



HealthConnect Systems Architecture Project Phase 2 – Systems Architecture Development

Standards Assessment

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HealthConnect Architecture Documents

Phase 1 of the Systems Architecture involved the definition of the requirement for the System Architecture project. This was then used in shaping the Systems Architecture Phase 2. The following listed documents form part of the reporting for this second phase of the HealthConnect Systems Architecture project and are available at www.healthconnect.gov.au.

If you click on the Systems Architecture link on that web page you will be able to obtain the listed documents.

The key Systems Architecture (Phase 2) documents comprise of:

HealthConnect Architecture Overview	Presents a high-level overview and conceptual model of HealthConnect.
HealthConnect Systems Architecture	Defines the HealthConnect Systems Architecture from the three design viewpoints of Data, Application and Technology. Provides an in-depth description of the HealthConnect Systems Architecture.
HealthConnect Implementation Strategy	Describes an implementation strategy for establishing HealthConnect as a national system of compatible health records systems.

Other System Architecture (Phase 2) documents, available at the above web address, are as follows:

HealthConnect Architectural Principles	Defines and describes the principles underpinning the architecture.
HealthConnect Financial Business Model	Describes options for the HealthConnect financial business model and how the business model might operate. It also explores questions like who might own the assets and data, funding sources for implementation and ongoing operations.
HealthConnect Business Architecture Models	Documents the business models derived from the Business Architecture (see above). The UML (Universal Modelling Language) models were prepared using Popkin's <i>System Architect</i> modelling tool. The document provides instruction on how to navigate the <i>System Architect</i> encyclopaedia (see below).
HealthConnect System Architecture Encyclopaedia	Web browser viewable set of the architectural models built using the Popkin <i>System Architect</i> tool.
HealthConnect Current Systems and Technology	Describes application systems and supporting technology currently in use in the health sector.

HealthConnect Standards Assessment(This document)	Reviews relevant standards that impact/enable HealthConnect.
Next Steps for the HealthConnect Systems Architecture	Identifies the activities that are required to complete the development of the HealthConnect architecture to a level of detail sufficient to guide future implementation activities.

The following documents available at the indicated web addresses are referenced in the draft Systems Architecture (Phase 2):

A Health Information Network for Australia	The report of the National Electronic Health Records Taskforce published in July 2000. The recommendations of the taskforce led to the initiation of the HealthConnect project. This document is available on the internet at: http://www.health.gov.au/healthonline/publications/publications.html#Pub00
HealthConnect Interim Research Report	The report comprises three volumes: Volume I, which provides an overarching view of the Project achievements and findings to date, and recommends a way forward for this important national project; and Volumes II and III which contain a number of research reports, case studies and evaluation reports as background materials. www.healthconnect.gov.au
HealthConnect Business Architecture	Describes the business requirements for HealthConnect. It was the starting point for the development of the Systems Architecture. Version 1.0 is being published in the HealthConnect Interim Research Report, which is being released at the same time as the Systems Architecture. www.healthconnect.gov.au

PLEASE NOTE

As well as being available on the web site www.healthconnect.gov.au all the HealthConnect Architecture documents and HealthConnect Interim Research Report are available on CD.

Printed versions of the HealthConnect Interim Research Report and HealthConnect (Phase 2) draft Systems Architecture document are also available.

If you would like a CD or printed document please send your request to healthconnect@health.gov.au or phone 02 6289 7716.

Glossary of Terms

Term	Definition
AEM	Authorised EHR Manager
ANSI	American National Standards Institute
CEN	Committee European de Normalisation
CEN/TC 251	European Committee for Standardisation's working group, responsible for standardisation of health informatics.
DICOM	The Digital Imaging & Communication in Medicine standard group of the American College of Radiation (ACR) and the National Electrical Manufacturers Association (AEMA).
DRG	Diagnostic Related Groups
EA	Enterprise Architecture
EAP	Enterprise Architecture Planning (as proposed by Spewark)
EHR	Electronic Health Record
FEAF	US Government's Federal Enterprise Architecture Framework
HL7	Health Level Seven - a most widely used messaging communication standard in medicine.
HRS	Health Record System
HTML	Hyper-Text Markup Language. This is the code sent from a Web site to a browser
ICD10	International Classification of Diseases
ICPC	International Classification of Primary Care
IEEE	Institute of Electrical and Electronics Engineers
ISO/TC 215	The International Organisation of Standardisation working group for Health Informatics
MBS	Medical Benefits Scheme
NHISAC	National Health Information Standards Advisory Committee
NOIE	National Office of the Information Economy
OOD	Object Oriented Design
PBS	Pharmaceutical Benefits Scheme
Popkin SA <i>System Architect</i>	Modelling Tool from Popkin Software
UML	Unified Modelling Language
W3C	The World Wide Web Consortium

XML	eXtensible Markup Language
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1 Introduction

1.1 Purpose of this Document

This document describes the relevant standards that will impact on and or enable HealthConnect.

The role of standards is discussed and relevant standards and standardisation initiatives are identified. The paper describes the relationship between ‘specifications’ and ‘standards’ highlighting the necessity for an ongoing change management process to manage both standards and specifications. Relevant standards are identified in relation to the three architectural views of data, application and technology. The discussion is deliberately focused on the developments in health data standards, as these are essential to defining the content and structure of the shared electronic health record.

There is a limited discussion of application and technology standards. For the application view, this is because HealthConnect requires a unique set of functionality that is specified in detail in the Systems Architecture document. For the technology view the intent is to avoid prematurely limiting the wide number of technology options available to system implementors, given that implementation is still some years off. In the first instance HealthConnect has been guided by the interoperability framework that is being developed by NOIE.

1.2 Relationship to Other Documents

The relationship of this document to the other HealthConnect System Architecture documents is shown in Figure 0-1.

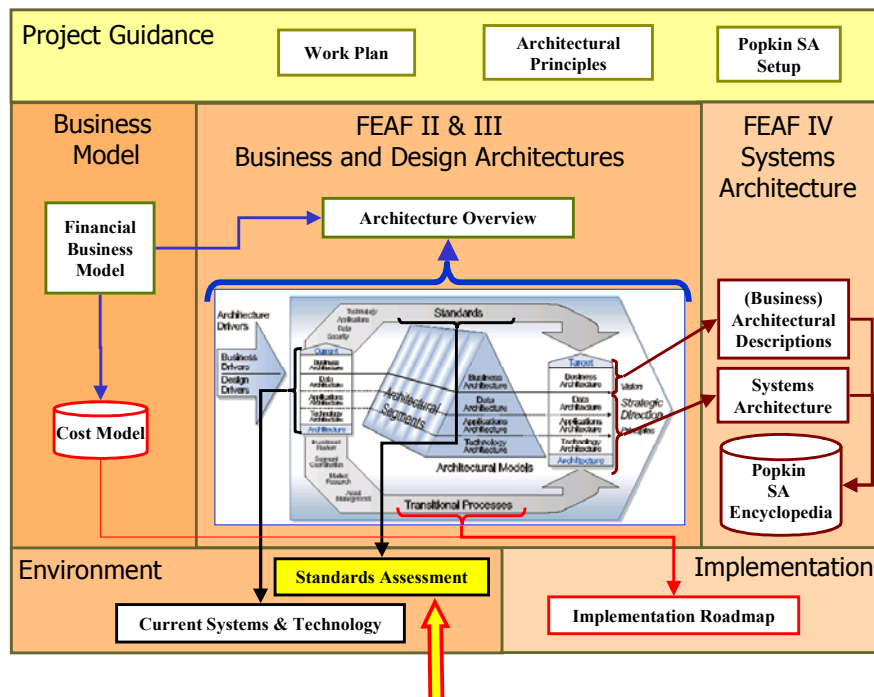


Figure 0-1 HealthConnect System Architecture Documentation

2 Standards Background

2.1 What are Standards?

The International Organisation for Standardisation (ISO), as the international peak standards development organisation, provides the following answer:

“Standards are documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines, or definitions of characteristics, to ensure that materials, products, process and services are fit for their purpose”

Standards Australia, the Australian standards peak body, adds:

“A key criteria is that a standard represents a consensus from a committee of technical experts who were specifically chosen to bring a broad range of viewpoints to the committee deliberations.”

Standards Australia also provides the following rationale for standards:

“Standards are vehicles of communication for producers and users. They establish a common language, which defines quality and establishes safety criteria. Costs are lower if procedures are standardized; training is also simplified. Moreover, consumers accept products more readily when they can be judged on intrinsic merit.”

It is important to recognise that standards are the outputs of a standardisation process that is managed by a standards body. It is the process that provides the forum for achieving technical consensus, however, the value of any particular standard comes not from its technical merit or the consensus process per se, but rather from how widely it is adopted throughout the industry.

Conformance with widely implemented standards reduces implementation costs because embedded support for the standard is available in off the shelf products reducing the need to develop special purpose software and through simplified interoperability between disparate systems.

Standards also inform vendor contracts and service levels between participating organisations and individuals by establishing clear rules against which progress towards contractual deliverables and compliance can be measured.

2.2 What are Specifications?

HealthConnect may, for business, clinical and technical reasons, “mandate” a range of technical specifications and provisions that, on the surface, appear similar to standards. Specifications are not derived through consensus, they are not standards, however they do provide the opportunity to be submitted to a standards body with a view to being established as new standards in their own right.

The Institute of Electrical and Electronics Engineers (IEEE) defines “a specification” as a document that prescribes, in a complete, precise, verifiable manner, the requirements or characteristics of a system or a system component.

When considering HealthConnect implementation and operation there may be common characteristics between specifications and standards. This overlap may, if

not managed appropriately, confound design and implementation decisions from time to time.

Specifications determined through developing the detailed requirements for HealthConnect are likely to evolve to become informatics and business practice consensus based standards for the Australian health care environment. Therefore, it is essential that specifications and standards are managed from a single perspective throughout the life of HealthConnect.

2.3 HealthConnect Standards

Standards will be necessary wherever the HealthConnect Systems Architecture stipulates the movement of health information between “disparate” or autonomous ‘systems domains’. The architectural objectives of HealthConnect demands that a robust set of standards and specifications are planned for, documented and managed within a consensus based change management framework that supports both the evolution of technology and changes in business needs.

HealthConnect will seek to take advantage of established and emerging standards in the Health and IT industries. Where appropriate HealthConnect may seek to facilitate the development of new standards.

Overseeing the identification, selection, adoption, evolution and communication of a “set” of HealthConnect standards and specifications is key to the successful implementation and take-up of the HealthConnect system. A comprehensive set of HealthConnect technical and business interoperability standards and specifications will collectively make up a HealthConnect standards profile.

2.4 Maintaining the Standards Profile

Standards identified for HealthConnect are likely to need modification and, where appropriate, registered with relevant national and international standards development organisations. Existing standards may require specific modifications or extensions specific to HealthConnect.

HealthConnect’s standards profile will evolve over the life of the HealthConnect system, needing a coordination and collaboration process managed by the people most appropriate to the task. There may be benefit in the establishment of a HealthConnect Standards Committee to direct the technical work involved in defining and developing relevant standards. The membership of such a committee should be balanced to represent the broadest possible range of the interests and responsibilities involved with implementing and operating the HealthConnect system.

The committee could have a sub-committee structure that reflects the three architectural views of HealthConnect: Data, Applications and Technology. Members of the Data and Applications sub-committees should have a strong clinical and research focus whereas the Technology committee focus should be on function and performance.

The Committee must have adequate resources to identify, define and maintain the HealthConnect standards profile. The Committee must also have quality and safety objectives as “first order” issues, rather than focusing on the more obvious standards for technical or operational needs. The HealthConnect Standards Committee could

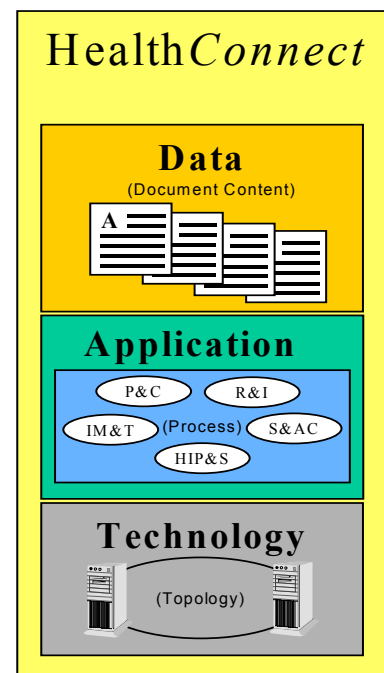
also participate in the work of the national and international standards bodies such as CEN and HL7, where such work is relevant to the implementation of the HealthConnect system.

3 Applicable Standards

3.1 HealthConnect Standards Architecture

HealthConnect standards and specifications are defined in terms of the three architectural views; data, applications and technology.

- **Data Standards** relate to the content of Electronic Health Records (event summaries). This is a wider health industry issue. The current status is discussed in Section 4.3. Developments in this area are discussed in detail in Sections 5 and 6.
- **Application Standards** relate to the HealthConnect system processes for storing and accessing event summaries. Application standards are discussed in Section 4.4, which should be read in conjunction with the Application Architecture section of the HealthConnect System Architecture document.
- **Technology Standards** relate to the system communication requirements of the HealthConnect Systems Architecture. Technology standards are discussed in Section 4.5, which should be read in conjunction with the Technology Architecture section of the HealthConnect System Architecture document.



The HealthConnect standards profile will draw on standards development work that may not be uniquely health informatics in nature but would be relevant to the evolution of the standards profile. The following sections outline some candidate standards development areas for consideration by the HealthConnect Standards Committee.

3.2 Quality Standards

The business objectives of the HealthConnect Systems Architecture are focussed towards improving the quality and efficiency of health care. Consumer and clinician confidence in the overall management environment of the HealthConnect environment is paramount in achieving the business objectives. Therefore, it is critical that HealthConnect systems are developed and managed in accordance with quality management standards such as the ISO 9000 series of standards¹.

3.3 Data Standards

3.3.1 Health Records

The Systems Architecture describes the HealthConnect system as a system for managing flexible electronic document structures, within an Extensible Data Model,

¹ www.standards.com.au/catalogue/script.asp

where the content of documents is constructed within the contributing clinical system.

Data Standards are necessary for disparate point-of-care clinical systems to exchange patient data accurately and securely with HealthConnect. As the HealthConnect infrastructure and services mature over time, clinicians and technology vendors are likely to call for increased interoperability between their systems and the HealthConnect system. Therefore, the range and number of relevant standards is likely to escalate to include extended data sets and business processes. This standardisation effort will require significant ongoing review, consultation and implementation of change management procedures.

Adopting and enhancing existing data exchange standards for acute care and diagnostic services would enable HealthConnect to be implemented for acute care and clinical results. Australian standards already exist for pathology results, patient administration and prescribing that are supported by a majority of health IT systems. These standards are identified at 4.2. Standards Australia's IT14-6-6 working group is developing a draft Australian Standard for discharge and referrals that may be adaptable to meet the HealthConnect definition of an event summary.

Formulating the attributes of event summaries may also require the establishment and adoption of a comprehensive set of patient related data standards for "clinical data" (ie. observation, procedure and treatment) and health professional related "setting data" (ie. location of service, profession and date). This work needs to be completed for each clinical speciality in order for clinical and setting data to be consistently and accurately captured at the point-of-care as an initial procedure.

It is apparent that such data analysis has not yet occurred within the specialities and institutions beyond reporting or administrative data. However, there are some clinically focussed groups, such as clinical registers, that have made some progress towards identifying requirements for consistent recording of information in specific clinical settings that may be able to be brought together as data standards. Examples that may be relevant are the cardiac and cancer registries.

The development of national approaches to patient clinical and context information standards is progressing under the National Health Information Standards Advisory Committee (NHISAC) through the National Health Concept Representation Task Group which commenced work in February 2003. The HealthConnect Clinical Information Project will also contribute in this context. Its twelve-month task is to:

- Develop an event summary framework
- Prototype event summaries
- Develop HealthConnect views and reports
- Develop a specification for a national hospital separation summary
- Recommend governance arrangements for ongoing development and maintenance of HealthConnect event summaries, views and reports
- Investigate issues of terminology/controlled vocabularies in relation to EHRs.

3.3.2 Health Care Client Identification

Unambiguous identification of individual receiving health care services is critical for the organisation providing contiguous services. Most organisations have comprehensive patient identification policies and procedures supported by computer systems that access patient demographic information to link patient information collected as services are provided.

With increased patient mobility and the swing in both health professional and patient expectation that relevant clinical information will be shared between health care organisations the need for common procedures for identifying patients is necessary.

This need is being addressed, to a large degree, by the work of Standards Australia's IT-014-09-03. The Working Group has published a draft Health Care Client Identification Standard. The draft is currently available for public comment.²

HealthConnect functional specifications for registration of individuals and subsequent linking and de-linking to the Event Summaries for an individual participant should be added to the Draft standard.

3.3.3 Health Terminologies

The clinical terms used in the various clinical computer systems providing information to HealthConnect cannot be automatically translated for use by other clinical systems without the creation and mapping of commonly used clinical terms and structures to a HealthConnect "reference terminology".

To understand the issues involved, an extract is presented from a recent paper by Dr Teng Liaw et al on health terminologies that describes the vocabulary needs of the health informatics community in three categories: Aggregating Terminologies, Reference Terminologies and Interface Terminologies. However, these distinctions are illustrative rather than definitive.

To quote Dr Liaw et al:

"The understanding is that reference, interface and aggregating terminologies are not formal entities on their own, but are formal transformations of one another, reflecting three overlapping functional dimensions of a terminology spectrum.

The single universal reference terminology is conceptualised as "an all-encompassing superset representation that either links to every other interface or reporting terminology or that supports most of the useful interface or analytic functions within its own structure".

Thus a clinical terminology may be conceptualised as comprising the functional dimensions of reference, interface and aggregating terminologies. The core is the reference terminology, where each concept is uniquely represented and described by its relationships. The interface terminology, comprising preferred terms and synonyms, may be an integral part of the

² The Draft Health Care Client Identification standard may be downloaded from www.standards.com.au/committees/it-014-09-03. The Draft was published for public comment in July 2001.

clinical terminology, but may also exist independently and be mapped or related to the corresponding concepts in a reference terminology.

While the relationship hierarchy in a terminology may take on the role of a classification, in the clinical setting this is a secondary purpose and is usually limited by the concept that relationships necessary to express a clinical concept are only described if “always true and necessary”. For practical purposes classifications or aggregating terminologies are best considered as parallel stand alone terminological structures, related to a reference terminology by mapping rather than being integrally linked in the one structure. Theoretically then, each interface or reporting terminology would only need to maintain its mappings to the universal reference terminology and through it, gain access to any other concept representation.”

Australian needs are well served in respect of Aggregating Terminologies with well-managed terminology development environments providing an Australian focus to the International Classification of Diseases (ICD10), International Classification of Primary Care (ICPC), Diagnostic Related Groups (DRG), Pharmaceutical Benefits Scheme (PBS), Medical Benefits Scheme (MBS) codes, etc.

Interface terminologies have been implemented worldwide on a strictly “local” or organisational basis even where terminology systems underpin clinical systems there is no unilateral approach.

The range of interface terminologies in use in Australia comprises nearly all of the international possibilities for terminology systems. Examples include Systematized Nomenclature of Medicine (SNOMED), ICPC-2 PLUS+, DOCTors Command Language, (DOCLE), ICD10-AM, Logical Observation Identifiers Names and Codes (LOINC), etc.

It is likely that providers will continue to use the terms of their profession or organisation (i.e. interface terms) simply for clinical proficiency.

To avoid major re-training of providers and re-configuration of their systems HealthConnect may need to automatically translate clinical terms used at the point-of-care to a reference terminology to improve the interoperability between HealthConnect and disparate point-of-care clinical systems.

Therefore, a high priority in achieving a successful implementation and use of the HealthConnect system will be the establishment and management of a national clinical reference terminology that is integrated with a “translation engine” that holds mappings to the clinically relevant terms used by existing clinical computer systems.

The NHIMG/NISAC³ Terminology Taskforce is attempting to address many of these issues through the establishment of an expert group to develop a national strategy. If this initiative is adopted work will progress under the Health Data Standards Committee and require significant input from health informatics experts experienced

³ The NHIMG/NHISAC Taskforce was established jointly by National Health Information Standards Advisory Committee (NHISAC and National Health Information Management Group (NHIMG) under the Australian Institute of Health and Welfare.

in the use of terminologies within both clinical and administrative computer applications, including the requirements of *HealthConnect*.

3.3.4 HL7 Standards Family - Vocabulary

HL7⁴ experts also recognise the issues involved in ensuring that clinical information can be shared in a well-defined and unambiguous manner; many areas of HL7 messaging data is represented in coded terms. This has the benefit of increased accuracy, shorter messages and sometimes language independence; although it does require communicating systems to be able to interpret the codes that the HL7 protocol specifies.

HL7 has a working group, the HL7 Vocabulary Technical Committee, to identify, organise and maintain the coded vocabulary terms used in HL7 messages.

HL7 achieves this by providing an organisation and repository for maintaining a coded vocabulary for use in conjunction with HL7 related standards. There are at least five domains referenced by the HL7 standard:

Domains where content is entirely controlled by HL7 committees.

- Domains where HL7 committees have included incomplete lists of terms or “starter sets” for a given domain.
- Domains that have a specific use but no data elements are defined by HL7, it is assumed that the coded values would come from one or more available coding systems such as SNOMED, ICD-10AM LOINC, Read, etc.
- Domains that fill the value field in, say, an OBX message for specific observation ID where coded values would come from one or more available coding systems such as SNOMED, ICD-10AM LOINC, Read, etc.
- Domains that are referenced in the HL7 standard, but for which the structure and contents of the tables is assumed to be locally defined.

HealthConnect's participation in this Technical Committee and any relevant Special Interest Groups is necessary to ensure that the balance of HL7 standards development either informs or is informed by the requirements of the *HealthConnect* Systems Architecture.

3.3.5 Messaging - HL7 Standard Version 2.x

HL7 (Health Level Seven) claims to be the most widely used messaging communication standard in medicine. The HL7 communication standard, originally developed for the health care system in the United States, has been used in Australia since 1989.

HL7, as an ANSI accredited standards developer, has evolved to a worldwide community seeking to coordinate its efforts with other standardisation organisations such as:

- CEN/TC 251, the European Committee for Standardisation's working group, responsible for standardisation of health informatics.

⁴ The HL7 organization is explained at Section 3.3.5

- DICOM, the Digital Imaging & Communication in Medicine standard group of the American College of Radiation (ACR) and the National Electrical Manufacturers Association (AEMA).
- ISO/TC 215, the International Organisation of Standardisation working group for Health Informatics, and
- W3C, the World Wide Web Consortium, the peak web standards developer organisation.

Approximately 25 HL7 international affiliates now operate around the globe with the common objective of promoting and using the HL7 family of standards.

HL7 standards development activities are directed towards a wide range of health care standards, the most widely used are the various incarnations of HL7 Version 2.x. The rapid development and adoption of messaging requirements through consensus often leads to a greater range of optionality than is desirable in a standard. As a result, Australia and other international affiliates have developed specific interpretations of the HL7 2.x standard. These are published as Standards Australia standards implementation guides that define national best practice use of the HL7 2.x standard.

3.3.6 Messaging - HL7 Standard Version 3

While HL7 2.x meets the demand to move data between systems, modern interchange and interface expectations have evolved, to not only move the data but, to be able to use it once it has been moved. HL7 Version 3.0 is being developed to meet this requirement.

Version 3 utilises a formalised methodology, the HL7 Message Development Framework (MDF) to create messages and trigger events with little opportunity for optionality. This process involves the ambitious task of producing and agreeing on a Reference Information Model (RIM), an object-oriented data model which provides a consistent view of the data being moved as well as that data's relationship to other data. The result is a structured approach to message development that will be sustainable in the future.

Version 3 will also take advantage of XML to increase interoperability by collaborating with the Clinical Document Architecture (CDA) working group⁵. Using CDA, Version 3 will enable systems to create XML documents that incorporate HL7 message content, to generate messages from document content and to exchange and process messages and documents between disparate systems.

Australian contributions to the development of Version 3 have been significant in recent times, however in terms of a standards development methodology “fitness for purpose” of Version 3 is yet to be proven. It is a complex standards development process with significant issues remaining to be resolved before it can be accepted as a standard for implementation in Australia.

⁵ CDA is explained at 3.3.7

3.3.7 HL7 Standards Family - Clinical Document Architecture (CDA)

The Clinical Document Architecture (CDA), which was until recently known as the Patient Record Architecture (PRA), is an XML-based clinical document architecture which provides an exchange model for clinical documents of varying complexity (such as discharge summaries and progress notes).

A CDA document is defined as a persistent information object that can exist outside a messaging context and/or can be a payload within an HL7 message. The scope of the CD Technical Committee is the standardisation of clinical documents (legally authenticated, persistent entries into the patient record) for exchange. The clinical content of CDA documents is defined in the HL7 Version 3 RIM.

By making use of XML, the HL7 Reference Information Model (RIM) and coded vocabularies, the CDA makes documents both machine-readable and human-readable. CDA documents can be displayed using XML-aware web browsers or wireless applications.

CDA Level 1 was approved as an ANSI Standard in November 2000. There are several comprehensive implementations of patient records systems based on CDA in the United States that are contributing significant clinical experience to the committee.

Membership of the CDA Technical Committee has attracted a number of Australian standards developers interested in electronic medical records and may provide a significant resource of expertise and definitions for the ongoing development and potentially the “organisation” or data structure of event summaries. The HealthConnect Standards Committee should maintain representation in this working group, particularly if the HL7 organisation takes on the international leadership for defining health XML Schemas.

3.4 Applications Standards

System processes are specified in the HealthConnect Systems Architecture document and deal with storage, administration and accessing of event summaries. Five core services have been identified as illustrated in Figure 3-1.

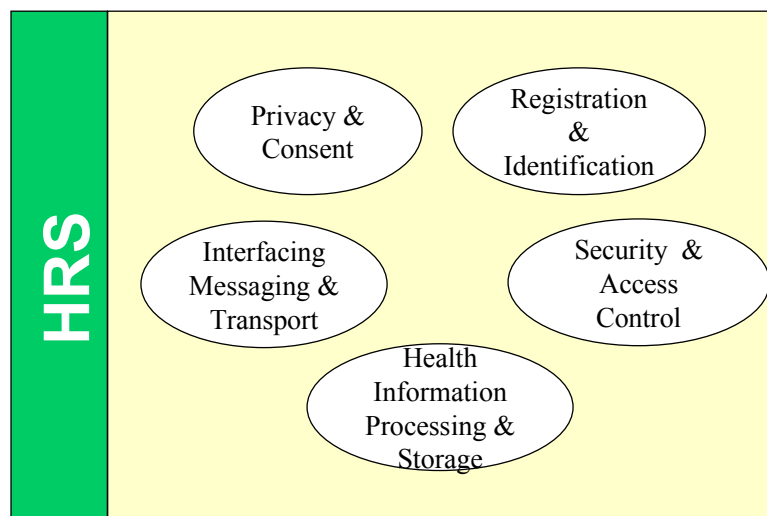


Figure 3-1 HRS Services

Whilst not essential for access to HealthConnect, it is highly desirable that providers (through their respective vendors) incorporate these services into their clinical information systems and or practice management systems.

No technical standards were identified as obvious candidates for the HealthConnect standards profile under this heading. Although, the document management nature of the HealthConnect system architecture might be able to draw on the management practices outlined in the Australian Standard for the Records Management, AS4390.x and its international manifestation, ISO 15489-2 Standard on Records Management and Guidelines.

3.5 Technology Standards

3.5.1 Internet Standards

The HealthConnect systems architecture assumes the use of the Internet as the preferred communications service for connecting HealthConnect to providers and consumers. HealthConnect is able to build on the work of significant national web and Internet standards based organisations through aligning the Technology Standards component of the HealthConnect standards profile with established and emerging Internet standards. Internet Standards

The technology standards for interoperability recommended by the National Office for the Information Economy (NOIE) should be adopted for the Technology Architecture elements of the standards profile where appropriate. The NOIE recommendations are for Internet standards including W3C, IETF, HTML, HTTP, SSL, PKI, TCP/IP, SOAP and XML.⁶

The NOIE recommendations are available at:

http://www.noie.gov.au/publications/NOIE/standards/Draft%20Interoperability%20Framework%20v2%20_07-05-02.pdf

3.5.2 XML

The eXtensible Markup Language (XML) family of standards has, and is continuing to, evolve from a document-modelling paradigm to include a data-modelling paradigm. Most database vendors are working within the World Wide Web Consortium's (W3C) standards development groups to specify XML database standards. Such standards will provide implementers with the ability to store and manage structured and unstructured data under a standard W3C XML data model, i.e. schemas. This means that the implementers of HealthConnect can collect and combine data from disparate systems into a standard data model or XML Schema, thereby reducing the complexity of managing data from different sources.

The XML family of standards offers the HealthConnect standards profile a credible health standards development environment. The applicability of XML has been established within the HL7 organisation where XML translators have been developed to cover the range of health messages.

⁶ W3C is the World Wide Web Consortium; IETF is the Internet Engineering Task Force; HTTP is Hypertext Transfer protocol; SSL is Secure Sockets Layer; PKI is Public Key Infrastructure; TCP/IP is Transmission Control Protocol/ Internet Protocol ; SOAP is Standard Object Access Protocol; XML is eXtensible Markup Language.

Further work is required to compare the Australian implementation specifications with the XML transformations and their applicability to the published Australian standards. This work also needs to be extended to reviewing Australian HL7 message standards to determine their applicability to identifying XML schemas for Australia.

The relationship and development activities of the various HL7 working groups and W3C technical committees working on XML should be monitored from a HealthConnect perspective. The Standards Committee will need to develop significant XML implementation skills amongst its technical members to manage any HL7/XML migration issues that may affect the HealthConnect system.

3.5.3 Information Security Management

HL7 itself is working on a health specific standard for network and Internet security at the application level independent of any underlying transport standards. While of interest to the technically minded, it will be more appropriate for HealthConnect to be guided by the NOIE Interoperability Framework publication. Therefore, the HL7 Security Special Interest Group will have little appeal to the HealthConnect Standards Committee.

A more applicable standard may be the AS/NZS ISO/IES 17799:2001 Information Technology – Code of practice for information security management and its companion guide, HB 174-2003 Information security management – Implementation guide for the health sector.

The practical experience with security and authentication tools gained by the HealthConnect fast track trials will provide guidance to the Standards Committee's considerations.

4 Standards Development

4.1 Overview

In the wider Australian health sector, health informatics standards developers have a well-established standards development environment through Standards Australia's IT14 Health Informatics Subcommittees and working groups.

This group is responsible for establishing consensus on health informatics standards and for publishing agreed standards for health informatics. Standards Australia's Subcommittee and Working Groups are:

- IT-014-02 -- Health Concept Representation.
- IT-014-04 -- System and Data Security, Integrity and Privacy.
- IT-014-06 -- Messaging and Communication.
- IT-014-06-03 -- HL7 Messages.
- IT-014-06-04 -- Prescription Messages.
- IT-014-06-05 -- Pathology Messages Working Group.
- IT-014-06-06 -- Referral Messages.
- IT-014-07 -- Data Storage and Offline Devices.

- IT-014-08 -- Links With External Standards Bodies.
- IT-014-09 -- Electronic Health Records and Harmonisation.
- IT-014-09-01 -- Modelling Coordination.
- IT-014-09-02 -- Electronic Health Records.
- IT-014-09-03 -- Person Identification and Linkage.
- IT-014-10 -- Electronic Commerce.
- IT-014-10-01 -- Supply Chain Messages.
- IT-014-10-02 -- Financial Messages.
- IT-014-10-03 -- Central Repository.
- IT-014-10-04 -- Product Identification.

4.2 Standards Australia –Health Informatics Standards

Standards Australia has been successful in facilitating and publishing the following standards:

- AS 4400-1995: Personal privacy protection in health care information systems.
- AS 47001- 1997: Implementation of Health Level Seven (HL7) Version 2.2 - Admission, discharge and transfer.
- AS 4700-1 1998: Implementation of Health Level Seven (HL7) Version 2.3 - Patient administration.
- AS 47001.1 – 2001: Implementation of Health Level Seven (HL7) Version 2.3.1. - Patient administration.
- AS 4700.2 – 1998: Implementation of Health Level Seven (HL7) Version 2.3 - Pathology orders and results.
- AS 4700.5 – 2002: Implementation of Health Level Seven (HL7) Version 2.3.1 - Immunization Messages.
- AS 4937 – 2002: Electronic messages for exchange of claim and related information.
- AS 5017 – 2002: Health care Client Identification.
- AS/NZS 4700.3 – 1999: Implementation of Health Level Seven (HL7) Version 2.3 - Electronic messages for exchange of information on drug prescription.
- AS/ANZS 4700.3 – 2002: Implementation of Health Level Seven (HL7) Version 2.3.1 - Electronic messages for exchange of information on drug prescription.
- HB 262-2002: Pathology electronic messaging - Guidelines for pathology messaging between pathology providers and health service providers - Implementation guide.

Standards Australia's working groups have developed rigorous interpretations of the HL7 2.x standard through consensus between Australian health organisations published as the Implementation Guides mentioned above.

In addition to this work, the definition and adoption of standards for health informatics has been considered under the auspices of the Committee European de Normalisation (CEN). CEN has been working towards health informatics standards for more than 10 years through its CEN/TC 251.

Australian involvement in CEN activities is coordinated through Standards Australian's technical committee, IT14, with CEN work items assigned to the IT14 Working Groups above.

5 Other Promising Standards Developments

5.1.1 HL7 Standards Family - Arden Syntax and other Clinical Decision Support Standards

The Arden Syntax for Medical Logic Systems version 2 is an approved ANSI standard. This standard is a rule-based language for representing and sharing medical knowledge among health workers, information systems and institutions to automatically assist clinicians in decisions and alerts.

This group also coordinates a range of special interest groups considering a range of other standards recommendations for systems supporting guideline representation including, amongst others, the Guideline Interchange Format (GLIF).

In respect of the HealthConnect Systems Architecture, clinical decision support functionality is not likely to be an early priority; nevertheless, HealthConnect should monitor the progress of this standards development working group.

5.1.2 HL7 Standards Family - The Clinical Context Management Specification

The Clinical Context Object Workgroup Technical Committee (CCOW) publishes standards for the visual integration of cooperative interaction among independently authored health care applications at the point-of-use. The term visual integration emphasises the specific scope the workgroup chose to address applications with graphical user interfaces operating together on a personal computer or workstation. The Standard supports the synchronisation and sharing of information between applications.

Specifically, the Context Management Standard defines a protocol for securely "linking" applications so that they "tune" to the same context. Context is represented as a set of subjects, each of which generally identifies a real-world entity such as patient or real-world concept such as an encounter. Linked applications remain automatically synchronised even when a context changes, for example, due to the user's inputs (eg. the user selects a different patient).

The CCOW Technical Committee may be relevant to the HealthConnect Systems Architecture standards environment because the committee is working towards defining standard context data items. In addition, the CCOW is working on the development of specifications for web browser interfaces and web based implementations of applications and components that conform to the CCOW Standard.

5.1.3 HealthOnline Program

There are wide ranges of activities taking place under the HealthOnline agenda that may inform the HealthConnect Standards Committee as it establishes the standards

profile. It will be some time before this work delivers specifications and definitions in sufficient detail to be useable by HealthConnect. The Standards Committee will need to monitor and provide input to these activities as the standards profile evolves.

The following sections highlight some of areas of interest for HealthConnect's standards and specification developers.

5.1.4 Privacy and Confidentiality

Establishing HealthConnect standards for privacy and confidentiality will be a key requirement of the standards profile. The HealthConnect Systems Architecture acknowledges the criticality of privacy and confidentiality in building provider and consumer confidence in the HealthConnect System. The development of the national health privacy framework will set the criterion for a national specification for the privacy and confidentiality standards for HealthConnect.

5.1.5 Provider Directory Project

This project will inform the Standards Committee on aspects of the registration and identification of providers that may lead to HealthConnect standards being specified for the wider range of individuals and entities that will need to be formally identified and managed as HealthConnect evolves.

5.1.6 HealthConnect fast Track trials

Two "fast tract" HealthConnect trials that commenced late 2002 will contribute practical information that the Standards Committee will be able to draw on in determining the HealthConnect standards profile.

5.1.7 General Practice Interface Terminology Project

This DoHA project under General Practice Computer Group (GPCG) activities intends to establish a "standardised set of terms" for general practice. The project will identify terms in common use by general practitioners to electronically record patient and clinical information during encounters. This would, in effect, be a collection of general practice terms and their relationships that can be categorised as an interface terminology for general practice.

The Standards Committee would need to consider the outputs of this project for suitability as a benchmark for evaluating potential reference terminologies. The GP term set may also be valuable in evaluating terminology translation engines for applicability for a primary care setting.

5.1.8 NSW Health's EHR*Net Project

There will be many implementations of electronic health records in various regional settings. The NSW EHR*Net project is an example of such EHR projects that the Standards Committee would need to monitor for impact and contribution to the standards profile.

5.1.9 MediConnect

This project, along with other HealthConnect specifications, will require close and active cooperation between the related projects.

5.1.10 OpenEHR Project

In recent times, the development of the Good European Health Record, originally a CEN initiative has progressed significantly. HealthConnect initiated OpenEHR projects to inform the structure and functionality of electronic health records that may be applicable to HealthConnect.