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# **Review of Shared Electronic Health Record Standards**

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This report has been prepared for NEHTA by Richard Dixon Hughes (Managing Director of DH4 Pty Ltd, who has extensive experience in e-health standardisation and is currently Deputy Chairman of Standards Australia).

It represents a synthesis of findings from a review of standards to support the deployment of shared electronic health records in Australia, which was carried out for NEHTA by DH4 Pty Ltd.

# 1 Executive Summary

Both in Australia and around the world, the potential contribution of electronic management of health information (e-health) to the delivery of safer, more efficient, better quality health care is increasingly being recognised.

International research shows that the benefits of e-health are significantly greater where electronic health record (EHR) information can be shared – via a Shared EHR - and used by all involved in an individual's care.

Achievement of this goal requires definitive standards for representing clinically-relevant information in a Shared EHR and for sharing it between systems. However, this standardisation is being approached in different ways that are still maturing and not yet widely implemented.

Developing Shared EHR specifications for use in the Australian health sector is an important part of the National E-Health Transition Authority (NEHTA) work program. NEHTA has commissioned DH4 Pty Limited (DH4) to carry out a consultancy to:

- review standards being developed around the world to define the structure and content of Shared EHR information
- assess their utility and potential impact on future Australian developments, and
- identify and recommend the most appropriate standards for sharing EHR information in the Australian health sector.

NEHTA is progressing the design of a Shared EHR by developing a description of the concept of operations for a Shared EHR, its high level requirements and architecture. In addition, developing a Shared EHR for use also depends on other work being progressed by NEHTA, principally:

- developing an **Individual Healthcare Identifier** system – that provides reliable identification and appropriate privacy protection for each person's information
- developing a **Healthcare Provider Identifier** - to enable authentication of EHR information and control of access to the Shared EHR
- work on **Clinical Terminologies, Medicines Terminology** and **Clinical Information** - as standards frameworks for accurate definition, recording and retrieval of EHR information, and
- **Secure Messaging** and **Interoperability Framework** - to underpin e-health information interchange and the standardised transport of Shared EHR content.

## Shared EHR standards for Australia

Two main types of standards and related specifications are needed to define and share EHR information effectively:

- **Shared EHR Architecture Standards** for specifying the content and logical structure of Shared EHR information and its relationship to clinical concepts, and
- **E-health Information Interchange Standards** for specifying the format (syntax and representation) of Shared EHR information for interchange between e-health systems.

Such a two-level approach allows high-level definitions of Shared EHR content to remain relatively stable over time, without being significantly impacted by subsequent changes in technologies used for interchange of Shared EHR content, such as messaging protocols.

The DH4 review addressed the most commonly accepted approaches for sharing EHR information, specifically focussing on:

- Use of *openEHR* technology
- European EN13606 standards and/or *openEHR* specifications
- HL7v3 RIM-based methodologies and standards
- HL7v3 CDA (Clinical Document Architecture) standards, and
- HL7v2 messaging standards.

Evolving e-health standards may allow Shared EHR content to be reliably communicated in automatically generated forms that are also widely interpretable but, until such approaches are developed and well accepted by Australian stakeholders, almost all interchange is expected to be represented in accordance with current e-health messaging standards.

## Recommended approach

The review took into account the needs of jurisdictional and other local stakeholders, the views of international e-health experts and development of e-health policy in Australia, the US, UK, Canada and Europe. It also noted that all potential architectures (including EN13606, HL7v3 and *openEHR*) are unproven in large-scale Shared EHR implementations.

In brief, the review's main findings and recommendations were to:

- Adopt the European EN13606 standard on EHR Communication (parts 1 to 3) as the basis of an Australian Shared EHR Architecture Standard for specifying Australian Shared EHR Content
- Interchange Shared EHR information:
  - Initially, by use of HL7v2.x messages specified in consultation with relevant stakeholders – including jurisdictions, suppliers and standards development organisations)
  - In the longer term, either by HL7 CDA release 2 or an XML serialization of EN13606 (subject to progress in global standardisation of archetypes, templates and terminologies)

HL7v3 could have been chosen as an alternative foundation for the Australian Shared EHR Architecture but this would be more complex, costly and take considerably longer than the recommended approach. As an underlying architecture, HL7 CDA is similarly disadvantaged but has promise as a contemporary interchange format. Widespread deployment of *openEHR* technology was not acceptable to stakeholders as a Shared EHR standard and would be difficult to implement; however, the CEN standard is closely related to the *openEHR* specification, and therefore any *openEHR* implementation (e.g. a Shared EHR repository) should be able to support the proposed architecture.

## Other factors

E-health standards continue to evolve rapidly to address gaps needing to be filled to achieve working, interoperable Shared EHR solutions and support new technologies (e.g. web services). It has been recommended that NEHTA undertake further investigation in the following areas to inform ongoing development and implementation of the proposed approach:

- Options for moving beyond HL7v2.x as the principal format for conveying Shared EHR content, specifically: CDA release 2 (and HL7 templates); XML representations of EN13606
- Methods for query/retrieval, identification and linking of Shared EHR Content, and
- Methods for managing versioning, update and correction of Shared EHR Content.

Other factors that need to be addressed in realising a stable platform for implementation of Shared EHR in Australia include:

- Long-term arrangements for on-going development, maintenance and promulgation of Shared EHR standards and specifications
- Gaining effective input from stakeholders in managing Shared EHR standards and specifications, and
- Adequacy of central resources and national skills to support the work.

## **Conclusion**

A deliberately “prudent” approach is proposed that focuses on the availability and use of Shared EHR information, while keeping down implementation cost by building progressively on existing capabilities, clinical information structures and interfacing technology.

## 2 Background

This section briefly discusses background to this report, its purpose and intended audience.

### 2.1 Benefits of e-health

The potential contribution of electronic management of health information (e-health) to the delivery of safer, more efficient, better quality health care is increasingly being recognised around the world. Major national initiatives involving significant investments are underway in the UK, US, Canada and some EU countries with patient safety and the high costs of inappropriate or inadequate health care as important factors needing priority action.

Effective application of e-health technologies is widely recognised as having the potential to facilitate significant improvements in:

- The continuum of care through multidisciplinary care teams delivering better-coordinated care, particularly for chronic disease management
- Responding to episodes of acute illness
- The quality and safety of health care provision and prevention of adverse outcomes (including the use of electronic decision support)
- Delivery of more uniform, relevant care irrespective of where a person resides or falls ill
- Collection of health status information to support evidence-based decision making in areas as diverse as: acute care, chronic care, health system resource distribution, and protection against bioterrorism
- Customisation of care delivery to meet the clinical needs of individuals, and
- Giving individuals greater access to relevant information and services.

Use of more advanced, better integrated clinical systems in ambulatory, hospital and long-term care also promises improvements through clinical decision support, evidence based medicine and better care coordination.

Within Australia, these potential benefits were widely recognised, at least in qualitative terms, in the original *Health Online* report [DHAC1999] and were supported by subsequent research by the National Health Information Management Advisory Committee [NHIM2001].

### 2.2 Sharing of EHR information

The US-based Center for Information Technology Leadership (CITL) [WALK2004a] has produced comprehensive financial models demonstrating that substantial improvements in economic efficiency of health service delivery are achievable through improved exchange of health information among health care providers. The models show that disproportionately higher benefits can be gained from so-called “Level 4” interoperability, where Shared EHR information is seamlessly shared and used by different clinical software applications throughout the care chain.

Achieving the goal of seamlessly sharing structured, coded, machine-interpretable EHR information throughout the care chain requires adoption and widespread implementation of definitive standards for representing clinically-relevant Shared EHR content and for communicating it between systems. Potential barriers to the achievement of this goal include:

- The information to be shared is complex; it arises in different clinical contexts and is communicated via many different types of transactions



- There are many different approaches to Shared EHR standardisation, many of which have yet to mature, and
- Access control and privacy policies must also be supported, while serving a diversity of stakeholders across the care domain.

Many different standards development organisations and others are working on e-health standardisation. These organisations include: HL7, CEN, ISO/IEC, ASTM, DICOM, OMG, IHE, IEEE, OASIS, Regenstrief (LOINC), SNOMED, WHO, UN/CEFACT, W3C and various universities, research institutes and national standards bodies. Much work is still required to resolve key issues and gain global acceptance of widely used standards for the representation and interchange of Shared EHR information.

## 2.3 Purpose of the review

One of the current major initiatives of the National E-Health Transition Authority (NEHTA) is the development of specifications for sharing of EHR information in Australia. It is intended that these specifications be developed in consultation with appropriate bodies and widely applied across the Australian health care sector including primary, acute, specialist, chronic and community care settings serviced by both public and private providers.

NEHTA is looking to identify appropriate standards which can be used as a commonly agreed framework for collecting, organising, accessing and using Shared EHR information and it therefore commissioned DH4 Pty Limited to carry out this consultancy review which:

- reviews standards being developed around the world to define the structure and content of Shared EHR information
- assesses their utility and potential impact on future Australian developments, and
- identifies and recommends the most appropriate standards for sharing EHR information in the Australian health sector.

The review is primarily focussed on standards for specifying the structure, representation and interchange of Shared EHR information and complements other NEHTA work on EHR design, standard clinical terminologies, clinical information modelling, systems interoperability, secure communications and the identification of individuals and providers.

In assessing alternative approaches, the consultancy was required to consider their impact on stakeholder activities and relative contribution within the broader business case for Shared EHR in Australia.

This report is intended to provide the Australian health jurisdictions, healthcare providers, e-health vendors and other stakeholder communities with an overview of the outcomes and recommendations of the Shared EHR standards review.

## 3 Conduct of the Review

A high-level work schedule and stakeholder consultation plan set the scene for the four major activities, which were largely conducted in parallel:

Activity 1 – identify and review existing EHR work

Activity 2 – investigate Shared EHR requirements and issues

Activity 3 – develop and analyse Shared EHR standardisation options

Activity 4 – submit draft report for review by two international moderators, Mr Ken Rubin, Health Systems Architect of EDS Inc and Dr Dipak Kalra, Clinical Senior Lecturer in Health Informatics at University College London.

The consultancy report was then updated in line with the reviewers' feedback and submitted to NEHTA.

### 3.1 Investigations

The principal focus of investigations was to understand and explore strategic e-health standardisation issues to assist in identifying options for Shared EHR standardisation, associated requirements and potential assessment criteria. Sources of relevant information included:

- Online research and literature reviews
- A program of consultation with key individuals and groups, particularly jurisdictional stakeholders and their commercial partners and leading experts from the global e-health standards community – many of whom freely gave of their time to provide detailed advice
- Standards documentation and proposals including:
  - ISO TS18308, which defines broad requirements for a shared EHR
  - European work on EN13606
  - Australian and European work on *openEHR* specifications
  - Specifications of HL7 RIM and v3 framework, CDA and v2.x updates
  - Others – IHE interconnectivity profiles, HL7/OMG services specifications, ASTM CCR, UN/CEFACT core components etc.
- An Ocean Informatics report "Standards and the shared EHR: applicability and impact" [OCEA2005], specifically commissioned to inform the review
- NEHTA Clinical Data Specifications and their application in the draft *HealthConnect* messaging handbooks
- Discussions at ISO/HIMSS Health IT Summit and ISO TC215 meetings in Hamamatsu, Japan and HL7 meetings in San Diego, California, and
- Work by the Pan-Canadian Collaborative on EHR standards [INFO2005a] and the OFFIS project in the EU [EICH2005].

DH4 amassed a considerable amount of contemporary material on requirements for Shared EHR standardisation in Australia and the alternative approaches that might be adopted. The main alternatives are introduced in Section 4 below and analysed further in Section 5.

## 3.2 Key requirements

The consultancy brief required that the proposed Shared EHR standards and specifications should:

- fit into the broader spectrum of contemporary health informatics and ICT activities, and
- provide support for key EHR features, in particular:
  - Medico-legal record keeping: versioning, attestation and auditing
  - A consistent framework for record structures that allows diverse multidisciplinary content to be easily searched and compared
  - A rich set of data types, including coded information, quantities, unstructured text, complex data and multimedia
  - EHR extracts for safely moving record content between systems
  - Labelling data for access control and consent management
  - Validation rules to ensure appropriate quality of record content
  - Management of content such as current medication lists, allergies and alerts, current problems, family history, care plans, etc
  - Information “states” (e.g. whether a problem is current or resolved)
  - Causal links (e.g. between observations, diagnosis or treatment), and
  - Extensibility - allowing evolving new information to be incorporated.

Research and stakeholder consultation identified other requirements:

- A need for two different levels of standards:
  - A Shared EHR Architecture Standard providing the models and means of capturing and specifying Shared EHR content
  - One or more e-health information interchange standards
- Adoption of stable, robust standards that are capable of implementation with sufficient rigour to minimise incompatibility and ambiguity
- Utilisation of existing e-health capabilities to minimise both entry costs and impact on existing investments
- Support for existing HL7v2.x message-based technology but with options to progress to structured documents and service-based technologies, and
- Adequate resources to maintain standards, specifications and a national metadata repository able to support the management of whole-of-life compatibility between multiple versions of Shared EHR content.

There was support among e-health experts for an approach that allowed Australia to continue developing the promise of constraints (archetypes, templates) as a means of capturing and specifying Shared EHR content.

In drawing requirements together from various sources, some 30 key aspects were identified that impact on the suitability of various Shared EHR standardisation solutions. These are summarised in Figure 1 below and were taken into account when assessing the suitability of alternatives.

- 1. Strategic Alignment**
  - 1.1 Comprehensive support for consolidated shared summary EHR concept
  - 1.2 Based on well-established e-health standards
  - 1.3 Vendor and Technology independence
  - 1.4 Compatibility with stakeholder legacy e-health investments
  - 1.5 Complements HealthConnect (point-to-point) implementation strategy
  - 1.6 Ability to build on NEHTA Clinical Information Initiative
  - 1.7 Potential to derive benefit from IHE processes
- 2. SEHR Information Architecture Structure, Content and Support for E-health Processes**
  - 2.1 Capacity to specify, represent and share full range of potential SEHR content
  - 2.2 Suitability and scope of existing SEHR content representation and code sets
  - 2.3 Record organisation, update and maintenance
  - 2.4 Supports structured and non-structured data organisation.
  - 2.5 Capacity to specify handling of managed, derived and maintained lists
  - 2.6 Richness and suitability of data types
  - 2.7 Capacity to specialise and constrain SEHR content (e.g. by archetypes or templates)
  - 2.8 Supports use of standard terminologies for health concept representation
  - 2.9 Approaches for search, query, view and retrieval of SEHR content
  - 2.10 Optional controls for visualisation/display of SEHR content
  - 2.11 Supports integration with clinical decision support
- 3. Communication of SEHR Information**
  - 3.1 Communication of SEHR content based on established service/message formats
  - 3.2 Communication payload readily derived from SEHR content
  - 3.3 Efficient, effective serialisation of SEHR content.
- 4. Stability**
  - 4.1 Development/implementation status of proposed standards
- 5. Ease of Acceptance and Cost of Realisation**
  - 5.1 Acceptability to Australian stakeholder communities
  - 5.2 Availability of low cost implementation options building on existing infrastructure
- 6. SEHR Content Development and Management**
  - 6.1 Effective coordination and governance of SEHR content
  - 6.2 Accessibility, speed and effectiveness of SEHR content generation process
  - 6.3 Development of semantic content supported by ontologies, libraries and editing tools
- 7. Privacy, Security and Management of SEHR Content**
  - 7.1 Supports appropriate privacy and security controls
  - 7.2 Supports Attestation, versioning, update, replacement and audit trail of SEHR contributions
  - 7.3 Labelling/support of data for privilege management and access control policy
  - 7.4 Capacity to preserve original of coded, translated and inferred content
  - 7.5 Records digital signature requirement/details
  - 7.6 Medico-Legal Validity

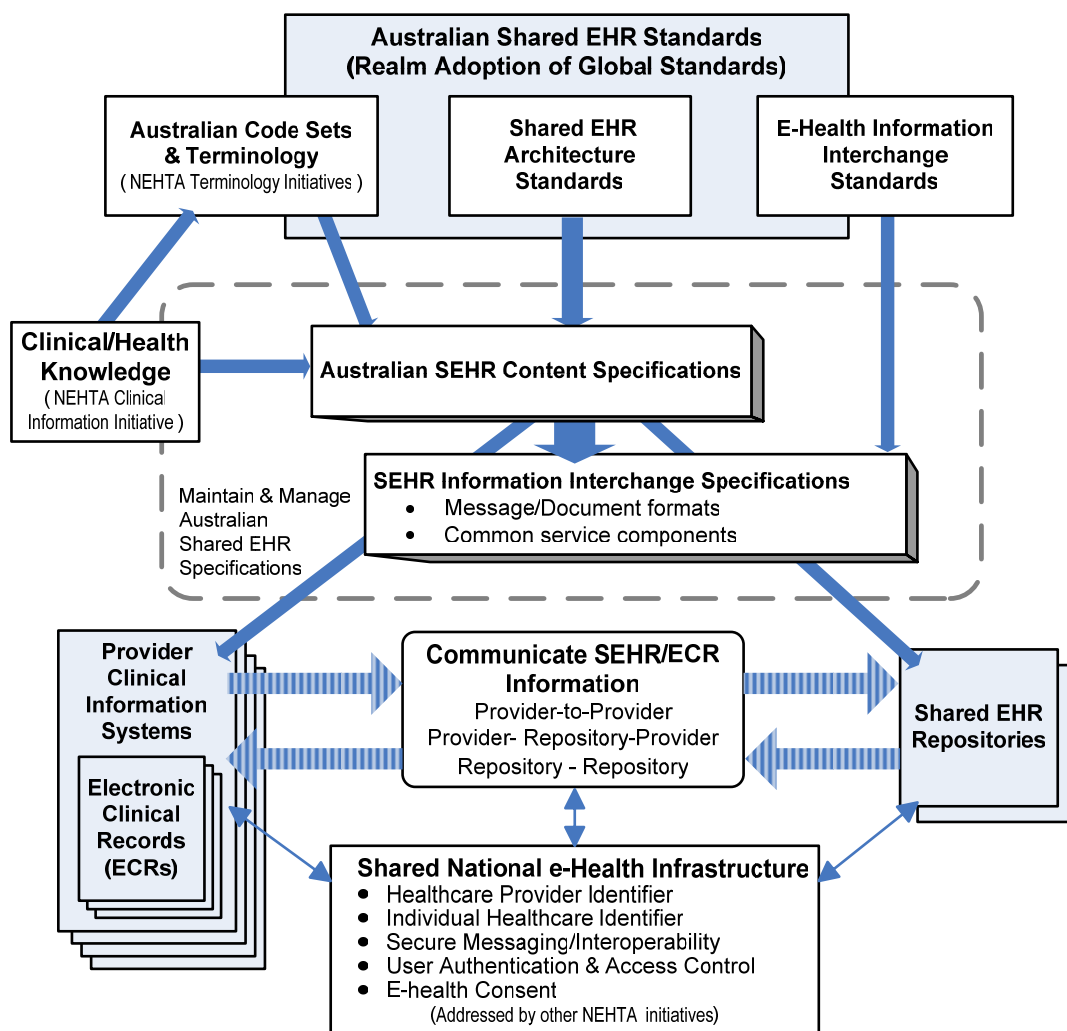
**Figure 1: Synopsis of Shared EHR standardisation requirements**

A centrepiece of the review was the formulation and assessment of alternative options for addressing the Shared EHR standards requirements and is the subject of Section 5 below.

## 4 Shared Electronic Health Record Standards

The Australian Health Information Council report *Foundations for the Future* [AHIC2005] identified ten fundamental standards-based building blocks needed to support shared EHR initiatives. The expected full compass of standards needed to support Shared EHR interoperability in Australia is summarised in Appendix C, along with an indication of their present status. Many of the required standards (notably individual health identifiers, health provider identifiers, clinical terminology, access control and secure communications) are being addressed by NEHTA, and therefore beyond the scope of this present review.

The review focused on those standards most directly concerned with processes for standardising the representation and interchange of Shared EHR information, as portrayed in Figure 2 below.



**Figure 2: Standardising Australian Shared EHR information**

As illustrated in Figure 2, proposed **Australian Shared EHR Standards** (based on Australian adoption of global standards) provide a framework that will support the capture of clinical/health knowledge as **Australian Shared EHR Metadata** (NEHTA specifications), detailing how Shared EHR information is represented for sharing between e-health systems.

For practical implementation, the Shared EHR specifications must be implemented by software running in provider CIS/ECR systems and within

shared EHR repositories. Other e-health infrastructure needed to underpin Shared EHR implementation is also illustrated for completeness.

**Australian Shared EHR Standards**, when endorsed by NEHTA, provide the framework needed to formally specify Shared EHR content and information interchange in Australia. There are three principal components:

- **Shared EHR Architecture Standards**, providing the common structure and rules for identifying and defining Australian Shared EHR Content Specifications.
- **E-Health Information Interchange Standards**, providing the syntax and rules for expressing defined Shared EHR content so that it may be reliably communicated (or shared) between systems without loss of meaning.

Shared EHR architecture standards and e-health information interchange standards were the principal focus of the review and are introduced further in sections 4.1 and 4.2 below.

- **Australian code sets and terminology**. Maintained outside the Shared EHR standards environment (e.g. by Australian Institute of Health and Welfare, government health departments and the proposed standards development organisation for SNOMED maintenance), these provide essential reference frameworks for contribution and interpretation of Shared EHR information.

**Australian Shared EHR Specifications** are documentation and metadata maintained by (or under the close direction of) NEHTA, comprising:

- **Australian Shared EHR Content Specifications** setting out the content, logical structure and semantic bindings of information held within compliant Shared EHR systems in Australia – in both human-readable and computer processable forms.

These specifications are based on the Australian Shared EHR Architecture standard and, once promulgated, are to be used to create information interchange specifications and, within the wider e-health community, for defining systems that supply and process Shared EHR information.

In the first instance, the preparation of these specifications is proposed to draw heavily from, follow and ultimately incorporate the existing NEHTA work on **Clinical Data Specifications**.

Once used to create Shared EHR content, each specification will need to be retained indefinitely to assist lifetime interpretation of Shared EHR information.

- **Shared EHR Information Interchange Specifications (IIS)** detailing the syntax and representation of particular Shared EHR content for interchange between compliant Shared EHR systems. Once each IIS has been developed and approved by NEHTA, suppliers can apply it in maintaining standardised interfaces and for sharing Shared EHR information between systems. It will also provide a basis for interface testing and certification.

## 4.1 Shared EHR architecture standards

Taken as a whole, the selected Shared EHR Architecture standards should provide a cohesive logical framework for consistently modelling and defining information in the shared EHR – supporting complete, precise, unambiguous specification of Shared EHR content. Aspects the standards must address include:

- A reference model - allowing all potential classes of Shared EHR information, their structure and inter-relationships to be identified and specified.

Leading examples include the HL7 RIM (and its derivatives) and the EN13606 and *openEHR* reference models.

- Composition/constraint method - allowing more detailed definition of the content, values, relationships, code sets and clinical concepts for particular Shared EHR components.

HL7 presently achieves this by deriving and restricting more detailed information models (with HL7 templates proposed for the future).

Archetypes provide the constraint capability in EN13606 and *openEHR*.

- Data types - fundamental representation of structured and unstructured Shared EHR information (including embedded files and multi-variable measures).
- Shared EHR functional support –features needed to support systems behaviour needed to maintain and protect Shared EHR content. This includes the management of information and methods for activities such as privacy protection, access control and audit trail.

The candidates identified for more detailed consideration as the underlying basis for an Australian Shared EHR Architecture Standard were:

- The HL7v3 RIM (including derived tables, D-MIMs and CMETS)
- HL7 CDA release 1 (r1) and release 2 (r2)
- Use of *openEHR* technology and/or *openEHR* published specifications, and
- European Standard EN13606 (Parts 1 to 3).

Possible candidates for Shared EHR Architecture not considered in depth included:

- Custom, in-house and vendor proprietary approaches. which do not offer a standards-based means of defining national Shared EHR content
- The existing clinical information health data model and architecture, which although close to EN13606, needs extension and is not a standard
- Older e-health architectures with minimal contemporary support (e.g. CorbaMed, the former ENV13606), and
- Global e-business/e-government architectures having negligible penetration in the clinical/health arena (e.g. ebXML)

## 4.2 E-health information interchange standards

Established e-health information interchange standards provide agreed formats and rules for communicating a wide range of clinical/health information between disparate systems in the health sector. Leading contenders for NEHTA to use with Shared EHR systems in Australia include:

- HL7v2.x messaging
- HL7v3 messaging, and
- HL7v3 Clinical Document Architecture (CDA) - for representing clinical documents in XML that are to be conveyed by other means.

DICOM and DICOM /SR are protocols used with radiology, medical imaging and PACS systems. While not recommending them for more general use, they should be considered for clinical images and associated reports.

EN13606 Part 5 is in early draft planned to provide the messaging context for sharing Shared EHR content and archetypes defined in accordance with earlier parts of EN1360.

There is considerable interest in a range of options for XML-based serialisation for Shared EHR information interchange but no clear alternative at present, other than widely accepted transformations for XML serialisation of the above messaging protocols.



## 5 Consideration of Alternatives

In the previous sections, it was identified that the selection of Australian Shared EHR standards needs to address requirements in two main areas:

- Shared EHR Architecture Standards to be used for specifying the content, logical structure, and semantic bindings of Shared EHR information, and
- E-Health Information Interchange Standards to be used for specifying the agreed syntax and formats for interchange of Shared EHR content.

The review identified a plethora of potential ways in which Shared EHR standardisation might be applied. These ranged from specification of particular technologies or local development of new standards through to use of generally accepted global standards.

In formulating alternative options, it became clear that there were no simplistic, clear-cut solutions that could be adopted and easily implemented to meet the full range of standardisation requirements – each contender addresses different aspects of the problem – and even the more obvious solutions (e.g. HL7v3) could be applied in a multitude of different ways.

To enable assessment, a limited number of broader “approaches” were defined, each focussed on a mainstream option and refined to incorporate the most practical combination of features needed to address requirements. These approaches and their broad fit with the two main areas of standardisation are summarised in the following table.

Approach	Shared EHR Architecture	Information Interchange
<i>openEHR</i> technology	Yes	Custom approach
EN13606	Yes	Under development
HL7v3 RIM methodologies & standards	Partial	Yes
HL7v3 CDA r2 standards	Partial	Partial
HL7v2 messaging standards	No	Yes

**Table 1: Summary of main approaches for Shared EHR standardisation**

It is noted that no potential Shared EHR Architecture is widely deployed in support of a large-scale Shared EHR implementation (although some are used in messaging and document management applications).

Uncertainty about the ultimate level of adoption of any architecture and the true cost of implementation are significant risks to be managed in selecting a Shared EHR architecture at this time.

All approaches only provide the underlying standards – the main cost arises in using them to capture, represent and maintain Shared EHR content as Shared EHR metadata. A proportion of this cost is common to all approaches.

The main features of each these approaches will now be discussed briefly followed by a comparison of the two most feasible approaches.

### 5.1 Overview of alternative approaches

#### 5.1.1 *openEHR* technology

In its purest form, the *openEHR* approach involves systems sharing EHR information by implementing elements compatible with those freely-available from the *openEHR* website. These elements support specified *openEHR*



reference and archetype models and use common definitions of clinical information provided via a shared archetype repository.

The *openEHR* approach aims to deliver functionality meeting ISO Technical Specification ISO TS 18308: *requirements for an electronic health record*. Although the approach is more “technology-based” than “standards-based”, *openEHR* design specifications can be used as Shared EHR interface standards.

For much of the past decade, *openEHR* has been supported as the most likely candidate for Australian Shared EHR initiatives and was deployed briefly in the Brisbane Southside HealthConnect Trial and several earlier projects.

The principal strengths of *openEHR* are its leading-edge architecture and comprehensive reference model, support for archetypes, coherent design philosophy, and plans for a Shared EHR solution fully compliant with TS18308. When deployed among *openEHR*-compliant systems, it offers a seamless, controlled, service-oriented means of sharing EHR information.

The principal drawbacks of deploying *openEHR* technology as the preferred approach to Shared EHR standardisation are:

- Resistance by stakeholders to incorporation of *openEHR* components - on grounds of cost, disruption and risk
- Despite years of effort, *openEHR* technology has extremely low uptake, appears difficult to implement and remains unproven in any medium- or large-scale implementation
- Notwithstanding considerable improvements, *openEHR* is still primarily a research and development platform subject to significant on-going change
- Its continued support is highly dependent on a few key individuals and the local pool of relevantly skilled personnel is extremely small, and
- *openEHR* specifications are not backed by a widely-accepted SDO.

Even if selected by NEHTA, it is most unlikely that there would be any significant adoption of *openEHR* technology by mainstream commercial software suppliers and jurisdictions even though there is some support for archetype-based approaches and a willingness to interface with repositories based on *openEHR*, should they be implemented as part of a national solution.

It was concluded that NEHTA should not adopt “use of *openEHR* technology” as a standard for sharing Shared EHR information. It was noted that the European EN13606 standard, which is discussed in Section 5.1.2 below, is heavily based on *openEHR* specifications and that key features of *openEHR* (including archetypes) could be more acceptably and easily addressed as part of an approach based on that standard.

### 5.1.2 EN13606 standards

The new (five-part) EN13606 *EHR Communication* standard, most of which is in the process of final release ballot, provides a comprehensive framework for defining the communication of Shared EHR content via archetypes.

CEN13606 defines a model of an EHR Extract for communicating parts or all of an individual's EHR between systems. Of the five parts of the EN13606 standard, Australia would principally base an Australian Shared EHR Architecture Standard on Parts 1 to 3 (which specify the EN13606 reference model, archotyping and term lists, and incorporate many *openEHR* concepts.)

While EN13606 provides a comprehensive means of defining Shared EHR content, it currently lacks a definitive, inherent, widely accepted format for interchanging content between systems. When eventually released, Part 5 of EN13606 will specify services-oriented exchange models, but it is unknown when, how or by whom they will be realised in the form of working software. In the interim, means of interchanging EN13606 archtyped content include:

- Mapping it to/from HL7v2.x messages (and/or developing a new “Archetype” message)
- Developing HL7v3 messages from a EN13606 D-MIM (presently in draft)
- Using XML documents conforming to an EN13606 XSD currently being refined for inclusion in the EN13606 standard, and
- Selecting different modalities for particular systems or interchanges.

Of these, the message-based approaches would incur more work in producing and maintaining information interchange specifications but would facilitate much wider usage by Australian stakeholders.

A benefit of the EN13606 approach is the ability to build directly on NEHTA’s existing clinical information work, which uses a similar reference model derived from the same sources as EN13606. EN13606 is documented as a normative standard, which can be comparatively easily revised and re-published as an Australian Shared EHR architecture standard.

Using EN13606 standards (supported by appropriate interchange methods including an HL7v2.x messaging) is one of the two preferred Shared EHR standards approaches and is compared further with HL7v3 in Section 5.2.

### 5.1.3 HL7v3 RIM-based standards

The HL7v3 Reference Information Model (RIM) and HL7 Development Framework (HDF) provide a means of modelling information across the health domain and then deriving consistent messages from the resulting models.

A pure HL7v3 approach to Australian Shared EHR standardisation would see the v3 RIM and HDF, along with derived models, codes and datatypes being used to define Shared EHR content, from which HL7v3 message specifications could be produced directly for interchange of Shared EHR information.

To use HL7v3 as the centrepiece of the Australian Shared EHR Architecture, an integrated HL7v3 information model (potentially an Australian Shared EHR D-MIM) would need to be developed and maintained. This model (along with attributes, code sets, vocabularies etc) would need to be complete (or at least in draft form) before more detailed specifications of specific Shared EHR content could be produced. Ultimately, HL7 “templates” may allow different types of clinical content to be easily represented using a few common information models, but that promise has yet to be realised.

Core elements of HL7v3 are formally approved ANSI standards and some have been submitted to ISO as potential international standards. A major benefit of the HL7v3 approach is the opportunity to draw on global work defining clinical content – particularly from Canada, the UK and the Netherlands, which have adopted HL7v3 as a cornerstone of their e-health strategies. However there are also major issues to be weighed up, notably:

- There is negligible uptake of HL7v3 messaging in Australia and, without major incentives and a much larger skills base, little justification or ability for vendors to use it
- There are significant costs and development delays before HL7v3 can be published and used as the Australian Shared EHR Architecture Standard
- There is no history of HL7v3 RIM being used as an ISO TS 18308-compliant EHR architecture and (with the exception of CDA) little focus on it becoming an enduring global standard for semantically interoperable retention of EHR information (as distinct from messaging), and
- Implications of large-scale HL7v3 implementations (such as network impacts of XML content representation) are unknown.

An HL7 RIM-based approach (preferably combined with elements of CDA, focussing on the “Clinical Statement” pattern and templates) is one of the two preferred approaches for Shared EHR standardisation. In Section 5.2, it is compared further with use of EN13606 standards.

#### 5.1.4 HL7 CDA (Clinical Document Architecture) standards

HL7 CDA is a subset of HL7v3 for transferring health documents in XML that are both human-readable and machine interpretable. CDA documents are delivered as payloads (typically embedded in HL7v2.x or v3 messages) with messaging rules defining how they are managed. In this sense, they do not fully address NEHTA needs for Shared EHR standards but, like EN13606, can be used in conjunction with one or more other common interchange methods.

HL7 CDA release 1 (CDA r1) is widely used in many parts of the world, although now superseded by CDA release 2 (CDA r2), which became a full ANSI standard in May 2005. The older CDA r1 cannot represent more complex Shared EHR content, is based on outdated XML constructs (DTDs) and is not recommended for uptake by NEHTA.

CDA r2 is flexible but needs HL7 templates for defining complex Shared EHR content; however, templates may not be ready for 1 to 2 years. CDA also needs extra functionality to manage EHR extracts containing multiple documents. Without issues such as these being resolved, CDA cannot be considered suitable as a Shared EHR architecture standard.

There is strong interest in CDA's potential as a native XML Shared EHR Information Interchange format that would align with the NEHTA Interoperability Framework. Other advantages are:

- CDA has growing international support and an IHE XDS profile, and
- It can capture less structured human readable EHR input today, while offering a seamless migration path to more fully structured data tomorrow, enabling more care providers to participate in Shared EHR.

However, there are also major issues, including:

- CDA is not presently implemented anywhere in Australia and stakeholders currently using HL7v2 do not see a need for it
- Design, implementation and cost implications of using HL7 CDA r2 for Shared EHR information interchange are unclear and need further investigation (as do its relationship to HL7v3 RIM and template classes), and
- There are almost no CDA skills in the country and a major initiative would be required if it were to be a preferred approach.

Although not suitable as an Australian Shared EHR Architecture, CDA r2 offers benefit as a contemporary XML-based Shared EHR Information Interchange Standard and is recommended for further investigation in this role.

#### 5.1.5 HL7v2 messaging standards

There is widespread acceptance in Australia of clinical messaging based on HL7v2 with implementations, on the whole, operating successfully. Use of HL7v2 is supported by Australian Standard implementation guides and an accumulation of local expertise, products and services. HL7v2 standards also continue to be developed in Australia and by HL7 globally – including new features aimed at carrying Shared EHR content.

Stakeholders consulted during the review strongly emphasised the essential on-going role of HL7v2 as their principal e-health communications technology and the fact that they presently have no plans to retire existing investments in favour of HL7v3 or other e-health communications technologies.

**HL7v2 messages have no underlying reference model** that identifies their semantic content and the inter-relationships between content. Therefore, on their own, they cannot meet the requirements for an Australian Shared EHR Architecture but they can be used to carry Shared EHR content specified using other Shared EHR architectures. This requires an explicit mapping between the Shared EHR content and a standardised set of HL7v2 messages. The advantages of this approach include:

- HL7v2 is widely supported throughout the Australian e-health community
- Lower stakeholder cost when interfacing systems to EHR repositories
- Speed of implementation, plus re-use of interfaces and mapping work
- In its native form, it is undemanding on telecommunications services, and
- Some HL7v2 messages are supported by vendors and IHE profiles.

If HL7v2.x connectivity is not available, it will greatly limit the potential for wide range of providers to participate in Shared EHR initiatives. However there are issues to be addressed in pursuing such an approach:

- There are costs maintaining the mapping between Shared EHR content and the HL7v2 message specifications, perhaps \$300,000-\$500,000 pa.
- HL7v2.x message formats are limited in their ability to handle complex clinical information, files and multimedia – development of more contemporary alternatives should be encouraged and fostered (e.g. HL7 CDA r2, DICOM)
- Quality of information received depends on how consistently vendors understand the overall Shared EHR architecture and can map it to messages, and
- Providing HL7v2x capability will reduce incentives to use new formats.

Initial provision of some support for HL7v2 messaging is considered essential for whatever architecture is adopted for sharing Shared EHR content and support for HL7 2.x messaging as an underlying Shared EHR transport protocol is needed until the marketplace is well advanced in its uptake of other approaches to e-health information interchange.

## 5.2 Comparing EN13606 and HL7v3

Considering the potential approaches to Shared EHR standardisation, only two substantially address requirements for an Australian Shared EHR Architecture, although others are useful for Shared EHR information interchange. Table 2 below summarises the key comparative features of the two main contenders:

- EN13606/*openEHR* standards (with HL7v2/other information interchange), and
- HL7v3 RIM-based standards and messaging.

From the table and the discussion above, HL7v3 has merit, but the adoption of an approach based on the EN13606 standard (possibly with some *openEHR* features) is preferred because:

- It is less complex and appears to offer a lower cost to all stakeholders – and the potential to benefit from archetypes
- It enables quicker realisation of required objectives, by building on existing NEHTA clinical information work and having shorter set-up lead times
- There is more capacity to adapt over time and co-exist with HL7v2 and potentially HL7v3 as well as with native EN13606 constructs.
- It does not force stakeholders and suppliers into new technology, and
- It recognises the limited HL7v3 skill sets in Australia.

Topic Area	CEN EN13606 + HL7v2 Interchange	HL7v3 Approach
Shared EHR Architecture Standards - Reference Information Model - Derived models	Australian adaptation of EN13606 Parts 1-3	Derive Australian HL7 RIM-based Models ex CDA R-MIM, CS etc (Possibly Aust Shared EHR D-MIM)
Time & effort to get Aust Shared EHR Architecture	Moderate short term effort. Need codes, archetype control etc Adapt & republish NEHTA clinical information guides	Moderate medium term effort. Need models, codes, control etc Develop/publish new guides
- Composition Method	EN13606 Archetypes Held in Australian repository	Derive and define R-MIMs, Attributes, HMD
- Constraint Method	EN13606 Archetypes Held in Australian repository	RIM-based models at first Templates in future but still unclear.
- Data Type Objects	CEN Data Types	HL7 v3 Data Types
Time & effort to revise & prepare Clinical Information/Clinical Data Specifications for use with new Shared EHR Architecture	Negligible lead time to start. Then short term effort to archetype and code existing CDS	Need Shared EHR Architecture first Then extensive effort to re-model CDS to RIM artefacts Moderate medium term effort.
Information Interchange Standards	Content mapped to HL7v2 msgs Review/define – HL7CDA r2 docs (map for new “Archtyped Data”) Possibly: CEN Extract exchange	Content mapped to HL7v2 msgs Review/define – HL7CDAr2 docs Possible long-term: HL7v3 messages
Time & effort to maintain ongoing v2.x mappings of Shared EHR content	Moderate effort Resolve + update legacy mapping Potentially declining with use of generic archtyped content Move to “Archtyped Data” maps	Longer and more costly Resolve + update legacy maps then migrate to use RIM artefacts New data groups need individual mapping (but prefer v3 message).
Time & effort to maintain to ongoing HL7 CDA mappings of Shared EHR content e	Moderate at first CDA use to be reviewed/defined Effort may decline with generic representation of archtyped content via templates.	Moderate at first. CDA use to be reviewed/defined Templates may avoid all new data groups being individually mapped.
Terminology Support	Available	Available
Content Modelling	Archetypes facilitate capture & expression; but still need detailed semantics from experts	Complex Possibly more precise but difficult to address material new to V3 RIM
Development Status of underlying modelling standards	All elements defined; Key elements accepted Remainder on route to acceptance	HDF, RIM, D-MIMs accepted or close to acceptance with many lead sites implementing for messaging
Installed Base of underlying modelling standards	Negligible	v3 RIM/HDF messaging growing (CA, UK, NL, EU, US, MX) but negligible use for structured Shared EHR
IHE Support	HL7v2x and CDA interchange being supported for lab, diagnostics, docs. Not likely for archtyped content	HL7v2x and CDA interchange being supported for lab, diagnostics, docs. Questionable for Aust/ other content

**Table 2: Shared EHR architecture – Comparing EN13606 and HL7v3**



## 6 Key Recommendations

The key recommendations of the review are outlined in this section, along with discussion of some of their implications.

### 6.1 Shared EHR architecture

**Recommendation 1** is that European Standard EN13606 (Electronic health record communication: Parts 1 to 3) be adopted as the basis for an Australian Shared EHR Architecture Standard (ASAS).

This standard, when formalised for use in Australia, would be the framework for producing and maintaining publicly available Shared EHR Content Specifications detailing the agreed content, logical structure and semantic bindings of Shared EHR information for use in Australia.

**Recommendation 2** is that Shared EHR Content Specifications be developed as both human-readable specifications (broadly following the ISO 11179 metadata standard) and as archetypes (in accordance with the ASAS).

These recommendations effectively continue the approach commenced by NEHTA in specifying priority event summaries and key data groups.

### 6.2 Shared EHR information interchange

There is also the need for adoption of established E-health Information Interchange Standards to provide the syntax and rules for producing Shared EHR Information Interchange Specifications. These specifications will define how the Shared EHR Content (specified by NEHTA) is to be represented when being communicated between systems.

**Recommendation 3** is that Shared EHR Information Interchange specifications be produced and maintained under the direction of NEHTA and be made publicly available via the Internet, along with implementation guidance and mappings to specific transport protocols.

**Recommendation 4** is that NEHTA support HL7v2.x messaging as an interchange format for representing specified Shared EHR Content, until such time as the marketplace is advanced in adopting any alternative format for e-health information interchange.

Draft mappings of NEHTA priority clinical information data groups to HL7v2.x were produced for *HealthConnect* in 2004/05. It is recommended that these be updated and incorporated into the Shared EHR Information Interchange specifications, with input from stakeholders and relevant Standards Australia committees.

It is also recommended that a generic v2.x message format able to carry all archetyped data be developed, to reduce costs and overheads and improve the accuracy of information transfer.

A contemporary XML-based interchange format will soon be needed to complement and ultimately, to replace HL7v2 messages as the primary Shared EHR information interchange standard.

**Recommendation 5** is that, within 12 to 18 months, a substantial review be undertaken of emerging standards for Shared EHR information interchange in support of the recommended Australian Shared EHR Architecture, to include consideration of:

- a. HL7 CDA r2 and HL7 templates
- b. The proposed XSD schema for EN13606, EN13606 Part 5 and/or messages based on the draft HL7v3 D-MIM for EN13606, and

- c. Work of the OMG/HL7 Healthcare Services Specification Project  
HL7 CDA r2 has considerable potential but substantial questions remain as to its development status and how it should be used as part of the proposed Shared EHR standards framework. Within the next two years, a range of other potential standards are expected to emerge for e-health information interchange using structured XML.

## 6.3 Management of Shared EHR specifications and archetypes

Once Shared EHR specifications start to be promulgated and used in a broad range of different ECR/EHR systems, continual rigorous maintenance of Shared EHR metadata will become essential to ensure the long-term validity and serviceability of Shared EHR information. This is an environment where the needs of clinical practice will continue to evolve, e-health standards are still maturing and even mature standards need to be revised and updated.

Alan Rector has noted [RECT2001] that overlapping definitions in e-health information models, terminology and clinical decision systems can lead to unsafe interpretation of clinical information. Disciplined choices need to be made in line with emerging international research on this issue to avoid potential problems.

The EN13606 approach uses archetypes to define and maintain Shared EHR content. In theory, this allows considerable flexibility in capturing clinical information; however, undisciplined creation and application of archetypes threatens the goal of semantic interoperability. A new generation of international standards has been proposed for organising, classifying and managing global sharing of archetypes but will probably take many months to be realised. A central repository will be needed for local management of Shared EHR archetypes used in Australia (at least until a more sophisticated approach becomes feasible and is accepted by stakeholders).

It is recommended that a registration authority and repository for relevant Shared EHR metadata and processes for configuration management be part of the e-health infrastructure provided to support Shared EHR standardisation.

## 6.4 Implementation

Implementing a national approach to shared EHRs, based on the above recommendations, will require support. The following supporting recommendations are therefore proposed, for incorporation into NEHTA's development program for Shared EHR specifications:

1. Systems for introducing and managing in the long-term Australia's Shared EHR Specifications should be identified and integrated with those proposed to support Australian clinical terminology.
2. Clinicians, e-health systems suppliers and jurisdictions should be engaged in national Shared EHR standardisation activities.
3. A process should be identified for periodically reviewing standards supporting shared EHR information - in light of changing needs, technologies, standards and outcomes.
4. The formalisation and promulgation of the Australian Shared EHR Architecture Standard (based on EN13606) as a full Australian Standard should be sought.
5. The methods for querying/retrieving Shared EHR content (including methods of data identification and linking) and also for versioning of SEHR content should be reviewed.

6. The development of Australian Shared EHR Specifications should identify and, where appropriate, directly adopt any relevant:
  - a. CEN archetypes (and vocabulary bindings)
  - b. HL7 models, templates, code sets and/or vocabularies – particularly those used with clinicalStatement Act Class and CDA r2.
7. Relevant committees and experts should be approached to ensure ISO, HL7 and CEN address Australian Shared EHR requirements (with *openEHR* inputs) and to maintain pressure for collaboration.

The following recommendations, although outside NEHTA's scope, are also proposed to support the implementation of a national approach to Shared EHRs:

8. The need for skills growth to achieve this and other e-health initiatives should be recognised.
9. Australia should maintain strong involvement in standards development activities affecting Shared EHR architecture and information interchange both locally and at the international/global level.
10. The case for using other e-health information interchange standards (including HL7v3, DICOM) to produce SEHR information interchange specifications should be driven by marketplace demand.



# Appendix A – Glossary

ADL	Archetype Definition Language. A formal language for expressing archetypes
ASTM	A US-based global standards development organisation
Archetype	A formal specification of the allowable structure and content of information held in an EHR system derived by constraining an EHR reference model. (CEN, <i>openEHR</i> )
CCR	Continuity of Care Record (ASTM)
CDA	Clinical Document Architecture. An HL7 standard specifying “clinical documents” that are persistent, attributed and can be interpreted by both humans and machines
CDS	Clinical Decision Support, Clinical Data Specifications
CEN	Comité Européen de Normalisation (European Standards Organisation)
CEN EN13606	European Standard for electronic healthcare record communication, now being finalised for issue in five parts: Part 1: Reference model; Part 2: Archetype interchange specification; Part 3: Reference archetypes and term lists; Part 4: Security; Part 5: Exchange models. An earlier version has been in use as a pre-standard (ENV) since 2000
CIS	Clinical Information System. A computer system designed to support healthcare providers deliver healthcare. (e.g. GP, Laboratory or Hospital systems)
DICOM	Digital Image and Communications in Medicine (an SDO)
D-MIM	Domain Message Information Model. An HL7 information model representing all the concepts needed for communication in a particular domain. (e.g. pharmacy domain)
DSTU	Draft Standard for Trial Use (HL7)
ebXML	Electronic Business XML. Use of Extensible Markup Language (XML) to standardise the secure exchange of business data. (OASIS & UN/CEFACT)
ECR	Electronic Clinical Record. An EHR maintained within a provider CIS.
E-health	Delivery, enablement or support of health care through the use of information and communications technology.
EHR	Electronic Health Record. A longitudinal collection of personal health information about an individual person, stored electronically.
EMR	Electronic Medical Record. Alternative term for ECR
EN13606	See CEN EN13606
GEHR	Good European Health Record – Later Good Electronic Health Record
Healthcare Provider Index (HPI)	A service accessible to authorised users that stores an index of identifiers for health care providers. See also <i>provider directory</i> .
HL7	Health Level 7 Inc. A global standards development organisation that specialises in standards for information interchange in health care.
HMD	Hierarchical Message Description (HL7). A specification of the exact fields of a message and their grouping, sequence, optionality and cardinality.
IHE	Integrating the Health Care Enterprise. A body supporting e-health connectivity.
Individual	A general term used for a person who accesses, uses or might use health services (preferred to ‘Patient’, ‘Consumer’, ‘Subject of Care’ and ‘Client’).
Individual healthcare identifier (IHI)	A universal number or code that uniquely identifies each person for use with the delivery of health care services.

Individual provider	A registered health professional involved in the delivery of health services to an individual. Individual providers include medical practitioners, registered nurses, pharmacists and allied health professionals.
ISO	International Standards Organisation
ISO/IEC 11179	A standard for standardising and registering of metadata elements to make data understandable and sharable.
LOINC	Logical Observation Identifiers Names and Codes – a set of clinical codes and terms developed by the Regenstrief Institute, widely used in pathology.
MDF	Message Development Framework (HL7)
Metadata	Data about data. Metadata describes how and when and by whom a particular set of data was collected, and how the data is formatted.
METeOR	METadata Online Registry . A knowledgebase of metadata items maintained by the Australian Institute of Health and Welfare (AIHW).
NHDD	National Health Data Dictionary (maintained by AIHW)
<i>openEHR</i>	An international not-for-profit foundation working towards interoperable, life-long electronic health records, proven in practice.
OASIS	Organization for the Advancement of Structured Information Standards (an SDO)
OWL	Web Ontology Language. A semantic web standard that provides a framework for the management, integration and sharing and reuse of data on the web.
PHR	Personal Health Record
Provider	A term encompassing individual health care providers and provider organisations.
Provider directory	A database holding provider detail and contact information enabling them to be contacted by various means including delivery or collection of e-health messages.
Provider organisation	A provider organisation may be any business entity (including a sole trader in the case of an independent practitioner) that delivers health services directly to individuals and may include other provider organisations.
RIM	Reference Information Model (HL7)
R-MIM	Refined Message Information Model (HL7)
SDO	Standards Development Organisation
Shared EHR (SEHR)	For the purposes of this report, a Shared EHR is equivalent to the Integrated Care EHR as defined in ISO TR 20514.
SNOMED-CT	Systematized Nomenclature of Human and Veterinary Medicine – Clinical Terminology.
TC 251	CEN Health Informatics Committee
UML	Unified Modelling Language
UN/CEFACT	United Nations Centre for Trade Facilitation and Electronic Business Information Standards.
W3C	World Wide Web Consortium
XDS	Cross Enterprise Document Sharing (IHE). XDS-MS: XDS – Medical Summary
XML	eXtensible Markup Language. A language for organising and annotating data for interchange between disparate information systems.

# Appendix B – References

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# Appendix C – Standards Map

The following table summarises the status of e-health standards needed to support sharing of EHR information and also indicates gaps where further work is required. **Bold** entries are specifically impacted by the recommendations of this report.

## Shared EHR Scope

Aspect	Standardisation Options	Preferred Standard (Source and/or Comment)
EHR Definition	ISO/TR 20514	<b>“Integrated Care EHR” (ISO/TR 20514)</b>
EHR Requirements	ISO TS 18308 HL7 EHR Functional Requirements	<b>No normative standard.</b> TS18308 is informative for national Shared EHR Services

## Data Definition

Aspect	Standardisation Options	Preferred Standard (Source and/or Comment)
Reference Model	CEN EN13606-1 Ref Model openEHR Ref Model HL7 v3 RIM	<b>Australian adaptation of CEN13606-1</b> (with review of how to address ‘ENTRY’ classes, instruction states)
Data Groups	NEHTA Clinical Information data groups openEHR Archetype Repository HL7 Clinical Statements Other attempts	<b>NEHTA Clinical Information data groups</b>  Note: to be integral part of Australian Shared EHR Metadata and foundation for Shared EHR Content Specifications
Terminology	SNOMED-CT LOINC, AMDT, ICPC2 Numerous alternatives	From NEHTA’s Clinical Terminology work SNOMED/CT agreed as foundation; Diagnostic, Medication, Core Mappings under review
Data Types	openEHR Data Types CEN Data Types HL7 V3 Data Types	<b>CEN Data Types with preference for support of HL7 harmonisation</b>
EHR Extracts	CEN Extract openEHR Extract	<b>CEN Extract EN13606-1</b>
Data Identification	ITU/ISO OID GUIDs X-Links URI	<b>* Area for review</b> (in conjunction with NEHTA’s Interoperability Framework) Possible combination required: URI + Another
Sensitivity Labels	CDA sensitivity labels CEN sensitivity levels	CEN sensitivity labels
Method of constraining reference model to support data groups	HL7 V3 Templates (schematron assertions) openEHR Archetypes CEN Archetypes	<b>CEN Archetypes EN13606-2 and 13606-3</b> (*templates to be reviewed with CDA r2)

Aspect	Standardisation Options	Preferred Standard (Source and/or Comment)
State management (e.g. for as medication prescriptions, dispenses and administration)	openEHR instruction states HL7v3 patient care HL7v3 orders and observations	<b>* Area for review</b> Potential extension to Australian reference model

## Interchange of EHR content

Aspect	Standardisation Options	Preferred Standard (Source and/or Comment)
Data Formats	XML, ER7, ASN.1	From NEHTA's work on Secure Messaging: XML
EHR Information Interchange - Content	HL7 CDA rel 1 HL7 CDA rel 2 HL7 Patient Care <i>openEHR</i> XML format XML CEN serialisation CEN EN13606 XSD HL7v3 from EN13606 DMIM HL7 v2	<b>HL7 v2 – for priority Clinical Information Data Groups covered by AS4700 (up to v2.7)(≥ 5yrs)</b>  <b>* MAJOR area for review:</b> Options for medium-term onward including CDA r2, EN13606 XDS, EN13606-5, HL7v3 other XML serialisation options.

## Services for Managing Content

Aspect	Standardisation Options	Preferred Standard (Source and/or Comment)
Service for Versioning EHR Content	IHE XDS+ ebXML CEN versioning <i>openEHR</i> Versioning Model HL7 v3 medical records	<b>* Consider CEN as preferred approach, Otherwise</b> address HL7 or ebXML in review of EHR Content interchange.
Service for Attesting EHR Content	CEN Attestation <i>openEHR</i> Attestation	Low intrusion methods under review by NEHTA
Service for Auditing	<i>openEHR</i> Auditing	From: NEHTA Shared EHR Design
Service for Managed Lists	<i>openEHR</i> persistent compositions CEN persistent compositions	<b>None</b> – address with Views, Update Entries and Shared EHR Service logic
Service for Linking	CEN links <i>openEHR</i> links IHE XDS – ebXML CorbaMed HILS	<b>CEN EN13606 Links and Link/Reference Data Types</b>
Service for Querying	HL7 v3 control/query IHE XDS+ ebXML XML Query <i>openEHR</i> Queries CorbaMed COAS	<b>* MAJOR area for review.</b> <b>Otherwise</b> consider HL7 or ebXML as part of EHR Content interchange review
Service for Access Control	SAML XACML PMAC	From: NEHTA's work on Secure Messaging User Authentication and Access Control SAML (under review) PMAC not favoured for Australia