Readers should be aware that this document was largely developed in 2008. Due to the nature of technology and technical standards it is likely that some of this material is no longer current. Readers should not rely solely on the information in this document and should investigate the current status of any standard or other information.
Operating principles 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). They have also benefited from external consultation and input from a range of clinicians, speciality groups and registry custodians. They have also 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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Clinical registers are databases that systematically collect health-related information on individuals who are:

- treated with a particular surgical procedure, device or drug, e.g. joint replacement;
- diagnosed with a particular illness, e.g. stroke; or
- managed via a specific healthcare resource, e.g. treated in an intensive care unit.

Clinical quality registers are a particular subset of clinical registers (Figure 1). The purpose of a clinical quality register is to improve the safety or quality of health care provided to patients by collecting key clinical information from individual healthcare encounters which enable risk-adjusted outcomes to be used to drive quality improvement. Clinical quality registers can provide the most suitable and accurate method of providing monitoring and benchmark data and, where applicable, offer the greatest potential to improve health care performance across institutions and providers. Clinical quality registers should be focused 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.

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

Figure 1. Clinical registers and clinical quality registers

Clinical 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 interoperability 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 operating principles and technical standards for Australian Clinical Quality Registries. These are registers that are:

- (potentially) national in coverage; and
- primarily focussed on supporting improvement in 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 registers 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 outlines a series of guidelines for the operation of Australian Clinical Quality Registries designed to help them achieve these goals.

Their purpose is to:

- Provide a means of improving existing clinical registers and enhancing the value of the information they provide;
- Provide guidance for the establishment and maintenance of new Australian Clinical Quality Registries aiming to measure quality of care; and
- Suggest a best practice model to which both new and existing Australian Clinical Quality registries should adhere.

Audience

The operating principles and technical standards are aimed at assisting those involved with or contemplating the development of clinical registries. This document is designed to assist:

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

Using this document

This document sets out the technical standards that an Australian Clinical Quality Registry should consider in their development and operation. There is a companion document describing the Operating Principles that should be used to govern the structure, governance and operations of Australian Clinical Quality Registries. This document does not set out how a registry should be developed or operated.
The two documents are complementary and highly inter-related. Use of the technical standards makes the attainment of many of the operating principles more readily achievable.

This document is composed of two sections:

- **Architecture Overview** – describes the architecture relevant to Australian Clinical Quality Registries. This includes a discussion of the ideal longer term national e-health environment and how Australian Clinical Quality Registries figure in such a landscape. There is also the shorter term view, also including suggested national infrastructure to enhance the sustainability and efficiency 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.

Readers should be aware that this document was largely developed in 2008. Due to the nature of technology and technical standards it is likely that some of this material is no longer current. Readers should not rely solely on the information in this document and should investigate the current status of any standard or other information.
This *Architecture Overview* describes:

- the short-term approaches which can realistically be implemented immediately to increase the consistency and value of information stored in clinical registries; and
- a longer term vision of a new approach to clinical 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.

The proposed new approach would provide significant efficiencies in data collection, accuracy and analysis through elimination of duplication, collection of more complete and accurate data and in increased ability to utilise data for research and statistical analysis.

**Infrastructure**

This section contains discussion of the following:

- NEHTA infrastructure
- Clinical registry infrastructure
- Application of this Architectural Overview

**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 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.

Unique Healthcare Identifiers (UHI)

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 Medicare Australia are developing both an individual healthcare identifier and a healthcare provider identifier.


(1) Individual healthcare identifier (IHI)

The IHI service will provide the facility to uniquely identify an individual for healthcare purposes and will link them correctly to their health information.

① 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 recognized across the entire healthcare sector.

The IHI 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.

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 (e.g., general practitioners, pharmacists, pathologists) and healthcare provider organisations (e.g., hospitals, pharmacies and pathology laboratories). The HPI service provides the ability to verify the provider is registered and authorised, and improve the reliability of manual and electronic communications between providers.

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. NEHTA is proposing a strong authentication system which will be achieved by applying digital identity management approaches.

Clinical information specifications and terminologies

Healthcare practitioners capture and record clinical information about their patients, to provide a history of care for ongoing clinical care and to share with other clinicians involved in the care of the patient. The ability to record the information in a standard and accurate format is critical to the process of its safe exchange. A standard clinical terminology, in conjunction with standard data 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 structured documents and re-useable data group specifications for use in care delivery. In contrast to the national minimum datasets currently used for statistical reporting, these specifications provide a comprehensive dataset and generic clinical information structure, that is sufficient to support clinical complexity, such as that encountered when reporting results of diagnostic investigations, and which can be specialised or further constrained where required.
In 2005 Australian Health Ministers endorsed NEHTA’s recommendation that the Systematised Nomenclature of Medicine, Clinical Terms (SNOMED-CT) should be adopted nationally. SNOMED-CT is a clinical terminology which uniquely identifies clinical concepts and their associated synonyms and relationships. Its purpose is to assist in the care of the patient by providing a consistent language that is both human-readable and computer-processable.

NEHTA has established the national service required to centrally maintain, update and distribute the national clinical terminology and clinical information specifications, including customisation of the terminology to meet Australian needs. Local extensions will be developed in line with the SNOMED-CT standard. Where local variations in terms exist, these will be mapped or linked to the core reference terminology.

Work is in train in Australia and internationally to develop mappings between terminologies and the classifications (such as the International Classification of Diseases) that are used in health statistics.

NEHTA is also working to develop specifications for standard exchange formats (HL7 and/or CDA, as appropriate).


**Individual Electronic Healthcare Record services**

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

Participation in the Individual EHR will be voluntary. The Individual EHR will maintain a longitudinal record of structured healthcare information for participating individuals. The Individual EHR will, with the patient’s agreement, be accessible from multiple points of care and will maintain a high standard of privacy and security. The Individual EHR 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 Individual EHR services whenever and wherever required.

NEHTA is currently collaborating with Australian, State and Territory Governments to develop a business case for a national approach to Individual EHR, which will be submitted to the Council of Australian Governments (COAG) in 2008. Assuming the business case is adopted, the Individual EHR will be progressively implemented in a number of urban and regional areas over the next five to ten years.

Australian Clinical Quality Registry infrastructure

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 Architecture 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 the architecture and standards developed by NEHTA and determine their applicability registries have been divided into four registry types (Figure 2). These types have been determined by the level of technology utilised in the collection, storage, cleansing, quality checking, analysis and reporting of data. Australia currently has registries representative of all four types. These are as follows:

1. Level 1: Stand-alone registry.
   - Paper-based submission of data to the registry; and
   - Data entry into a stand-alone computer system for analysis and reporting.

2. Level 2: Web-based submission of data into the registry.
   - Allows some or all contributors to submit data to the registry electronically via web browser user interface, this may be combined with paper-based reporting.

3. Level 3: Web-based submission of data into the registry and electronic cross-checking of data or linkage of data with an external system.
   - Allows some or all contributors to submit data to the registry electronically via web browser user interface, this may be combined with paper-based reporting; and
   - Cross-checks data with external sources for validity (either in real time or after data entry), or
   - links with external systems to link data.
4. Level 4: All level 3 plus automatic data collection from local clinical systems.

- Local clinical system is the primary vehicle for data collection, relevant data is either automatically sent or prompted to be sent to the relevant registries.

![Diagram of Registry Levels](image)

**Figure 2. Registry categories**

An alternate classification, based on functionality, could also be developed.

**Application of Architecture Overview**

Application of the architecture to clinical registries is expected to occur over time. NEHTA has developed both a short-term and a medium to long-term architecture to accommodate the Australian Clinical Quality Registries timelines and to account for the varying levels of technical maturity for Australian clinical registries.

The short-term architecture recommends the creation of a common registry portal and applying a more standards-based approach to the individual registries with technology choices and design that will migrate to a better interconnected e-Health system in the future. The level of technical maturity achieved by a clinical registry will determine the extent to which the standards will need to be applied. Although some registries in Australia are quite technically mature and may be classified as Level 4, the recommended short term architecture is independent of the individual registries and can be applied to all levels.

The medium to long-term architectural vision would cater for clinical registries at all levels and is intended to prompt thinking and discussion about the way clinical registries operate and the long-term goals of registries in an ideal environment.
It would be unrealistic to attempt this scale of change for all registries in the short term. The proposed short-term architecture has been specifically designed to be realistic in the short term but allowing migration to the longer term vision. The short-term architecture acknowledges the fact that currently clinical registries often begin as a small stand-alone database and develop into large, highly sophisticated systems. Some of the more mature registries may be ready to adopt additional aspects of the longer term architecture sooner, and could look to leverage components of the national e-health infrastructure as they become available.

**Short-term architecture**

This section proposes the first steps in changing the approach taken to clinical registries. It is designed to be achievable in the short term. The aim is to make improvements where possible in a way that allows subsequent progression in the direction of the vision.

The longer term vision is characterised as a national approach supported by national infrastructure that:

1. assembles the many different registries together under a consistent portal for the convenience of individual providers; and
2. applies a standards-based discipline to improve sustainability.

The short-term architecture recommends a National Portal providing a very basic, and therefore achievable, directory of registries. This national infrastructure is a placeholder where the more sophisticated functions of the vision can be added over time.

The short-term architecture also recommends applying a more standards-based approach to the individual registries with technology choices and design that will migrate to a better interconnected e-Health system in the future.

**Constraints**

In Australia clinical registries have been established in a variety of health care settings for a range of purposes over time. This has resulted in a large number of registries that have differing organisational, informational and technical processes. These variations constrain what can be immediately achieved through implementation of the short-term architecture.

The following are the main constraints that determine what may be achievable in the short to medium term:

- National registries currently lack a shared national infrastructure and standards that would enable them to harness benefits emerging from the implementation of e-health. The main issue in temporarily filling the gaps is to ensure it is done in a way that can be migrated to the national infrastructure in the future. Note some of this national infrastructure will be provided through the NEHTA work program – of particular relevance is the NEHTA work on identifiers, data specifications and terminologies.
The current approach to achieving direct system interfaces between the source, capture systems and the registry systems is costly and unlikely to be sustainable in the long term. Establishment of these interfaces is on a point by point basis and the stability of the systems and the quality of the data capture (mainly due to static, non-extensible software and unconstrained user interfaces) causes significant operational overhead. Again, NEHTA’s current work on web services and secure connectivity is of relevance and may provide alternative mechanisms for connectivity.

Web browser user interfaces generate double data entry environments.

Browser user interfaces are only better than paper-based systems as the quantity and complexity of data capture increases. For very simple data capture sticky printed labels (found in abundance in hospital settings) containing most of the relevant details and stuck on a paper form along with marking some checkboxes can literally take a few seconds to complete. This process leads to high quality data capture with minimal error. With barcode scanners this efficiency and quality can also be achieved at the point of central data entry into the system.

Browser user interfaces can improve data quality as the data capture is closer to the proximity and time of the event. It is, however, much harder for central data entry staff to clarify and/or correct data captured on paper forms (kilometres away and/or weeks ago).

Browser user interfaces generally require compensation to offset the overhead imposed in a clinical setting. This compensation could be business value, additional resources, monetary, etc.
National infrastructure

The national infrastructure envisioned by NEHTA includes:

- a national portal for Australian Clinical Quality Registries
- e-health infrastructure elements that NEHTA is developing that are relevant to Australian Clinical Quality Registries.

National registries portal

A directory of registries is a new element of infrastructure recommended by NEHTA. It will act as a single point of contact between the individual providers and the national registries. The directory (Figure 3) would be set up as a National Portal or website which provides basic details and links as a convenience for individual providers and would be a reliable mechanism to expose the existence of registries to the individual providers who perform the critical task of data capture.

Individual providers would go to the National Portal to:

1. Determine what registries may be appropriate for a particular care event.
2. Review provider participation and patient consent requirements.
3. Review the required data capture and download the latest printable forms.
4. Navigate to the individual portal of any registry.

Figure 3. National registries portal

NEHTA suggest that this is a key element of the short-term architecture. However, it is not funded as part of NEHTA’s work program, and a relevant body would need to seek funding for its establishment.
**NEHTA infrastructure**

Other elements of the short-term architecture are already planned as part of national infrastructure development through the existing NEHTA work program. In particular, the following national infrastructure services are scheduled to come on-line by the end of 2010, and should be leveraged to provide short to medium term value for registries:

- Individual Healthcare Identifier (IHI)
- Healthcare Professional Identifier – Individual (HPI-I)
- Healthcare Professional Identifier – Organisation (HPI-O)
- National Product Catalogue (NPC)
- Clinical Terminologies (SNOMED/AMT) and Data Specifications
- NEHTA Standards Catalogue.

Each of these areas has published recommended standards that can be used in system design and development to ensure compatibility with the national infrastructure and alignment to the NEHTA direction. Standards Map lists the applicable standards in each of these areas along with specific usage criteria for Australian Clinical Quality Registries.

Regardless of whether data capture is paper or electronic-based, the use of these data sources as soon as possible will increase the efficiency and effectiveness of registry data capture and analysis.

**Data capture**

There are three major options for data capture:

- Paper collection;
- Direct entry into a registry portal via electronic form; and
- Direct entry into CIS and integrated simultaneous (or near real-time) update of registry portal.

Some existing registries allow contributors to submit data using one of a number of methods. There is also an option for batch update from the local clinical system to the registry. However, this approach can lead to difficulties associated with lack of standardisation and delayed submission. Some registries have also developed data collection and submission software for local data providers to use. Such systems can be useful in incorporating data entry validation and quality checks while also ensuring standardised collection and submission of data. However, such an approach can be expensive and time-consuming and may only be effective in complex areas where large-scale de novo collection of data is necessary.
One of the key issues facing registries today is to ensure that data captured by any of these methods is consistent. Collection fields on paper and electronic forms need to be consistent. Data fields and specifications used for registry design should be consistent with the emerging standards for data entry into other clinical information systems and electronic health records systems. These standards are being developed by NEHTA and include the use of agreed data specifications and clinical terminologies (SNOMED CT). Although they will align with the existing data standards, minimum data sets (NMDS) and classifications (such as ICD10) recommended by the Australian Institute of Health and Welfare (AIHW) for statistical data sets wherever possible, there may be differences, because data used for clinical care is more extensive and granular than data used for 'secondary purposes'. NEHTA and AIHW are undertaking work in this area to explain the distinctions, and appropriate use of these standards.

For the short term, paper capture of registry data at the point of care may still be the preferred and/or optimal method for data collection in certain cases. NEHTA is not recommending that wholesale change to electronic capture is the best approach in the short term, and the short-term architecture for registries includes paper capture as well as browser capture for data. Integrated data capture through clinical systems at the point of care is unlikely to be achievable in many cases until the introduction of more sophisticated systems within hospitals and community practices is further advanced. Registries need to be vigilant for opportunities for direct capture, as opportunities need to be assessed and included early in the design or implementation phases of new IT system roll-outs.

The most appropriate method will depend on the quantity and type of data captured for the registry, but in any case there is expected to be local preferences and constraints that will lead to use of the sub-optimal method and so it is proposed that both paper capture and electronic capture are made available, at least in the short to medium term.

The architecture also allows for direct system to system connectivity. As more sophisticated clinical systems are implemented in the health sector in the coming years, these systems will be expected to communicate seamlessly, and the NEHTA work on the Individual EHR will pave the way for this improvement in interoperability. But in the short term, system to system connectivity is expected to be problematic due to the lack of standards and the (in)flexibility of the local clinical systems. There are a few existing examples of data capture applications with a high degree of context sensitive validation which are already providing a valuable direct data source for registries (such as the AORTIC application developed by ANZICS). However, in general, direct system to system connectivity is hampered by the lack of clear, agreed business processes for exchange of information, the lack of adherence to national information standards, and the delays imposed by batch submission of data to the registry which can lead to a number of practical difficulties for data quality and completeness.
System to system connectivity is more easily achieved at a micro level, where data is then aggregated up to a macro level. Unfortunately, in Australia clinical registries currently do not have consistent organisational governance structures to allow effective and efficient national aggregation of multiple repositories. It is hoped that national collaboration to establish an Individual EHR will need to address and answer many of these issues – including development and assessing compliance with required standards.

As shown in Figure 4, the optimal use of paper-based capture involves a smaller number of simple data fields that can be barcoded and scanned. This method is especially attractive where the content can be obtained from sticky labels (as commonly used in hospitals). The labels make capture at the point of care extremely efficient and accurate. The use of barcodes makes central data entry also efficient and accurate.

**Figure 4. Paper-based data capture**

Where the data set involves a larger number of complicated fields, direct browser entry via a web-form at the point of care is expected to be the preferred method unless level 4 integration with the local clinical system can be achieved. This is particularly preferred as identification and correction of errors can be performed within the context (timeframe, staff and location) of the care event. Correcting errors at this point (as opposed to a week later at a central facility in another city by data entry staff) is far more efficient and successful.

The major draw back of the direct data entry is the overhead imposed in the care setting. Use of barcode scanning will also provide benefit during direct browser entry.
National registries portal

A directory of registries is a new element of infrastructure recommended by NEHTA. It will act as a single point of contact between the individual providers and the national registries. The directory would be set up as a National Portal or website which provides basic details and links as a convenience for individual providers and would be a reliable mechanism to expose the existence of registries to the individual providers who perform the critical task of data capture. The following sections provide further details.

Provider participation

Individual providers will need to identify themselves and agree to the terms and conditions of participating in a registry. This function will accept provider credentials, record their agreement and enable access to the registry.

Longer term, it will be ideal if the HPI was used to identify the individual providers and the National Identity Management infrastructure was used to validate their credentials.

In the short term, a number of local identifiers will need to be supported and demographics collected. Medicare Australia certificates could be used to authenticate individual providers for the purposes of registration and also subsequent logins. Alternatively, there may need to be a manual step to authenticate the identity of individual providers during registration.

To enable transition from the short term to the use of the HPI, it is important that multiple identifiers (such as a hospital identification number and others numbers, such as Medicare or Veterans Affairs number) are supported for a single individual provider. Not only will this help manage the many disparate identifiers in use today, it will allow the addition of the HPI more readily when it becomes available. The demographics collected should also align to the minimum needed by the HPI service to perform a unique search. For further information on minimum standards for identifiers, refer to the Standards Map section.

To assist with maintaining unique identifiers, the local identifiers will support the addition of a namespace prefix. Once an identifier is associated with an individual provider, it can be used to identify the provider to any of the registry functions.

The individual provider will be supplied with login credentials to access the registry functions. Once the Identity Management infrastructure is in place, these registry specific credentials can be retired and the national credentials used to access all registries.

Patient consent

Individual providers will be responsible for gaining and recording patient consent. This process may also record the identity of the patient. This process would be supported either via paper or directly via the browser.
Longer term, it will be ideal if the IHI was used to identify the patient, thereby allowing confidence in the aggregation of longitudinal patient-centric data to maintain currency of the required data and/or to collect outcome data.

In the short term, each register will need to allocate a new patient identifier and support the searching functions to allow providers to find existing patient identifiers to reduce duplicates.

The registry will need to support the use of multiple identifiers, qualified with a namespace to allow linkage between other data sources and to simplify inclusion of unique identifier when it becomes available.

To support patient privacy, the identifiers kept in the registry may point to an independent external party that is custodian of linkages to other data sources. This may also apply for linkage to the IHI for certain de-identified registries.

**Registry events**

Individual providers will be responsible for collecting the required registry data. Assuming consent has been confirmed and/or gained, this will involve filling out the data as specified by the registry, either via paper or direct browser entry.

Over time, all captured data should be captured and coded in a standardised fashion according to national standards i.e. with agreed terminology (SNOMED/AMT) being used to populate standardised data sets (NEHTA data specifications, AIHW, etc.). For further details refer to the Standards Map section.

The data which relates to an entity should also be identified via a standardised unique identifier, including identifying the Individual Providers involved (HPI), the Patient (IHI), and the products used (NPC).

In the short term, each register will need to publish (via the National Registry Portal) a comprehensive guide to encourage individual providers to collect consistent and coded data. The guide will need to contain clear descriptions of each field, unambiguous definitions of the data values, and a list of the applicable codes.

The difficulty in transitioning to use national standards is that the transition will impact the historical integrity of the existing data captured. This is generally handled by conversion of historical data, generic real-time mapping from older versions to the current version, or a combination of both. All approaches can introduce errors and all approaches impact on the resource usage/profile of the system. Early adoption of these standards, specifically SNOMED, AMT, NPC, and the data specifications, while increasing short-term cost and requiring fine tuning, would reduce the potential disturbance at some point in the future.
Report requests

Individual providers will need convenient access to information derived from their data capture efforts. Registries should optimally support:

- Online requests for reports which are returned to the provider while they wait.
- Scheduled reports to be generated periodically and automatically sent to the provider.

The available reports will need to include two types of reports:

1. Reports that contain analysis of the data contributed by the individual provider (requester). These reports may contain identified data.
2. Reports that compare aggregated data (e.g., benchmarks) between the individual provider (requester), peer groups, regions (e.g., states) and nationally (or even internationally).

Reports will need to support some customisation, via the collection of pre-determined parameters that are used to generate the report. Typically these parameters will be report-specific and include, date ranges, filter criteria, and sort criteria.

Design considerations

The following sections describe some of the design considerations that should be borne in mind when developing a registry.

Authentication

The short-term architecture does not address the issues around consistent login credentials for access to the registries. Each registry has the potential to issue the individual provider with a separate set of credentials. At a minimum each registry should allow individual providers to select their own passwords, PIN codes, etc so they can achieve some consistency between registries. In addition, assuming multiple identifiers are supported for all registries, the individual provider may be able to use one of their identifiers consistently across all of them, until they have a HPI.

It is also expected that individual providers will need to authenticate themselves multiple times throughout their day and from multiple locations. When multiplied across multiple registries and taking into account the many local systems they are required to access, this may create an unreasonable burden. A distributed approach to authentication could be considered which allows individual providers to gain a token that can be re-used until it expires. The OpenID framework is recommended for this purpose.

Secure messaging

Most interactions with a registry contain private information. These interactions need to be protected from intercept, access and modification. It is expected that the NEHTA Secure Messaging standards will be applied for all interactions between individual providers and the registries.
Application tiers

As shown in Figure 4, whether the individual provider is using paper or a browser, the data entry, and interaction with the system is likely to be via a browser. The user interface tier is likely to be via a web application user interface framework.

It is recommended that the user interface tier be built on top of a middle tier of web services. The web services would conform to the NEHTA Secure Messaging standard. The main advantage is that this middle tier supports the transition to direct connections with other systems, as shown in Figure 5.

It is expected that the database tier is based on a Relational Database Management System (RDBMS) product with access via Structured Query Language (SQL). However, irrespective of the product used, the key functionality is the ability to inter-connect.

![Figure 5. Application tiers](image)

It is possible that other channels may also be used, such as mobile devices, thick client over web services, integration with third-party applications, etc. The architecture will need to be flexible enough to support evolution of interfaces.
Long-term architectural vision

This section is intended to prompt thinking about the way clinical registries operate and the long-term goals of registries in an ideal environment. It is recognised that such a vision may not be achieved. It is unrealistic to attempt this scale of change in the short term. The proposed short-term architecture has been specifically designed to be realistic in the short term, but to also allow for migration to the longer term vision described in this section.

Business issues

NEHTA has identified that the two main business issues related to architecture currently facing clinical registries in Australia are:

1. Duplicate recording of clinical data (both for local use at point of care and separate capture repeated potentially across multiple registries) increases data captures errors and is resource intensive requiring skilled staff and their time.

2. The current system relies on the registry knowledge of each individual clinician that can lead to under-reporting or inappropriate reporting.

Vision overview

The long-term architecture vision (Figure 6) is specifically designed to tackle both of the identified business issues.

Figure 6. Long-term architecture overview
In Figure 6, the national infrastructure connects the individual providers, shown on the left, with the clinical registries, shown on the right. The national coordination components are logically central and represent central management of the functions. It is this central nature that addresses the first business issue of appropriately connecting the individual providers nationally with the many registries.

This, however, does not mean that the national coordination components all physically sit on a single national server. Ideally, selected components of the national infrastructure would be implemented in a distributed fashion.

The individual providers will use local clinical systems to perform the normal clinical data entry as required by the primary task of providing care to the patient. It will be the responsibility of these systems to prompt the individual providers when an event of patient care qualifies for entry into a registry (this may be the first defining registry event or follow-up to obtain outcome information). It will also be the responsibility of these systems to prompt the individual providers in an efficient manner to obtain any necessary consent and capture the necessary clinical data to be submitted into the registry. This addresses the guiding principle to minimise the impact on individual providers and automate tasks.

The clinical registries, shown on the right, would all interface with the national infrastructure, providing by default a consistent, single point of access. The national infrastructure will also support a standards-based approach to the implementation and management of the registries.

It is assumed here that registries will remain separate, purpose-built information stores. Registries may also gather data from many sources, including administrative datasets, the Individual EHR and non-clinical registries. There could be the capacity for a registry to notify the Individual EHR when the Individual EHR is missing data that may be uncovered during the consistency check processing. The submit processing may also copy registry events to the Individual EHR.

If analysis highlights that additional information is required, the registry can be augmented to store the additional information permanently or temporarily link to it from another source.

The following sections provide a more detailed description of the proposed national infrastructure components.

**Eligibility criteria and data specifications**

The primary responsibility of this component will be to publish and maintain the eligibility criteria and data specifications for each registry to the local clinical systems (Figure 7).

The eligibility criteria will be in a computer-processable form and will allow automated assessment of a patient event. Determination of whether any data needs to be captured for any of the registries will be based on:

- the individual provider and their role (for example either the treating provider or the pathologist reports the event – not both);
- the patient (for example demographics); and
Each registry entity will be responsible for maintaining the eligibility criteria and data specifications in this component. It is expected that this would be a manual task. Local clinical systems will automatically synchronise with this component to receive any updates.

The local clinical systems will automatically process each patient event (in real time) to determine if the event has registry implications. The local clinical system will notify the individual provider of the candidate registries that a patient event qualifies for. The local clinical system will then assist the individual provider to satisfy the registry requirements. This would include:

- Pre-filling the patient and individual provider demographic details required;
- Prompting the individual provider to collect the appropriate consent;
- Pre-filling any clinical data required from the data already captured;
- Prompting the individual provider to collect any clinical data gaps required by the data specifications for the registry; and
- If the registry was mandatory and the required data has already been captured, the local clinical system may be able to fulfil all the registry requirements without even interrupting the individual providers (workflow or attention).
**Patient consent and provider participation**

This component is responsible for ensuring the patient consent and participation of providers for each registry is recorded in a secure, consistent and appropriate way. This component will provide a centralised function that brokers the registration of patient consent and provider participation on behalf of each registry. The final acceptance of each request will be the sole responsibility of each individual registry (Figure 8).

![Figure 8. Long-term architecture – Participation](image)

The persistent storage of the record of consent/participation will be the joint responsibility of this component and each registry. This component will be the master record of the patient wishes/provider agreements and the registries will be the master of what they have individually accepted.

The local clinical systems will forward the collected consent/participation details to this central component which will provide authentication, audit, pre-qualification of conditions and non-repudiation services for the request providing proof of the data's origin and integrity. Successful requests to participate are then forwarded to the relevant registries for acceptance.

**Submitting events**

This component is responsible for providing authentication, audit and non-repudiation services and accepting (from the local clinical system) the required data to submit into a registry. The submission is forwarded to the relevant registries for acceptance (Figure 9).

This component will not retain any data other than an audit trail. The registries are solely responsible for storing the clinical data.
Figure 9. Long-term architecture – Event submission

This component will be distributed close to the data source end points. Submission will be directly to the registries and will not go through a central hub. The component may be implemented directly in local clinical systems or as part of the common infrastructure along side the local clinical systems.

**Reporting**

This component is responsible for providing a central point of access to the reporting capabilities of each registry. It will present a list of the applicable registries (that is those where the provider is registered) and provide authentication services. This provides convenient access to all the reports available to an individual provider (Figure 10).
Users will be able to request a report online or schedule reports to be sent to them. Online reporting will allow selection from the available reports, parameters, and output format. Scheduled reporting will allow selection from the available reports, parameters, preset frequencies (for example, weekly) and destination email address where the report will be sent.

This component is not responsible for executing the reports, the request for a report is sent directly to the registry and the response is returned directly to the user from that registry.

Where a registry has its own reporting portal, the user may be referred directly to it. In this case the user would then interact directly with the registry's own reporting portal and this component would simply be a single access or referral point.

It is expected that only the results of the reports will be accessible to the users and that they will not be able to access raw data. It is also expected that they will not only be able to print the reports, but they will be able to receive the results in a number of different formats (CSV, XML, MS Access, etc.).

**Linkage for checking consistency and completion**

This component is responsible for improving the quality of the registry content. It will provide data consistency and quality checking by comparing data in the clinical registries with each other and the following external sources, as shown in Figure 11:

- other registries (i.e., Births, Deaths and Marriages, National Death Index);
- the Individual EHR; and
- other sources of clinical and administrative data.
Figure 11. Long-term architecture – Checking linkages

This checking will be specific to each pair of compared data sources, for both the method of access to the data and the logic required to validate the consistency. Checking will occur both before and after submitting data to a registry.

Ideally, checking would be performed during data capture, or immediately before the event is actually submitted to a registry. This provides timely feedback to the provider while they are still able to efficiently correct any errors.

This component would be notified of the entered data and would then trigger a number of cross checks with other data sources. The logic may be executed centrally by this component or delegated to services provided by the registries themselves.

Any inconsistencies would ideally be sent back to the provider during data entry. For example, the identity of the patient is incorrectly entered and the provider is immediately notified that the identity specified is known to be deceased. The provider can correct the mistake before it even makes it to the registry.

It is important to ensure that data entry is not delayed if the consistency checks are not possible or can not be completed in time. This would normally imply that the checking is performed asynchronously.

Certain cross checking will need to be done in bulk/batch mode, where a large quantity of records is checked one-by-one against another set of records. In some cases full database scans may be required that would need the local registry infrastructure to execute the query and checking logic.
This type of cross checking would be scheduled in off-peak times and would not form part of the data entry process. For example, checking all the procedures performed in the last six months from a clinical registry against a payment database.

Linkage can also be used to check completeness of data held in the registry or to upload identified information into a registry. For example, an outcome registry that records information from multiple providers may benefit from uploading of certain identified data fields from a single point of collection such as the Individual EHR, as opposed to uploading duplicate data provided by multiple clinicians via a web upload or other type of submission.

**Unique Healthcare Identifier**

This component will be nationally provided infrastructure (independent of the registry infrastructure) to support the allocation of a unique identification number for all patients, individual health care providers and healthcare organisations.

The other components would use the Unique Healthcare Identifier (UHI) services to find the unique identifier for patients and health care providers and then use these identifiers internally to register providers and capture data against the correct patient.

For further information on UHI Services please refer to the NEHTA website: http://www.nehta.gov.au/connecting-australia/healthcare-identifiers

**Authentication, access control and secure messaging**

This component will be nationally provided infrastructure (independent of the registry infrastructure) to protect the security of the systems and exchanges of information. Services provided will allow authentication of users, assignment of privileges, and support to communicate clinical data between organisations and systems so that it cannot be tampered with or viewed along the way. The latter relates to Secure Messaging which will include a number of standards that are applied to the development of the interfaces.

An important part of electronic communications is that, in order to communicate with others you require knowledge of which parties and services are available for communication. All the services provided by the national infrastructure and each registry would be published in a Service Instance Directory (SID). This will be provided by this component.

The other components would use these services and apply the required standards to make sure only authorised Providers can contribute protected data about their identified Patients. In addition, Providers will only be able access data they have been authorised to access.

For further information on Identity Management please refer to the NEHTA website: http://www.nehta.gov.au/

For further information on Secure Messaging please refer to the NEHTA website: http://www.nehta.gov.au/connecting-australia/secure-messaging
Clinical communication

This component will be nationally provided infrastructure (independent of the registry infrastructure) to support the capture of clinical and product data in an unambiguous way.

In order to achieve interoperability, the use of structured data specifications, standardised terminology and codesets will ensure that clinical content from any of the data sources can be understood accurately by any of the providers and enable computer systems to understand and compare the content. This will require application and integration of data standards from numerous sources such as NEHTA (SNOMED CT, Clinical Information Data Standards), AIHW (National Health Data Dictionary).

Using a standardised National Product Catalogue (NPC) for medical product identification will ensure that the identification of products used in health care is associated with clinical context and individuals. This supports detection of faulty designs and batches due to outcome analysis and the identification of affected individuals.

The other components would use these services to make sure the clinical and product data is captured and stored in a standardised way that can be later analysed as required without error.

For further information on Clinical Communication please refer to the NEHTA website: http://www.nehta.gov.au/connecting-australia/terminology-and-information
Standards Map

The Standards Map lists standards that those developing and implementing an Australian Clinical Quality Registry should be cognizant of. It is not intended as a prescriptive 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 (2008). 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 Architecture 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 the architecture and standards developed by NEHTA and determine their applicability registries have been divided into four registry types (Figure 2). These types have been determined by the level of technology utilised in the collection, storage, cleansing, quality checking, analysis and reporting of data. Australia currently has registries representative of all four types. These are as follows:

1. **Level 1**: Stand-alone registry.
   - Paper-based submission of data to the registry; and
   - Data entry into a stand-alone computer system for analysis and reporting.

2. **Level 2**: Web-based submission of data into the registry.
   - Allows some or all contributors to submit data to the registry electronically via web browser user interface, this may be combined with paper-based reporting.
3. **Level 3**: Web-based submission of data into the registry and electronic cross-checking of data or linkage of data with an external system.
   - Allows some or all contributors to submit data to the registry electronically via web browser user interface, this may be combined with paper-based reporting; and
   - Cross-checks data with external sources for validity (either in real time or after data entry), or
   - links with external systems to link data.

4. **Level 4**: All level 3 plus automatic data collection from local clinical systems.
   - Local clinical system is the primary vehicle for data collection, relevant data is either automatically sent or prompted to be sent to the relevant registries.

An alternate classification, based on functionality, could also be developed.

The following matrix (Table 1) provides an overview of the standards map noting the NEHTA-relevant standards and their applicability to each type 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 standard (or group of standards) 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 website (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 from the NEHTA Standards Catalogue.

The standards documents can be downloaded from the Standards Catalogue on the NEHTA website which is available at: http://www.nehta.gov.au/standards-catalogue
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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
- Unified Modelling Language v2.0
- TOGAF “Enterprise Edition” v8.1
- 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.
Unified Modelling Language v2.0

Overview

constructing, and documenting the artefacts of distributed object systems. UML 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 “Enterprise Edition” v8.1

Overview

The Open Group Architecture Framework (TOGAF), Enterprise Edition is an architecture framework – a set of methods and tools for developing a broad range of different IT architectures. It enables IT users to design, evaluate, and build the right architecture for their organisation, and reduces the costs of planning, designing, and implementing architectures based on open systems solutions. There are four main parts to the TOGAF document:

► PART I – Introduction: This part provides a high-level introduction to some of the key concepts behind enterprise architecture and in particular the TOGAF approach.

► PART II – Architecture Development Method: This 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 – Enterprise Continuum: This part describes the TOGAF Enterprise Continuum, a virtual repository of architecture assets, which includes the TOGAF Foundation Architecture, and the Integrated Information Infrastructure Reference Model (III-RM).

► PART IV – Resources: This part comprises the TOGAF Resource Base – a set of tools and techniques available for use in applying TOGAF and the TOGAF ADM.
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.

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:


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 organizational 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 standardized formal description techniques). Over the years, ISO/IEC 17046, as a standardization 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 organizational 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 standards pertinent to clinical communications for Australian Clinical Quality Registries. These cover:

- Data specifications
- Terminology
- Data exchange
- Datatypes.

Data specifications

Overview

NEHTA has developed a suite of data specifications 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 mid-2008, the list of data specifications includes:

- NEHTA 0013:2006 Medication Data Specifications v1.0
- NEHTA 0032:2006 National Discharge Summary Data Content Specification v1.0
- NEHTA 0058:2007 General Practitioner and Specialist/Critical Care Referral Data Content Specifications v1.0
- NEHTA 0082:2007 Pathology Data Specification v1.0
- NEHTA 0093:2007 Diagnostic Imaging Data Specification v1.0
- NEHTA 0133:2007 Adverse Reaction Data Specification v1.0
- NEHTA 0134:2007 Alert Data Specification v1.0
- NEHTA 0135:2007 Clinical Intervention Data Specification v1.0
- NEHTA 0136:2007 Clinical Synopsis Data Specification v1.0
- NEHTA 0137:2007 Immunisation Data Specification v1.0
- NEHTA 0138:2007 Observation Data Specification v1.0
Standards Map

- NEHTA 0139:2007 Problems and Diagnosis Data Specification v1.0

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

These data 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 data specifications are aimed at standardising the information structure and language used to name and describe clinical concepts, and to provide the necessary contextual constraints to remove 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 i.e., General Practice and Acute Care.

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

These specifications should be applied when data is captured for storage in a registry that overlaps with any of the topics in the data groups or documents. It is expected that the data groups will be more applicable in the Registry setting than the clinical documents.

Terminology

Overview

SNOMED CT (Systematised Nomenclature of Medicine, Clinical Terms) is a comprehensive and precise clinical reference terminology. Terminology is used to populate data specifications. It provides an extensive list of clinical terms and identifiers that allows complex clinical concepts to be described in a way that computers can interpret. SNOMED CT operates at many levels including history, examination, provisional diagnosis, test results, and treatment.

The Australian Medicines Terminology (AMT) release is a national extension of SNOMED CT for use within information systems within Australia to define and describe medicines and related concepts. This release 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. The terminology is for use by medication management computer systems, in both primary and secondary health care.

As of mid-2008, the relevant terminology specifications are:

- NEHTA 0143:2007 Australian Medicines Terminology v1.0 – Data
- NEHTA 0144:2007 Australian Medicines Terminology v1.0 - UML Class Diagram v7.0
- NEHTA 0145:2007 Australian Medicines Terminology v1.0 - Editorial Rules v2.0

It is recommended that readers confirm the currency of the above relevant terminology 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**

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 and the AMT extension. These specifications will assist technical stakeholders in adopting standard terminologies in software applications used to store clinical information.

**Usage criteria**

These terminology specifications should be applied to all 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 the global Health Level Seven standard (for the various selected 2.x versions) for communication of patient administration and clinical information. Australia currently uses HL7 version 2 for data exchange. However, NEHTA has recommended and supports the move to HL7 Clinical Document Architecture (CDA). These specifications are suitable for use within Australian public and private healthcare organisations.
The clinical specifications provide 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 selected these 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 in the Standards for E-Health Interoperability v1.0 is based on 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.
Unique healthcare identifiers

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

- Provider identification and
- Client identification.

For further information, also refer to Unique Healthcare Identifiers (UHI) on page 8.

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) 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.
**Comments**

NEHTA has contracted Medicare Australia to design, build and test the Unique Healthcare Identification (UHI) service which includes the HPI and Individual Healthcare Identifier (IHI). To obtain an HPI, participants will need to be currently registered and have signed a participation agreement. Further details will be provided on the NEHTA website as the service is developed ([http://www.nehta.gov.au](http://www.nehta.gov.au)).

**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.

**Comments**

NEHTA has contracted Medicare Australia to design, build and test the Unique Healthcare Identification (UHI) service which includes the HPI and IHI. Further details will be provided on the NEHTA website as the service is developed ([http://www.nehta.gov.au](http://www.nehta.gov.au)).
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:

- Authentication Assessment Methodology v1.0
- Framework for Analysing, Planning and Implementing Identity Management v1.0
- Identity Management Resource Set
- Australian Government Authentication Framework
- ACSI 33
- Security techniques
- 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 Security techniques section.

Authentication Assessment Methodology v1.0

Overview

The Authentication Assessment Methodology describes a business process to be followed when attempting to establish authentication requirements for online healthcare transactions. It presents a risk-based approach which closely follows the structure of the Australian Government Authentication Framework (AGAF). For further information about AGAF, refer to Australian Government Authentication Framework on page 49.
**Motivation**

The purpose of this document is to provide healthcare organisations a single point of reference to use when analysing their user authentication requirements. The risk-based analysis helps identify the level of authentication required and assist with the selection of authentication mechanisms and implementation planning.

**Usage criteria**

The process outlined in this methodology should be applied when assessing authentication requirements for access to Australian Clinical Quality Registries.

**Framework for Analysing, Planning and Implementing Identity Management v1.0**

**Overview**

This document provides a framework to assist in the analysis, planning and implementation of Identity Management within healthcare systems. It identifies the issues that all healthcare providers and all E-Health infrastructural services will have to ‘agree upon’ in order to ensure security and trust across the E-Health Community, as well as technical and process robustness, and interoperability of identity and access elements across all stakeholders.

**Motivation**

The purpose of this document is to assist with the identification of the issues that healthcare providers and infrastructural service providers will need to address in order to specify, implement and maintain a secure and trusted e-health environment. As such this document provides the background to and overview of NEHTA’s Identity Management (IdM) initiative. It introduces and positions a range of detailed IdM resources that will guide organisations and communities within the sector towards secure, efficient and seamless E-Health transacting across the sector.

**Usage criteria**

Although this document is broader than the architecture and design of the registry software systems, this document is essential background reading for users who have an interest or responsibility in the area of securing online healthcare environments. Having a common and shared understanding of the issues involved with the identification and authentication of individuals and organizations as they transact electronically is essential in order to ensure the successful implementation of national E-Health systems.
Identity Management Resource Set

Overview
The Identity Management Resource Set describes at various levels all the components needed to design and implement identity management solutions for healthcare systems. The set contains the following standards:

- NEHTA 0100:2007 Identity Management Resource Set Building Blocks Layer v1.0
- NEHTA 0102:2007 Identity Management Resource Set Standards Layer v1.0
- NEHTA 0103:2007 Identity Management Resource Set Templates Layer v1.0

The Building Blocks layer of the Resource Set is comprised of the Identity Management components, technologies and techniques that an organisation may utilise to assess and develop their identity management requirements.

The Guidelines Layer contains positions and guidelines to key issues identified as being on the critical path for health organisations wanting to join the e-health environment or improve their own identity management systems.

The Standards Layer provides details on standards that organisations and e-health initiatives can utilise to determine the best fit for their identity management needs in line with the National E-Health Identity Management Framework.

The Template Layer presents a collection of useful models and checklists that organisations can use to progress various aspects of the design, development and deployment of intra-organisational and cross-sectoral identity management.

Motivation
The purpose of this document is to provide a ‘toolbox’ from which identity management solutions in health can be constructed.

The components, technologies and techniques presented provide details that can be utilised by health organisations to determine the best fit for their identity management needs in line with the National E-Health Identity Management Framework.

The selection of existing standards where possible upon which to build identity management solutions for health is seen as desirable to both capitalise on existing expertise in identity management and promote interoperability between systems.

In particular, for NEHTA 0101:2007, the identification of and response to key identity management issues for e-health is intended to help focus attention where it is most needed.
**Usage criteria**

These documents should be used when the registry systems are being analysed, designed, and implemented to help guide the identity management aspects of the solution and ensure conformity with the NEHTA-prescribed Identity Management Framework.

The standards included cover multiple aspects of identity management system components development ranging from the risk based assessment of authentication needs to the specific implementation of a selected authentication mechanism.

The guidelines are particularly relevant during the analysis phase, but are still useful to keep in mind during the whole development process.

**Australian Government Authentication Framework**

**Overview**

The Australian Government e-Authentication Framework (AGAF) for Business standard (AGIMO AGAF:2005) provides a set of guidelines and practices for establishing the authentication requirements for an organisation, including a systematic approach to the evaluation of all online transactions for that organisation.

AGAF utilises a risk-based system of assessing the level of assurance of identity required for each transaction and provides a means of mapping the level of assurance to a suitable authentication mechanism. Once this assessment is completed AGAF then assesses the feasibility of the authentication approach.

**Motivation**

AGAF provides a good contextual basis for working with the Australian government and its agencies. It contains a thorough approach and detailed documentation to aid the provision of seamless national online services. Its generic approach also provides an effective and accessible process for analysing requirements. It has a high degree of compatibility with existing Commonwealth identity management programs, and close alignment with state-based programs also using AGAF as their basis.

**Usage criteria**

AGAF should be used as a basis for determining the authentication requirements of the registry organisations.

**ACSI 33**

**Overview**

The Australian Government Information and Communications Technology Security Manual (also known as ACSI 33) has been developed by the Defence Signals Directorate (DSD) (http://www.dsd.gov.au) to provide policies and guidance to Australian Government agencies on how to protect their ICT systems.
The ACSI33 manual references various standards relating to information security and information systems management, including media management, handling and disposal. It provides a framework of principles with associated objectives, risks and suggested control, guidance, references and examples.

**Motivation**

The ACSI 33 guidelines are a solid and thorough set of principles developed to scope computer systems which must work in an environment which has data security implications.

**Usage criteria**

Registry architecture and design should follow the recommendations made in this standard in conjunction with recommendations made by the NEHTA User Authentication Initiative.

**Security techniques**

**Overview**

The following standards apply to Information Security Management Systems:


The AS/NZS ISO/IEC 27001:2006 standard establishes guidelines and general principles for initiating, implementing, maintaining, and improving information security management in an organization. The objectives outlined provide general guidance on the commonly accepted goals of information security management.

AS/NZS ISO/IEC 17799:2006 specifies the requirements for establishing, implementing operating, monitoring, reviewing, maintaining and improving documented ISMS (Information Security Management System) within the context of the organization's overall business risks. It specifies requirements for the implementation of security controls customized to the needs of individual organizations or parts thereof.

**Motivation**

Healthcare organisations are moving towards higher adoption levels for information technology systems as part of a connected e-health sector. The data stored within these systems as part of patient care delivers significantly improved health outcomes compared to older paper-based systems, but it also brings the requirement to carefully protect this sensitive information, especially as the transition to a more connected e-health environment continues to progress.
These standards address the issues associated with information security management. While this is essentially outside the scope of Identity Management in particular, it does form part of the landscape into which Identity Management fits. It is expected that health organisations will have an information security management system in place prior to or as part of addressing their Identity Management requirements.

IT and data security, including perseveration of confidentiality, are whole of organisation concerns. By following these standards healthcare organisations can be confident that they are following accepted and proven methodologies to protect the sensitive information they hold.

Usage criteria

Although these standards are much wider than the architecture and design of registry software systems, following these standards will have implications for the software which will need to be accounted for.

Application of this standard should initially be driven from a security risk assessment, as described in HB 231:2004.

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:

- Web services and
- XML.

Web services

Overview

The following documents describe the standards, guidelines and approaches recommended for application to application exchange:

- NEHTA 0009_2.0:2006 Web Services Standards Profile v2.0
- NEHTA 0033:2006 Technical Architecture for Implementing Services v1.0
- NEHTA 0067:2007 Guidelines for Implementing Interoperable Web Services v1.0

Web Services Standards Profile recommends the use of HTTP 1.1, SOAP 1.2, MTOM and XOP, WS-Addressing, WSDL 1.1, and WS-Security as the standards that NEHTA supports.

The Technical Architecture for Implementing Services defines a service-oriented approach to the national e-health environment.

The Guidelines for Implementing Interoperable Web Services describes how to implement Web services in an interoperable manner.

The Web Services Security standards contain many options, which can result in incompatible implementations. These guidelines suggest ways to avoid those problems. These guidelines cover how to use WSDL, SOAP, WS-Addressing, and WS-Security.

The Web Services Security specification describes enhancements to SOAP messaging that provide message integrity and confidentiality. The specified mechanisms can be used to accommodate a wide variety of security models and encryption technologies.

Motivation

The purpose of these publications is to provide guidance on the standards and approaches to use when implementing secure Web services. The Web services standards are designed to be composed together in different combinations. There are many Web services standards to choose from.
Usage criteria
Web service interfaces are required between capture systems, the national infrastructure, and with and between registry systems. These specifications are recommended for use when designing the services presented by these systems and the interfaces between them.

XML
Overview
The following are XML standards that are applicable to exchanging secure messages between systems:

- IETF RFC 3076:2001 Canonical XML Version 1.0
- IETF RFC 3275:2002 (Extensible Markup Language) XML-Signature Syntax and Processing

A logical XML (Extensible Markup Language) document can be represented in a number of different physical XML documents. They contain equivalent information, but the serialised representation is different. The Canonical XML standard defines a method to create a single canonical representation which can be used for signing and comparing documents.

The XML-Signature Syntax and Processing specifies how to digitally sign XML data. It defines the rules and process of how to create a signature, and additionally how it is to be validated. It also defines the syntax for representing digital signatures in XML.

Motivation
The purpose of these publications is to define the approach to use when digitally signing XML.

Usage criteria
Digitally signing XML is needed when XML content needs to be signed to ensure its integrity, authenticate the message, or authenticate the signing party.

The XML content must be canonicalised before it is digitally signed, as well as canonicalised before a digital signature is validated. These standards must be used when using WS-Security to sign SOAP messages.

Most messages transmitted to and from the national infrastructure and Australian Clinical Quality Registries will contain personal data and will often include clinical data. This data needs to be protected by applying these standards.
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.
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 effective 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

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>ACSQHC</td>
<td>Australian Commission on Safety and Quality in Health Care</td>
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<tr>
<td>AGAF</td>
<td>Australian Government Authentication Framework</td>
</tr>
<tr>
<td>AIHW</td>
<td>Australian Institute of Health and Welfare</td>
</tr>
<tr>
<td>AMT</td>
<td>Australian Medicines Terminology (AMT) – a national extension of SNOMED CT for use within information systems within Australia.</td>
</tr>
<tr>
<td>audit</td>
<td>An examination or review that established the extent to which a condition, process or performance conforms to predetermined standards or criteria. Audits may be carried out on the provision of care, compliance, community response and completeness of records.</td>
</tr>
<tr>
<td>benchmark</td>
<td>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. A standard or point of reference.</td>
</tr>
<tr>
<td>bias</td>
<td>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.</td>
</tr>
<tr>
<td>clinician</td>
<td>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.</td>
</tr>
<tr>
<td>CRE PS</td>
<td>NHMRC Centre of Research Excellence in Patient Safety, Monash University</td>
</tr>
<tr>
<td>Guideline</td>
<td>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.</td>
</tr>
<tr>
<td>HL7</td>
<td>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.</td>
</tr>
<tr>
<td>HPI</td>
<td>Healthcare Provider Identifier – for both individual providers (HPI-I) and for provider organisations (HPI-O). Also see UHI.</td>
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<tr>
<td>HTTP 1.1</td>
<td>HyperText Transfer Protocol 1.1 – a communications protocol for the transfer of information on the Internet.</td>
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<tr>
<td>HTTPS</td>
<td>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.</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
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<tr>
<td>ICD10</td>
<td>International Statistical Classification of Diseases and Related Health Problems, Tenth Revision</td>
</tr>
<tr>
<td>ICD10-AM</td>
<td>International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification</td>
</tr>
<tr>
<td>IdM</td>
<td>Identity Management</td>
</tr>
<tr>
<td>IEC</td>
<td>Institutional Ethics Committee</td>
</tr>
<tr>
<td>iEHR</td>
<td>Individual Electronic Health Record</td>
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<tr>
<td>IHI</td>
<td>Individual Healthcare Identifier – a unique identifier for users of health care. Also see UHI.</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
</tr>
<tr>
<td>MeTEOR</td>
<td>Metadata Online Registry – Australia’s repository for national data standards for health, housing and community services statistics and information.</td>
</tr>
<tr>
<td>Minimum data set</td>
<td>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.</td>
</tr>
<tr>
<td>MTOM</td>
<td>Message Transmission Optimization Mechanism – a method of sending binary data to and from web services.</td>
</tr>
<tr>
<td>National Health Data Dictionary</td>
<td>The national metadata standards for the health sector are published in the National Health Data Dictionary by the Australian Institute of Health and Welfare.</td>
</tr>
<tr>
<td>NCRIS</td>
<td>National Collaborative Research Infrastructure Strategy</td>
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<td>NEHTA</td>
<td>National E-Health Transition Authority</td>
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<tr>
<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
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<tr>
<td>NMDS</td>
<td>National Minimum Data Set</td>
</tr>
<tr>
<td>NPC</td>
<td>National Product Catalogue</td>
</tr>
<tr>
<td>OASIS</td>
<td>Organization for the Advancement of Structured Information Standards (<a href="http://www.oasis-open.org/home/index.php">http://www.oasis-open.org/home/index.php</a>)</td>
</tr>
<tr>
<td>ODP</td>
<td>Open Distributed Processing</td>
</tr>
<tr>
<td>OMG</td>
<td>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.</td>
</tr>
<tr>
<td>PBS</td>
<td>Pharmaceutical Benefits Scheme</td>
</tr>
<tr>
<td>quality of care</td>
<td>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).</td>
</tr>
</tbody>
</table>

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| **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.$^1$ |
| **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.$^1$ |
| **registry** | The system of ongoing registration for individuals entered into a register.$^1$ |
| **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 |
| **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.$^1$ |
| **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).$^1$ |
| **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. |