AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

Infrastructure & Technical Standards

Australian Clinical Quality Registries

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Infrastructure and Technical Standards for Australian Clinical Quality Registries have been developed in collaboration with the NHMRC Centre for Research Excellence in Patient Safety (CRE PS) at Monash University and the National E-Health Transition Authority (NEHTA). The *Standards* have benefited from external consultation and input from a range of clinicians, speciality groups and registry custodians. Additionally, the *Standards* have undergone testing and validation with a number of clinical quality registries.

The Australian Clinical Quality Registries project is one of the Australian Commission on Safety and Quality in Health Care's Information Strategy. For more information about the Information Strategy visit the Commission's website: **http://www.safetyandquality.gov.au/**

For more information about the National E-Health Transition Authority visit their website: **http://www.nehta.gov.au/**

For more information about the NHMRC Centre for Research Excellence in Patient Safety visit their website: **http://www.crepatientsafety.org.au/**

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Introduction

Clinical quality registries (CQRs) are organisations that systematically collect longitudinal health-related information on the quality of care provided to individuals. They focus on conditions and procedures where outcomes are thought to vary and where improvements in quality have the greatest capacity to improve quality of life and/or reduce costs. They potentially provide a strong evidence base for determining the efficacy, safety and quality of providers, interventions, medications, devices and treatments.

The purpose of clinical quality registries is to monitor the safety and quality of health care provided to patients by systematically gathering, analysing and making widely available what is being done and the results of that clinical activity. Clinical quality registries build on data collected from events in daily health care and use this information to assess the appropriateness and effectiveness of health care and support quality improvements where required.

The system or organisation governing the register is known as the *registry*.

Figure 1. Clinical Registers and Clinical Quality Registries

Clinical Quality Registries are established and operated with the aim of improving patient care and outcomes through greater understanding of events, treatments and outcomes. The data collected by a registry over time are analysed and used to identify positive and negative trends and these analyses can be used, generally by clinicians, to lead to improvements in practice, and in medication and device usage.

An Australian Clinical Quality Registry is a registry whose purpose is to improve the safety or quality of health care provided to patients. Australian Clinical Quality Registries build on data collected from events in daily health care and use this information to assess care provision and implement quality improvements where required.

It has been noted that:

- No national standard exists against which funding applications by clinical registries can be written or assessed.
- No routine processes exist to ensure that clinical registries improve safety and quality. For example, many registries take a significant period of time to collate data, reducing their ability to provide timely information to health care providers and to support clinical quality assurance and improvement.
- Registry processes, data and technology are neither uniform nor standardised, creating significant inefficiencies and hampering inter-operability with other information systems.
- Some registries collect data items that do not conform to national definitions, thereby limiting the utility and comparability of the data.
- Data quality, including completeness, is often compromised. Some registries seek information from the routine administrative collections to determine completeness or to match data with administrative collections (including hospital statistics or deaths) to extend or validate the registry information.

Purpose and scope of this document

The Australian Commission on Safety and Quality in Health Care, the NHMRC Centre of Research Excellence in Patient Safety and the National E-Health Transition Authority (NEHTA) have collaborated to develop *Infrastructure and Technical Standards for Australian Clinical Quality Registries*.

Australian Clinical Quality Registries are registries that are:

- (potentially) national in coverage; and
- primarily focussed on supporting improvement in the quality of clinical practice, particularly clinical safety and quality.

A core function of Australian Clinical Quality Registries must be that they have the ability to improve clinical practice and health outcomes and be capable of accurately capturing the state of health care in Australia. For registries to meet their full potential in informing the state of health care in Australia, confidence is needed in the quality and relevance of the data.

This document sets out the technical standards that an Australian Clinical Quality Registry should consider in their development and operation.

Audience

Infrastructure and Technical Standards for Australian Clinical Quality Registries are aimed at assisting those involved with or contemplating the development of clinical quality registries. This document is designed to assist:

- Organisations involved in the funding of clinical quality registries whose purpose includes the monitoring and/or benchmarking of quality of care;
- Individuals and organisations responsible for interpreting data derived from clinical quality registries; and
- Researchers and stakeholders contemplating the development of new Australian Clinical Quality Registries.

Using this document

This document should be read in conjunction with its companion document; *Operating Principles for Australian Clinical Quality Registries*[1] which should be used to develop and evaluate the structure, governance and operations of Australian Clinical Quality Registries. This document does not set out how a registry should be governed or operated.

The two documents are complementary and highly inter-related. Use of the Infrastructure and *Technical Standards* makes the attainment of many of the O*perating Principles* more readily achievable.

1 http://www.safetyandquality.gov.au/wp-content/uploads/2012/03/Operating-Principles-for-Australian-Clinical-Quality-Registries-Brochure-2011.pdf

This document is composed of two sections:

- *Infrastructure Overview* – describes the national infrastructure that is relevant to Australian Clinical Quality Registries. Leveraging this infrastructure aims to enhance the sustainability, efficiency and interoperability of registries.
- *Standards Map* – a listing or mapping of the various technical standards that may be relevant to an Australian Clinical Quality Registry. There is recognition that there may be varying levels of technical sophistication required depending on a given registry's scope and purpose and identifies the different standards that may be applicable for each level. The Standards Map identifies standards that may be relevant to clinical quality registries in the following areas:
  - Interoperability
  - Clinical communications
  - Unique healthcare identifiers
  - Identity management
  - Secure messaging
  - Supply chain
  - Engagement and adoption.

By adopting standards registries can better ensure their interoperability (ability to interact with and share information between registries, etc.), security, reliability, standardisation of processes and practices, etc. over both the short and longer terms.

Most of the technical standards referred to in this document are industry-neutral. That is, they are not specific to the health sector. Rather they are standards that have application or relevance for clinical quality registries and can be considered as best practice technology standards that can be applied to e-health and to clinical quality registries.

Infrastructure overview

This *Infrastructure Overview* describes:

- How both current and future national infrastructure can be leveraged by Clinical Quality Registries

The National E-Health Transition Authority (NEHTA) had defined the scope of its work in clinical registries as primarily focusing on high-quality, high-value registries that operate on a national level and have the potential to support the adoption and implementation of NEHTA specifications on a large scale. These national registries are considered likely to grow in number and purpose in the future, and hence steps taken to improve the consistency across registries, in terms of information collected and technologies deployed, are likely to reap future benefits in terms of usability and interoperability.

Infrastructure

This section contains discussion of the following:

- Healthcare Identifiers (HI)
- National Authentication Service for Health (NASH)
- Personally Controlled Electronic Healthcare Record System (PCEHR)

NEHTA infrastructure

The National E-Health Transition Authority (NEHTA) was established in July 2005 to set the necessary foundations for the widespread and rapid adoption of e-health across the Australian health sector.

Although electronic exchange of clinical information is already occurring in some areas, significant issues can arise from a lack of standards and agreed ways of working. Accelerating the adoption of information technology within the health sector will require a common set of standards and policies that allow people, organisations and electronic systems to work together – that is, it will require 'interoperability'.

To address this lack of standards generally, NEHTA has developed an overarching e-health interoperability framework. To address the lack of standards for Australian Clinical Quality Registries, NEHTA has developed this Architectural Overview and associated Standards Map.

The Interoperability Framework[2] provides guidance on identifying and defining key concepts which must be addressed at the organisational, information and technical levels before systems can effectively communicate and interoperate. It also provides the basis for an e-health architecture including identifying e-health requirements, specifying e-health technical approaches through products and technologies, testing conformance to interoperability requirements, value assessment; and change management.

Increased sharing of clinical information will only be acceptable to consumers and clinicians if it occurs within a trusted environment, and so privacy is critical to the success of e-health. NEHTA is committed to developing the national foundations for the electronic exchange of healthcare information in a way that ensures the privacy of individuals' information is appropriately protected. A Privacy Management Framework has been developed to ensure privacy is managed effectively across the entire NEHTA work program. A range of key stakeholders have received this framework positively, in particular privacy regulators and consumer advocates. The Privacy Management Framework will continue to inform, guide and support NEHTA's privacy work.

The following sections provide further details on key NEHTA building blocks and national infrastructure relevant to Australian Clinical Quality Registries.

Healthcare Identifiers (HI)

The ability to accurately identify healthcare providers, healthcare organisations and individuals who are interacting with the healthcare system, is critical to health IT interoperability. To achieve this end, NEHTA and The Department of Human Services have developed both an individual healthcare identifier and a healthcare provider identifier, this service commenced operations in 2010.

For more information about healthcare identifiers, refer to **http://www.nehta.gov.au/connecting-australia/healthcare-identifiers**

(1) Individual healthcare identifier (IHI)

The HI service will provide the facility to uniquely identify an individual for healthcare purposes and will link them correctly to their health information based on the individual's IHI Number.

ⓘ No clinical information will be stored on the IHI record.

The IHI is essential for the safe electronic exchange of patient information, as it ensures that it is accurately attributed to the correct patient. An IHI will be recognised across the entire healthcare sector.

The HI service will make available both a number and a record of information. The record of information will be divided into three sections – a summary record, an identification record, and a demographic record.

[2] Interoperability Framework 2.0 [REF01]

The summary record will contain the minimum number of data fields to enable the matching of an individual to their IHI (e.g., name and date of birth).

The identification record also contains any additional data fields required for the positive identification and association of an individual with their IHI.

The demographic record includes data fields not essential to accurately identify an individual, but which could assist in the provision of quality health care (e.g., an individual's mobile phone number could be part of their demographic record).

Activation of an IHI will occur subject to individual consent. However, an individual's eligibility to receive health services is not affected if an IHI is not activated.

(2) Healthcare provider identifier (HPI)

The purpose of the HPI is to uniquely identify both healthcare provider *individuals* (eg, general practitioners, pharmacists, pathologists) and healthcare provider *organisations* (eg, hospitals, pharmacies and pathology laboratories). Healthcare Provider Individuals are assigned a unique HPI-I number by the HI Service and Organisations are assigned a unique HPI-O number.

National Authentication Service for Health (NASH)

In addition to accurate identification of healthcare providers, there will also be a requirement to authenticate their identity, i.e. to confirm they are who they say they are, in order to support electronic processes such as prescribing which currently requires a paper-based form and signature.

This functionality such as authentication and digital identity management will be delivered by the National Authentication Service for Health.

For more information about the National Authentication Service, refer to **http://www.nehta.gov.au/connecting-australia/nash**

Clinical information specifications and terminologies

Healthcare practitioners capture and record clinical information about their patients, to provide a history of care to support decisions on continuing clinical care and to share with other clinicians involved in the care of the patient. The ability to record the information accurately and in a standardised, semantically unambiguous format is critical to the process of accurate exchange and safe consumption. A standard clinical terminology, in conjunction with standard data structure specifications can provide clinical data with both consistent meaning and context, enabling entry, storage and communication of clinical information in ways that allow it to be safely and consistently reused, retrieved and processed by different software applications.

Through consultation NEHTA has developed a range of reusable detailed clinical models (DCMs) and structured content specification (SCSs) for supporting standardised clinical documentation and information exchanges. In contrast to the national minimum datasets currently used for statistical reporting, these DCMs and SCS specifications provide a comprehensive set of clinical information structures, that is sufficient to support complex clinical documentation, including reporting results of diagnostic investigations, and which can be specialised or constrained where required.

In 2005 Australian Health Ministers endorsed NEHTA's recommendation that the Systematised Nomenclature of Medicine- Clinical Terms (SNOMED CT[3]) should be adopted nationally. SNOMED CT is a clinical terminology which can be used to uniquely identify clinical concepts and their associated synonyms and relationships between concepts. Its purpose is to assist in unambiguous clinical documentation and information exchange by providing a consistent language that is both human-readable and computer-processable. NEHTA has established the National Clinical Terminology and Information Service (NCTIS) to centrally maintain, update and distribute the Australian extension of SNOMED CT (SNOMED CT-AU[3] also see the SNOMED CT-AU **FAQ**s[4])and NEHTA's clinical information specifications. SNOMED CT-AU is based on SNOMED CT with some additional Australian content and customisation as required to support Australian requirements. The customisation includes creation of reference sets (subsets of content also known as refsets) and selection of relevant synonyms as the Preferred Term for Australia.

The International Health Terminology Standards Development Organisation (IHTSDO[5])[3] has entered into a collaborative arrangement with the World Health Organization (WHO) which will provide mappings and linkages from SNOMED CT to the International Classification of Diseases (ICD) codes (a classification system supports epidemiology and statistical reporting). Phase 1 of this project produced mappings from 9,500 SNOMED CT concepts to ICD-10 codes. Phase 2 of this project aims at mapping 110,000 ICD-10 concepts to SNOMED CT. Within Australia, the SNOMED CT-AU Emergency Department Reference Sets were developed based on a set of ICD-10-AM (Australian Modification of ICD-10) codes for ED reporting.

NEHTA is also developing mapping of SCS contents to standard exchange formats (such as HL7 Clinical Document Architecture, CDA) and implementation guides.

The Australian Medicines Terminology (AMT) is the national standard for the identification of medicinal concepts and medicinal products approved for use in Australia. This terminology is available to support prescribing, , dispensing, administration of medications and transfer of such information within and between Australian e-Health applications.

As part of the transition to electronic health systems, the need for an accessible standard terminology to uniquely identify and describe the medicines available in Australia for computers, clinicians and patients is essential. AMT has been created to provide:

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[3] "IHTSDO®, SNOMED® and SNOMED CT® are registered trademarks of the International Health Terminology Standards Development Organisation."
[4] SNOMED CT-AU FAQs [REF10]
[5] IHTSDO Website [REF11]

- a standard code for identifying branded and generic medicines; and
- standard naming conventions to accurately describe medicines.[6]

For more information about the clinical information specifications, refer to **http://www.nehta.gov.au/connecting-australia/terminology-and-information/clinical-information-mi**

And;

http://www.nehta.gov.au/connecting-australia/terminology-and-information

This page includes information on:

- Exchange Specifications
- Structured Content Specifications
- Detailed Clinical Models
- Other Implementation Advice

Personally Controlled Electronic Healthcare Record System (PCEHR)

The primary purpose of the PCEHR will be to support the delivery of safer and higher quality health care. The PCEHR will contribute to this by improving the availability, quality and sharing of selected healthcare information to support clinical decision making. Secondary uses of the PCEHR include public health and policy planning, and supporting safety initiatives, disease detection, research and education.

Participation in the PCEHR will be voluntary. The PCEHR will maintain a longitudinal record of structured healthcare information for participating individuals. The PCEHR will, with the patient's agreement, be accessible from multiple points of care and will maintain a high standard of privacy and security. The PCEHR is designed to record key facts about participants (such as current medications, allergies and alerts, problems, etc.) and to make them accessible to all those involved in providing care to the individual. Copies of clinical documents (such as discharge summaries, pathology results, radiology reports and other event summaries) may also be stored and be accessible to authorised users via the PCEHR services whenever and wherever required.

For more information about the PCEHR, refer to **http://www.nehta.gov.au/ehealth-implementation/what-is-a-pcher**

[6] AMT FAQs (page 04_09) [REF09]

Standards Map

The Standards Map lists standards and specifications that those developing and implementing an Australian Clinical Quality Registry should be aware of. It is not intended as a proscriptive list of standards that every registry must comply with. Given the scope and purpose of a given Australian Clinical Quality Registry a varying subset of these standards may be relevant.

ⓘ The standards listed here are current at the time of writing (2012). It is recommended that you check the current status, and version where applicable, for any given standard.

♦ Overview

The number of clinical registries in Australia has grown markedly in recent years as has interest in the establishment of new clinical registries to ensure quality in the provision of health care. To date there is no single standard or shared methodology for the development, establishment and ongoing management of clinical registries. Clinical registries in Australia vary in their purpose, design, scale, and scope and as such there is little continuity in their design.

The *Infrastructure Overview* and *Technical Standards* recommended by NEHTA will have varying degrees of application at different stages of development, dependent on the maturity of each individual registry. For example, a small local registry with a paper-based data collection entered into a Microsoft Excel or Microsoft Access database in a non-networked computer will have very different needs to a large international registry that uses a browser-based user interface to collect information and electronically cross-checks information for validity in real time with external data collections.

To enable those individuals and agencies responsible for clinical registries to easily navigate and apply the infrastructure, specifications and standards developed by industry, standard organisations and NEHTA the below map divides registries into four levels of maturity. Level 4 represents the most mature and conformant repository, Level 1 refers to the least mature repository. These levels have been determined by the level of technology and standards utilised in the collection, storage, cleansing, quality checking, analysis and reporting of data.

The following matrix (Table 1) provides an overview of the standards map noting the NEHTA-relevant specifications and standards as well as their applicability to each level of registry (levels 1–4). Whilst this may identify some standards as optional in some settings, this will always be a value-judgement which needs to be considered in the context of future capacity or plans to expand the scope, nature or purpose of the registry.

This standards map has been organised based on the NEHTA domains. For each domain a list of the recommended standards is provided. Each specification or standard (or grouping of) is documented with the following sections containing content applicable to the proposed architecture:

- Overview
- Motivation
- Usage criteria
- Comments (where applicable).

The majority of the content for the Overview, Motivation and Comment sections has been taken from the Standards Catalogue on the NEHTA web site (**http://www.nehta.gov.au**).

The Usage Criteria has been tailored to be applicable to clinical registries and describes how the document relates to Australian Clinical Quality Registries. Only those standards with some relevance to Australian Clinical Quality Registries have been included.

ⓘ The table below lists the identified standards and specifications for use within Clinical Quality Registries. For further information on which specific standards and specifications have been identified please see the relevant section below the table.

Relevant standards	NEHTA recommended standards and technical specifications	Level 4	Level 3	Level 2	Level 1
Interoperability Framework (eg. Architecture)	Interoperability Framework 2.0	Recommended	Recommended	Optional	Optional
	eHealth Interoperability Framework	Recommended	Recommended	Optional	Optional
	Unified Modelling Language v2.0	Recommended	Recommended	Not required	Not required
	TOGAF	Recommended	Recommended	Optional	Optional
	Information Technology – Open Distributed Processing	Recommended	Recommended	Optional	Optional
Clinical Communications	Terminology	Required	Required	Required	Recommended
	Data Specifications	Required	Required	Required	Required
	HL7 Messages	Required	Required	Not required	Not required
	Datatypes ISO/IEC 11404	Required	Required	Required	Required
	ISO 21090	Required	Required	Optional	Optional
Healthcare Identification	Healthcare Provider Identification	Required	Required	Required	Required
	Health Care Client Identification	Required	Required	Optional	Optional
Identity Management	NESAF	Recommended	Recommended	Optional	Optional
	NASH	TBA	TBA	TBA	TBA
	OASIS eXtensible Access Control Markup Language (XACML) TC	Optional	Optional	Optional	Optional
	OASIS Security Services (SAML)	Optional	Optional	Optional	Optional
Secure Messaging	Web Services	Recommended	Recommended	Not required	Not required
	XML	Recommended	Recommended	Recommended	Not required
Supply Chain (where applicable)	Supply Chain	Required (where relevant)	Required (where relevant)	Required (where relevant)	Recommended (where relevant)
Engagement & Adoption	Understanding Standards	Optional	Optional	Optional	Optional
	CGOI and Communication Technology	Recommended	Recommended	Optional	Optional

Table 1. Technical standards overview

E-health interoperability

NEHTA has identified a number of standards pertinent to ensuring the interoperability of Australian Clinical Quality Registries. These include:

- Interoperability Framework v2.0
- eHealth Interoperability Framework
- Unified Modelling Language v2.0
- TOGAF Version 9
- Information technology – Open Distributed Processing.

Interoperability Framework v2.0

Overview

The Interoperability Framework (IF) is a common reference point that provides guidance to business and IT experts in delivering interoperable e-health systems in Australia – while allowing for the evolutionary and emergent aspects of business, policy and technology. The IF2.0 can serve as a toolset for the design phases of a registry and helps ensure that appropriate standards are identified and implemented.

Version 2.0 provides a number of extensions, refinements and guidelines for applying the interoperability approaches and concepts to e-health systems, including enterprise architecture, certification principles and interoperability maturity model.

Motivation

The Interoperability Framework is developed to promote a shared understanding about different aspects of e-health system and for various e-health stakeholders involved. This understanding is enabled through interoperability concepts and patterns, addressing separate, but related aspects of e-health systems i.e., organisational, informational and technical aspects.

The IF includes a methodology, which emphasizes a disciplined approach in delivering fit-for-purpose systems, where specifications play an important role, providing a bridge between requirements and conformant systems.

Usage criteria

The IF concepts and patterns can be used within various e-health projects and jurisdictions to deliver specifications for e-health systems based on clearly stated organisational, informational and technical requirements. These specifications will need to include definition of conformance points to facilitate certification of implementations against specifications. The IF concepts and patterns are valuable tools in delivering downstream enterprise architectures at national, State, Territory or domain levels.

eHealth Interoperability Framework

Overview

The eHealth Interoperability Framework provides a shared language for defining business context for eHealth systems, designing eHealth solutions and supporting standards-based conformance processes. The aim is to provide an increasing level of semantic interoperability both between humans involved in designing and building systems and between eHealth systems.

The framework was developed in response to the National eHealth strategy with the aim of supporting national alignment and coordination, in terms of co-existence of national and local solutions while balancing regulation and competition/innovation.

The framework adopts the approach of the HL7 Service Aware Interoperability Framework (SAIF) and the earlier versions have been used to structure NEHTA specifications, in particular the ETP and PCEHR specifications. NEHTA is now further validating this framework to support tool-based development of its specifications.

Motivation

The framework thus provides a set of concepts, principles and approaches needed to support the building of cross-jurisdictional and cross-organisational eHealth solutions at both the local and national level. It includes a set of recommended document types and can be used to supplement existing enterprise architecture frameworks in cases when eHealth organisations require building solutions that span organisational boundaries, such as eDischarge, eReferrals, eMedications and reporting of clinical findings.

Usage criteria

It describes a common approach to delivering interoperable eHealth solutions for use within the eHealth environment by promoting shared conversation among the following stakeholders groups:

- eHealth specification and standards developers – providing architecture foundations for building interoperable systems
- system and software vendors - to ensure delivery of interoperable eHealth infrastructure and eHealth solutions
- system integrators – to integrate new and existing systems
- system testers – to ensure that the vendor solutions are of high quality and satisfy specifications.

Unified Modelling Language v2.0

Overview

UML is used for constructing and documenting the artefacts of distributed object systems and is a set of specifications published by the Object Management Group (OMG). UML can be used to describe requirements for building a system, model structural and behavioural relationships between components in a software system and support the expression of business process models.

Motivation

UML has become a de facto modelling notation used for describing business requirements, structural and behavioural models constituting architecture of software systems. UML plays a central role in many software development methodologies.

Usage criteria

UML can be used as a modelling notation to represent different architecture modelling concepts proposed by the NEHTA Interoperability Framework, as well as Enterprise Architecture and Solution Architectures.

UML 2.0 is based on better semantic foundation allowing more precise expression of modelling concepts such as UML activity diagrams. Therefore, NEHTA recommends UML 2.0 (in preference to UML 1.4.2) for use as a modelling notation.

TOGAF Version 9

Overview

TOGAF is an architecture framework — The Open Group Architecture Framework. TOGAF provides the methods and tools for assisting in the acceptance, production, use, and maintenance of an enterprise architecture. It is based on an iterative process model supported by best practices and a re-usable set of existing architecture assets.

There are four main parts to the TOGAF document:

- *PART I – Introduction*: This part provides a high-level introduction to the key concepts of enterprise architecture and in particular the TOGAF approach. It contains the definitions of terms used throughout TOGAF and release notes detailing the changes between this version and the previous version of TOGAF.
- *PART II – Architecture Development Method*: This part is the core of TOGAF. It describes the TOGAF Architecture Development Method (ADM) — a step-by-step approach to developing an enterprise architecture.
- *PART III – ADM Guidelines and Techniques:* This part contains a collection of guidelines and techniques available for use in applying TOGAF and the TOGAF ADM.

- *PART IV – Enterprise Content Framework*: This part describes the TOGAF content framework, including a structured metamodel for architectural artifacts, the use of re-usable architecture building blocks, and an overview of typical architecture deliverables.
- *PART V – Enterprise Continuum & Tools*: This part discusses appropriate taxonomies and tools to categorize and store the outputs of architecture activity within an enterprise.
- *PART VI – TOGAF Reference Models*: This part provides a selection of architectural reference models, which includes the TOGAF Foundation Architecture, and the Integrated Information Infrastructure Reference Model.
- *PART VII – Architecture Capability Framework*: This part discusses the organization, processes, skills, roles, and responsibilities required to establish and operate an architecture function within an enterprise.[7]

Motivation

The Open Group Architecture Framework (TOGAF) is an open standard that provides a technology neutral framework for developing enterprise architectures, covering the constituent business, information systems and technical architectures, while providing guidance for the architecture deployment and governance.

TOGAF can be tailored for the needs of specific industries or sectors such as e-health. NEHTA's tailoring of TOGAF includes the use of the NEHTA Interoperability Framework concepts as an architecture description language for building interoperable systems. This combination provides a powerful basis for long-term evolution of enterprise architectures in the Australian e-health environment in spite of technological, business, regulatory or legislative changes.

Usage criteria

TOGAF can be used to develop Enterprise and Solution Architectures for various e-health segments, within or across organisational or jurisdictional boundaries. NEHTA has chosen TOGAF as a vehicle for facilitating a disciplined and consistent approach to architecture development for national e-health infrastructure with which NEHTA is tasked. The NEHTA Interoperability Framework provides a set of modelling concepts essentially forming an architecture description language for national e-health infrastructure developments.

Comments

In order to achieve the highest degree of e-health alignment and effective engagement among stakeholders within the Australian e-health environment, NEHTA recommends the adoption of TOGAF for respective enterprise architecture developments.

[7] TOGAF9M (Page 4) [REF03]

The use of TOGAF and UML in combination can allow for the mapping of business processes, technology components, documents, definitions, etc. to a source standard, with the UML traceability better understanding of the effect of changes to standards.

Information technology – Open Distributed Processing

Overview

The following documents provide detail on understanding and applying Open Distributed Processing (ODP) as specified in the ISO/IEC 10746 group of standards:

- ISO/IEC 10746-1:1998 Information Technology - Open Distributed Processing - Reference Model: Overview - Part 1
- ISO/IEC 10746-2:1996 Information Technology - Open Distributed Processing - Reference Model: Foundations - Part 2
- ISO/IEC 10746-3:1996 Information Technology - Open Distributed Processing - Reference Model: Architecture - Part 3
- ISO/IEC 10746-4:1998 Information Technology - Open Distributed Processing - Reference Model: Architectural Semantics - Part 4
- ISO/IEC 15414:2006 Information Technology - Open Distributed Processing - Reference Model - Enterprise Language

Motivation

There is currently a lack of an existing precise framework for modelling enterprise aspects of open distributed systems, which is of great relevance for cross-organisational and cross-jurisdictional nature of e-health systems in Australia. The ODP-EL (enterprise language) provides a generic framework, yet with a sufficient precision, needed for the organisational perspective of the Interoperability Framework.

These standards provide a technology-independent architecture framework, supporting the ‘separation of concern’ principle, which allows for the specification of complex systems from different viewpoints. It has a high level of precision commensurate with the formalism adopted (and which exploits constructs from different standardised formal description techniques). Over the years, ISO/IEC 17046, as a standardisation framework, has influenced development of a number of specific industry standards such as OMG and OASIS.

Usage criteria

NEHTA recommends compliance with these specific standards when describing the organisational roles, processes, policies and communities as a context for positioning computing systems and other technology solutions in support of delivery of healthcare services.

The modelling concepts, structuring rules and architecture principles from these standards can be used to provide architecture specifications of complex systems, from different viewpoints and in a technology-neutral manner. The standards also provide a clear conformance and compliance framework that can be used for various certification purposes, which has been leveraged within the NEHTA Interoperability Framework.

Clinical communications

NEHTA has identified a number of clinical models and structured content specifications pertinent to clinical communications for Australian Clinical Quality Registries. These cover:

- Data specifications
- Terminology Data exchange
- Datatypes
- ISO 21090

Data specifications

Overview

NEHTA has developed a suite of data specifications (e.g. DCMs and SCS) to standardise various clinical concepts to form structured clinical documents. These data specifications are intended for use at point of care. NEHTA is working with the Australian Institute of Health and Welfare (AIHW) to ensure data specifications are consistent with the National Minimum Data Set (NDMS) and metadata in MeTEOR (the Metadata Online Registry). For further information about the AIHW and MeTEOR, refer to the AIHW website at **http://www.aihw.gov.au**.

The library contains both:

- *Data Specifications* for particular health topics i.e., foundation 'data groups' such as problem/diagnosis, clinical intervention, adverse reactions; and
- *Content Specifications* for structured clinical documents such as discharge summary and referral, which make use of the foundation data groups.

As of Early 2012, the list of data specifications includes:

- NEHTA Discharge Summary
- NEHTA eReferral
- NEHTA ePrescription
- NEHTA Prescription Request
- NEHTA eDispense Record
- NEHTA Shared Health Summary
- NEHTA Event Summary
- NEHTA MBS/DVA Repository

- NEHTA ACIR Repository
- NEHTA PBS Repository
- NEHTA AODR
- NEHTA Consumer Entered Hs
- NEHTA Consumer Entered Notes
- NEHTA Advanced Care Directives
- NEHTA Consolidated View
- NEHTA Allergies & Adverse Reactions V3.0
- NEHTA Medications Action V3.0
- NEHTA Action V3.0
- NEHTA Instruction V3.0
- NEHTA Problem/Diagnosis V3.0
- NEHTA Requested Services V3.0
- NEHTA Lab Test Results V2.0
- NEHTA Diagnostic Imaging Result V2.0
- NEHTA Anatomical Location V3.0
- NEHTA Participation Data Specifications V3.3

ⓘ It is recommended that readers confirm the currency of the above recommended data specifications when applying them to clinical registries to ensure they are up to date by checking the Standards catalogue on the NEHTA website:
http://www.nehta.gov.au/standards-catalogue

Motivation

The DCM specifications can be used by system designers to implement level 4 (semantic) interoperability in the Australian health care setting. Semantic interoperability means that the information exchanged by different computer systems can be interpreted by both computer applications and human users.

Usage criteria

NEHTA specifications are aimed at standardising the information structure and language used to name and describe clinical concepts, and to provide the appropriate contextual constraints, hence avoiding potential ambiguity in clinical statements. They are not intended to be software or messaging design specifications. Instead, they represent the clinical information requirements for data collection and information exchange required for facilitating safe and effective continuity of care across health care sectors e.g.., General Practice and Acute Care.

It is recommended that these specifications will be used in conjunction with other NEHTA-provided specifications such as the Australian Medicines Terminology (AMT) and other SNOMED CT-AU-based clinical terminologies.

Where applicable or relevant these specifications should be applied in in data design for storage in a clinical registry.

Terminology

Overview

SNOMED CT-AU is a comprehensive granular clinical reference terminology. The terminology can be used to standardise and codify clinical concepts in clinical documentation and information exchange. It provides an extensive list of clinical terms including diseases, examinations, procedures, results and anatomical structures. Each concept and its descriptions have numerical identifiers that computers can understand and reason with.

The Australian Medicines Terminology (AMT) is a standard terminology for use within Australia to define and describe medicinal concepts and products. It contains the products listed on the Schedule of Pharmaceutical Benefits.

The AMT delivers standard identification of branded and generically equivalent medicines and their components. It also provides standard naming conventions and terminology to accurately describe medications. AMT is intended for use by medication management applications, in both primary and secondary health care.

It is recommended that readers view the up to date Standards catalogue on the NEHTA website: **http://www.nehta.gov.au/standards-catalogue**

Motivation

NEHTA is responsible for defining a national approach to clinical terminology, to support the efficient and accurate electronic recording and exchange of clinical information across the health sector. Essential to this work is access to SNOMED CT-AU and the AMT. These terminologies will assist stakeholders in adopting standard terminologies in software applications used to capture, store and exchange clinical information.

Usage criteria

These terminology specifications should be applied to relevant clinical data captured for storage in a registry.

Access to this material is limited to those holding license agreements managed by NEHTA:

- The SNOMED CT Affiliate License Agreement for access to SNOMED CT Core; and
- The Australian National Terminology Release License Agreement to provide access to extensions and derivatives supplied by NEHTA.

Data exchange

Overview

Defines how Australian healthcare organisations implement Health Level Seven standard (HL7) (selected 2.x versions and/or CDA) for communication of patient administration and clinical information. Australia currently uses HL7 version 2.x for data exchange. However, NEHTA has recommended and supports the move to HL7 Clinical Document Architecture (CDA). These exchange standards are suitable for use within Australian public and private healthcare organisations.

The clinical content specifications provide guide for consistent use of data definitions as well as commentary and references to the International Organization for Standardization (ISO) and the National Health Data Dictionary.

The list of recommended messages can be found on the NEHTA website on the following URL: **http://www.nehta.gov.au/**

Motivation

Standardised messages support independent system vendors developing interoperable interfaces. NEHTA has endorsed HL& CDA as exchange format standards because of its capability to support exchange of semantically interoperable, clinically rich and complex data. NEHTA also works with its eHealth stakeholders on HL7 v2.x standards because they are currently in use in a number of different sites in the Australian health care environment and are consistent with the direction recommended in the *Standards for E-Health Interoperability v1.0, 08/05/2007*.
NEHTA's recommendation for the use of these standards is on an interim basis. As discussed above, the future direction recommended by NEHTA is based on augmenting and adopting the capability of a document centric paradigm such as CDA.

Usage criteria

These standards should be used when transferring messages containing the relevant content from the capture systems to the registry storage systems. In general, the more recent versions of the standards are preferred. Older versions are used when interfacing with existing ICT systems that do not support the more recent versions of HL7 interfaces.

Datatypes

Overview

The ISO/IEC 11404 international standard specifies the nomenclature and shared semantics for a collection of datatypes commonly occurring in programming languages and software interfaces, referred to as the Language-Independent (LI) Datatypes. It specified both primitive datatypes, in the sense of being defined without reference to other datatypes, and non-primitive datatypes, in the sense of being wholly or partly defined in terms of other datatypes.

Motivation

These datatypes are foundational components that are used in many industries, not just health care. Standardising across industries will facilitate software developers and language-specific implementations to more readily interoperate without a requirement to introduce error-prone mappings.

Patient safety and the quality of data for decision support and secondary use depends on standardised and known representations of fundamental datatypes. The volume of systems potentially exchanging and processing information dictate such a requirement. Furthermore, e-health requires standardised additional compound datatypes such as quantities and special timing datatypes that need to be built from the standardised primitive datatypes described in ISO/IEC 11404.

Usage criteria

The data definitions used in the design of all the registry components, including data capture interfaces, databases and reporting, should be based on the datatypes in this standard.

Comments

ISO is currently considering a proposal for additional datatypes to meet the specific requirements of health care.

ISO 21090

Overview

ISO 21090:2011, Health Informatics – Harmonized data types for information exchange, is a comprehensive standard supporting the exchange of health information. It derives from ISO/IEC 11404, General purpose datatypes, and is designed to support the duel worlds of CEN 13606, EHR System Communication, as well as HL7 v3. HL7 International has pledged a move toward ISO 13606 as the future data type basis for HL7 standards.

Motivation

Data types are the fundamental building block for more complex expression of health concepts. Prior to 21090, there was no common data type work that bridges the worlds of HL7 and 13606/Open EHR. While not meeting the goal of a single unified data type, it did manage to bring along two of the major standards communities.

Usage criteria

There has been some resistance to 21090 as some consider it to be overly complex. This is somewhat inevitable given the complex stakeholder group. The standard is a foundation for data type work and may require profiling to make it useful for different domains of application.

Healthcare Identifiers

A number of health identifiers (HIs) have been under development and should be available and useful for Australian Clinical Quality Registries. These refer to both:

- Healthcare Provider Identification
- Client identification.

For further information, also refer to the Section on Healthcare Identifiers (HI).

Healthcare Provider identification

Overview

The AS 4846-2006 standard provides a framework for improving the positive identification of health care providers. The standard applies in respect of all providers of health care services to the Australian health care system. It defines demographic and other identifying data elements suited to capture and use for identification in health care settings and provides guidance on their application. It also makes recommendations about the nature and form of health care provider identifiers. It includes only the minimum dataset required for unambiguous identification. It is a generic set of identifying information which is application-independent.

The objective of this standard is to promote uniform good practice in:

- Identifying both individual and organisational health care providers;
- The recording of health care provider identifying data; and
- Ensuring that data being associated with any given health care provider, and upon which clinical communication and data aggregation are based, are appropriately associated with that individual or organisation and no other.

Motivation

This standard was used as a foundation standard for Healthcare Provider Identifier (HPI-I and HPI-O) data elements, process of information collection (recording) and data management (data matching and linking).

This standard is currently being used as the basis for capturing provider identity information in some jurisdictional systems.

Usage criteria

This standard should be used when recording identification and demographic details for a healthcare provider. This is relevant for both participation in Australian Clinical Quality Registries and to identify authorship of clinical data.

Client identification

Overview

The AS 5017-2006 standard provides a framework for improving the positive identification of clients in health care organisations. This standard applies in respect of all potential or actual clients of the Australian health care system. It defines demographic and other identifying data elements suited to capture and use for client identification in health care settings, provides guidance on their application, and provides an overview of data matching strategies. It also makes recommendations about the nature and form of health care identifiers.

Accordingly, this standard includes only the minimum dataset required for unambiguous identification. It is recognised that specific applications may require additional data to fulfil their purposes. The standard provides a generic set of identifying information, which is application independent.

Motivation

This standard is used by NEHTA as a foundation standard for the IHI system, particularly in the area of the implementation of client master indices and the use of appropriate and thorough searching techniques for the IHI system in ensuring that any existing client data will be linked to the relevant health care client.

This standard is currently being used as the basis for capturing client identity information in some jurisdictional systems.

Usage criteria

This standard should be used when recording identification and demographic details for a healthcare client. This is relevant for both participation in Australian Clinical Quality Registries and to identify the subject of clinical data.

♦ Identity management

Identity management involves ensuring that users only gain access to the information that they are entitled to view. Identity management (IdM) can be regarded as an integrated system of policies, processes and technologies that allow organisations to facilitate and control users' access to applications and information while protecting confidential personal and business information from unauthorised users.

NEHTA has identified a number of standards pertinent to identity management for Australian Clinical Quality Registries. These include:

- National eHealth Security and Access Framework
- National Authentication Service for Health (NASH)
- OASIS eXtensible Access Control Markup Language (XACML) TC
- OASIS Security Services (SAML) TC v2.0.

In addition to these standards, it is pertinent to note that standards for Security Techniques, such as ISMS ISO/IEC17799, ISO/IEC27002 or AS/NZS ISO/IEC 27002:2006, could also be usefully consulted. This standard provides best practice recommendations on information security management for use by those who are responsible for initiating, implementing or maintaining information security management systems. Information security is defined within the standard as the preservation of confidentiality (ensuring that information is accessible only to those authorised to have access), integrity (safeguarding the accuracy and completeness of information and processing methods) and availability (ensuring that authorised users have access to information and associated assets when required). For further information refer to the Implementer Blueprint as part of the National eHealth Security and Access Framework section.

National eHealth Security and Access Framework

Overview

The NESAF document framework comprises a suite of documents designed to provide specific views of the NESAF for business, clinical, technical and consumer audiences.

The third revision of the framework concentrates on the following:

- Core Framework
- Business Blueprint
- Implementer Blueprint
- Framework and Controls
- Standards Mapping

The NESAF development team will be seeking further engagement on the guides as well as exploring the additional guides discussed during the workshops held in October and November 2011.

Motivation

Some of the key benefits of the NESAF for use in the Australian eHealth environment include:

- Promotion of a consistent, risk-based approach to eHealth security and access.
- Consistent interpretation of relevant standards for application in the Australian eHealth environment.
- Provision of a holistic view of security and access requirements within an organisation that includes controls that are implemented at a business-, healthcare-, information technology- and eHealth-specific levels, with a greater focus and detailed guidance provided in relation to eHealth-specific controls.

- Contemporary better practice guidance on specific eHealth security and access practices.
- A document suite that provides different views on the framework for different audiences – business, clinical, technical and consumer.

It is expected that broad application of the NESAF within healthcare organisations will contribute to engendering trust within the national eHealth system, thus increasing adoption and uptake of these systems and maximising the expected benefits from these investments.

Usage criteria

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- Promotion of a consistent, risk-based approach to eHealth security and access.
- Consistent interpretation of relevant standards for application in the Australian eHealth environment.
- Provision of a holistic view of security and access requirements within an organisation that includes controls that are implemented at a business-, healthcare-, information technology- and eHealth-specific levels, with a greater focus and detailed guidance provided in relation to eHealth-specific controls.
- Contemporary better practice guidance on specific eHealth security and access practices.
- A document suite that provides different views on the framework for different audiences – business, clinical, technical and consumer.

It is expected that broad application of the NESAF within healthcare organisations will contribute to engendering trust within the national eHealth system, thus increasing adoption and uptake of these systems and maximising the expected benefits from these investments.[8]

National Authentication Service for Health (NASH)

Overview

The National Authentication Service for Health (NASH) is a foundation component of NEHTA's overall programme of work to deliver Australia's first nationwide secure and authenticated service for healthcare organisations and personnel to exchange e-health information. The NASH technology will ensure there is a standardised way for medical practitioners across Australia to strongly assert their identity and electronically sign documents so that all digital transactions remain encrypted and private.

[8] NESAF (Executive Summary) [REF04]

It will provide capability that simplifies healthcare interaction, whilst ensuring that e-health transactions are private, traceable and only conducted by known (and trusted) identities, based on established Healthcare Identifiers.

Motivation

NASH provides the required strong authentication of healthcare providers and organisations, and is an important foundation service in the developing e-health community. It will:

1. Establish a national supply of trusted digital credentials available to all entities in the health sector, allowing the traceability of e-health transactions to trusted identities;

2. Allow healthcare communities to issue and manage authentication credentials locally, supported by national infrastructure;

3. Provide a governance approach that would allow health sector participation in the operational policies and services NASH would develop;

4. Support software vendors to transition their products to use nationally-recognised digital certificates; and

5. Provide sufficient flexibility to leverage investment from organisations such as Medicare Australia.

Usage criteria

The NASH program of work will result in the establishment of a set of national authentication services intended to be used by healthcare provider organisations and e-heath infrastructure service operators. For example, the HI service uses NASH services to issue HI credentials to the healthcare individuals and organisations who request them and the following systems use NASH services to find and validate NASH credentials:

- Access control systems
- Client server applications
- Enterprise applications
- Identity management systems
- Messaging applications
- Operating systems
- Single Sign On
- Web applications
- Web services applications

OASIS eXtensible Access Control Markup Language (XACML) TC

Overview

The OASIS XACML (Extensible Access Control Markup Language) v2.0 open standard is an XML-based language designed to express security policies and access rights to information for Web services, digital rights management, and enterprise security applications. XACML was developed to standardise access control through XML so that, for example, a worker can access several affiliated Web sites with a single logon. XACML is sometimes referred to as Extensible Access Control Language (XACL).

XACML was designed to work in conjunction with Security Assertion Markup Language (SAML), another OASIS standard.

Motivation

The area of standardised access control in Web services is still relatively new and there is no mature solution currently available. As a maturing access control standard XACML promises the desired mix of a standard way of defining access rights along with compatibility with other OASIS standards such as SAML.

Usage criteria

Registries should use XACML to define their access policies for user and system access to registry functions and data.

OASIS Security Services (SAML) TC v2.0

Overview

The OASIS SAML (Security Assertion Markup Language) v2.0, developed by the Security Services Technical Committee of OASIS, is an XML-based framework for communicating user authentication, entitlement, and attribute information. As its name suggests, SAML allows business entities to make assertions regarding the identity, attributes, and entitlements of a subject (an entity that is often a human user) to other entities, such as a partner company or another enterprise application.

Motivation

SAML is an XML-based framework for communicating user authentication, entitlement, and attribute information from a trusted source to a relying party. As such it can be used to distribute identity information to multiple services allowing for the construction of flexible and scalable identity regimes.

Usage criteria

SAML should be used to minimise the number of times users will need to authenticate while interacting with the many different registries and infrastructure components. Each separate component and registry should be designed to accept and trust previously established authentication, entitlement, and attribute information.

Secure messaging

NEHTA has identified a number of standards pertinent to secure messaging for Australian Clinical Quality Registries. These include:

- E-health Web Service Profiles
- E-health XML Secure Payload Profiles
- E-health Secure Message Delivery
- Endpoint Location Service

E-health Web Service Profiles

Overview

This Technical Specification defines profiles of the SOAP Web services specifications. It defines a base set of specifications for Web services, so that interoperable Web services can be defined for e-health. It also defines profiles for securing the Web services transport.

This Technical Specification does not define any service interfaces. The profiles in this document can only be implemented when there is a service interface specification, but this document does not define any. Each service interface is defined to meet a specific set of requirements, and it is outside the scope of this document to know what those requirements might be. Instead, these profiles provide a set of mechanisms that the service interface author can use to meet their particular requirements.

Motivation

The profiles defined in this Technical Specification have been designed with the goal of achieving interconnectivity between implementations using Web services toolkits. Compared to the Web services specifications and other Web services profiles, it provides details that improve interconnectivity.[9]

E-health XML Secure Payload Profiles

Overview

This Technical Specification defines mechanisms for representing signed XML data and encrypted XML data.

The profiles in this Technical Specification are designed for data represented as XML. If data is not in XML, it will need to be converted to an XML format before it can be used with these profiles.

[9] E-health web service profiles (page 4) [REF05]

This Technical Specification defines four profiles:

1. Signed Container Profile
2. Encrypted Container Profile
3. XML Signature Profile
4. XML Encryption Profile

Motivation

This Technical Specification contains conformance points that define the format of XML Secured Payloads. The format directly implies certain obligations for programs that create XML Secured Payloads or consume XML Secured Payloads, but explicitly defining those obligations is outside the scope of this Technical Specification.

Usage criteria

This Technical Specification does not specify when these mechanisms are used—that is the responsibility of the organizations that use this Technical Specification. Signing and encrypting are mechanisms for obtaining different security properties: authentication, integrity, confidentiality and non-repudiation. It is outside the scope of this Technical Specification to determine the levels of security an application requires and whether these mechanisms are suitable for that application. Security also depends on a number of external factors, such as key management and policies, which are also outside the scope of this Technical Specification. [10]

E-health Secure Message Delivery

Overview

This Technical Specification defines a set of roles and their associated interfaces and behaviour. The intent of these interfaces and behaviour is to support the transmission of electronic messages between software systems at two distinct organizations.

Motivation

To enable a flexible and viable secure messaging environment to support e-health, a standards based approach has been adopted. NEHTA's secure messaging specifications will align with existing standards where applicable or NEHTA will collaborate with standards organisations to develop new standards where needed.

Usage criteria

The specification has a number of key constraints, notably:

1. The specification is intended for transmission of messages from a sender to an identified receiver. The specification is not intended to provide repository capability or to deliver messages to an unknown, to-be-nominated recipient.

[10] E-health Secure Message Delivery (page 6) [REF06]

2. The specification does not constrain the message payload, defining only the control and routing information necessary to transmit the message in a safe and secure manner.
3. The specification does not attempt to capture the business processes or business services of the parties, defining only the externally visible behaviour necessary to implement interconnected messaging.

While it is expected that the Secure Message Delivery mechanism will have many applications, these constraints should be considered when determining if this specification is suitable for a particular purpose.

Endpoint Location Service

Overview

An Endpoint Location Service (ELS) is a simple directory of technical services. In the short term, these services will be Web services facilitating message/document exchange. However, an ELS implementation could allow clients in the e-health community to locate any electronic service offered by healthcare provider organizations.

ELS can facilitate any kind of electronic service resolution, but is primarily used for determining how to transfer clinical documents. It allows a message producer (source) to transfer its message to an intended recipient (target), even if the producer has no prior knowledge of the method chosen by the recipient to handle such a transfer.

Information required to perform an ELS lookup includes the target healthcare organization and kind of message.

Motivation

Endpoint Location Service (ELS) usage will be a key process in the national e-health environment. An application attempting to establish communications with some service can use an ELS to dynamically discover the service implementation.

Usage criteria

Services resolvable through the ELS are not restricted, however in the short term it will be used to facilitate the exchange of clinical documents. Other scenarios can be realized by extending service Interface types and their associated semantics. ELS interfaces need not change simply because new kinds of services are deployed in the future. For example, an ELS could be implemented to resolve the endpoints of other ELS instances or to resolve services that return disclosure statements, quality of service agreements, organizational charters, etc. [11]

[11] Endpoint Location Service (page 8) [REF08]

Supply chain

Overview

Where a clinical quality registry may record information about materials and products, possibly including medical devices and pharmaceuticals, it may be appropriate to adopt standards relating to supply chain information.

These documents provide the architecture for the e-procurement solution at the business and technical levels:

- NEHTA 0090:2007 E-Procurement Business Architecture v1.0
- NEHTA 0088:2007 E-Procurement Technical Architecture v1.0
- NEHTA 0131:2007 Addendum to NEHTA's E-Procurement Technical Architecture v1.0
- NEHTA 0091:2007 E-Procurement WSDL v1.0

The E-Procurement Business Architecture document specifies the organisational roles and processes in the e-procurement community. It also explains how the e-procurement solution's technical and informational perspectives are related to the organisational roles and processes.

The E-Procurement Technical Architecture document provides the technical architecture detailing the paradigm of interactions between the three roles in e-procurement: buyers, hubs and suppliers. It also explains the technical requirements in the implementation of Web Services for e-procurement.

The E-Procurement WSDL is a zip archive that provides WSDL and XSD files for use with the E-Procurement Technical Architecture v1.0. These Web services interfaces can be implemented by buyers, suppliers and e-procurement hub service providers when implementing the exchange of e-procurement business documents i.e., an e-procurement solution.

Motivation

NEHTA recommends the use of these standards to understand the e-procurement solution. This document can be used by e-procurement hub service providers, buyers and suppliers in implementing an e-procurement solution.

Usage criteria

Registries that record products (for example, device or implant registries) will ideally interact with the National Product Catalogue (NPC) to ensure effective unique product identification. These standards will guide the use of the NPC and the design of the interfaces with the NPC.

For more information about the Supply Chain, refer to **http://www.nehta.gov.au/connecting-australia/e-health-procurement**

Engagement and adoption

NEHTA has identified a number of issues or standards pertinent to engagement and adoption for Australian Clinical Quality Registries. These include:

- Understanding standards and
- Corporate governance of ICT.

Understanding standards

Overview

HB 107-1998 explains the concept of standardization and assists readers of Australian Standards and other similar documents in their use and understanding of these documents.

Motivation

Standards must be properly understood to ensure effect use. Therefore, this handbook assists in the selection and use of standards.

Usage criteria

NEHTA recommends this handbook to assist with all standards implementation activities such as adoption, uptake and implementation.

Corporate governance of ICT

Overview

AS 8015-2005 provides guiding principles for Directors of organizations (including owners, board members, Directors, partners, senior executives, or similar) on the effective, efficient, and acceptable use of Information and Communication Technology (ICT) within their organisation.

The standard applies to the governance of resources, computer-based or otherwise, used to provide information and communication services to an organisation. These resources could be provided by ICT specialists, within the organisation or external service providers, or by business units within the organisation.

Motivation

The guiding principles this standard provides for effective, efficient, and acceptable use of ICT within an organization can be applied to all organisations regardless of size and extent of ICT use.

Usage criteria

NEHTA encourages suppliers, developers, purchasers and implementers to assess their own governance structures and planning activities and identify the best way to implement the standards endorsed by NEHTA. NEHTA recommends the use of this particular standard to guide organisations with their reviews.

Comments

This standard was recommended for use in Supporting National E-Health Standards Implementation – Adoption, Uptake and Implementation published by NEHTA on the 02/02/2007.

Glossary

ACSQHC	Australian Commission on Safety and Quality in Health Care
AGAF	Australian Government Authentication Framework
AIHW	Australian Institute of Health and Welfare
AMT	Australian Medicines Terminology (AMT) – a planned national extension of SNOMED CT-AU for use within information systems within Australia.
audit	An examination or review that established the extent to which a condition, process or performance conforms to predetermined standards or criteria.[1] Audits may be carried out on the provision of care, compliance, community response and completeness of records.
benchmark	A slang or jargon term, usually meaning a measurement taken at the outset of a series of measurements of the same variable, sometimes meaning the best or most desirable value of the variable.[1] A standard or point of reference.
bias	Deviation of results or inferences from the truth, or processes leading to such deviation. Any trend in the collection, analysis interpretation, publication or review of data that can lead to conclusions that are systematically different from the truth.[1]
CDA	Clinical Document Architecture – an XML-based markup standard for specifying the encoding, structure and semantics of clinical documents for exchange. Part of the HL7 standard. Also see HL7.
clinician	A health professional whose practice is based on direct observation and treatment of a patient, as distinguished for other types of health workers, such as laboratory technicians and those employed for research.
clinical quality registry	Organisations that routinely collect health-related information on the quality, safety and outcome of care provided to individuals who are: • treated with a particular procedure, device or drug, • diagnosed with a particular illness, or • managed via a specific health care resource, e.g. treated in an intensive care unit.
CRE PS	NHMRC Centre of Research Excellence in Patient Safety, Monash University
Guideline	A formal statement about a defined task or function. In the terminology developed by the European Community, directives are stronger than recommendations, which are in turn stronger than guidelines.
HL7	Health Level Seven (HL7), is an all-volunteer, not-for-profit organisation involved in development of international healthcare standards. HL7 is also used to refer to some of the specific standards created by the organisation.

HPI	Healthcare Provider Identifier – for both individual providers (HPI-I) and for provider organisations (HPI-O). Also see UHI.
HTTP 1.1	HyperText Transfer Protocol 1.1 – a communications protocol for the transfer of information on the Internet.
HTTPS	Hypertext Transfer Protocol over Secure Socket Layer – indicates a secure HTTP connection; a communications protocol for the transfer of information on the Internet with enhanced security compared with HTTP.
ICD-10	International Statistical Classification of Diseases and Related Health Problems, Tenth Revision
ICD-10-AM	International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification
IdM	Identity Management
IEC	Institutional Ethics Committee
iEHR	Individual Electronic Health Record. Now known as Personally Controlled Electronic Health Record (PCEHR).
IHI	Individual Healthcare Identifier – a unique identifier for users of health care. Also see UHI.
ISO	International Organization for Standardization
MeTEOR	Metadata Online Registry – Australia's repository for national data standards for health, housing and community services statistics and information.
Minimum data set	A widely agreed upon and generally accepted set of terms and definitions constituting as core data acquired for medical records and employed for developing statistics suitable for diverse types of analyses and users.[1]
MTOM	Message Transmission Optimization Mechanism – a method of sending binary data to and from web services.
National Health Data Dictionary	The national metadata standards for the health sector are published in the National Health Data Dictionary by the Australian Institute of Health and Welfare.
NCRIS	National Collaborative Research Infrastructure Strategy
NEHTA	National E-Health Transition Authority
NHMRC	National Health and Medical Research Council
NMDS	National Minimum Data Set
NPC	National Product Catalogue
OASIS	Organization for the Advancement of Structured Information Standards (**http://www.oasis-open.org/home/index.php**)
ODP	Open Distributed Processing
OMG	Object Management Group – a consortium, originally aimed at setting standards for distributed object-oriented systems, focused on modelling (programs, systems and business processes) and model-based standards.
PBS	Pharmaceutical Benefits Scheme
PCEHR	Personally Controlled Electronic Health Record

quality of care	A level of performance or accomplishment that characterises the health care provided. Ultimately, measures of the quality of care always depend upon value judgements, but there are ingredients and determinants of quality that can be measured objectively. These ingredients and determinants have been classified by Donabedian into measures of structure (staff, facilities), process (diagnostic and therapeutic procedures) and outcome (fatality rates, disability rates, level of patient satisfaction).
record linkage	A method of bringing together the information contained in two or more records – e.g. in different sets of medical charts, and in vital records such as death certificates – and a procedure to ensure that each individual is identified and counted only once. Record linkage makes it possible to relate significant health events that are remote from one another in time and place or to bring together records of different individuals, e.g. members of a family.
register	The file of data concerning all cases of a particular disease or other health-relevant condition in a defined population such that the cases can be related to a population base. With this information, incidence rates can be calculated. If the cases are followed up, information on remission, exacerbation, prevalence and survival can also be obtained.
SAML	Security Assertion Markup Language – an XML-based standard for exchanging authentication and authorization data between security domains, i.e., between an identity provider (a producer of assertions) and a service provider (a consumer of assertions)
SNOMED CT	Systematised Nomenclature of Medicine- Clinical Terms
SNOMED CT-AU	The Australian Localisation of SNOMED CT
SOAP 1.2	A protocol for exchanging XML-based messages over computer networks, normally using HTTP/HTTPS.
standard	Something that serves as a basis for comparison; a technical specification or written report drawn up by experts based on the consolidated results of scientific study, technology and experience aimed at optimum benefits and approved by a recognised and representative body.
TOGAF	The Open Group Architecture Framework – a framework for Enterprise Architecture providing a comprehensive approach to the design, planning, implementation, and governance of an enterprise information architecture.
TOGAF ADM	The Open Group Architecture Framework Architecture Development Method
UHI	Unique Healthcare Identifier, see IHI and HPI
UML	Unified Modelling Language – a standardised general-purpose software engineering modelling language. UML includes a set of graphical notation techniques to create abstract models of specific systems, referred to as UML model.

validity (study)	The degree to which the inference drawn from a study, warranted when account is taken of the study methods, the representativeness of the study sample, and the nature of the population from which it is drawn. Two varieties of study validity are distinguished: internal validity and external validity (generalisability).
validity measurement)	An expression of the degree to which a measurement measures what it purports to measure. Several varieties are distinguished, including construct validity, content validity, and criterion validity (concurrent or predictive validity).[1]
WSDL 1.1	Web Services Description Language – an XML-based language that provides a model for describing Web services.
XACL	Extensible Access Control Language. See also XACML
XACML	Extensible Access Control Markup Language – a declarative access control policy language implemented in XML and a processing model, describing how to interpret the policies.
XML	Extensible Markup Language – a general-purpose specification for creating custom markup languages. It is classified as an extensible language as it allows its users to define their own elements. Its primary purpose is to help information systems share structured data, particularly via the Internet.
XOP	XML-binary Optimized Packaging – a convention for serialisation of XML Infosets that have a mix of binary and textual data, and, more generally for storing binary data in XML tags.

Reference List

Reference Number	Resource Name	Details
REF01	Interoperability Framework 2.0	http://www.nehta.gov.au/connecting-australia/ehealth-architecture
REF02	eHealth Interoperability Framework 1.0	http://www.nehta.gov.au/component/docman/doc_download/1404-ehealth-interoperability-framework-v10
REF03	The Open Group Architecture Framework	http://www.opengroup.org/togaf/
REF04	National eHealth Security and Access Framework	https://www.ehealthcollaborate.com.au/
REF05	ATS 5821-2010: E-health web Service profiles	http://www.nehta.gov.au/connecting-australia/secure-messaging
REF06	ATS 5821-2010: E-health XML Secure Payload Profiles	http://www.nehta.gov.au/connecting-australia/secure-messaging
REF07	ATS 5822-2010: E-health Secure Message Delivery	http://www.nehta.gov.au/connecting-australia/secure-messaging
REF08	TR 5823-2010: Endpoint Location Service	http://www.nehta.gov.au/connecting-australia/secure-messaging
REF09	AMT FAQs	http://www.nehta.gov.au/connecting-australia/terminology-and-information/clinical-terminology/australian-medicines-terminology
REF10	SNOMED CT-AU FAQs	http://www.nehta.gov.au/component/docman/doc_download/1150-SNOMED CT-au-faqs
REF11	The International Health Terminology Standards Development Organisation Website	http://www.ihtsdo.org/