INTERNATIONAL STANDARD

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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

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Foreword

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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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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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.

2.2
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

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"*[5] (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.