow-up. The information in
 the surveillance and reporting systems used for these purposes is not available or used in direct
 patient care. Other inputs for such uses at the national level come from outside the health system,
 including agriculture, border protection and quarantine services, law enforcement and environmental
 protection agencies.
- Other registries. There are many other national clinical registries used to support clinical research, process improvement, monitoring and evaluation – but these are also not used as the primary treatment record.

A special class of register is the tissue matching register used to identify, match and track donors and potential recipients of organs, blood products and other transplantable body parts.

4.2.4.4 Monitoring and evaluation

Many of the above initiatives have a monitoring and evaluation component, supporting a long-standing clinical safety and quality movement seeking to continuously improve the delivery of healthcare in Australia.

In addition, many national and state/territory programs are aimed at monitoring, evaluation and improvement of healthcare delivery and healthcare outcomes, in particular:

- The Australian Commission on Safety and Quality in Healthcare (ACSQHC) a joint agency of the Australian, state and territory governments formed in 2006 to develop a national strategic framework and work program for improving safety and quality across the healthcare system in Australia. For more information about the Commission, see http://www.safetyandquality.gov.au/.
- State/Territory quality management and performance evaluation units
- Business intelligence and clinical costing systems used to optimise resource allocation

4.2.5 National eHealth architecture stage of development

Work on development of a national eHealth architecture is progressing in pragmatic stages led by NEHTA and, until emergence of the PCEHR as a national priority, was more focused on implementing components for secure information interchange and basic interoperability between existing health information systems in the areas of:- discharge/referral, secure communication of laboratory and diagnostic results and medication management – along with work on national clinical terminology, identifiers and supply chain.

NEHTA's proposed approaches for each of the major components of the national eHealth program are described in the NEHTA Blueprint^[12], which contains a section on high-level eHealth architecture, with the following being particularly relevant aspects:

Architectural approach

The key driver behind having a national approach to eHealth is to facilitate *interoperability* across the Australian health sector in order to improve health system outcomes around effectiveness, safety, responsiveness, continuity of care, accessibility, efficiency and sustainability.

In order to facilitate interoperability, NEHTA is promoting the use of a service-oriented architecture (SOA) combined with national and international standards, independent conformance testing (where required) and a national change and adoption program. In this context, the definition of a service is considered from the business, information and technical viewpoints, following principles developed in the NEHTA Interoperability Framework^[13] and TOGAF^[14].

Target state architecture

In the context of a national approach to eHealth, the target state aims to facilitate local systems at the point of care (or, where relevant, in the home) being able to access a full range of services, including

- national infrastructure services, such as the healthcare identifier service, PCEHR, NASH, National Product Catalogue, secure messaging. ePrescription; eReferral and diagnostic orders/results;
- public or private operated online services, including pathology services, radiology services, prescription exchange services, etc.

In relation to PCEHR, several architectures have been put forward at different times including – virtual shared EHR (assembled at time of use), a federated network of state/territory EHR systems, a more flexible network of consumer-centric EHR repositories, a massive EHR repository operated as a single national resource, and supporting entry of private PHR systems (provided they meet minimum interoperability requirements). NEHTA continues to work on details of the preferred PCEHR architecture; however, the general thrust is toward an extensible solution using a virtual approach in which the most important information is available on demand with other information being assembled as required – with the primary focus being to deliver meaningful summary information to support the clinician at the point-of-care.

Standards

Nationally consistent standards and specifications for electronic information sharing are essential to overcome current problems of communicating clinical information between providers across a diversity of application platforms. Even where relevant standards exist, interoperability is reduced by inconsistent implementation. Key characteristics being pursued include:

- Supporting an agreed set of capabilities to enable the 'meaningful' exchange of information, so that
 information can be safely assimilated and stored in receiving systems;
- Ensuring a common approach to connectivity facilitating successful participation for new and existing systems as well as systems developed both locally and internationally;.
- Consolidating requirements for standards for the national eHealth program and working with existing standards development organisations (SDOs) in Australia and globally to accelerate the identification, agreement and development of these standards;
- Reducing variability in standards implementation by: further specifying and profiling standards for local application, developing guidelines for implementing standards and profiles; and commissioning standards-based products for use in particular domains (such as reference sets of SNOMED CT);
- Providing mechanisms to test conformance with standards and profiles.
- Supporting harmonisation of standards to reduce the number and inconsistency of approaches.
- Accelerating the pace of standards development and adoption through improvements in eHealth standards governance and provision of resources and tooling that can support more rapid development and implementation of eHealth standards.

• Integration architecture

Practical achievement of eHealth requires defined pathways for integration of both existing and future end-point systems used by healthcare organisations, both large and small – connecting them via national eHealth infrastructure to support access and interoperability. A variety of techniques such as web services gateways, portals and secure messaging approaches have been foreshadowed.

Security and access framework

Maintaining the trust of both the general community and clinicians is an essential prerequisite to successful implementation of eHealth. Individuals' information must be appropriately protected by privacy and security controls and clinicians must have confidence that information is accurate and has been managed appropriately. These aspects are to be addressed by NEHTA preparing a Security and Access Framework that is intended to realise relevant principles including:

- Consistent control and monitoring of access to consumer health information as it transitions through independent organisations, business processes, and systems; and
- Traceable provenance of health information from creation at a verifiable trusted source through its transition and possible augmentation en route to its destination/s.
- Having trusted sources of data identity for individuals, providers and organisations through: allocation of healthcare identifiers to individuals, providers and organisations and use of digital credentials;
- Managing access controls and consent; and
- Audit of activity and acting on potential breaches.

In terms of overall progress in delivering the required architectural foundations for eHealth, Australia has a high degree of ICT usage to support delivery of healthcare within healthcare organisations and private clinical practice (and for basic delivery of diagnostic reports from service providers to treating clinicians). It also has advanced capabilities in the use of coding and classification schemes to measure what happens in its health system and to improve the quality of care provided and it has national institutions to exploit these opportunities. The clinical workforce is highly specialised and depends heavily on diagnostic services and the timely exchange of accurate information in delivering quality care.

Through its national eHealth program, Australia is now seeking to move to a new level of maturity with the ability to unlock the power of Web services and the Internet for controllable sharing of clinical information about a person across organisational boundaries. This has involved national projects, now well advanced, to identify healthcare consumers, individual providers and provider organisations uniquely and securely, to improve the use of clinical terminology, to introduce new modes of secure communications and the development of policies, standards and controls for security, privacy and access needed to achieve these ends in ways acceptable to the broader community. In addition to a personally controlled EHR, projects are aimed at greater interoperability in key areas of information interchange (referrals, specialist reports, hospital discharge, drug prescriptions and medications and the ordering and reporting of diagnostic tests).

4.2.6 National data warehouse

Data warehouses of summary data are assembled at both state/territory and national level for many types of health data including:

- Inpatient morbidity statistics
- Neonatal and perinatal statistics
- Notifiable diseases for population health and biosurveillance
- Many others

At the national level, data relating to health services and health conditions are assembled into a suite of 'National Minimum Data Sets' (NMDS), for which the Australian Institute of Health and Welfare (AIHW) are the data custodians. NMDS data are available for policy and program design and evaluation and for research.

Specialized clinical registries have been established to collect summary data on a wide range of diseases and treatment. These include a national network of cancer/tumour registries run as part of a national program through AIHW.

For much of the last ten years the question as to whether a national EHR system (if one were to be developed) could facilitate the aggregation of individuals' clinical information, since a data warehouse for secondary uses was under active consideration. The PCEHR is now being pursued as a tool for individual care and it is not presently proposed to try and warehouse this data in ways that facilitate secondary data analysis for questions related to functioning of the health system as a whole.

4.2.7 Standards in use

4.2.7.1 Clinical vocabularies and classification systems:

- ICD-10 AM is in widespread use for disease and procedure coding
- ICPC-2 in primary care (plus proprietary interface terminologies e.g. DOCL)
- LOINC for diagnostic reporting and orders
- SNOMED CT (being introduced as primary clinical terminology) key subsets for specific applications
- Australian Medicines Terminology (managed by NEHTA's Australian Clinical Terminology Centre)

© ISO 2012 – All rights reserved

4.2.7.2 Interoperability

The NEHTA Blueprint identifies that the following areas of standardization are pivotal to the success of the national eHealth program:

- Web Services and XML for data exchange.
- HL7 V2 (AS 4700.2 Series) and HL7 V3 Clinical Document Architecture (CDA) for health communication messaging.

HL7 v2.x is the primary messaging standard used for clinical and patient administration applications and has a very large following supported by the AS 4700 series of implementation guides. There is very little HL7 v3 messaging. Although NEHTA policy recognises the need to integrate with HL7v2.x, most current work is about defining the preferred future state based on web services.

NEHTA is proposing HL7 v3 CDA R2 as a core eHealth interoperability standard and is working with the Standards Australia IT-014 health informatics committee and the Australian eHealth community on how CDA will be implemented.

- Methods for capturing and recording business requirements for clinical content. NEHTA has been
 capturing clinical information requirements using an approach based on archetypes, which are then
 cross referenced across various domains to ensure consistency, with a view to being available as
 version-controlled detailed clinical models (DCMs). For use in CDA documents, a form of CDA
 template is generated for each major class of clinical document based on using the DCMs for
 particular content to constrain the underlying HL7 CDA reference model.
- SNOMED CT for Clinical Reference Terminology (mappings between SNOMED CT, ICD-10-AM, ICPC and LOINC are also considered essential).
- GTIN for product identification.

There are several commercial suppliers of health messaging services – Argus Connect, HealthLink and Medical Objects – with a strong market presence for communication of laboratory/diagnostic orders and requests between GPs and lab/diagnostic services and some use for referrals. An element of the NEHTA work program is the secure message delivery (SMD) service for the health sector. It is unclear whether and how this will complement or compete with the established commercial services for eHealth messaging.

Medicare Australia also has a proprietary claims-management protocol (with roots in early work in HL7v3)

4.2.7.3 Security

- Australia is a key supporter of ISO 27002 and its application in healthcare through ISO 27799.
- National Identifiers see previous comments on IHI, HPI I, HPI O
- Medicare Australia has a group that manages PKI certificates and tokens for authorization and authentication of healthcare providers to support reimbursement of medical benefits under Medicare. These are being extended to support the HPI-I service to form the basis for the National Authorisation Service for Health (NASH).
- Medicare Australia also has a secure database of internal identifiers for individual Australians to underpin the medical and pharmaceutical claims system. Legislative approval has been given to transform them to form a secure basis for the IHI service
- NEHTA secure message delivery (SMD) specifies security requirements and standards for its secure messaging stack – which have been published as a series of Australian Standards through Standards Australia committee IT-014

 Commercial messaging suppliers have implemented secure messaging based on their own interpretations of HL7, ISO and other standards for security key handling and digital signatures.

4.2.8 Standards Development Organizations (SDOs) and Health Informatics Associations

4.2.8.1 Non-government associations and SDOs:

Standards Australia Committee IT-014 Health Informatics (with around 10 active sub-groups) is the principal SDO responsible for managing the development of publicly accepted national standards for eHealth. It is the Australian mirror committee for ISO/TC 215 and, with the support of HL7 Australia, publishes HL7 implementation guides for use in Australia.

Non-government organisations in Australia that are represented on and contribute to Australian work on health informatics standards through IT-014 include:

- Health Informatics Society of Australia (HISA) [http://www.hisa.org.au/]
- Australasian College of Health Informatics (ACHI) [http://www.achi.org.au/]
- Professional colleges and representatives of clinical practices, including RANZCR (radiologists), RCPA (pathologists), RACGP (general practitioners), RACMA (medical administrators), RCNA (nursing), HIMAA (health information managers), ADIA (diagnostic imaging), APPA (pathology practices), AHHA (Hospitals and healthcare), and Engineers Australia.
- Medical Software Industry Association (MSIA) [http://www.msia.com.au/]
- HL7 Australia Inc., the local HL7 affiliate which contributes to national eHealth standards development through active involvement in IT-014 and by running education, training and joint enterprises [http://www.hl7.org.au/]
- IHE Australia, an open not-for-profit initiative that supports the interoperability needs of eHealth Standards users in Australia as the local deployment group of IHE International. IHE Australia was originally formed with support from MSIA, HISA, RANZCR and HL7 Australia. For more information see:[http://www.ihe.net.au/]

4.2.8.2 Regulatory, statutory and quasi-government bodies:

- Australian Institute of Health and Welfare (AIHW) [http://www.aihw.gov.au], which in association with the National Health Information Standards and Statistics Committee (NHIISC), oversees the development and promulgation of: a National Health Data Dictionary (NHDD) and national minimum data sets (NMDS) for health, welfare and housing. Australian Collaborating Centre of the WHO Family of International Classifications (WHO-FIC) – managed through AIHW.
- NEHTA particularly as a developer of specifications for standard elements under the national eHealth program, which are outlined throughout in this section and as the national IHTSDO member body for Australia. Many of NEHTA's specifications are expected to form the basis of Australian standards produced and approved by Standards Australia committee IT-014. [See: http://www.nehta.gov.au/]
- National eHealth Information Principal Committee (peak advisory group to AHMAC/AHMC on eHealth and information strategies and to facilitate collaboration between the Commonwealth, States and Territories to implement these strategies, tasked with:
 - Developing a national eHealth Strategy to improve health outcomes through national collaboration in agreed priority areas for action over the next 5 years;
 - Developing a national information management and technology implementation plan that reviews the scope, funding, governance and timetabling of existing IM&T projects

© ISO 2012 – All rights reserved

- Therapeutic Goods Administration (TGA) particularly in relation to pharmacovigilance and safety of medical devices – increasingly including computer software supporting clinical functions.
- Australian Government Department of Health and Ageing which is responsible to the Australian Government for administering delivery of the national eHealth program.
 [See: http://www.health.gov.au/]
- Australian Commission on Safety and Quality in Healthcare (ACSQHC)
- Australian Bureau of Statistics, which conducts population surveys and censuses to gather data on the health, health-related behaviours and other characteristics of the Australian population. [See: http://www.abs.gov.au/]

4.2.9 National reporting infrastructure for individual and/or summary data

State/territory data collections contain some individual data (admitted patient morbidity and perinatal statistics) but mainly provide summary data to national collections – see response to previous questions.

The Australian Institute of Health and Welfare (AIHW) was established by agreement between the Australian and state/territory governments and maintains the national statistical reporting framework and national data collections on behalf of the Australian, State and Territory Governments.

Each state/territory has programs that feed into these programs.

4.2.10 Households with Internet access

About 70% of households have internet access.

4.3 Brazil

4.3.1 National health system

SUS (Sistema Único de Saude), the Brazilian National Health System was created in 1988 as part of the new Brazilian Constitution^[15]. However, SUS is an evolving project whose history stretches back to as far as the 1970s. SUS is required to provide free-of-charge health services based on the principles of: universality, integrality (comprehensive care with a holistic approach), and equity of care, meaning that all individuals are equally entitled to integral treatment, but in proportion to increased need (vulnerability and risk). SUS has a complex organization with well-marked spaces of management and social control. It is funded, run and supervised jointly by the three levels of Government and Social Control: federal, state and municipal. Under SUS, ideally, health services will be delivered and managed at city level, according to pre-defined and agreed programs, which are constantly deliberate and monitored by the three levels^[16].

Within the management structure, the Bipartite Commission in each state is a forum that gathers together representatives from the State Health Secretariat and representatives of Municipal Authorities. The Tripartite Commission is formed by Representatives of the Ministry of Health, state and municipal secretariats. Those forums work by consensus that leads to "Pacts". Structures of social control include health councils at the three levels, in which users have a strong representation (50%), but where the participation of managers, health workers and entrepreneurs of health is ensured by bylaws. Those structures are forums for debate and clash between actors. Also periodically local, state and national health conferences are organized and carried out. [17]

4.3.2 Focus of national health system

4.3.2.1 National health system (SUS)

The national health system, SUS, is strongly based on Primary Care and on Family Health Programs, which have been responsible for a drastic change in health indicators in the country in the last 20 years^[15]. Under

SUS, patient flow should follow a three-layered referral - counter-referral model. On the entry layer lies primary care, on the second lies specialized treatment, and high-complexity treatment lies on the third. Patient flow to the second and third layers – and back – follows recommended regional pathways, thus creating the referral - counter-referral model.

Although every inhabitant of Brazil is entitled to free health care, SUS is responsible for some 70% of all procedures and some 50% of the expenditure, covering around 160 million people who rely solely on the public system. Overall, including both private and public sectors, Brazil spends some USD 120 billion a year in healthcare.

4.3.2.2 Private Health Insurance Market (PHI)

The Private Health Insurance Market (PHI) has been operating in Brazil since 1960, offering voluntary private health care. PHI accounts for 23% of the Brazilian population of 190 million people, but represents some 55% of health expenditure^[18]. There are different kinds of health plans such as physicians' and dentists' groups, insurance companies, self-managed plans and health management organizations, either for profit or not (philanthropic). For many years this sector grew without being regulated by the state. In 1998, the Brazilian Congress passed a law creating the foundations for regulating this market sector and, in 2000, a federal regulatory agency – "Agência Nacional de Saúde Suplementar – ANS" was created with the mission of regulating PHI activities in Brazil and ensuring market efficiency, quality of care and protection of policy holders rights.

The PHI market has been reorganized, with stricter financial and economic rules for entrance and exit in the market for insurers; prohibition of risk selection and of unilateral breaking of contracts. ANS has set predefined waiting periods and a minimum mandatory package of benefits. Contractual instruments for beneficiaries and for a network of healthcare providers and penalties for those who did not comply with regulations of the agency were set.

Currently, there are 1 065 health plan carriers that cover 44 million lives, of which more than 70% represent employer-based insurance. Individual contracts are subject to stricter control by the agency. As an example, the annual adjustment of premiums for individual contracts is defined by ANS, whereas the Agency only oversees the readjustment of the employer-based contracts^[19].

4.3.2.3 Brazilian Telehealth Program

The reorganization of SUS that strengthened Primary Care (PC) through the Family Health Strategy (FHS), around 2 000, brought important advances in health and living conditions of the Brazilian population. [20] Today, more than 30 000 staff members are responsible for the care of more than half the Brazilian population. The FHS has had a positive impact on infant mortality, on the reduction of hospitalization for conditions sensitive to primary care, and on the quality of prenatal care and childcare, as well as expanding access to health services for vulnerable populations in poor socio-sanitary conditions. On the other hand, several studies have shown that there are differences in quality of care provided by the FHS teams, as well as challenges to expand its capacity to respond to new and old grievances that characterize health in Brazil. One of the strategies advocated for the improvement of the FHS is the use of Permanent Health Education (PHE).

The National Telehealth Program, funded by the Ministry of Health, has since 2007 developed strategies for classifying and qualifying Family Health Teams (FHTs), involving 9 states. University centres have been responsible for 1 361 Telehealth connection points for FHTs within 1 113 cities. The deployment of such points was done in favour of cities with populations under 100 000 people, low human development index, fair local connectivity, already covered by the FHS, and were located in remote areas (including all of the Amazon Region)^[21].

In general the Telehealth Program offers support to FHTs through asynchronous and synchronous teleconsultation. Teleconsultation is characterized as a permanent educational activity for those using this service under the FHS. These activities are called Formative Second Opinion (SOF), i.e. they are carried out with educational character, aimed at increasing the resolving capacity of the worker who asks for that service. SOF is based on the best available scientific evidence, tailored to local realities and following the principles of SUS and Primary Care. The object of a SOF is typically either a discussion of a clinical case concerning a specific patient or situations involving an entire family or community. It can also be a complete subject or even

© ISO 2012 – All rights reserved

a health issue concerning the process of work teams within the FHS. At the end of 2010, the National Telehealth Program entered a new phase aimed at expanding geographically, initially to five additional states before being nationwide, and also by making Telehealth a regular and regulated activity within SUS.

The National Telehealth Program is also supported by the Telemedicine University Network (RUTE)^[22], another national program sponsored by the Ministry of Science and Technology, from January 2006. RUTE is building and updating the application-level infrastructure of university hospitals, in the major cities of the country. The project goal is to allow all the participating hospitals to use the academic network to run Telemedicine and Telehealth applications including video conferencing for information exchange, second opinion, continuous education and web-conferencing. It builds the basis for the inter-hospital collaboration. RUTE counts on a council which includes members from a broad spectrum of stakeholders which discuss and define policies, procedures and all aspects of the Telemedicine Network.

4.3.3 Components of the national health information system

4.3.3.1 History of evolution of the national health information system

Brazil has a long tradition of using Health Information Systems, and SUS data collection is impressive. However, the history of health information systems has been characterized by fragmentation as most applications were developed to sort out specific problems, thus using specific vocabularies, and patient and worker IDs. As a result of that, there exist more than 200 health information systems of different complexities without any integration whatsoever^[23].

That scenery started to change when, in 1999, the Ministry of Health (MoH) proposed the National Health Card Project aiming at defining standards for uniquely identifying the individual, the health organization and the healthcare worker as well as defining a core patient dataset for registering clinical data. In 2003, the MoH unified the registries of healthcare (HC) providers and workers, creating a national registry with unique identifiers. The use of this registry is mandatory for all HC providers in the country no matter whether public or private. These two projects had a major impact on how health information systems became to be regarded^[24]. The national database of uniquely identified persons holds 180 million people and the national registry of HC providers has 228 thousand records with 2,7 million HC workers.

In 2000, the Health Ministry commissioned the development of SisReg – a patient flow control system, which is regarded as the cornerstone for optimizing health resources and ensuring equity of access to health services. Patient flow control means intelligent scheduling of specialized consultations, exams and inpatient admission. Intelligent scheduling means that allocating resources to answer to an individual's needs takes into account all relevant factors, such as distance, effectiveness, budget and cost. Although all treatment under SUS is offered free of charge, several procedures have to be authorized before being carried out. Therefore, part of patient flow control relates to authorizing procedures and inpatient admissions as well.

By the beginning of 2003 it was clear to most public health managers that national standards were vital and that patient flow control is an essential tool if SUS is ever to become a reality throughout the nation. SUS relies on several information systems to help monitor its performance. The MoH is the coordinator of these systems, through Datasus, the Health Informatics Department of SUS. Datasus coordinates the information systems and is the guardian of the national databases, maintaining about 300 health domain tables and vocabularies. These are used by information systems throughout the country and include vocabularies such as medical procedures, gender, cities, admission types and discharge types. Anonymized information is made freely available to health managers and the population through the offer of a query tool (Tabnet) that accesses those databases on the Internet www.datasus.gov.br.

4.3.3.2 Country health information systems and national databases

A summary list of major systems and their aim is given below. These systems are used by city and state departments of health to input production and billing data that are sent to the state and federal levels.

 Primary health care Information system (SIAB) - SIAB records basic healthcare actions and services carried out by the Family Health Program (PSF). It uses three forms for data entry: the first one for family surveys and living conditions, a second for health information, and the third for information on production and bench marks for evaluation.

- Hospital-based information system (SIH-SUS) this system generates monthly data on hospital services provided by SUS. It includes, among others, data on resources allocated to each hospital belonging to SUS network, on hospitalizations, procedures, average length of patient stay in the hospital, by city and state. The information can be disaggregated by gender, age, place of care and patient's address.
- Outpatient information system (SIA) makes available information on SUS outpatient services. Data can be disaggregated by region, city, type of care, type of facility, facility and expenditure.
- Mortality information system (SIM) records mortality data based on death certificates, collected by the state health departments, with information on place and cause of death and identification and demographics of the deceased (gender, age, race, and place of residence).
- Vital Registration (SINASC) provides the vital registration of all born-alive babies for epidemiological, statistical, and demographic analyses, with the most significant attributes of all newborns, such as gender, birthplace, type of delivery, prenatal care, and birth-weight, among others. Data collection is based on a standard and mandatory document, the declaration of live birth (DN).
- National immunization program information system (SIPNI) contains records on dispensed immunobiologicals and the vaccinated population. Reports can be provided by age group, in a given period of time, and in a given geographical area. SIPNI is made up of two modules. The Immunization Program Evaluation Subsystem (API) collects data on vaccination coverage (routine and campaign), and dropouts. It provides immunization bulletins for the federal, state, regional, and municipal levels. The second module, the Immunobiologicals Supply and Distribution Subsystem (EDI), controls the supply and distribution of immunobiologicals at the state and federal levels.

National disease notification system (SINAN) - collects and processes data on notifiable diseases from the entire country, providing analytical information on the morbidity profile.

 Prenatal information system (SIS PRE-NATAL) – collects data on pregnant women. Its use is mandatory in all cities that adhered to the humanized prenatal care and childbirth program. SUS managers and health workers can monitor the program by tracking each pregnant woman.

4.3.4 National eHealth policies

There are several formal bills, rules and policies as well as established codes of practice that guide the development and use of health information systems in Brazil. Above the health domain, the federal government has decided on strategies and policies regarding e-Gov. e-PING – the Electronic Government Interoperability Standards architecture defines a minimum group of premises, policies and technical specifications that regulate the use of Information and Communication Technology (ICT) in the Electronic Government Services, establishing conditions for them to interact with the other branches and spheres of government and with the society in general.

Still beyond health care, there is federal legislation that protects data privacy, confidentiality and security, as well as legislation, codes of practice and watch-dogs to guard consumer rights. As far as health and healthcare are concerned there are several players that make decisions or influence them. The most important of those players are the ones that are within SUS, as they define standards and practices for the whole country and affect directly some 160 million people that rely on SUS. From the description so far it is possible to infer that even before SUS creation, in 1988, the Brazilian Government has always seen value in health information systems. As in many other countries, a series of "siloed systems" were built to support vertical programs. The vertical programs themselves represented the policies for notifiable diseases, hypertension, prenatal care and others, as mentioned before. A unifying formal "National Health Information and Informatics Policy" started to be written around 2000. It is currently in its second version, from 2004. The policy has been built under the sponsorship of SUS and validated at the National Health Conference, the highest consensus building forum for public health in the country^[25]. The policy offers a set of 19 guidelines, including among others:

strengthening of Health Information System;

- pursuing integrated EHR systems;
- building unique identifiers for patients, healthcare organizations and healthcare providers;
- defining health information standards in the guest for interoperability, using open processes;
- building data warehouses for public access to unidentified data.

In practice, the policy has not led to a coordinated action from all healthcare players, but it has influenced public health decision-makers, healthcare workers, professional bodies, scientific societies and other health informatics organizations. As a result, there is a plethora of health information systems that use national standards whenever available, whereas there are still plenty of "siloed systems" being used. Therefore, it is possible to state that the adherence to existing national standards and best practices is inhomogeneous and that the existing policy has not contaminated or been enforced throughout the country. One of the most important steps regarding applying the national policy to the real world is the recent proposal of an eHealth platform by the Ministry of Health. This item is presented in the eHealth Architecture section below.

4.3.5 National eHealth architecture stage of development

The Brazilian Ministry of Health (MoH) has been working towards the adoption of an eHealth platform based on a self-consistent set of specifications, including information, service and content models. The draft proposal developed by the Standards and Interoperability Subcommittee, a task force created by the MoH has been presented to a workgroup composed of health IT managers of all levels of SUS, the National Supplementary Health Agency, and from Brazilian Health Information organizations, such as the Health Informatics Standards Committee of the Brazilian Standards Organization (ABNT), HL7 Brazil, IHTSDO, Object Management Group (OMG) and OpenEHR Foundation.

There is a proposed ministerial order, establishing the standards for interoperability to be adopted nationally, by all health information systems of the various levels of SUS. Although still a draft, it has been approved of by all bodies it has been submitted to and now awaits final approval by the MoH. The proposed interoperability platform consists of a set of basic assumptions, operational rules and technical specifications to regulate the exchange of information between public and private, municipal, state and federal health information systems, also setting up conditions of interaction with the other spheres of government and society in general.

The standards are to be made publicly available and updated on the Datasus website. The standards chosen so far are as follows:

EHR information model: OpenEHR

Clinical reference terminology: SNOMED CT

Clinical documents: HL7 CDA

 Record location: IHE PIX (Patient Identifier Cross-Referencing) and PDQ (Patients Demographics Query)

4.3.6 National data warehouse

All raw health data collected by SUS, and even data collected before SUS was created, are classified and made publicly available on the Datasus website www.datasus.gov.br. An impressive collection that stretches as far back as the 1970s can be found there. However, in order to produce information derived from all the, many times "siloed", health databases, and expand the analysis to include social and geographical data, a great deal of analysis and consolidation is required.

RIPSA (Brazil's Interagency Network of Information for Health) brings together national institutions with responsibilities for the production and analysis of such information. As a network of organizations, RIPSA coordinates national entities responsible for the collection and analysis of health, geographical, social and

population data. Through the work of subcommittees, RIPSA is responsible for the technical quality, coverage, validation, and harmonization of core data including aspects of dissemination of information. [26]

The processes data is organized in a paper as well as an electronic yearly brochure called Basic Health Data and Indicators (IDB)^[27]. IDB can be found on www.datasus.gov.br/idb.

4.3.7 Standards in use

- e-Gov and e-PING e-PING follows the guidelines set out by the Executive Committee for Electronic Government, created by a bill of 18 October, 2000. From its earliest day, e-PING documentation has been available on www.eping.e.gov.br, in order to ensure public access to information that is of general interest, and to respect the transparency that is intrinsic to the initiative. The Brazilian government is committed to guaranteeing that the policies and specifications set by e-PING remain in line with the society's needs and follow the evolution of the IT market.
- MoH Standards in use for the public sector have been mostly defined by the MoH and include Brazilian codes for Procedures, Unique Patient, Healthcare Providers, and Health Workers Identification, including Family Health Teams. There are standards for describing households and communities, an essential object in primary care. There are also national standards for: an essential clinical dataset and for billing. AIH (Inpatient Admission Authorization Standard) has been in place since the early 80s and is used for claiming and statistics. A similar set of standards is used when reporting outpatient care and generating statistics from it.
- Vocabularies used throughout SUS include ICD-10 for diagnostics, and Brazilian codes for procedures, authorization and referral. Demographics make use of Brazilian standards, such as those for cities, districts, and streets for addresses, telephone area codes, occupations, race, marital status, social security and other ID numbers.
- ICP Brazil there is a nationwide Public Key Infrastructure the use of which has been increasingly more important.
- TISS and TUSS to help improve the efficiency of compiling data for eligibility, authorization, billing and payment within the private health insurance market, the federal regulatory agency for supplementary health, Agência Nacional de Saúde Suplementar (ANS), set out the standards for the exchange of information between health plans and healthcare providers: TISS that sets the standards for messaging, vocabulary, content, structure, privacy and security. TUSS is a recent initiative that defines vocabularies for medical and other health procedures. Both TISS and TUSS are used for billing purposes^[26].

4.3.8 Standards Development Organizations (SDOs) and Health Informatics Associations

The list below describes some of the important organizations in Brazil regarding adopting, adapting or developing standards and some of their work. This list is not exhaustive, as its intent is solely to provide a landscape scenario on this theme:

- Ministry of Health (MoH) as the coordinator of SUS, the MoH develops and keeps several standards, including vocabularies for describing medical procedures.
- Datasus the SUS Department of Informatics is not directly involved in developing standards but they
 develop and maintain systems for all instances of SUS. In practice, Datasus defines de facto and de
 jure standards as it deploys the health information systems for all the public sector.
- ANS to help to improve the efficiency of compiling data for eligibility, authorization, billing and payments within Private health Insurance, ANS has set out legislation and mandatory requirements for the exchange of health information between healthcare providers and health plans. As part of that, ANS sets standards for messaging, vocabulary, content, structure, privacy and security for the exchange of health information within the supplementary health sector. ANS has developed its standards using a mixed approach, which includes bottom-up and top-down processes.

© ISO 2012 – All rights reserved

- National Health Surveillance Agency (ANVISA) defines the adoption of standards for many domains of health and healthcare, including medications, devices, services and equipment, among others.
- Federal Medical Council (CFM) the most important professional body as far as Health Information Systems are concerned, as it defines specific aspects related to privacy, confidentiality and use of data. CFM and the Brazilian Health Informatics Association (SBIS) have developed a joint EHR systems certification process that has been fully operational since the end of 2009. The SBIS—CFM certification process is largely based on ISO 20514, ISO 17799 and ISO 18308.
- City and State Departments of Health although not involved in developing standards, local and regional Departments of Health play a major role in choosing standards and architectures for their own systems. Important examples of such are the Minas Gerais State bid process for EHR systems whose RFP demanded compliance with ISO 13606; São Paulo city Health Information System which was built using a strong architecture and all available national standards, including, more recently, HL7 v3 CDA R2 for lab data exchange; and Santa Catarina State Health Information System which is a fully DICOM-compliant system.
- Brazilian Health Informatics Association (SBIS) founded in 1986, SBIS is an active technical and scientific society, member of the International Medical Informatics Association (IMIA) and IMIA-LAC (IMIA Latin American and Caribbean) as well. SBIS has become very influential in the last few years, partly owing to the EHR system certification process. SBIS carries out its National Health Informatics Conference every other year and EHR Conference in between.
- Health Informatics Standards Committee of the Brazilian Standards Association (ABNT) created in the end of 2006 and became a "P" member of ISO/TC 215 in June 2007. Ever since then, it has become an active member of ISO. Currently Brazil co-leads two standards projects within that TC.
- HL7 Brazil founded in 2004. Its main activities are related to training and the dissemination of knowledge. HL7, ABNT and SBIS usually work together to organize national and international meetings.
- GS 1 Brazil facilitates the GS1 Local Healthcare User Group, a group of leading healthcare manufacturers, distributors, hospitals, pharmacies and governmental bodies which works together for alignment with the Global GS1 Healthcare User Group. The aim of the local group is to provide national input to the creation and maintenance of global healthcare standards thereby learning from other countries' experience.
- Brazilian Computer Society (SBC) was established in 1978, as a scientific and educational
 organization dedicated to the advancement of Computer Science and the associated technologies and
 applications in Brazil. SBC is a leading forum for researchers, students and computing professionals,
 being the largest computer society in South America. The Computers Applied to Health Special
 Commission has as its mission to organize, motivate and disseminate research in computer science
 applied to health and healthcare. Among other activities, the Commission organizes the Workshop on
 Medical Informatics (WIM), an annual event that had its 10th edition in 2010.

4.3.9 National reporting infrastructure for individual and/or summary data

Almost all data collected from the very early years were aggregated from identified data. One important exception used to be the clinical and billing data associated to outpatient care, that were not part of any vertical program. Although health workers and healthcare providers have always been identified, the patient ID was not stored for that class of data. This has just changed as the MoH determined that routine outpatient data must also be associated with identified patients.

4.3.10 Households with Internet access

A total of 24% of the Brazilian households count on Internet access, of which 59% are some sort of broadband (mostly cable, ADSL, or 3G). For Brazil South and Southeast Regions that figure raises to 33%.

In terms of access location, 45% of the population has access to the Internet from home, office or a LAN house. Of those, 58% access the Internet on a daily basis.

The Brazilian Broadband Plan aims at offering broadband at low cost for all populations. One of its major goals is to connect all health facilities to the Internet by 2014^[27].

4.4 Canada

4.4.1 National health system

4.4.1.1 Overview

In Canada, healthcare is provisioned by ten provincial and three territorial (p/t) governments under the auspices of the Canada Health Act, (CHA)^[28]. It is a single payer system but not a single national healthcare system like the UK. As well, several federal health programs for special population groups are added to the mix. All of these systems interlock and operate under the same principles and guidelines set out in the Canada Health Act.

The Canada Health Act's primary purpose is "to protect, promote and restore the physical and mental well-being of residents of Canada and to facilitate reasonable access to health services without financial or other barriers." Under this federal legislation, each province and territory is required to pay for necessary healthcare services for its residents.

It should be noted that, for comparison to other countries, the mix of public and privately funded healthcare requires an analysis of what is specifically included in the publicly and privately funded services, as this varies from country to country.

There are five basic tenets of the CHA that guide the administration and delivery of healthcare in Canada:

- 1. Public administration: The program must be administered on a non-profit basis by a public authority accountable to the provincial and territorial government.
- 2. Comprehensiveness: The program must cover all medically necessary hospital and medical services.
- 3. Universality: 100% of the eligible residents must have access to public healthcare insurance and insured services on uniform terms and conditions.
- 4. Portability: Provinces and territories must cover insured health services for their citizens while they are temporarily absent from their province/territory of residence or Canada; the home province/territory must pay for out-of-province services at the host province rates and must pay for out-of-country services at the home province rate.
- 5. Accessibility: Reasonable access to insured health services must be neither obstructed, either directly or indirectly, by financial charges nor discriminated against on the basis of factors such as income, age and health status.

It is important to note, however, that these provisions mainly apply to hospital and medical services. Provinces/territories have the autonomy to establish extended healthcare programs to cover all or part of drug and long-term care costs, chiropractic services, etc. These services often have eligibility requirements (e.g., specific income levels) and often involve patients sharing in the costs. Therefore Canada is not fully publicly funded. The mix (according to the *OECD Health Data 2011*) is that healthcare was approximately 70% publicly and 30% privately funded in 2009. Most healthcare delivery services are provided by third-party agencies and independent physicians, pharmacies and other providers that are paid using largely public funds.

According to the Canadian Institute for Health Information (CIHI), healthcare in Canada will cost over CAD 191 billion in 2011. This is a growth of CAD 9,5 billion from 2010 or 5,2%. About 60% of that cost is accounted for by hospitals, drugs and physician fees for services. CIHI reported total healthcare spending in 2007 equivalent to 10,1% of the gross domestic product (GDP).

© ISO 2012 – All rights reserved 27

4.4.1.2 Governance^[29]

The federal government, through its department Health Canada, is responsible for setting national healthcare policy and direction. Health Canada exercises its responsibilities partly by controlling federal transfer payments to the provinces. For example, the federal government can use its constitutional spending power to attempt to influence provincial healthcare policies and programs by requiring the provinces to meet certain federal standards in order to receive federal funds. Health Canada collaborates closely with provincial and territorial ministries of health through various committees that engage the respective program and policy experts in shaping healthcare policy and ensuring coordination on major national priorities (e.g., wait times reduction, access to primary healthcare). Health Canada is also responsible for certain regulatory functions, such as the approval of drug products and medical devices as well as product and food safety programs.

Various departments within the federal government also deliver direct health services to specific groups, including war veterans, First Nations people living on reserves, inmates of federal penitentiaries, members of the Canadian Armed Forces and the Royal Canadian Mounted Police (RCMP). Responsibility for Aboriginal health services is shared by the federal, provincial and territorial governments with on-reserve health services increasingly being provided by Aboriginal organizations that are funded by the federal government.

Also operating at the federal level are a number of agencies with various mandates. One of the key agencies is the Public Health Agency of Canada (PHAC), responsible for several major health programs including management of chronic and infectious diseases, natural and man-made disasters, disease outbreaks and epidemics. PHAC's primary goal is to strengthen Canada's capacity to protect and improve the health of Canadians and to help reduce pressures on the healthcare system. The Agency works closely with the provincial and territorial governments and other health agencies in carrying its mandate.

The provincial and territorial governments are responsible for managing and delivering healthcare services in their respective jurisdictions. This responsibility includes:

- Establishing strategic direction and policy for the health system
- Determining the structure and scope of healthcare services (each province is responsible for determining which additional services it will cover beyond the core services set out by the Canada Health Act)
- Controlling the flow of money to healthcare delivery organizations and their accountability and adherence to program criteria to ensure consistency
- Delivering certain services (e.g., operation of medical and drug claims processing programs and in some cases certain specialized public laboratories)
- Registering citizens and assigning of their eligibility for the various services
- Licensing and regulating healthcare providers, and funding of training programs

Provincial governments also frequently establish or regulate other agencies through legislation to carry out certain functions at arm's length, many of them complementing the work of agencies at the national level. These include organizations that:

- Provide specialized services such as cancer treatment or communicable disease protection
- Operate information technology networks and provide centrally hosted information systems that serve health regions and other points of care
- Regulate health professionals such as physicians and nurses
- Analyse healthcare quality
- Carry out health research and analysis.

Over the past decade, most provinces and territories have established regional health authorities (RHAs) to assume responsibility for the delivery of a broad range of health services within a defined geographic area. RHAs vary in size, structure, scope of responsibilities and even the number per province, but usually they have appointed or elected boards of governance and manage the funding and delivery of community and institutional health services within their designated regions.

4.4.2 Focus of national health system

See Reference [29].

Canada's healthcare system, like those of other major countries, faces many challenges. These include:

- access and wait times for care
- · patient safety
- quality-of-care
- the supply and distribution of health human resources
- increasing incidence of chronic disease
- an aging population
- the long-term sustainability of our health system given rising costs, government fiscal constraints and the continuing introduction of new and often expensive medical technologies.

Wait times are a major public concern, and while governments have implemented a number of initiatives in recent years to address wait times, experience to date has shown this is a complex and many-faceted issue that is likely to present an ongoing challenge. Even finding ways to measure the time that patients wait before they attain access to healthcare services is difficult given the diverse business processes, data definitions and both paper and electronic systems involved. All these considerations highlight the need to develop improved information and tools (such as wait list registries), which are necessary for targeting investments and improving patient assessment, referral and scheduling processes.

Canada's first ministers met in the fall of 2004 to address the issue of wait times. Collectively, they listed "timely access to quality care" at the top of their agenda, and they agreed to focus on better management of wait times and reducing waits longer than medically acceptable. Specifically, the first ministers committed to achieving meaningful wait time reductions in priority areas such as cancer, heart disease, diagnostic imaging, joint replacements and sight restoration by March 2007, recognizing different starting points, priorities and strategies across jurisdictions.

The provinces have made significant progress in improved wait time metrics. Although some wait time measurement systems are still rather basic, the information being collected across provinces is now much more standardized. In terms of wait times themselves, improvements have definitely been made, but all provinces still need to make progress in some areas^[30].

As Accreditation Canada notes in a 2009 report^[31], patient safety and quality of care are inextricably linked. These two factors have become a major concern as international evidence mounts about medical error and the risk to patients of "medical misadventure" in our increasingly complex healthcare system. The major safety issues identified include medication errors, falls and/or injuries due to restraints, errors related to access/waiting, procedural errors and communication/documentation errors. For many of these concerns, information and information systems will play an important role in supporting ongoing efforts to reduce patient safety risks.

The issues of accessibility and quality of care are further exacerbated by human resource shortages of physicians, nurses and allied health professionals such as pharmacists, physiotherapists, occupational therapists and diagnostic technicians particularly in rural areas, but increasingly in cities as well. These shortages are negatively impacting healthcare services at all levels. The average age of physicians and nurses is a major concern coupled with other issues such as nurses leaving the profession and physicians opting for a better lifestyle and not choosing primary care practice. Governments have acknowledged these issues and strategies to address them are slowly having an effect e.g. initiatives to expand training programs, find ways to attract professionals to underserved areas and retain professionals, emphasize new care delivery models that utilize multidisciplinary teams, and support programs to better educate the public in preventing illness and managing chronic disease through a greater emphasis on self-care. Technologies such as

electronic health records that coordinate care between professionals, telehealth that offers remote patient monitoring in the home and patient portals are expected to become increasingly important as means of supporting new and more effective care in the future.

Rising costs will continue to put pressure on the sustainability of the Canadian healthcare system. Continuing cost pressures emanate from several sources, including new technology, pharmaceuticals, increase in chronic and new diseases, and changing demographics and expectations. As well, salary settlements and agreements for healthcare providers also increase the cost of healthcare since healthcare provider costs make up 70% to 80% of expenditures for most services.

Ensuring sustainability will require increased attention not only to containing costs, but more fundamentally to finding much more effective ways to deliver services and reduce the future impact of an aging population and increasing demands. Sustainability is most likely to be achieved by effectively engaging the public as informed and active participants in managing their individual health supported by appropriate and sustainable investment in information technologies.

4.4.3 Components of the national health information system

See Reference [29].

Currently there is a wide range in the adoption of automation of patient health information in the various practice settings in Canada. The highest level of adoption and use of electronic records is in the hospital sector; nearly all larger community and tertiary care centres now have electronic records systems that span the various clinical services and programs. Smaller hospitals have a lower level of automation, but nonetheless have generally automated many core functions. In the ambulatory clinic environment, electronic record usage is still limited.

Despite a number of heavily funded initiatives, physician adoption of electronic medical records in primary care is very low in Canada compared to many OECD countries as shown in Figure 1^[32]. Progress has been made since 2006, but Canada still lags in this important regard. Primary care adoption is generally around 20%, although as high as 60% in some jurisdictions e.g., Alberta.

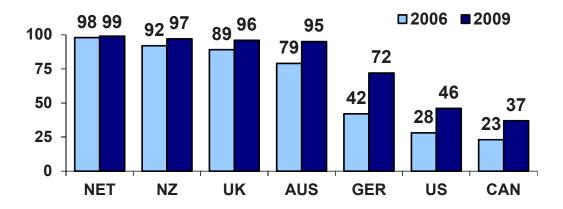


Figure 1 — EMR adoption in primary care (OECD)[32]

Few specialists are using electronic records with the exception of dentists, who have a high adoption and use rate, and specialists in hospitals e.g., radiologists. Adoption and use remains low in most other care sectors, but community/home and LTC facilities are moving forward with common systems in several jurisdictions.

Figure 2 shows the implementation of health ICT systems for the province of Quebec, which is Canada's second largest province by population. This figure, from 2006, was excerpted from the Branham Report and is intended to be exemplary only. The finance and administration systems as well as the clinical systems shown are fairly representative of systems that exist in other jurisdictions across Canada. Level of deployment of core finance and administration systems is high. However, level of deployment of clinical systems varies significantly by province and territory.

Finance & Admin Systems		Clinical Systems				
ABS	Abstracting	CARDIO	Cardiology	EMERG	Emergency	
ACCT	Accounting	сс	Critical Care / Intensive Care	LAB	Laboratory	
ві	Business Intelligence	CDR	Clinical Data Repository	PACS	Picture Archiving & Communication Systems	
DIS	Document Imaging & Scanning	CLINDOC	Clinical Documentation	ORDER	Order Communications	
HRIS	Human Resource . Systems	СРОЕ	Computerized Physician Order Entry	PHARM	Pharmacy	
PIS	Patient Information System	DICT	Dictation & Transcription	RIS	Radiology Information Systems	
wM	Workload Management	eMAR	Electronic Medication & Administration Record	SURG	Surgery	

Figure 2 — eHealth Applications Categories in Quebec^[33]

Electronic personal health records (PHRs) have made their way onto the national agenda since 2005, with national Canadian conferences on PHRs, several major surveys on related topics and special reports from key PHR advocacy groups.

Since early in 2004, one of the major differentiators of the Canadian health information system landscape has been the development of a common Electronic Health Record Solution (EHRS) Blueprint and the pan-Canadian standards necessary to support EHR interoperability. This is discussed in detail in 4.4.5.

4.4.4 National eHealth policies

There are policies in place in Canada, and in some cases, separate provincial policies for:

- Health Information Privacy
- Digital Signature, including for clinical orders
- Electronic Health Records and their medico-legal status, and guidelines regarding records retention and protection
- Mandated health indicators reporting, including some public health statistics and alerts that must be reported (e.g. hospital discharge abstracts, HIV positive test results, etc.)
- A WHO report 2009^[34] Atlas: eHealth Country Profiles, ranked Canada 21st in terms of information technology progress among 159 nations just ahead of Estonia but well behind much of Scandinavia, Europe and the Republic of Korea.
- This part of ISO/TR 14639 concluded that Canada's e-health deficiencies include a lack of supportive federal laws and regulations, national procurement and technology policies, educational policies and scholarships, and evaluations to monitor progress on important areas such as the capacity to deliver health information to patients via mobile telephones. Various calls to action by healthcare leaders will result in further undertakings in regard to eHealth policy issues. It was also noted that the timing of the WHO survey in 2009 coincided with advance planning for other health priorities in Canada, so unfortunately not all of the provinces and territories were able to provide input to the survey. In addition, limitations included the interpretation and applicability of the questions. eHealth applications were difficult to assess and the responses may not apply equally across the country.

4.4.5 National eHealth architecture stage of development

Canada Health Infoway, a public not-for-profit organization funded with CAD 2,1 billion by the federal government, has been mandated to foster and accelerate the deployment of an interoperable electronic health record (iEHR) in Canada. The corporation is governed by all of the provincial and territorial deputy ministers of health and an independent board of directors. Effectively, each province and territory will deploy systems that will hold key clinical data for all citizens. They include medications and medication orders, laboratory results, diagnostic images and reports, clinical reports (e.g. discharge summaries) and immunizations. Registries to hold unique identifiers with demographic information for clients (citizens), providers and locations of care are being deployed. The iEHR serves to facilitate the sharing of key clinical information across the continuum of care and geographically dispersed healthcare delivery organizations.

Infoway has also dedicated funding towards integration and interoperability services via an enterprise service bus using a service oriented architecture (SOA) approach (shown as the HIAL – Health Information Access Layer in Figure 4)^[35].

Other Infoway funding has been applied to broaden deployment of telehealth networks, particularly in rural and remote areas and into First Nations communities. A system for public health surveillance, specifically infectious diseases, is being deployed. It will be used for infectious disease surveillance, reporting, case management, vaccine inventory management and immunization tracking.

Recently, Infoway received funding to assist in the deployment of Electronic Medical Record (EMR) systems in community physician settings. Work has begun too in furthering the integration of EMR, hospital, ambulatory care, and pharmacy systems to the iEHR. This will allow clinicians to more easily share their data with others and to view data from other sources (e.g. diagnostic tests).

Other areas of investment are targeted at innovation pilots such as chronic disease management, consumer health solutions (e.g. patient portals), and synoptic reporting (that provides a synopsis or summary with a standardized nomenclature, a standard set of findings and a consistent structure).

Figure 3 provides an overview of all Infoway investment areas^[36].

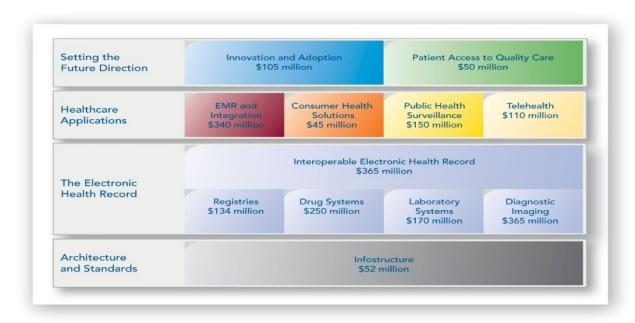


Figure 3 — Health Infoway Investment Model^[36]

A pan-Canadian Electronic Health Records Solution (EHRS) Blueprint (Figure 4) has been developed by Canada Health Infoway. This Blueprint is currently at version 2.0 and will soon be released in version 3.0^[35].

The Blueprint includes an "infostructure" specification which describes the elements of the service oriented architecture (SOA) which must be present and a set of detailed HL7v3-based interaction specifications which describe the message formats for data exchange. Provincial EHRS projects which are funded by Infoway must abide the design elements of the Blueprint.

The approach used to build the EHRS Blueprint was:

- Getting common business and technical architecture accepted by jurisdictions and vendors
- Including the linking of local clinical systems with jurisdictional and regional registries and repositories using a data-sharing approach
- Using it to serve as a reference model for Infoway investments
- Making it extensible and scalable to support new functions
- Federating jurisdictions to create a national view
- Having it freely available on the Infoway website.

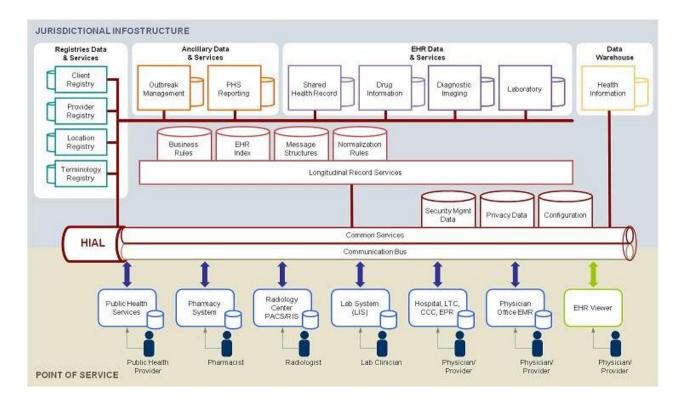


Figure 4 — Canada EHR Infostructure^[35]

The progress to date of Infoway's investments in EHRS implementations in Canada, by province, by EHR domain, is shown in Figure $5^{[37]}$.

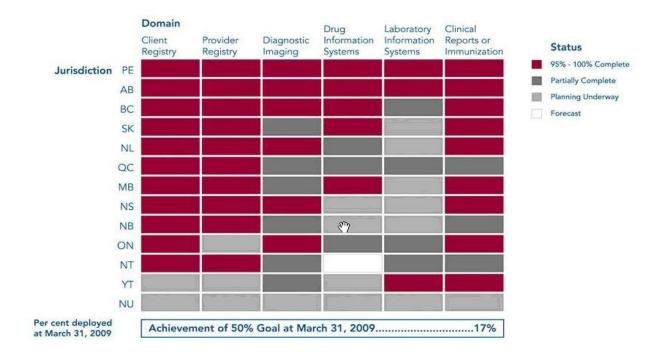


Figure 5 — The progress to date of Infoway's investments in EHRS in Canada^[37]

4.4.6 National data warehouse

Health system management information is collected primarily by a national organization, the Canadian Institute for Health Information (CIHI). Certain health indicators are reported on a mandatory basis (hospital discharge abstracts, for example); others are reported on a voluntary basis. Information in the data warehouse is analysed by CIHI and used to inform Canadian public policy regarding healthcare. There are a variety of other health data organizations operating within the provinces, most associated with university research institutes e.g. Health Care Quality Center (University of Saskatchewan); Institute for Clinical Evaluative Sciences (Toronto and Ottawa, Ontario). These institutes access and analyse data from multiple sources on the basis of formal data-sharing agreements. They conduct research on behalf of governments and other organizations as well as propose research studies in support of health system planning, policy-making, development of legislation and determination of needed standards and guidelines and related matters affecting the health and healthcare of individuals and populations.

4.4.7 Standards in use

Canada has generally adopted HL7v3 as the standard for health information messaging, CDA for documents and SNOMED CT as the primary vocabulary standard. The Integrating the Healthcare Enterprise Cross-Enterprise Document Sharing – Imaging (IHE XDS-I) protocol has been adopted as a national standard for diagnostic imaging. CIHI information is collected using the ICD-10-CA (Canadian Amendment) and CCI (Canadian Classification of Health Interventions) coding standards. For security, authentication, and digital signing, public key infrastructure (PKI) based on X.509 certificates has been broadly adopted. For unique identifiers, many provinces are using individuals` health insurance ID numbers as unique identifiers or as proxies for an internal Globally Unique Identifier (GUID) maintained within the EHRS. Health professional colleges (physician, nurse, etc.) have unique identifiers (IDs) for their members; these are typically employed by the provincial EHRS as proxies for a GUID or as an ID.

4.4.8 Standards Development Organizations (SDOs) and Health Informatics Associations

Canada is an active participant in HL7, IHTSDO, IHE and ISO/TC 215 including acting in leadership positions in these organizations. Canada Health Infoway, the developer of the national eHealth architecture Blueprint, has created the Standards Collaborative at the national level to act as the umbrella organization under which

the various SDOs engage, coordinate and collaborate to identify, prioritize, adopt/adapt/develop if needed, and approve health information messaging, vocabulary and related technical standards for implementation in provincial EHR solutions. Canada also has an active health informatics professional body: COACH, Canada's Health Informatics Association. Recently, COACH developed and made available a professional health informatics credential in association with the Health Information Management Systems Society (HIMSS) US – the CPHIMS-CA (Certified Professional in Healthcare Information and Management Systems – Canada).

4.4.9 National reporting infrastructure for individual and/or summary data

The national reporting infrastructure is presently based primarily on Canadian Institute for Health Information (CIHI) data collections and other health data organizations operating within the provinces as previously described. There is an expectation that the Infoway pan-Canadian EHRS infrastructure, once fully built out, will also support data collection and reporting.

4.4.10 Households with Internet access

YEAR	Population	Users	% Penet.	Usage Source
2000	31,496,800	12,700,000	40.3 %	<u>ITU</u>
2003	32,050,369	20,450,000	63.8 %	C.I.Almanac
2005	32,440,970	21,900,000	67.5 %	C.I.Almanac
2008	33,212,696	28,000,000	84.3 %	I.T.U.

Figure 6 — Canada Internet Utilization^[38]

- *ITU International Telecommunication Union (agency of the United Nations)
- *CI Almanac (Computer Industry Almanac)

Based on current statistics (Figure 6), over 70% of Canadians have a mobile phone and over 20% of Canadian mobile phone users employ their phone for internet access^[38].

4.5 India

4.5.1 National health system

In India, healthcare is the responsibility of constituent states and territories of India. The Constitution charges every state with "raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties". The National Health Policy was endorsed by the Parliament of India in 1983 and updated in 2002^[39].

- A phased, time-bound program for setting up a well-dispersed network of comprehensive primary healthcare services, linked with extension and health education, designed in the context of the ground reality that elementary health problems can be resolved by the people themselves;
- Intermediation through 'health volunteers' having appropriate knowledge, simple skills and requisite technologies;
- Establishment of a well-worked out referral system to ensure that patient load at the higher levels of the hierarchy is not needlessly burdened by those who can be treated at the decentralized level:
- An integrated network of evenly spread specialty and super-specialty services; encouragement of such facilities through private investments for patients who can pay, so that the draw on the Government's facilities is limited to those entitled to free use.

PD ISO/TR 14639-1:2012 **ISO/TR 14639-1:2012(E)**

The Central Government Health Scheme (CGHS) in India provides healthcare facilities to CGHS beneficiaries, which include All Central Government Servants paid through Civil Estimates, Pensioners drawing pension from Civil Estimates and their family members, Members of Parliament (MPs) and Ex-MPs, Judges of Supreme Court of India, Ex-Governors and Ex-Vice Presidents, former prime Ministers, Employees and Pensioners of Autonomous Bodies, Former Judges of Supreme Court of India and High Courts and Freedom Fighters.

Under CGHS, health services are provided through Allopathic, Homeopathic and the Indian system of medicines, which comes under the Department of AYUSH (Department of Indian Systems of Medicine and Homoeopathy - ISM&H - was created in March 1995 and re-named as Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy or AYUSH in November, 2003). The medical facilities are provided through dispensaries/polyclinics and the chief medical officers/medical officers are in charge of the dispensaries for the smooth functioning of the scheme.

The Directorate General of Health Services (DGHS), a repository of technical knowledge, is an attached office of the Ministry of Health and Family Welfare (MoHFW), Government of India.

The Central Bureau of Health Intelligence (CBHI), under the DGHS, MoHFW, and headed by Deputy Director General & Director, has four divisions: (i) Policy & Infrastructure, (ii) Training, Collaboration & Research, (iii) Information & Evaluation, and (iv) Administrative, along with Six Health Information Field Survey Units (FSUs) located at Bangalore, Bhopal, Bhubaneswar, Jaipur, Lucknow and Patna and the Regional Health Statistics Training Centre (RHSTC) at Mohali, Punjab (near Chandigarh).

4.5.2 Focus of national health system

See References [40], [41] and [42].

India suffers from high levels of disease including malaria and tuberculosis. One third of the world's tuberculosis cases are in India. In addition, India along with Nigeria, Pakistan and Afghanistan is one of the four countries worldwide where polio has not as yet been eradicated. There are national programs for controlling each of these:

- HIV Ongoing government of India education about HIV has led to decreases in the spread of HIV in recent years. The number of people living with AIDS in India is estimated to be between 2 and 3 million. However in terms of the total population this is a small number. The country has had a sharp decrease in the estimated number of HIV infections. The 2005 reports had claimed that there were 5,2 million to 5,7 million people afflicted with the virus.
- Malnutrition Half the children in India are underweight, one of the highest rates in the world and nearly the same as Sub-Saharan Africa. India contributes to about 5,6 million child deaths every year, more than half the world's total. Most Indian women are malnourished. The average female life expectancy today in India is low compared to many countries, but it has shown gradual improvement over the years. In many families, especially rural ones, the girls and women face nutritional discrimination within the family, and are anaemic and malnourished.
- Maternal mortality Maternal mortality in India is the second highest in the world. Only 42% of births in the country are supervised by health professionals. Most women deliver with help from women in the family who often lack the skills and resources to save the mother's life if it is in danger.
- Water supply and sanitation In India, the availability and quality of basic requirements is still far below expectations, despite longstanding efforts by the various levels of government and communities at improving coverage. The situation is particularly inadequate for sanitation, since only one of three Indians has access to improved sanitation facilities (including improved latrines). While the share of those with access to an improved water source is much higher than for sanitation (86%), the quality of service is poor and most users that are counted as having access receive water of dubious quality and only on an intermittent basis. As of 2003, it was estimated that only 30% of India's wastewater was being treated, with the remainder flowing into rivers or groundwater. The lack of toilet facilities in many areas also presents a major health risk; open defecation is widespread even in urban areas of India, and it was estimated in 2002 by the WHO that around 700 000 Indians die each year from

diarrhoea. No city in India has full-day water supply. Most cities supply water only a few hours a day. In towns and rural areas the situation is even worse.

4.5.3 Components of the national health information system

Currently, barring a few new hospitals, digitalization is almost unheard of. Most telemedicine activities are in project mode, supported by the Indian Space Research Organization (ISRO) and the Department of Information Technology and being implemented through state governments. A few corporate hospitals have developed their own telemedicine networks, prominent among them being the Apollo and Amrita groups. More than 500 telemedicine nodes are in place across the country. National telemedicine standardisation and practice guidelines have been developed by the Department of Information Technology. A National Telemedicine Task Force to evaluate the pros and cons of introducing eHealth in India has been set up by the Health Ministry. The External Affairs Ministry is analysing the Pan-African e-Network Project and the South Asian Association for Regional Cooperation (SAARC) Telemedicine Network Projects.

The National Knowledge Commission (NKC), a high level advisory body to the Prime Minister of India, with the objective of transforming India into a knowledge society, had also set up a Working Group for the development of an Indian Health Information Network - i-HIND^[43]. This working group has proposed to design, develop, and integrate an end-to-end electronic healthcare informatics network framework in India to improve public health, health research, and the delivery of healthcare. The other related WGs have been for the India Health Portal and Health Literacy and for Emergency Medical Services. A Standards Committee is being set up to recommend suitable standards for healthcare interoperability. Further, the NKC had proposed the setting up of the National Health Information Authority - NHIA - that will oversee all these activities.

4.5.4 National eHealth policies

- The proposed National Health Information Authority (NHIA) will oversee the policy development for the health information system (HIS) and EHR.
- There has been a National Cancer Registry^[44] under the auspices of the ICMR (Indian Council of Medical Research).
- Some Public health statistics (malaria, TB, leprosy, kala-azar, dengue, cholera, plague, goiter, HIV/AIDS) are available from the Central Bureau of Health Intelligence (CBHI)^[45].
- The Directorate General of Health Services (DGHS) maintains a separate site for updated reports on TB^[46].
- The respective national programs for malaria, TB, HIV and the other diseases noted above have established policies for monitoring and evaluation.

4.5.5 National eHealth architecture stage of development

The proposed National Health Information Authority (NHIA) will oversee the policy development for eHealth architecture. The Ministry of Health and Family Welfare (MoHFW) is responsible for approving the establishment of the NHIA.

4.5.6 National data warehouse and national reporting infrastructure for individual and/or summary data

The Central Bureau of Health Intelligence (CBHI) maintains all national data related to healthcare including all data for monitoring and evaluation. (http://cbhidghs.nic.in/).

4.5.7 Standards in use

There is no particular health informatics standard adopted nationwide. The unique Identification Authority of India (UIDAI)^[47] has been set up to give a unique ID to all people present in the country.

PD ISO/TR 14639-1:2012 **ISO/TR 14639-1:2012(E)**

In September 2010, the Ministry of Health and Family Welfare of the Government of India formed an Expert Committee for Standardization of Electronic Medical Records. The Committee is scheduled to present its interim recommendations to the Ministry by April 2011.

4.5.8 Standards Development Organizations (SDOs) and Health Informatics Associations

India has the following key organizations:

- Indian Association for Medical Informatics [48] (IAMI is the IMIA Affiliate from India)
- Telemedicine Society of India^[49] (TSI is the Indian affiliate to ISfTeH, the International Society for Telemedicine and e-Health)
- Medical Computer Society of India^[50] (MCSI)
- HL7 India^[51]

There is no ISO/TC 215 Mirror Committee in India.

The Bureau of Indian Standards^[52] lists all the SDOs and includes the Ministry of Health and Family Welfare (MoHFW).

4.5.9 Households with Internet access

- In 2005, hardly 1.4% of urban households had Internet access^[53] and practically none in rural India.
- By 2010, about 4% of rural households had internet access^[53]. Other estimates put it at 7%^[54].

4.6 Kenya

4.6.1 National health system; focus of national health system

In Kenya, healthcare is provisioned by the central government under the auspices of the Ministry of Health (MoH). It is run by government, Faith-based organizations (FBOs), Non-governmental organizations (NGOs) and private institutions. The healthcare system is structured in a step-wise manner so that complicated cases are referred to a higher level. Gaps in the system are filled by private and church-run units. The structure consists of dispensaries, private clinics, health centres, sub-district hospitals and nursing homes, district hospitals and private hospitals and Provincial and National hospitals. The health services have been regulated by three important institutions through the acts of parliament, namely the Medical Practitioners and Dentists Board, the Clinical Officers Council and the Nursing Council of Kenya.

The Pharmacy and Poisons Act, Cap 244^[55] is an Act of parliament to make better provision for the Control of the Profession of Pharmacy and trade in drugs and poisons. The Pharmacy and Poisons Board (PPB) is established as a body corporate, under the Pharmacy and Poisons Act, Cap 244 Laws of Kenya. The PPB is a regulatory body within the Ministry of Medical Services. The health services are funded through facility improvement funds (FIF) (pay for service) and insurance firms through rebate which varies depending on the hospital status and ranges of services. Most health facilities are staffed by government (50%), community (2,2%), FBO (12,3%), NGO (1,9%) and private institutions (33,7%). The growth of health facilities has been driven by the constituency development fund, which supports the people's decisions to have health facilities constructed that will bring health services closer to them.

The Kenya 2010 new constitution will recognize two levels of government in health-related matters – at the National level and the County level. National government will be dealing with referral health facilities and policy formulation while County government will be supporting county health facilities, ambulance services, promotion of healthcare, licensing and control of health services.

4.6.2 Components of the national health information system

4.6.2.1 Overview

The Kenya health information system (HIS) initiative was established in 1972 when a committee including representatives from the Ministry of Health, WHO, Central Bureau of Statistics and the Attorney General Chambers was formed. The task of this committee was to design a HIS for Kenya. A pilot project was designed and tested in three districts. The pilot project was completed in 1976 and the suggestions and recommendations were adopted. In 1982, another committee of professionals was formed to investigate the accuracy and efficiency of all health data collection forms. The committee suggested a number of changes.

The Ministry has a fragmented data-based information system. At the Central level there are stand-alone information systems, which operate within the Ministry. This tends to support a vertical reporting function with little integration. At provincial and district levels information is equally fragmented and designed to provide information to centrally managed provincial and district health service units and hospitals. With this situation, essential information is largely unavailable for effective planning, monitoring and evaluation at all levels.

Key HIS statistical constituencies include: civil registration system whose vital events include registration of live births, deaths, marriages, divorces, adoptions, recognition, and legitimating; the Kenya National Bureau of Statistics (KNBS), the custodian of all government statistical information that maintains a database for all national surveys including national population and housing censuses and population-based health statistics derived from national surveys and AfriAfya (African Network for Health Management and Communication), a consortium of seven Kenya-based health development agencies.

In 1984, in response to the national policy on District focus for Rural Development, the Ministry of Health decentralized its reporting activities by establishing Health Information Systems offices in all districts where all health data from all health facilities would be processed. The Kenya National Health Sector Strategic Plan (1999 – 2004) articulated the ministry's strategy to strengthen its co-ordination function with the private sector and NGOs in healthcare delivery. Proper design and implementation of integrated health information systems was deemed critical.

Health information system strengthening efforts are embraced through standardization of some functions within the system. Some of the activities include harmonization and standardization of health sector indicators with a minimal set of health sector indicators defined which inform data capture registers and summary tools, defined with clear Standard Operating Procedures.

More effort has been put in place to adopt standards for electronic medical records which look into the interest of the clients and supply of the systems i.e. District Health Information Software (DHIS) and EHR system. A Community Health Information System has also been established with rationalization and establishment of reporting tools for community units.

The implementation of interoperability of existing systems within the health sector master health facility list has been developed which addresses the comprehensiveness of health facilities, assigning health facility unique identifiers (codes) which have been used in all organizations handling direct or indirect services to the health facilities. There is a good mechanism of regular updates of the health facilities as shown in the Kenya Health Facility List, Figure 7^[56] with the ultimate goal of a health information system (HIS) as Figure 8^[59] below depicts.

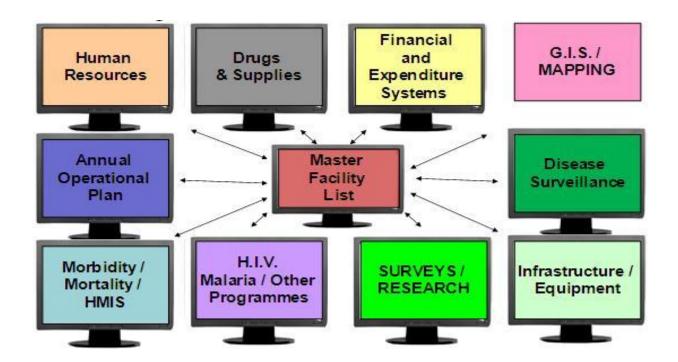


Figure 7 — Health facility master list in Kenya project^[56]

The existing HIS experienced some challenges in implementation of some of the operations e.g. inadequate human resources, limited skills in technology.

Although there are still some vertical reporting systems, the current plan is to integrate data and link all users of data. Most of the routine health services data from facilities are linked to surveillance data from the Kenya National Bureau of Statistics and Vital Registration of births and deaths. Human resources and financial systems are also linked to service workload. New models of care anticipate improved sharing of clinical information.

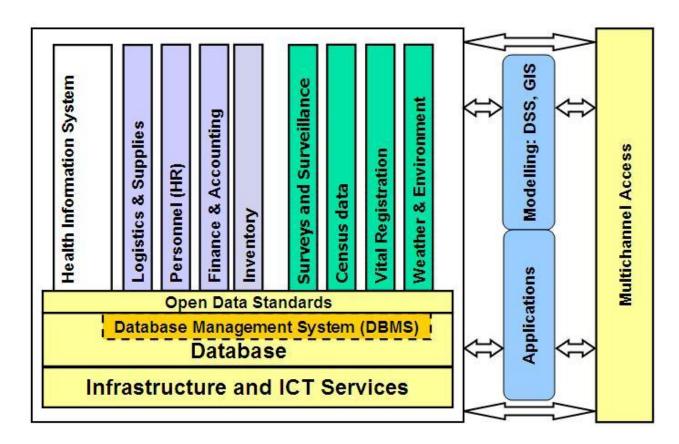


Figure 8 — Kenya components of the national health information system^[59]

4.6.2.2 Data sources

Population-based data in Kenya is collected through various sources which include censuses first conducted in 1948 and lastly in 2009 and repeated every ten years. Population-based surveys like the Demographic Health Survey are done every five years to determine the impact various interventions have achieved. Also, civil registration is collected on occurrence of events like births and deaths which occur in the community and health institutions. Surveys conducted to date include the Demographic Health Survey for 1989, 1993, 1998, 2003 and 2008/2009^{[57][58]}, the Malaria Indicator Survey for 2000 (http://www.nmcp.or.ke/section.asp?ID=23, AIDS Indicator Survey for 2003 and 2008, Household Health Expenditure Survey 2007 and Household Budget and Tracking Survey 2006.

Health services-based data are collected through routine disease records (surveillance) and Inpatient Morbidity and Mortality and Outpatient Morbidity cases. Other sources include administrative and service records (Immunization, TB, HIV/AIDS, and Administrative statistics) and health facility surveys/censuses like service workload and Kenya Provision Service Assessment (assesses basic services such as maternal and child healthcare, infection control, HIV/AIDS services). Some of the various reports on service- based data include the Annual Health Status Report 2002, 2003-2004, 2005-07; 2008, 2009, annual operational plan 1-5, NHSSP II midterm review report, Facts and Figures on health and health--related indicators 2006, 2008, 2010 and program specific reports i.e. EPI (Environmental Performance Indicators), HIV, TB, Epidemiological Bulletins and cancer registry.

In Kenya, various facility assessments have already been done which include Service Provision Assessments 1999 and 2004, Service Availability Mapping 2004, IMCI (Integrated Management of Childhood Illness), Health Facility Survey 2006 and client satisfaction surveys (MoH). Administrative data surveys carried out include Finances: Poverty Eradication Recovery (PER), National Health Account (NHA) (2001, 2006), Human resources for national data base, professional databases and training institutions records and road traffic accidents (KIPPRA study), infrastructure report on the national database of health facilities (public) and poverty maps (KNBS).

Health information systems also gather reports on mortality and causes of death from Vital registration systems and Demographic/AIDS Surveillance Systems (Nairobi, Kilifi, Kisumu) while others obtain reports from research studies done on overall level of health, and trends since 1994. There are also coverage reports generated on critical interventions, showing impacts on overall level of health especially on child health, maternal health, HIV, TB, malaria, emerging conditions, non-communicable diseases (NCDs), injuries, and nutrition data showing trends and distributions. Additional coverage reports with critical inputs are needed to provide trends and distribution on Human Resources for Health, Infrastructure, Commodities, and Financing.

Kenya reporting mechanisms for health data from health facilities use standard reporting tools per service using paper-based forms submitted to district levels where data is captured in electronic reporting to the next level, with clear timeline requirements. Data-sharing is done at various levels of the health system i.e. regional.

4.6.3 National eHealth policies

Based on the Health Policy Framework Paper (1994 - 2010), implementation plans (1996), Health Information System Needs Assessment Report (2003)^[59] and the current National Health Sector Strategic Plan II (NHSSPII) (2005 – 2010), Kenya is reversing the current trends and has also outlined those areas that require immediate attention - the provision of integrated data collection and reporting tools, improvement of data flow mechanisms, support for districts in supportive supervision, provision of clear policy guidelines on HIS and improved feedback mechanisms at all levels. Investing in the development of effective HISs would have multiple benefits and would enable decision-makers at all levels to:

- detect and control emerging and endemic health problems, monitor progress towards health goals and promote equity;
- empower individuals and communities with timely and understandable health-related information and drive improvements in quality of services;
- strengthen the evidence base for effective health policies, permit evaluation of scale- up efforts and enable innovation through research;
- improve governance, mobilize new resources and ensure accountability in their use;
- frequently monitor short-term programme outputs and support performance-based resource allocations;
- enhance reporting of health outcomes to monitor Millennium Development Goals (MDGs, the WHO anti-poverty goals);
- provide a foundation for sound informed decision-making.

Strengthening national, provincial and district HIS will also require a collaborative effort.

There is a health information system (HIS) policy which stipulates the design, sharing, reporting and ownership of health data.

The MoH teams are working on a draft eHealth strategy with ereadiness assessment, so as to create a formal eHealth strategy. Although not formally written, some concepts have been well established within the MoH, including avoiding vertical systems and pursuing interoperability and data integration.

Part of the defined policies includes the decentralization of data collection to districts, which has been pursued ever since 1984. A revision of the health sector indicators and minimal datasets was carried out in 2005 and in 2008, the introduction of FTP to all districts has managed to replace vertical programs. A second version of sector indicators was established from March to November 2010.

Since the establishment of the file transfer protocol (FTP), the monitoring and evaluation (M&E) program has been strengthened. There is good collaboration among partners, including eHealth development partners on supporting M&E within the health sector. M&E is done systematically. There are quarterly and annual sector reviews with written reports, the analysis of which ends up with a summit.

4.6.4 National eHealth architecture stage of development

From a healthcare perspective, a formal system architecture is still to be described. The country's major concern is to build a Health Information System (HIS) that gradually integrates all aspects of healthcare. Some of the major initiatives to be considered are:

- health & disease records (surveillance) that collect data on inpatient morbidity and mortality, as well as outpatient morbidity;
- administrative and service records, that collect and make available data on immunization, TB, HIV/AIDS and administrative statistics;
- reporting mechanisms that include paper-based as well as electronic means for the systematic collection and aggregation of data from facility to national level;
- databases of Human Resources that have been developed, linked to the Master facility and coded for
 interoperability; The human resource observatory team is working on national identifiers and datasharing. Data from districts are still paper-based, except for nursing, which has a system at the
 regional level and links to the national level. There is no linkage of human resources among private
 sector organizations and FBOs/NGOs but once a year human resources are factored by district in
 their plans as part of the district annual operational planning.
- Kenya Medical Supplies Agency (KEMSA) which is in charge of procuring and maintaining supply chains at all levels. Every quarter they distribute the logistics to regional depots and districts. District management distributes to health facilities on a monthly basis, based on consumption levels. There is no established system used in district to report on logistics but paper-based systems are tying to a pilot in Nairobi.
- data for lab services still poor due to lack of harmonized tools. The National Reference Lab generates reports and shares them with the HIS.
- Some private health facilities have an EMR system e.g. Moi Teaching and Referral Hospital which is not fully integrated with other systems or customized to meet their needs. However, the country is at the final stages of work on standards for the EHR and EMR. National data warehouse.

There is currently no national data warehouse as the strategies are still in development to establish one. There are standards for health summary data but are only used in written reports at this time.

The country is in the process of developing robust software to address the collection of individualized patient data. Currently, data is collected and analysed from primary source documents and patient files, which are grouped by age and sex.

4.6.5 Standards in use

Vocabularies for medical data are not in place at the moment, but are recognized as important and are part of the country's strategic plan.

As part of the concern with interoperability, assessment is currently being done on how existing HIS comply with standards for interoperability in order to help define strategic actions.

Admitting facilities in Kenya are using ICD-10 for coding diagnostics.

PD ISO/TR 14639-1:2012 **ISO/TR 14639-1:2012(E)**

As part of implementing electronic medical records there has been effort towards standardization of the facility naming and assigning of unique codes which will facilitate the undertaking of achieving interoperability in the health sector.

4.6.6 Standards Development Organizations (SDO) and Health Informatics Associations

The Kenya Association of Health Records and Information Officers was formed in the early 1990s and Kenya has been a "P" member of ISO/TC 215 since June 2009.

4.6.7 National reporting infrastructure for individual and/or summary data

Every 5th day of the month, health facilities send their activity reports to the district level using standard paper forms. At the district level, health workers fill the data into a standard spreadsheet which forms the District Summary. Once validated, this summary is submitted to the national data server by the 15th of each month, using the File Transfer Protocol (FTP) to upload the file. Once the file is uploaded, the data is linked to all levels in real time.

4.6.8 Households with Internet access

Current estimates state that 8% of houses in Kenya have Internet access. Not all towns are connected yet, but the e-government initiative has plans to make them become digital villages.

5 International Monitoring and Evaluation frameworks

5.1 Overview

This section identifies the current international experience on data collection at the point of care and data aggregation, considering surveillance, vital statistics, and health services and program monitoring. Since the focus of this part of ISO/TR 14639 is resource-poor countries, the emphasis is on primary care, socio-demographic issues, monitoring and public health. Standards currently used to define and transmit aggregate data and indicators are reviewed.

Monitoring and Evaluation (M&E) frameworks, national frameworks, and maturity models are considered to insure that the architecture model detailed in Part 2 is appropriate for a low-resource environment.

5.2 Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM)

To support the monitoring and evaluation of programs, GFATM and partners have developed a toolkit for these three diseases^[60]. The purpose of the toolkit is to provide in one place the "essentials" of agreed-upon best practices as well as references to key materials and M&E, and frequently asked questions and answers.

5.3 Joint United Nations Program on HIV/AIDS (UNAIDS)

UNAIDS is a joint venture of the United Nations, bringing together the efforts and resources of the UNAIDS Secretariat and ten UN system organizations in the AIDS response. The Secretariat headquarters is in Geneva, Switzerland — with staff on the ground in more than 80 countries. The Cosponsors include UN Refugee Agency (UNHCR), UN Children's Fund (UNICEF), UN World Food Programme (WFP), UN Development Programme (UNDP), UN Population Fund (UNFPA), UN Office on Drugs and Crime (UNODC), International Labour Organization (ILO), UN Educational, Scientific and Cultural Organization (UNESCO), WHO and the World Bank.

It aims to achieve global commitments to universal access to comprehensive interventions for HIV prevention, treatment, care and support. It has been a leader in M&E activities, including indicator management and development of country monitoring systems. The Country Response Information System (CRIS) has been implemented in 60 countries with half of those reporting indicator data from the district level for programme management and international reporting^[62].

5.4 Pan American Health Organization (PAHO) Framework

The Regional Core Health Data and Country Profile is a PAHO Initiative that was launched in 1995 to monitor the attainment of health goals and its compliance with the mandates of PAHO Member States. This is a collective effort of Member States and the PAHO through its country offices, technical areas, programs and projects, coordinated by the Health Information and Analysis Project^[62].

5.5 Brazilian Health Indicators Framework

There are two frameworks of health indicators in Brazil. The expectation is to integrate them into a single collection:

- Brazilian Basic Health Indicators (IDB) is a matrix of indicators meant for analysis of the health condition of the population and its affecting factors. The indicators are classified as: demographic indicators; socioeconomic indicators; mortality indicators; morbidity indicators and risk factors; resource indicators; and coverage indicators. The full list of selected indicators for the IDB is found in the Indicator Matrix, which provides its denomination, concept, calculation method, categories of analysis and sources of data^[63].
- Primary Care Pact is a matrix of indicators focused on primary care including the monitoring and
 evaluation of the Brazilian Family Health Program. These indicators are categorized as: elderly
 population assessment, uterus and cervix cancer control, maternal and child health, disease centred
 indicators (dengue, malaria, tuberculosis, hepatitis, influenza and HIV), health promotion, family and
 community health program assessment, violence, mental health, disabilities program assessment,
 workers health, immunization, disease notification, surveillance, water and sanitation, health
 education and health management according to SUS regulations.

5.6 Canadian Health Indicators Framework

The Canadian government has invested heavily in measuring and reporting on the performance of its health system at various levels. In doing so and in line with its longstanding 'health determinants' approach to national health policy, Canada takes a broad *health performance* approach to quantifying health and healthcare progress. This has entailed the development and use of a multi-dimensional 'health indicators framework'. This Canadian Health Indicators Framework (CHIF) has four main tiers:

- health status (health conditions, human functions, well-being, deaths);
- non-medical determinants of health (health behaviours, living & working conditions, personal resources, environment factors);
- health system performance (acceptability, accessibility, appropriateness, competence, continuity, effectiveness, efficiency, safety)
- community and health system characteristics (community, health system, resources).

The Canadian Institute for Health Information (CIHI) Health Indicators Annex is a client-services website that provides definitions for all indicators and lists them according to their placement in the Health Indicators Framework. It is also home to other useful documentation, including technical notes, model specifications, information about the standardization methodology, sources of population estimates, health region assignment and sample annotated SAS (Statistical Analysis Software) programs. All of this information helps jurisdictions calculate and/or interpret preliminary health indicators data prior to its public release^[64].

5.7 United States Health Indicators Frameworks

Several frameworks are currently in use, addressing the needs of different health sectors.

- Federal Health IT Strategic Plan^[72]
- The United States has e-health initiatives, infrastructure, policies and processes currently and new efforts for the future at the national, regional, state and local community levels. This description

PD ISO/TR 14639-1:2012 **ISO/TR 14639-1:2012(E)**

focuses on the national level which is to a large extent related to US federal programs. The description includes key facts about variation at the state and local levels, particularly in cases where such experience may inform e-health at the national level in the future. State of the USA (SUSA)^[65]

- The Institute of Medicine established the Committee on the State of the USA Health Indicators to provide guidance to the State of the USA, Inc. (SUSA) on 20 potential indicators that could be used to track progress in the areas of health and healthcare. SUSA is a non-profit corporation established in 2007 to provide Americans with high-quality information about changing societal, economic, and environmental conditions. The indicators selected should be those that best reflect: (i) the overall health of the nation and the factors that are important in determining the current and future health of the nation and (ii) the effectiveness and efficiency of the U.S. healthcare and public health systems. http://www.data.gov/raw/2159
- Health Data Interactive (HDI)^[66]

Health Data Interactive (HDI) presents a broad range of important public health indicators through an interactive web-based application that provides access to pre-tabulated national and state data for the US. The primary objective is to provide national estimates of public health measures cross-tabulated by a common set of variables. http://www.data.gov/tools/2196

Community Health Status Indicators (CHSI)^[67]

Community Health Status Indicators (CHSI) to combat obesity, heart disease, and cancer are major components of the Community Health Data Initiative. This dataset provides key health indicators for local communities and encourages dialogue about actions that can be taken to improve community health (e.g., obesity, heart disease, cancer). http://www.data.gov/raw/2159

Health.Data.Gov^[68]

A public resource designed to bring together high-value datasets, tools, and applications using data about health and healthcare from agencies across the Federal government with the goal of improving health for all Americans. http://www.data.gov/communities/health

• Health Indicators Warehouse (HIW)[69]

HIW indicators are categorized by topic, geography, and initiative. Each indicator in the HIW is associated with one or more topic area, such as disease, condition, age group or sociodemographic characteristics. http://www.healthindicators.gov/

6 Key findings

The key findings from this sample of national eHealth initiatives are as follows:

Monitoring and Evaluation (M&E)

All countries have Monitoring & Evaluation (M & E) systems in place, from the district to the national level; in Kenya it is based on aggregate data while in the others it is a mix of patient-centred and aggregate data. In addition to using summary data from multiple sectors in M & E, a key difference in how LIC and HIC architectures evolve may be in their use of summary data as a starting point for reporting patient-related data.

 Australia – Many initiatives have a monitoring and evaluation component, supporting a longstanding clinical safety and quality movement seeking to continuously improve the delivery of healthcare in Australia. In addition, many national and state/territory programs are aimed at monitoring, evaluation and improvement of healthcare delivery and healthcare outcomes, in particular:

- Brazil All raw health data are classified and made publicly available. An impressive collection that stretches as far back as the 1970s can be found there. However, in order to produce information derived from "siloed", health databases and expand the analysis to include social and geographical data, a great deal of analysis and consolidation is required.
- Canada Health system management information is collected primarily by a national organization, the Canadian Institute for Health Information (CIHI). Certain health indicators are reported on a mandatory basis (hospital discharge abstracts, for example); others are reported on a voluntary basis. Information in the data warehouse is analysed by CIHI and used to inform Canadian public policy regarding healthcare.
- o India The respective national programs for malaria, TB, HIV and the other diseases noted above have established policies for monitoring and evaluation.
- Kenya Reporting mechanisms for health data from health facilities use standard reporting tools per service using paper-based forms submitted to district levels where data is captured in electronic reporting to the next level, with clear timeline requirements. Since the establishment of the file transfer protocol (FTP), the monitoring and evaluation (M&E) program has been strengthened. Fragmented systems make data use challenging.
- Patient-centric approach
- All countries identified the importance of moving from siloed provider-centric app roaches to a patientcentric approach that will ultimately allow for the construction of a shared electronic health record Importance of standards

All countries recognized the importance of standards and their adoption to guarantee interoperability between health information systems.

- Australia Standards Australia Committee IT-014 Health Informatics (with around 10 active sub-groups) is the principal SDO responsible for managing the development of publicly accepted national standards for eHealth. It is the Australian mirror committee for ISO/TC 215 and, with the support of HL7 Australia, publishes, publishes HL7 implementation guides for use in Australia.
- o Brazil Standards in use for the public sector have been mostly defined by the MoH and include Brazilian codes for Procedures, Unique Patient, Healthcare Providers, and Health Workers Identification, including Family Health Teams. There are standards for describing households and communities, an essential object in primary care. There are also national standards for: an essential clinical dataset and for billing. Many standards development organizations are active in Brazil.
- Canada Canada is an active participant in HL7, IHTSDO, IHE and ISO/TC215 including acting in leadership positions in these organizations. Canada Health Infoway, the developer of the national eHealth architecture Blueprint, has created the Standards Collaborative at the national level to act as the umbrella organization under which the various SDOs engage, coordinate and collaborate to identify, prioritize, adopt/adapt/develop if needed, and approve health information messaging, vocabulary and related technical standards for implementation in provincial EHR solutions.
- India A number of standards developing organizations are represented in India. However, there is no particular health informatics standard adopted nationwide. The unique Identification Authority of India (UIDAI)^[47] has been set up to give a unique ID to all people present in the country.

 Kenya - There is a high level of interest in health informatics standards and eHealth architecture in Kenya with ongoing efforts in a number of areas. Kenya has been a "P" member of ISO/TC 215 since June 2009.

Common components in eHealth architecture

A common set of foundational components emerged in the eHealth architecture of all countries, including national registries of health facilities and healthcare professionals, common terminologies, and standards for security and privacy and interoperability.

- O Australia There are nationally agreed and widely adopted specifications for classification of clinical information and statistical reporting of healthcare status and activities. These are applied at the level of individual healthcare facilities, state/territory and on an Australia-wide basis and are used to support statistical reporting, performance evaluation, health service planning and activity based funding predominantly for institutional care. Under the proposed National Health Reform Agreement, most public hospital reimbursement is planned to be based on activity.
- o Brazil The MoH is the coordinator of HIS systems, through Datasus, the Health Informatics Department of SUS. Datasus coordinates the information systems and is the guardian of the national databases, maintaining about 300 health domain tables and vocabularies. These are used by information systems throughout the country and include vocabularies such as medical procedures, gender, cities, admission types and discharge types.
- Canada Currently there is a wide range in the adoption of automation of patient health information in the various practice settings in Canada. The highest level of adoption and use of electronic records is in the hospital sector; nearly all larger community and tertiary care centres now have electronic records systems that span the various clinical services and programs. Smaller hospitals have a lower level of automation, but nonetheless have generally automated many core functions. In the ambulatory clinic environment, electronic record usage is still limited.
- o India The National Knowledge Commission (NKC), a high level advisory body to the Prime Minister of India, with the objective of transforming India into a knowledge society, had also set up a Working Group for the development of an Indian Health Information Network i-HIND^[43]. This working group has proposed to design, develop, and integrate an end-to-end electronic healthcare informatics network framework in India to improve public health, health research, and the delivery of healthcare. The other related WGs have been for the India Health Portal and Health Literacy and for Emergency Medical Services. A Standards Committee is being set up to recommend suitable standards for healthcare interoperability. Further, the NKC had proposed the setting up of the National Health Information Authority NHIA that will oversee all these activities.
- Kenya Although there are still some vertical reporting systems, the current plan is to integrate data and link all users of data. Most of the routine health services data from facilities are linked to surveillance data from the Kenya National Bureau of Statistics and Vital Registration of births and deaths. Human resources and financial systems are also linked to service workload.

Unique identifiers

Unique identifiers for persons was also a common topic across initiatives, along with associated privacy concerns

Australia - Identifier services (for individuals, providers, and organizations) have been developed for NEHTA and the Australian Government by contractors working through Medicare Australia and were put into initial production in 2010, with some improvements being considered for incorporation as a result of initial stakeholder feedback. Use of healthcare identifiers is protected by amendments to national privacy legislation.

- Brazil In 2003, the MoH unified the registries of healthcare (HC) providers and workers, creating a national registry with unique identifiers. The use of this registry is mandatory for all HC providers in the country no matter whether public or private. Policy exist for identifiers for patients, healthcare organizations and healthcare providers.
- Canada Through Canada Health Infoway, registries to hold unique identifiers with demographic information for clients (citizens), providers and locations of care are being deployed. For unique identifiers, many provinces are using individuals` health insurance ID numbers as unique identifiers or as proxies for an internal Globally Unique Identifier (GUID) maintained within the EHRS. Health professional colleges (physician, nurse, etc.) have unique identifiers (IDs) for their members; these are typically employed by the provincial EHRS as proxies for a GUID or as an ID.
- India There is no particular health informatics standard adopted nationwide. The unique Identification Authority of India (UIDAI)^[47] has been set up to give a unique ID to all people present in the country.
- Kenya The implementation of interoperability of existing systems within the health sector master health facility list has been developed which addresses the comprehensiveness of health facilities, assigning health facility unique identifiers (codes) which have been used in all organizations handling direct or indirect services to the health facilities. Databases of Human Resources have been developed, linked to the Master facility, and coded for interoperability. The human resource observatory team is working on national identifiers and data-sharing.

National eHealth architecture

The need for a national eHealth architecture was also present in all reports.

- Australia has several proposals for adopting a national system of electronic health records that are currently being reviewed.
- Brazil has a national project for an eHealth architecture but its implementation is scattered around the country.
- Canada has already defined a national blueprint for its EHR Solution (EHRS) architecture and has established national standards for interoperability.
- o India is developing a national eHealth architecture project.
- Kenya has a national project to create an integrated eHealth architecture.

7 Need for an eHealth Architecture Maturity Model (eHAMM)

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. The variety in country HIS described in this part of ISO/TR 14639 suggests the need for an eHealth Architecture Maturity Model (eHAMM) and methodology for describing country capacity to provide direction in health system strengthening.

An eHealth architecture model has been developed upon which the maturity model described in ISO/TR 14639-2 is based. This model can be used for system analysis and development of strategy. By defining indicators against this framework, priorities and gaps can be identified. The countries described would show different profiles, which would be consistent with their level of maturity and strategic direction.

While beginning with a high-level approach to the development of a maturity model, it is expected that this effort will stimulate further development of a methodology for describing HIS and maturity. The impact of a shifting IT environment with respect to public-private compensation, mHealth, socioeconomic requirements, and other issues may impact this model.

Drawing from experience in other domains, development of indicators to augment qualitative descriptions and use of Monitoring and Evaluation (M&E) frameworks may be useful for more rigorous analyses of HIS evolution. While this part of ISO/TR 14639 introduces these issues into the discussion of eHealth architecture, ISO/TR 14639-2 provides the space for that work to be elaborated.

Figure 9^[70] below shows this model of eHealth architecture and the relationship of the components that impact healthcare delivery. In ISO/TR 14639-2, 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.

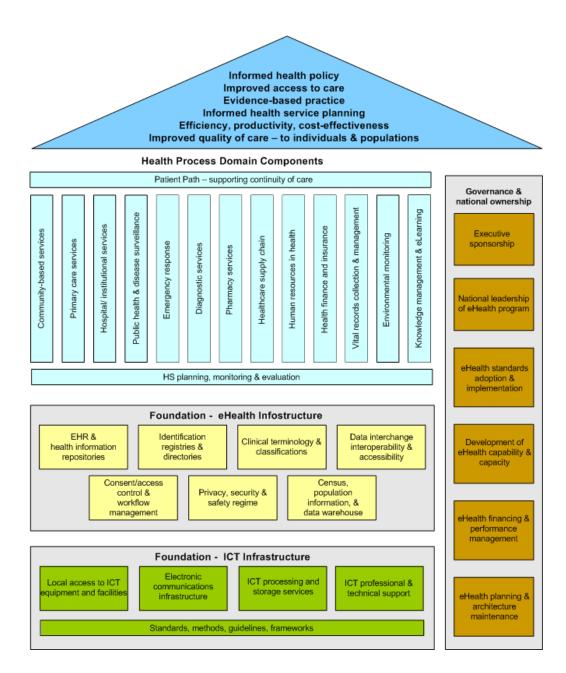


Figure 9 — Model of an eHealth architecture^[70]

The methodology introduced here will be useful at the international level to assist with strategy development, resource mobilization, and alignment with initiatives like the Millennium Development Goals (MDGs), the eight goals that all 191 UN member states have agreed to try to achieve by the year 2015. 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^[71].

The following hypothetical graphic, Figure 10^[70] 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 profiles might not be as suitably aligned.

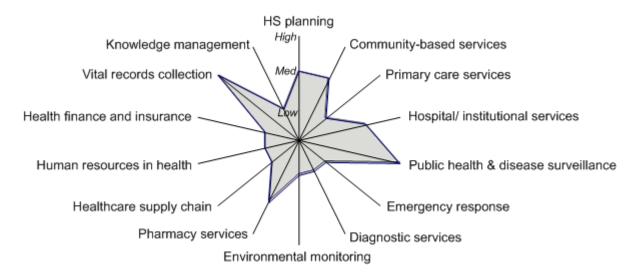


Figure 10 — Health process domain components in low income countries^[70]

Describing the state of a country's HIS does not address capacity-building. There is a need for wider access to international standards for the development of eHealth architectures. The maturity model concepts introduced here will be incorporated into an ISO and WHO-sponsored standards portal. www.hiwiki.org[70] which is under development. By describing the model and associated standards in a user-friendly manner, it will assist countries in the use of international standards. Navigating through the eHealth architecture model and other visual aids will present both international standards and other guidelines documents to aid and support development of national eHealth architectures.

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. The framework introduced here is a tool to frame requirements that change over time while aligning them with an eHealth architecture that supports development of an increasingly sophisticated HIS. 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 health care.

The generous support of the WHO and the Rockefeller Foundation in providing financial subsidies and the use of their facilities to enable experts from around the world to progress this work is gratefully acknowledged.

Bibliography

- [1] WHO Health Metrics Network Framework and Standards for Country Information Systems. Available at: www.who.int/entity/healthmetrics/documents/hmn framework200803.pdf
- [2] WHO Health Metrics Network Toolbox. Available at: http://www.who.int/healthmetrics/tools/en/
- [3] Making the eHealth Connection. Available from: http://www.ehealth-connection.org/
- [4] International Telecommunication Union. *Measuring the information society.* ITU, Geneva; v1.01; 2010. Available from: http://www.itu.int/ITU-D/ict/publications/idi/2010/index.html
- [5] Commonwealth of Australia. *A national health and hospitals network for Australia's future*. March 2010. Available from: http://www.yourhealth.gov.au/internet/yourhealth/publishing.nsf/Content/nhhn-report-toc/
- [6] Council of Australian Governments (COAG). Heads of Agreement National Health Reform. Attachment A to Communiqué of COAG meeting on 13 February 2011. Available from: http://www.coag.gov.au/coag_meeting_outcomes/2011-02-13/docs/communique_attachment_20110213.pdf
- [7] Australian Institute of Health and Welfare (AIHW). Australia's Health 2010. Available from: http://www.aihw.gov.au/publication-detail/?id=6442468376
- [8] Commonwealth of Australia. *A national health and hospitals network for Australia's future: Delivering the reforms.* July 2010 ("The Brown Book"). Available from: http://www.yourhealth.gov.au/internet/yourhealth/publishing.nsf/Content/DeliveringTheReforms/
- [9] Health*Connect* Project Office, Health*Connect* Project Overview, September 2002. Available from: http://www.health.gov.au/internet/hconnect/publishing.nsf/Content/BA6DCE09CA000739CA25712 8007B7EB1/\$File/projovw.pdf
- [10] Health*Connect* Project Office, What is Health*Connect*?, November 2003. Available from: http://www.health.gov.au/internet/hconnect/publishing.nsf/Content/8B76541C5CD5ADC1CA257128007B7E92/\$File/hcu.pdf
- [11] Communio (for Commonwealth of Australia, Department of Health and Ageing) HealthConnect Evaluation, 24 August 2009, Available from: http://www.health.gov.au/internet/main/publishing.nsf/Content/B466CED6B6B1D799CA2577F30 017668A/\$File/HealthConnect.pdf
- [12] National E-Health Transition Authority, NEHTA Blueprint, Version 1.1, Draft for Consultation, August 2010. Available at: http://www.nehta.gov.au/about-us/nehta-blueprint.
- [13] National E-Health Transition Authority (NEHTA) Interoperability Framework Version 2.0, August 2007, Available at: http://www.nehta.gov.au/component/docman/doc_download/391-interoperability-framework-v20/
- [14] The Open Group. The Open Group Architecture Framework (TOGAF), Version 9. 2009 Available at: http://www.opengroup.org/togaf/
- [15] Brazil. Constitution of the Federative Republic of Brazil. (In Portuguese). Brasillia, Brazil, 1988.
- [16] Brasil. Ministério da Saúde. Portaria nº 234, de 07 de fevereiro de 1992. Edição da Norma Operacional Básica do Sistema Único de Saúde para 1992 (NOB-SUS/92). Brasília, 1992.
- [17] Santos F P, Merhyll E E. Public regulation of the health care system in Brazil A review. Interface vol. 2 no.se Botucatu 2006. Available from: http://socialsciences.scielo.org/pdf/s icse/v2nse/scs a09.pdf

- [18] Macinko J, Guanais F C, Marinho de Souza M F. Evaluation of the impact of the Family Health Program on infant mortality in Brazil, 1990–2002. J Epidemiol Community Health 2006; 60:13–19. doi: 10.1136/jech.2005.038323. Available from: http://www.ncbi.nlm.nih.gov/pubmed/16361449
- [19] Ugá M A D, Lima S M L, Portela M C, Vasconcellos M M, Barbosa P R, Gerschman S. Uma análise das operadoras de planos próprios de saúde dos hospitais filantrópicos no Brasil. Cad. Saúde Pública 2008 Jan; 24(1): 157-168. Available from: http://www.scielo.br/scielo.php?script=sci arttext&pid=S0102-311X2008000100016&Ing=en. doi: 10.1590/S0102-311X2008000100016.
- [20] Ministério da Saúde. GM/MS. PORTARIA Nº 402, DE 24 DE FEVEREIRO DE 2010. Available from: http://www.telessaudebrasil.org.br/php/level.php?lang=pt&component=42&item=16
- [21] Coury W M, L.Filho J.Simões N.Sasso G.Barbosa S.Behring L.Aguiar G.de-Campo J. *Implementing RUTE's Usability the Brazilian Telemedicine University Network Online*, Brazilian Journal of Nursing. 2010 December 15; 9(3). Available from: http://www.objnursing.uff.br/index.php/nursing/article/view/3176
- [22] Brasil. Ministério da Saúde. A experiência brasileira em sistemas de informação em saúde / Ministério da Saúde, Organização Pan-Americana da Saúde, Fundação Oswaldo Cruz. Brasília : Editora do Ministério da Saúde, 2009. Available from: http://dtr2001.saude.gov.br/editora/produtos/livros/zip/experiencia brasileira sistemas saude vo lume1.zip
- [23] Leão BF, Costa CG, Facchini LA, Bandarra EB, Gonçalves SF, Bretas Jr N, Ferla A. The Brazilian health informatics and information policy: building the consensus. Stud Health Technol Inform. 2004; 107(Pt 2):1207-10. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15361004
- [24] PAHO. Brazil: development of an Integrated Information Network for health. Epidemiological Bulletin. Dec 1997: [18:4]. Available from: http://www.paho.org/english/sha/epibul 95-98/be974bra.htm
- [25] REDE Interagencial de Informação para a Saúde Indicadores básicos para a saúde no Brasil: conceitos e aplicações / Rede Interagencial de Informação para a Saúde Ripsa. 2. ed. Brasília: Organização Pan-Americana da Saúde, 2008. Available from: http://tabnet.datasus.gov.br/tabdata/livroidb/2ed/apresent.pdf
- [26] ANS. TISS Standards Exchange of Supplementary Healthcare Information Agência Nacional de Saúde Suplementar (ANS) Rio de Janeiro Brazil Version 2.01 2007. Available from: http://www.ans.gov.br/portal/site/ hotsite tiss/f materia padrao tiss.htm
- [27] CETIC. ICT Survey 2009. ICT Households and ICT Enterprises Survey 2009. Available from: http://www.cetic.br/tic/2009/index.htm
- [28] Canada Health Act. (RSC, 1984) c. 6, s. 3. http://laws-lois.justice.gc.ca/eng/acts/C-6/
- [29 COACH: Canada's Health Informatics Association. *CPHIMS-CA Canadian Supplemental Examination Review Guide* May 2010. Available from: http://coachorg.com/publications/cphims-ca-review-guides/ca-review-guide.htm
- [30] Canadian Institute for Health Information. Wait Times Tables A Comparison by Province, 2010 (Toronto: CIHI, 2010). Available at: http://secure.cihi.ca/cihiweb/products/wait_times_tables_2010_e.pdf.
- [31] Accreditation Canada. 2009 Canadian Health Accreditation Report: A Focus on Patient Safety Using Qmentum to Enhance Quality and Strengthen Patient Safety. Ottawa: Accreditation Canada, 2009. Available at: http://www.accreditation.ca/uploadedFiles/CHAR-2009-EN.pdf

PD ISO/TR 14639-1:2012 **ISO/TR 14639-1:2012(E)**

[32] The Commonwealth Fund: A Survey of Primary Care Physicians in 11 Countries, 2009: Perspectives on Care, Costs and Experiences. Available

from: http://www.commonwealthfund.org/Content/Publications/In-the-Literature/2009/Nov/A-Survey-of-Primary-Care-Physicians.aspx

- [33] Branham Group. eHealth in Canada Study 2006 edition. Available from: http://www.branhamgroup.com/_webapp_1795059/200601121_-
 http://www.branhamgroup.com/_webapp_1795059/200601121_-
 http://www.branhamgroup.com/_webapp_1795059/200601121_-
 http://www.branhamgroup.com/_webapp_1795059/200601121_-
 http://www.branhamgroup.com/_webapp_1795059/200601121_-
 http://www.branhamgroup.com/
 http://
- [34] WHO Atlas: *ehealth Country Profiles*. Available at: http://www.who.int/goe/publications/goe_atlas_2010.pdf
- [35] Canada Health Infoway *EHRS Blueprint v.* 2. Available at: https://www.infoway-inforoute.ca/lang-en/component/content/article/115-knowledgeway/657-ehrs-blueprint-v2
- [36] Canada Health Infoway Annual Reports. Available at: https://www.infoway-inforoute.ca/lang-en/annual-reports-and-business-plans
- [37] Canada Health Infoway Annual Report 2008/2009, *Building a Healthy Legacy Together*. Available at: https://www2.infoway-inforoute.ca/Documents/ar/Annual Report 2008-2009 en.pdf
- [38] Internet World Stats. Available at: http://www.internetworldstats.com/am/ca.htm
- [39] National Health Policy (India) 2002. Available from: http://www.mohfw.nic.in/np2002.htm
- [40] Shiv Lal, G.S. Sonal, P.K. Phukan, *Status of Malaria in India*. Journal of Indian Academy of Clinical Medicine, 2000 Mar; 5(1): 19-23
- [41] WHO Media Center, Joint News Release American Red Cross/CDC/UN Foundation/UNICEF/WHO. *Global measles deaths drop by 78%, but resurgence likely.* 3 December 2009.
- [42] WHO Report on Infectious Diseases. Removing Obstacles to Healthy Development, Chapter 16, 1999.
- [43] NKC Consultations Health Information Network, India. Available from: http://www.knowledgecommission.gov.in/consultations/wg.health.asp
- [44] Development of an Atlas of Cancer in India First All India Report. Available from: http://www.canceratlasindia.org/Discussion 1.htm
- [45] Central Bureau of Health Intelligence (India) http://cbhidghs.nic.in/chap10(2000-01).asp
- [46] Revised National TB Control Programme (RNTCP) (India). Available from: http://www.tbcindia.org/rntcp.asp
- [47] UID Cards India. Available from: http://www.uidaicards.com/
- [48] IAMI Indian Association for Medical Informatics http://www.iami.org.in/
- [49] Telemedicine Society of India http://www.tsi.org.in/
- [50] MCSI -Medical Computer Society of India http://www.mcsiindia.com/aboutus.html
- [51] HL7 India http://www.hl7india.org/
- [52] Bureau of Indian Standards http://www.bis.org.in/
- [53] Internet Access in India. Available from: http://www.marketresearch.com/product/display.asp?productid=2754213

- [54] India Internet Usage and Telecommunications Reports. Available from: http://www.internetworldstats.com/asia/in.htm
- [55] National Council for Law Reporting. The Pharmacy and Poisons Act, Cap 244. Revised Edition 2009 (1989). Published by the National Council for Law Reporting with the Authority of the Attorney General. Available at:
 http://www.kenyalaw.org/Downloads/Acts/The%20Pharmacy%20and%20Poisons%20Act%20(Cap.%20244).pdf
- [56] Kenya Master Health Facility List. Available at: http://www.ehealth.or.ke/facilities/
- [57] Central Bureau of Statistics (CBS) [Kenya], Ministry of Health (MOH) [Kenya] and ORC Macro. 2004. Kenya Demographic and Health Survey 2003: Key Findings. Calverton, Maryland, USA: CBS, MOH and ORC Macro. Available at: http://www.measuredhs.com/pubs/pdf/SR104/SR104KE03.pdf
- [58] Kenya National Bureau of Statistics (KNBS) and ICF Macro. 2010. Kenya Demographic and Health Survey 2008-09. Calverton, Maryland: KNBS and ICF Macro. Available at: http://www.measuredhs.com/pubs/pdf/FR229/FR229.pdf
- [59] Luoma, Marc, Julie Doherty, Stephen Muchiri, Tiberius Barasa, Kate Hofler, Lisa Maniscalco, Charles Ouma, Rosalind Kirika and Josephine Maundu. August 2010. Kenya Health System Assessment 2010. Bethesda, MD: Health Systems 20/20 project, Abt Associates Inc. Available at: http://www.healthsystems2020.org/files/2760_file_Kenya_HSA_Report_Final.pdf
- [60] The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). *GFATM Monitoring and Evaluation* (*M & E*) *Toolkit*. Available from: http://www.theglobalfund.org/en/me/guidelines tools/?lang=en#toolkit
- [61] UNAIDS UNGASS Monitoring and evaluation guidance and tools. Available from: http://www.unaids.org/en/dataanalysis/tools/monitoringandevaluationguidanceandtools/
- [62] Pan-American Health Organization (PAHO). Basic Indicators. Available from: http://www.paho.org/english/dd/ais/coredata.htm
- [63] RIPSA Interagency Network of Information for Health. *Basic Health Indicators in Brazil 2008 2nd edition*: Book: Indicators for Health in Brazil: Available from: http://www.ripsa.org.br/php/level.php?lang=en&component=68&item=20
- [64] Canadian Institute for Health Information (CIHI). CIHI External Portal. Available at: http://www.cihi.ca/CIHI-ext-portal/internet/EN/Home/home/cihi000001

http://www.cihi.ca/CIHI-ext-portal/internet/EN/SubTheme/health+system+performance/indicators/cihi010653

- [65] State of the USA (SUSA) http://www.data.gov/raw/2159
- [66] Health Data Interactive (HDI) http://www.data.gov/tools/2196
- [67] Community Health Status Indicators (CHSI) Available at: http://www.data.gov/raw/2159
- [68] Health Data Gov http://www.data.gov/communities/health
- [69] Health Indicators Warehouse (HIW) http://www.healthindicators.gov/
- [70] ISO Health Iinformatics wiki. Available at: www.hiwiki.org
- [71] Millennium Development Goals. Available at: http://www.who.int/topics/millennium_development_goals/en/

[72] Federal Health IT Strategic Plan. Available at: http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=3581&PageID=23952

Relevant international and other SDO standards:

- [72] ISO 1087-1:2000, Terminology work -- Vocabulary -- Part 1: Theory and application
- [73] ISO/IEC 2382-8:1998, Information technology -- Vocabulary -- Part 8: Security
- [74] ISO/IEC 6523-1:199, Information technology -- Structure for the identification of organizations and organization parts -- Part 1: Identification of organization identification schemes
- [75] ISO/IEC 7816-4:2005/Amd 1:2008, Record activation and deactivation
- [76] ISO/IEC 10036:1996, Information technology -- Font information interchange -- Procedures for registration of font-related identifiers
- [77] ISO 13606-1:2008, Health informatics -- Electronic health record communication -- Part 1: Reference model
- [78] ISO/TS 16058:2004, Health informatics -- Interoperability of telelearning systems
- [79] ISO/TR 18307:2001, Health informatics -- Interoperability and compatibility in messaging and communication standards -- Key characteristics
- [80] ISO 18308:2011, Health informatics -- Requirements for an electronic health record architecture
- [81] ISO/TR 20514:2005, Health informatics Electronic health record Definition, scope and context
- [82] ISO/TR 21089:2004, Health informatics -- Trusted end-to-end information flows
- [83] ISO/TR 22221:2006, Health informatics Good principles and practices for a clinical data warehouse
- [84] ISO/TS 22600-1:2006, Health informatics -- Privilege management and access control -- Part 1: Overview and policy management
- [85] EN 13940-1:2007, Health informatics. System of concepts to support continuity of care. Basic concepts

Sources of definitions not listed elsewhere:

- [86] Blobel B. Application of the component paradigm for analysis and design of advanced health system architectures. International Journal of Medical Informatics. 2000; 60(3):281-301
- [87] Canadian Electronic Drug Messaging (CeRx) Standards 1-2010/03/29. Available from: http://www.skmtglossary.org/
- [88] CDC OSELS Public Health Surveillance Concept Plan for the Implementation of the National Biosurveillance Strategy for Human Health. Available at: http://www.cdc.gov/osels/pdf/Concept Plan V1+5+final+for+print+KMD.PDF
- [89] European 2011 eHealth Strategies Final Report, January 2011 (eHStrategies) About the Study Available at: http://www.ehealth-strategies.eu/
- [90] Canada Health Infoway EHRS Blueprint v1 2003. Available at: https://www.infoway-inforoute.ca/working-with-ehr/knowledgeway/knowledge-center/658
- [91] Medical Conditions Dictionary. http://medconditions.net/teleconsultation.html, 2010
- [92] Merriam-Webster Dictionary http://www.merriam-webster.com/dictionary/

- [93] Starfield B. Primary care: concept, evaluation and policy. New York: Oxford University Press, 1992.
- The Global Fund. Definition of monitoring and evaluation. Available [94] at: http://www.theglobalfund.org/documents/me/ME Concepts.pdf
- [95] US National Center for Health Statistics http://www.cdc.gov/nchs/
- WHO | Definition of Health. 1948. Available at: http://www.who.int/about/definition/en/print.html
- [97] WHO | Definition of eHealth. Available at: http://e-healthexpert.org/defehealth
- WHO | Education and training. Available from: http://www.who.int/hrh/education/en/ [98]
- WHO | Health workforce data and statistics. Available from: [99] http://www.who.int/workforcealliance/knowledge/data/en/index.html
- [100] WHO | International Health Regulations (IHR). Available from: http://www.who.int/ihr/en/
- [101] WHO | Monitoring and Evaluation (M&E). Available from: http://www.who.int/hiv/strategic/me/en/
- [102] World Bank Country Classifications. Available from: http://data.worldbank.org/about/countryclassifications

Miscellaneous

- [103] ISO/TR 14639-2, Health informatics Capacity-based eHealth architecture roadmap Part 2: Architectural components and maturity model¹
- [104] EN 13940-1, Health Informatics: System of Concepts to Support Continuity of Care Part 1: Basic Concepts
- [105] World Health Report, January 01, 2006

¹ Under preparation.



ICS 35.240.80

Price based on 57 pages



British Standards Institution (BSI)

BSI is the independent national body responsible for preparing British Standards and other standards-related publications, information and services. It presents the UK view on standards in Europe and at the international level.

BSI is incorporated by Royal Charter. British Standards and other standardisation products are published by BSI Standards Limited.

Revisions

British Standards and PASs are periodically updated by amendment or revision. Users of British Standards and PASs should make sure that they possess the latest amendments or editions.

It is the constant aim of BSI to improve the quality of our products and services. We would be grateful if anyone finding an inaccuracy or ambiguity while using British Standards would inform the Secretary of the technical committee responsible, the identity of which can be found on the inside front cover. Similary for PASs, please notify BSI Customer Services.

Tel: +44 (0)20 8996 9001 Fax: +44 (0)20 8996 7001

BSI offers BSI Subscribing Members an individual updating service called PLUS which ensures that subscribers automatically receive the latest editions of British Standards and PASs.

Tel: +44 (0)20 8996 7669 Fax: +44 (0)20 8996 7001 Email: plus@bsigroup.com

Buying standards

You may buy PDF and hard copy versions of standards directly using a credit card from the BSI Shop on the website **www.bsigroup.com/shop.** In addition all orders for BSI, international and foreign standards publications can be addressed to BSI Customer Services.

Tel: +44 (0)20 8996 9001 Fax: +44 (0)20 8996 7001 Email: orders@bsigroup.com

In response to orders for international standards, BSI will supply the British Standard implementation of the relevant international standard, unless otherwise requested.

Information on standards

BSI provides a wide range of information on national, European and international standards through its Knowledge Centre.

Tel: +44 (0)20 8996 7004 Fax: +44 (0)20 8996 7005 Email: knowledgecentre@bsigroup.com

BSI Subscribing Members are kept up to date with standards developments and receive substantial discounts on the purchase price of standards. For details of these and other benefits contact Membership Administration.

Tel: +44 (0)20 8996 7002 Fax: +44 (0)20 8996 7001 Email: membership@bsigroup.com

Information regarding online access to British Standards and PASs via British Standards Online can be found at

www.bsigroup.com/BSOL

Further information about British Standards is available on the BSI website at **www.bsi-group.com/standards**

Copyright

All the data, software and documentation set out in all British Standards and other BSI publications are the property of and copyrighted by BSI, or some person or entity that own copyright in the information used (such as the international standardisation bodies) has formally licensed such information to BSI for commerical publication and use. Except as permitted under the Copyright, Designs and Patents Act 1988 no extract may be reproduced, stored in a retrieval system or transmitted in any form or by any means – electronic, photocopying, recording or otherwise – without prior written permission from BSI. This does not preclude the free use, in the course of implementing the standard, of necessary details such as symbols, and size, type or grade designations. If these details are to be used for any other purpose than implementation then the prior written permission of BSI must be obtained. Details and advice can be obtained from the Copyright & Licensing Department.

Tel: +44 (0)20 8996 7070 Email: copyright@bsigroup.com

BSI

389 Chiswick High Road London W4 4AL UK

Tel +44 (0)20 8996 9001 Fax +44 (0)20 8996 7001 www.bsigroup.com/standards

