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**Standards for E-Health  
Interoperability**

**An E-Health Transition Strategy**

Version 1.0 – 08/05/2007

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# 1 Introduction

## 1.1 Purpose

The purpose of this document is to recommend a standards approach for both the long-term and the short term that will deliver the most effective support for a broad range of e-health information interchange requirements in Australia including referral, discharge, health profiles, prescribing, dispensing, requests and reports for diagnostic tests such as pathology and radiology. The application of standards in these areas, when combined with unique health identifiers, clinical terminologies and secure communication standards, are essential to support reliable, consistent communications between disparate health care organisations and will provide the building blocks for a national approach to Shared Electronic Health Records (Shared EHR).

## 1.2 Background

In 2005, NEHTA commissioned a review to recommend the most appropriate standards for sharing EHR information in the Australian context. The review noted global developments in e-health standards emerging at that time and indicated that successful achievement of longer-term strategy would depend on the ability of its standards to support clinical terminology, constraints (archetypes and templates), structured documents and service-oriented technologies.

The review recognised the current dominance of HL7 version 2 in Australia, suggested that the emerging European EN 13606 EHR communication standard be considered as a logical structure for sharing EHR information, and narrowed the field of standards for potential future information interchange to HL7 Clinical Document Architecture (CDA) standard or one of several proposed serialisations of EN 13606. The review could not be more specific in its recommendations at that time, because many of the candidate standards were still either unproven or in development – and it therefore recommended that the situation be revisited within 18 months.

After publishing the review, NEHTA sought and received feedback from stakeholders. Lessons are also being learnt from e-health standards development and implementations around the world and, most importantly, progress with a range of NEHTA initiatives is leading to evolution in the longer-term requirements for standards to be used for e-health interoperability and information interchange in Australia.

The purpose of this document is to recommend a standards approach that will, over time, deliver the most effective support for the broad range of e-health information interchange requirements in Australia, including the national approach to Shared EHR.

## 1.3 Intended Audience

NEHTA has developed this document to identify the relevant standards environments to be pursued in achieving e-health interoperability and to guide further work on detailed specifications to support interconnectivity – particularly for referral, discharge, prescription, dispensing, diagnostic services and Shared EHR applications.

Therefore, this document is primarily intended for:

- Jurisdictional health authorities and public and private health service providers – to aid the specification and acquisition of new health information systems and interconnectivity solutions that facilitate sharing and interchange of information across the wider health sector –

and to provide these participants with the opportunity and refine the proposed approach by giving feedback;

- Health ICT solution suppliers, including providers and potential providers of tooling, message testing and certification services– to inform them of NEHTA’s proposed strategy for e-health standards and to give them opportunities to contribute to the development and practical realisation of the strategy; and
- Standards Australia Committee IT-014, HL7 Australia and the wider Australian health informatics and e-health standards communities – to provide a basis for collaboration in developing required standards, specifications and capabilities needed to realise the proposed approach.

This document assumes the reader is familiar with issues surrounding selection and development of standards and specifications for e-health information interchange in Australia.

## **1.4 How to use this document**

This document is intended to provide the community with an understanding of the general direction in standards implementation that NEHTA is progressing toward and support the e-health community in decision making around future e-health investments.

For standards that NEHTA currently recommends, readers are invited to look at the NEHTA standards catalogue (available at [www.nehta.gov.au](http://www.nehta.gov.au)). As the NEHTA work program moves forward and specifications and standards are developed in line with the direction identified in this document, the standards catalogue will be updated.

Written feedback on this document should be directed in email to: [standards@nehta.gov.au](mailto:standards@nehta.gov.au).

## 2 Drivers for change

### 2.1 NEHTA progress

The NEHTA work program includes a range of initiatives that affect Australia's requirements for e-health standards, including the development of unique health identifiers for individuals and providers, introduction of SNOMED CT and medicines terminologies, specification of information and data structures for use across a variety of clinical settings. It also includes the establishment of frameworks to facilitate the use of service-oriented technologies in the Australian health sector.

Specific progress on some particular NEHTA work items since the review paper was published includes:

- The publication of NEHTA's recommendation that secure messaging should be based on Service Oriented Architecture (SOA), Web Services and XML.
- The establishment of the International Health Terminology Standards Development Organization (IHTSDO) to maintain SNOMED CT; and the release of NEHTA's work towards establishing an Australian medicines terminology. The proposed standards approach must be capable of effectively and reliably integrating with multiple clinical terminologies, specifically SNOMED CT and the Australian medicines terminology.
- The publication of a specification for discharge summaries and is working up a range of other clinical documents.
- Confirmation that Jurisdictions are on the whole dependent on their preferred vendors being able to support any proposed e-health standards. Therefore any choice of e-health interoperability standards must be capable of being supported by commercial off the shelf products.

NEHTA has also confirmed the Jurisdictions' interest in using web services and SNOMED CT in future systems implementations, but the timing of changes in e-health interoperability standards and introduction of services-oriented architectures or new terminologies would most likely be synchronised with major upgrade or replacement of existing systems. In this regard, the earlier review identified the importance of HL7v 2.x as the basis for most current e-health interoperability in Australia but also recognised the need to adopt and move toward a more formal, model-based approach to secure longer-term benefits.

### 2.2 International developments

International activities are changing the range, types and capabilities of standards available to support e-health information interchange. Under pressure from vendors and national programs in the US, UK, Canada and across Europe, standards bodies are collaborating more openly in the development and progression of standards.

Major implementations of HL7 v3 are now operational, with resulting experience being fed back into the standards development process – bringing the prospect that long-standing issues surrounding data types, tooling, templates and information representation will be resolved.

Progress on international activities of particular relevance to the adoption of a proposed approach to e-health connectivity standards includes:

- Formation of the IHTSDO that will oversee maintenance of the SNOMED CT terminology on behalf of the international user community.

The need for rigorous application of clinical terminology as the foundation of semantic interoperability for clinical information is now generally accepted with SNOMED CT is being released for widespread use at reasonable cost throughout the world. In parallel, there has been increased interest in technologies such as archetypes and templates as a way of mutually constraining the use of structure and terminology to assure more reliable semantic interoperability.

- The NHS Connecting for Health (CfH) program has adopted CDA R2 for its national summary care record and will be releasing some of its specifications for formal adoption and world-wide publication by HL7.

Initial CfH experience in implementing HL7 v3 messaging led the NHS undertaking significant work to refine its in-house HL7 v3 capabilities, improve tooling, reduce diversity of implementation and facilitate use of the HL7 v3 message development framework. This work is being undertaken with the knowledge and consent of the HL7 Board and is expected to drive further improvements in the underlying HL7 standards and their recommended use (see [NHS\_2006a]).

- European and international adoption of the five-part EN 13606 EHR Communication Standard (recommended by the review for consideration as an architecture for sharing EHR information) did not proceed as rapidly as was expected. Although the final version of the reference model has just become a full European standard, it lacks some technical features sought by Australia and, as yet, there is no health facility known to be using the standard in live production.
- HL7 is considering, balloting or in the process of publishing new versions of:
  - Data Types (guided by efforts to harmonise EN 13606, *openEHR* and HL7 data types);
  - UML ITS (guided by implementation experience within the UK);
  - Templates Specification (guided by implementation experience within the UK);
  - CCD (Continuity of Care Document): a CCD is a CDA R2 implementation of the Continuity of Care Record (CCR), which is statutorily required for patient referrals in the US, in Ballot cycle two opened.
- The potential for the health sector to exploit industry-standard service-oriented approaches has been recognised. The Healthcare Services Specification Project (HSSP) being run jointly by HL7 and the Object Management Group (OMG) is well advanced in producing the first of a new generation of services-oriented specifications for information interchange across the health sector. While the HSSP specifications are still proceeding through the development process and are yet to be completed, there is strong vendor support for HSSP, which should ensure that fully implementable specifications emerge within an appropriate timeframe
- Among many other relevant activities, the ISO TC215 (Health Informatics) Committee:
  - has now published the HL7 RIM and HL7 V2.5 as full international standards;
  - is expected to complete adoption of HL7 CDA R2 soon;
  - Is currently balloting Parts 1, 2 and 4 of EN 13606 as full international standards; and
  - Has revived work on updating the HISA (Health Informatics Services Architecture).

### 2.2.1 Support for the Shared EHR

A national approach to Shared Electronic Health Records (Shared EHR) requires a comprehensive, uniform standards approach that will enable a wide range of clinical information to be specified and seamlessly represented for interchange between applications.

As the business case for a national approach to Shared EHR progresses, issues around "which standard" become more urgent as sufficient work needs to be undertaken to ensure that the preferred standards are fit for use within the national approach to Shared EHR.

This approach also needs to facilitate use of the same information in other e-health applications, including: referrals, discharge summaries, pathology, radiology, prescribing/dispensing and a proposed Shared Health Profile, noting that information stored in the Shared EHR is often created in other contexts and information from a Shared EHR is also likely to be reused in other contexts.

### 2.2.2 Jurisdictional feedback following previous review

Jurisdictions were generally supportive of the findings in the review and indicated their preference for standards that are:

- More likely to be supported by commercial off the shelf solutions (such as patient administration systems, pathology systems, clinical information systems, etc) as most Jurisdictional agencies tend to buy rather than build; and
- Able to work well with other NEHTA recommendations, such as recommendations for identifiers, secure messaging, clinical information and terminologies.

### 2.2.3 Public feedback following previous review

Organisations and individuals associated with Standards Australia Committee IT-014 (Health informatics) also provided a substantial amount of feedback on the review. Comments included:

- The distinction between an interchange format for EHR content and the services offered by a full record architecture (e.g. versioning, querying, extensibility, etc) was required;
- There is a need to distinguish the document-oriented aspects of EHR content from some of the action-related aspects handled by messages (e.g. request, response, acknowledgement, cancel, replace, etc). Furthermore, it was noted that a document standard by itself was not going to be sufficient going forward, and some support for messaging oriented standards was going to be required;
- The relationship between imaging standards (such as DICOM), implementation profiles (such as IHE and Australian HL7 v2 implementation guides) and Shared EHR standards needs to be considered in more detail;
- Standards for data storage should be considered;
- Issues around unstructured documents and human readability need to be discussed;
- Concerns were raised about the risk of recommending a standard which diverges from HL7 v3, at a time that it is starting to be supported by vendors within the UK and USA;
- In contrast to the previous point, concerns were raised about adopting anything which had emerged from a standards development process

which was largely international may have unwanted additional baggage that may not be relevant in the Australian context;

- The risk of recommending a currently untested specification, namely EN 13606, was identified; and
- The distinction between what will be required by legacy systems and what will be required by newer systems needs to be clarified.

### 3 Summary of e-health standards requirements

Based on consideration of the above drivers, including needs emerging from the NEHTA work program, lessons learnt from implementing the various standards (including the NHS CfH [NHS\_2006a], existing statements of requirements (such as ISO TS 18308 [ISO\_2004a], HL7 EHR Functional Requirements [HL7\_2004]), and by comparing features of the standards that are currently available, a hierarchical set of requirements for e-health interoperability standards was produced.

The final set of requirements are summarised under the broad headings of "Features", "Ease of Implementation" and "Community Support", as follows:

- Features – suitable approaches should provide formal, consistent processes and models for representing a broad range of e-health content based on internationally agreed e-health standards and enabling achievement of semantic interoperability.

Other important features include: availability of automated tooling for capturing and modelling e-health content, support for proper use of clinical terminologies (including SNOMED CT); and use of constraint structures for simplified specification and control of clinical content.

Approaches should also be designed for use with contemporary services-oriented architectures (SOA) for e-health interoperability and enable e-health information to be represented, used and re-used in different contexts as structured documents or as messages.

- Ease of implementation – factors considered in this area included implementation complexity and consistency (and their relationship to the level of implementation maturity), migration path and the emergence of supporting tools for specifying content and implementing the approach.
- Community support – as the whole field of e-health standards is still evolving, the size of the support communities in Australia and overseas, the commitment to actual implementation and the investment and quality of work being undertaken each of the various approaches have strategic importance.

The current Australian portfolio of e-health standards (which are predominantly based on use of HL7 v2 messages for information interchange) do not effectively support many of the requirements now emerging in Australia, particularly formal clinical terminology, structured documents and services-oriented architectures. Meeting the requirements will involve the adoption of new standards and the replacement and update of some existing standards.

## 4 Analysis approach

As outlined above, the first steps in determining the proposed approach to e-health interoperability standards were to:

1. Consider the initial review and analyse the feedback that had been received following its release;
2. Identify and consider impacts of additional drivers emerging from more recent NEHTA work, progress in developing each of the relevant e-health standards and international experience with implementation; and
3. Identify and document a hierarchical set of requirements for e-health interoperability standards.

The following were identified as potential candidates for assessment as e-health standards approaches for use in the short, medium and longer terms:

- Continuing with an *HL7 v2 approach*. This involves retaining and extending HL7 v2.x for discharge/referral, prescribing, pathology and diagnostic imaging messages and defining further extensions to meet Shared EHR and other requirements.

The assessment noted that such an approach could potentially include using HL7 v2.x to carry more detailed clinical information represented as *openEHR* or EN 13606 archetypes or CDA documents.

- Migrating to a *Document/Services-Centric HL7 v3 approach* focussed on using services based on HSSP (in preference to messages) to share structured documents formally specified using HL7 v3 CDA Release 2 and templates standards. If necessary, some HL7 v3 messages may also be defined in some specific domains based on the full suite of message-centric specifications within the HL7 v3 standard.

The assessment took into account enhancements to the HL7 v3 specifications that are being made as a result of international implementation experience with in the UK, US and Canada, in particular, refinements to the Data Types, ITS, TermInfo, Templates, Clinical Statements and Continuity of Care Document (CCD).

- Migrating to an *EN 13606 approach* that assumes all 5 parts of the EN 13606 standard would be completed and implementable in accordance with identified Australian requirements for harmonised datatypes, archetype path representation and lower-level modelling constructs.
- Migrating to an *openEHR approach* which uses the specifications currently available on the *openEHR* website.

A detailed evaluation was carried out in which each of the four approaches was assessed.

Each of the approaches and the strengths and weaknesses of each are discussed in Section 0.

On the basis of this assessment, migrating to a *Document/Services-Centric HL7 v3 approach* was selected as the preferred longer-term direction, complemented by support for continued use of HL7 v2.x and development some limited extensions in the short-to-medium term.

In addition, some consideration was given to whether two other potential approaches should be separately assessed:

- a purely message-centric HL7 v3 approach (as had been discussed in the earlier review); and
- Potential for use of HL7 v3 CDA with the IHE XDS.

In both cases, it was considered that each of these approaches would have much in common with, but be lesser than the document/services-centric HL7 v3 approach. Migration to HL7 v3 messaging in the short- to medium-term would be costly but yield little more than current HL7 v2.x capabilities, whereas in the longer-term, practical application of HL7 v3 messaging was expected to converge with the document/services-centric approach.

The possibility of using XDS was raised during the course of the assessment, after the preferred approach path had been identified. It was noted that the XDS specifications provide a pragmatic response to document sharing and are expected to evolve considerably in coming years. Aspects of the present XDS specification do not accord with other NEHTA specifications (notably the preference is for a more contemporary approach based on the W3C WS-\* web services stack, stronger harmonisation with formally derived approaches is desired, and adoption of XDS at this time would pre-empt decisions about national Shared EHR architecture). If an evolved form of XDS later became a preferred interchange format in Australia, this could be accommodated as an extension of the document/services-centric HL7 v3 approach but the reverse would not be true.

The process of confirming the principal findings also involved consultation and consideration of input from the following parties:

- All material was circulated within Jurisdictions for comment;
- The material was reviewed by four different independent groups of consultants; and
- Stakeholder feedback on the previous review was considered.

In moving forward, NEHTA also expects to receive feedback on this document from the affected community of interest, which will be used to help shape ongoing work.

## 4.1 Assessment of alternatives

The proposed e-health standards strategy described above was recommended following NEHTA's consideration of four potential approaches against the identified key requirements, also summarised above. In broad terms, the four candidate approaches for the longer-term were:

- Continuing with HL7 v2;
- Migrating to a document/services-centric approach using HL7v3 CDA R2 and HSSP;
- Migrating to an EN 13606 approach; and
- Migrating to an *openEHR* approach.

### HL7 v2 approach

As identified in the earlier report on shared EHR standards, HL7v2.x is the predominant means of communicating e-health information in Australia and is very effective for traditional message-based interconnectivity applications within well-controlled ICT environments. Its capabilities also continue to be extended – although it is unclear how many of these more recent extensions have yet to be used in practical implementations.

It has a large community support in Australia and internationally, its current range of uses is well supported by existing knowledge, tooling, consulting services and implementation guides and rapid replacement would be costly and potentially unworkable.

Notwithstanding these benefits, it lacks many of the functions and features now being sought in an e-health standards framework. In particular:

- High flexibility, coupled with inconsistent implementations makes it progressively harder to interconnect large numbers of users that already operate in their own environments (e.g. for state-wide projects);
- It is not based on a comprehensive information model able to unambiguously represent the required range of e-health content;
- Whilst HL7 v2 messages are a common means of transporting CDA documents, HL7 v2 itself does not support any structures or processes for rigorous specification of clinical documents; and
- Whilst it can be carried across a web-services transport layer, it has limited potential to exploit services-oriented architecture.

Indeed, it was for many of these reasons that the HL7 organisation embarked on the development of HL7 v3, which is now becoming much more accepted.

Therefore Australia is now adopting a longer-term pathway that leads beyond HL7 v2 to a contemporary e-health standards approach that can be transparently used with structured documents, SOA and clinical terminology to achieve reliable, semantically correct, interchange of e-health information.

Given that migration to the new approach will necessarily be progressive and, in some cases, governed by relatively long system replacement cycles, NEHTA is supporting use of HL7v2, along with a limited range of extensions that will extend its utility for the short-to-medium term. Some of these extensions, such as the proposed collaborative care messages will also provide bridging capability for NEHTA initiatives.

In supporting use of HL7 v2 for the short-to-medium term, steps to reduce diversity of implementation and to provide services-oriented transport infrastructure are also proposed.

## HL7 v3 approach

Significant factors which favoured migration to a document/services-centric implementation of HL v3 as the preferred longer-term approach were:

- Features: HL7 v3 is currently the only approach considered that combines a formal methodology with established models and value sets needed to express the full range of specifications and other artefacts being sought for interoperability in e-health, including specifications for prescribing, referrals, and discharge summaries. The approach also closely fits with identified medium-to-long term requirements for:
  - Integration of clinical terminology - particularly, through work on TermInfo;
  - Structured documents – through CDA Release 2 and the emerging use of templates as constraints; and
  - Integrated support for services - through the HSSP initiative.
- Ease of implementation: While it is unlikely that any of the assessed approaches make it easy to meet longer-term requirements, as of today, HL7 v3 has relative advantages in that:
  - HL7 v3 technologies have been implemented and are now working at national scale in the UK NHS (and to a lesser scale in Canada, US, Europe and some other countries);
  - There is now a significant amount of HL7 v3 tooling and increasing levels of technical support available in the international community, although as yet very little in Australia;
- Community Support: The size of the relevant community of interest supporting HL7 v3 is unique; the investments this community has made in implementing and continuing the development of HL7 v3 and its

active inclusion of clinical and other specialist groups are significant positive factors positioning HL7 v3 as the mainstream.

In particular, adopting an HL7 v3 approach enables Australia to work closely with and share tools, expertise and methods with CfH in the UK, Canada Health Infoway, US Government health agencies and, also, to support vendor interoperability through IHE and similar processes.

On-going criticism of some technical aspects of HL7 v3 including the structure of its data types, complexity of its clinical information representation, size of its messages and the low maturity and limited capability of HL7 templates as constraints were noted; however, these aspects have not stopped HL7v3 and CDA technology being successfully deployed on a large scale and this has led to major investments to improve the associated methodologies, standards and support tools.

## openEHR approach

*openEHR* technology is comprehensively documented as a series of rigorous information models, which allow clinical content to be defined as universally applicable archetypes that facilitate sharing of EHR content between applications that conform to the *openEHR* specifications. The relevant strengths and weaknesses of the *openEHR* approach were assessed as:

- Features: *openEHR* provides the richest capability for representing detailed clinical content in a semantically interpretable form (as archetype constraints), has good support for clinical terminology and was designed to conform to the ISO TS 18308 (EHR Architecture) standard. It also provides services-oriented interfaces for managing records and archetypes in an EHR context.

On the other hand, the *openEHR* approach fell short of the identified requirements (and the proposed document/services-centric HL7 v3 approach) in the following respects:

- *openEHR* assumes that e-health information is presented and managed as EHR extracts or compositions, which are unnecessarily complex for simpler e-health documents and messages – this has been raised as a significant factor limiting potential vendor and jurisdictional acceptance; and
- It also gives little support for specifying other types of e-health interactions (e.g. medication prescriptions), structured documents, messages or human-readable material.
- Ease of Implementation: Specification of *openEHR* archetypes is reasonably easy and is supported by various different tools that are available as open-source and commercial products; however, a range of potential implementation difficulties also emerged:
  - Effective measures are still needed to maintain semantic interoperability faced with potential duplication, incompatibility and variable quality of open-ended archetype developments;
  - Despite the availability of an open-source reference implementation, integration and/or interfacing with existing applications is complex and has very limited tooling support; and
  - It assumes an EHR object model that some major stakeholders consider unacceptably intrusive and costly to implement.
- Community Support: While *openEHR* is now commercially implemented and supported in some sites, predominantly as an EHR repository, and is under review for national implementation in Chile, the main overseas programs and vendors relevant to Australia remain committed to HL7 v3. The nature of the *openEHR* governance structure, the extremely small pool of engaged experts, the rate of specification

evolution, the processes for maintaining specifications and the imposition of an EHR model on e-health communication have been raised as concerns in jurisdictional and vendor feedback.

Globally, there are also very few technical resources, or vendors with significant *openEHR* skills or the capacity to integrate an *openEHR* solution into existing products.

The ability to leverage vastly superior community support for HL7 v3 as reflected by the extent of working implementations, its use in national programs, availability of tools, and level of vendor support, remains a significant reason for not proposing an *openEHR* approach.

The UK NHS has a project in train to assess the potential of using *openEHR* archetypes to model clinical content, but still within the NHS overall national commitment to HL7 v3, CDA and templates. The international Detailed Clinical Modelling (DCM) expert group are also assessing potential of *openEHR* archetypes and tools as a common means of recording clinical information models and associated terminology bindings.

In a similar vein, even though now proposing a document/services-centric approach, it is proposed that Australia continue to strongly support ongoing efforts to harmonise constraints, data types and clinical models, but within the overall context of employing the outcomes within the proposed HL7 v3 approach.

### **EN 13606 approach**

EN 13606 is a five-part European Standard for EHR Communication, which is currently being finalised and published, and is also expected to be approved as a full International Standard over the next 6 to 12 months. The review in 2005 recommended that the EN 13606 reference model be considered for adoption as the basis for interchange of shared EHR information in Australia.

EN 13606 draws heavily on aspects of *openEHR* relevant to EHR communication and uses archetypes to represent clinical information. Acceptance as a European and potentially an International Standard gives EN 13606 considerable legitimacy in some countries, opening doors for its use where *openEHR* might face hurdles.

Broadly speaking, an approach based on EN 13606 has similar technical features to *openEHR* (as discussed above) and also similar technical strengths and weaknesses, except that the standard allows interchange of less structured content and was designed to be backward compatible with some message-based implementations. On the other hand, the adequacy of some of its technical features has been questioned, with implementation experience having led *openEHR* to make changes not reflected in EN 13606. A vote from Standards Australia seeking to correct these shortcomings in the international version of the standard is not expected to be accepted, with negative implications on stakeholder support for EN 13606 in Australia.

Community support is even more of a problem for EN 13606 than for *openEHR* and the proposed HL7 v3 approach. Obtaining final approval for EN 13606 as a European standard has taken considerably longer than first expected, with Norway, Germany and the Netherlands continuing to oppose. There is, as yet, no active support community for the standard in its current form and it has not been used outside the research environment anywhere in the world. Consequently, there remains a significant risk that EN 13606 has not evolved sufficiently to continue to be recommended as the basis for a national e-health interoperability program for Australia.

# 5 Analysis summary

## 5.1 Findings

Based on the evaluation of alternatives, there was no “perfect” solution which meets all requirements for the short, medium and long term.

For most user and supplier organisations in Australia, there is little to be gained by moving from the current HL7 v2 standards to a new standard in the short term. However, despite the strength of local community support for HL7 v2, it is on the verge of being surpassed in the medium term by other standards which provide a more unified, feature rich and contemporary implementation approach.

For these reasons, it was clear that HL7 v2 should continue to be supported in the short to medium term, but within the context of a plan of migrating to a longer-term approach that has integrated support for rigorous semantics, structured documents, compatibility with constraint-based representation of clinical information and services-oriented workflow management.

Migration to a document/services-centric implementation of HL7 v3 emerged as the strongest option from the assessment process for the medium-to-longer term, for the following reasons.

### 5.1.1 Features

While *openEHR* had some superior strengths in its ability to capture and structure detailed clinical content, the proposed HL7 v3 approach provided the most rounded and consistent package of features to address the required range of functionality, including:

- Being the only framework having a formal specification development methodology with established models and value sets needed to express the multitude of different kinds of specifications and other artefacts being sought for interoperability in e-health;
- Having addressed many issues associated with the logical integration and combination of clinical terminology with underlying information models - particularly, through on-going TermInfo work;
- Having the most widely utilised and best developed approach to structured documents – through CDA Release 2. This is now accepted as the norm in several national programs and is being supported in IHE profiles. Although use of templates as constraints on CDA documents is still being refined, recent advances provide workable approaches (now in ballot); and
- Providing integrated support for services - through the HSSP initiative.

It was also noted that further evolution of the underlying HL7 v3 standards and tools is underway to address shortcomings revealed in earlier implementations. Full Australian implementation needs to anticipate, investigate and exploit technical improvements to the support of templates and terminologies and better tools for aiding specification development and simplifying implementation.

While the EN 13606 EHR Communication standard is based on archotyping and shares many features with *openEHR*, there are some concerns about the adequacy of some of its technical features, with implementation experience having led *openEHR* to adopt positions that differ from those reflected in EN 13606. These shortcomings were reflected in a recent “supportive but negative” vote from Australia in the recent ISO ballot for adoption of EN 13606 as a Draft International Standard. (Notwithstanding, the standard did progress to Final Draft International Standard (FDIS) ballot).

### 5.1.2 Ease of implementation

While it is unlikely that any of the assessed approaches make it easy to meet longer-term requirements, as of today, HL7 v3 has relative advantages in that:

- HL7 v3 technologies have been implemented and are now working at national scale in the NHS CfH (and to a lesser scale in Canada, US, Europe and some other countries); and
- There is now a significant amount of HL7 v3 tooling and increasing levels of technical support available in the international community, although as yet very little in Australia. A second generation of more advanced tools are now emerging based on experience in large implementations.

While *openEHR* and EN 13606 archetypes provide an easy means of capturing clinical content and the *openEHR* approach is also supported by tooling – current archetype proposals address only part of the wider requirement and these approaches still involve considerable difficulty integrating with existing applications.

### 5.1.3 Community Support

With some 6,000 paying participants and over 30 International Affiliates, the relevant community of interest actively supporting HL7 v3 is a significant proportion of the worldwide e-health community. Support for HL7v3/CDA has been boosted by its being implemented by the national programs in the UK and Canada and having been adopted for use across US Government agencies (including DoD, HIPAA, VHA DHHS, CDC and all who deal with them), by the NATO forces and by the Dutch, German, Mexican and Croatian government health services. It is also the technology of choice for most US NHIN prototypes and many RHIOs. Overall, the investments this extended community has made in implementing and in continuing the development of HL7 v3 (including engagement with clinical and other specialist groups) are significant positive factors positioning HL7 v3/CDA as being the mainstream direction in international e-health standardisation.

Adopting an HL7 v3/CDA approach would therefore enable Australia to work closely with and share tools, expertise and methods with CfH in the UK, Canada Health Infoway, US Government health agencies and, also, to support vendor interoperability through IHE and similar processes.

Feedback from larger international health systems suppliers and a handful of small local suppliers indicated that they have already built HL7 v3 support into their products or have immediate plans to do so. Most of the supplier community also accept and continue to support HL7 v2 - some to the exclusion of considering or accepting any other approaches.

The supplier and user support community for *openEHR* is small (estimated at less than 100 active participants) but is highly committed to the approach, its perceived design integrity, the flexibility of its archetypes and the potential to use the reference implementation as a low cost entry point for greenfield and research implementations. The approach is understood to have been used in EHR repository and other products in Australia, the UK, the Netherlands, Turkey and Brazil and is under consideration for adoption as the basis of a national EHR in Chile. As identified in several major reviews<sup>1</sup> and by some in *openEHR* itself, the processes used for control and governance of archetype development need refinement, if different implementations are to semantically interoperable (noting that similar comments could apply to the use of similar constraint-based representations of clinical content – including HL7 v3 templates on the Clinical Statement and EN 13606 archetypes).

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<sup>1</sup> See [NHS\_2006b]

The current version of the European EN 13606 standard has so far only been implemented in a single academic research environment but its development as a European and International Standard for EHR communication and its harmonisation with both HL7 v3 and *openEHR* is being actively supported by a small but significant community that includes the HL7 organisation, the *openEHR* Foundation and many of those already committed to HL7 v3 and to *openEHR*. Notwithstanding this support and very recent approval of the first parts as a full European Standard, finalisation has taken longer than expected (with Norway, Germany and the Netherlands continuing to oppose and being unlikely to adopt it, even when approved).

Without any organisation actually having committed to implement or comply completely with the EN 13606 standard there remains a significant risk that it has not evolved sufficiently to be recommended as the basis for a national e-health interoperability program for Australia and it therefore lacks the level of significant community support needed in order for it to be recommended.

### 5.1.4 Conclusion

On the basis of the above considerations, and particularly the capacity to provide a rigorous framework for standards development addressing the required features and scope with such extensive and relevant community support, the assessment concluded that Australia should adopt, develop and, over time, migrate to a document/services-centric implementation of HL7 v3, based on:

- Using HL7v3 Clinical Document Architecture (CDA) Release 2 to represent e-health information (constrained by HL7v3 templates) for information interchange; and
- Using web services specified in accordance with the joint HL7/OMG Health Services Specification Project (HSSP) to provide the technical functions needed for the electronic interchange of clinical documents, management of clinical workflow and application of health information in operational contexts.

As this longer-term goal will take some time to be fully achieved, it is proposed that HL7 v2 continue to be supported in the short- to medium-term, within the bounds of what is both practical and technically feasible, based on:

- HL7 v2 messaging continuing as the primary means of interchanging e-health information in areas where it is currently delivering benefit (such as in patient administration and pathology), until superseded by proposed document/ services-oriented approaches and in parallel with the Australian Standard HL7 v2 implementation guides being updated to reflect recent and emerging NEHTA recommendations; and
- A web-services transport layer being specified to deliver HL7 v2.x message content, giving vendors and jurisdictions a means of migrating their e-health communications towards a more service-oriented approach

In parallel with pursuing the approach proposed above, NEHTA is continuing to track developments in *openEHR*/EN 13606 archetypes and associated tools for capture and representation of clinical content and to encourage collaboration between HL7, CEN, ISO and *openEHR* to maximise potential interoperability and convergence in the areas of basic data types, constraints, clinical information models and service-oriented architecture.

It is no longer proposed that Australia adopt EN 13606 or any other standard implying an EHR storage architecture to represent e-health content for information interchange. Standards Australia's recent decisions to vote for changes to the current EN 13606 Draft International Standard and to publish EN 13606 as part of a Technical Report, rather than adopting it as an Australian Standard, were also noted.

## 6 Recommendation

It is recommended that Australia adopt, develop and, over time, migrate to a document/services-centric implementation of HL7 v3, based on:

- Using HL7v3 Clinical Document Architecture (CDA) Release 2 to represent e-health information (constrained by HL7v3 templates) for information interchange; and
- Using web services specified in accordance with the joint HL7/OMG Health Services Specification Project (HSSP) to provide the technical functions needed for the electronic interchange of clinical documents, management of clinical workflow and application of health information in operational contexts.

As this longer-term goal may take some time to be fully achieved, it is proposed that HL7 v2 continue to be supported in the short- to medium-term, within the bounds of what is both practical and technically feasible, based on:

- HL7 v2 messaging continuing as the primary means of interchanging e-health information in areas where it is currently delivering benefit (such as in patient administration and pathology), until superseded by proposed document/ services-oriented approaches;
- All current HL7 v2 standards, as identified by Standards Australia, should be placed on the NEHTA standards catalogue;
- In time, Australian Standard HL7 v2 implementation guides should be updated to reflect recent and emerging NEHTA recommendations; and
- A web-services transport layer being specified to deliver HL7 v2.x message content, giving vendors and jurisdictions a means of migrating their e-health communications towards a more service-oriented approach

In parallel with pursuing the approach proposed above, NEHTA is continuing to track developments in *openEHR*/EN 13606 archetypes and associated tools for capture and representation of clinical content and to encourage collaboration between HL7, CEN, ISO and *openEHR* to maximise potential interoperability and convergence in the areas of basic data types, constraints, clinical information models and services architecture.

Under the proposed approach, document-centric specifications for e-health information content (including the existing NEHTA clinical data groups) will be developed by directly constraining the proposed document architecture, rather than as EHR extracts constrained by archetypes under a EHR architecture. Accordingly, NEHTA will not be adopting the European EN13606 standard on EHR Communication (parts 1 to 3) as the basis for e-health information interchange specifications (as recommended in the earlier report).

# 7 Benefits and further considerations

## 7.1 Benefits of proposed approach

Key benefits of the recommended longer-term approach are

- Australia can build on extensive implementation experience, standards development work, tooling and vendor capability arising from use of HL7 v3 and CDA 2 in major programs, including those of Connecting for Health (CfH) in the UK, Canada Health Infoway, US Government health agencies, RHIOs and the IHE consortium;
- It provides much better and more integrated support for services, clinical terminology, structured documents and constraints - compared with the capabilities of the current suite of HL7 v2 standards;
- It also has a more unified, and coherent framework for developing specifications for e-health information interchange based on rigorous application of model-based semantics across domains;
- Being document-centric, it allows many existing paper based clinical documents to be directly translated to an electronic equivalent;
- By using services and documents together, clinical content can be decoupled from workflow restrictions (which is currently a restriction in a messaging based approach); and
- The HL7 approach to services allows the future national Shared EHR to accommodate both centralised and federated architectures.

The benefits of continuing support for HL7 v2.x in the short-to-medium term include:

- Getting maximum return from the existing widespread support for HL7 v2 within the Australian and international community; and
- Providing owners of existing systems with a staged migration path to services-oriented interconnectivity and greater time in which to make a move to document/services-centric HL7 v3 technology.

## 7.2 Issues for further consideration

There are a number of issues that arose during NEHTA's consideration of the requirements for evaluating different e-health standards approaches. This section provides further background on the thinking behind some of NEHTA's requirements and the trade offs that are being made in relation to:

- Co-existence of HL7 v2 and HL7 v3;
- Ongoing HL7 v3 development issues;
- Extensibility and localisation;
- Structured documents and services vs. messages;
- XML vs. compact message size;
- Semantic interoperability; and
- Standards for EHR storage.

### 7.2.1 Co-existence of HL7 v2 and HL7 v3 CDA/HSSP

The approach recommended in this document does not intend to enforce a rapid and sector wide replacement of existing HL7 v2 interfaces with HL7 v3

CDA/HSSP based interfaces. The preferred approach is to allow both HL7 v2 and HL7 v3 CDA and HSSP based interfaces to co-exist and over a long period of time HL7 v2 would be phased out slowly as legacy systems are refreshed as part of the investment cycle.

This means that some systems and/or interface engines will need to support a combination of HL7 v2 interfaces with existing legacy systems and HL7 v3 CDA and HSSP based interfaces with newer systems. The decision to implement HL7 v2 interface or a HL7 v3 CDA / HSSP based interface is based on the business requirements of the application under consideration. For example if a system needs to interface with an older application, such as a legacy patient administration system, then HL7 v2 is likely to be required, if the system needs to be interfaced with a newer application, such as a Shared EHR, then HL7 v3 CDA / HSSP should be used.

It is acknowledged that such an approach is likely to make system integration more complex for system managers in the medium term, but it is considered to be a more pragmatic approach compared to a large scale high risk / high cost replacement of all existing interfaces between systems.

### 7.2.2 Ongoing HL7 v3 development issues

Uncertainty about the ultimate level of adoption of any approach and the true cost of implementation are significant risks to be managed in selecting an standards approach for e-health information interchange.

No significant inherent risks were identified in adoption of the proposed short/medium-term direction based on use of HL7 v2.<sup>2</sup>

The risk inherent in adopting the longer term direction is there are presently a number of unresolved issues within HL7 v3 that adversely affect its suitability for adoption today. For example, the HL7 3 clinical statement currently makes the representation of detailed clinical content more complex than it needs to be. Issues such as this will take time to address through the standards processes, which in turn may affect the timely availability of a standard for use within the rollout of the national approach to Shared EHR. Such risks can be mitigated through:

- Undertaking an exploratory project to examine in detail the technical issues prior to further standards development;
- Contributing to the path of standards development in HL7 to ensure that it goes in the desired direction, giving particular attention to tools, authoring and feedback from implementations;
- Fostering ongoing harmonisation of HL7 v3, EN 13606 and *openEHR*;
- Collaboration with other implementing nations such as the UK and Canada; and
- Supporting the collaboration between HL7 and OMG, particularly in relation to HSSP (and this may require appropriate new involvement in some OMG activities).

### 7.2.3 Extensibility and localisation

International standards are necessarily the result of collaboration and compromise between multiple competing interests. The different interests may be different values, cultures and languages, or different experts,

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<sup>2</sup> However, it was noted that many implementers have been averse to interfacing various HL7 V2.x sub-versions. This would be required to derive maximum benefit from the proposed approach, which will introduce new profiles for collaborative care, referrals and discharge summaries that are native to later sub-versions of HL7 v2 (i.e. v2.4+). This is an education issue which Standards Australia IT-014 Committee currently intends to address by producing a handbook clarifying how to mix sub-versions, without wholesale upgrades.

organisations and countries. Inevitably, the standard will fail to meet some goals of each of the participants.

One way of resolving this is for the standard to leave options open to the implementer. This allows implementations to diverge and still claim to be conformant to the specification, which is both good and bad. It's bad because it prevents easy interoperability between different implementations of the standard. On the other hand, it's good, because it allows the standard to be used more widely, and because implementers of the standard can reuse more existing functionality as they encounter different applications of the standard. Each standard strives to find the right balance in allowing for options and extensibility.

Given the diverse business and clinical practices throughout the world, international standards necessarily allow for options. The standard needs to provide a framework for expressing how these options are constrained to provide meaning within the NEHTA implementation context. HL7 V3 provides templates and 13606/openEHR provide archetypes. In each case these are fundamental parts of the system that allow for very open optional content models to be tailored to very specific use cases.

However some of the requirements will fall outside the scope allowed by the standard; it is not possible to use existing information structures to express the requirements. Generally these cases arise where the business cases have been agreed, and often full contracts have already been signed. Given a solid governance structure, it is generally possible to take these requirements forwards to the standards controlling body and have support for the features added to the standard. However political, operational and commercial pressures often require the feature to be adopted prior to the standards body even beginning to examine the issue.

One possible outcome of taking such an issue to the standards body is that the feature will be rejected. This is possible for a variety of reasons, and most often due to incompatible business process modelling. But this does not alter the requirement for supporting such features on an ongoing basis within the framework.

For this reason, it is important that the standard provides some framework for outright extension and additionally for graceful migration from a local extension to a more standard way of implementing a feature once the standard does finally adopt it. Although it is clearly better not to need such extensibility, experience with standards adoption in healthcare with HL7 V2 in Australia and HL7 V3 in UK indicates that it is inevitable that such requirements will be encountered, and using the extensibility conservatively is better than not being able to deliver the features that are required.

Each of the possible standards evaluated here are compared against their ability to support customisation and outright extension as this is a very important part of the risk of adopting a standard.

#### **7.2.4 Structured documents and services vs. messages**

The proposed document/service-centric HL7v3 approach differs from a purely message-centric HL7v3 approach in that HL7v3 CDA models and templates are used with clinical terminology to represent e-health information for interchange as clinical documents, independently of their workflow context (such as originating trigger events).

Reasons for following an approach based on structured documents and services in preference to a pure messaging based approach include:

- The current clinical environment is predominantly a document driven world and it is believed that the use of structured documents will make the mapping of real world requirements to electronic form easier than mapping to messages;

- Messages conflate control flow and content within the body of the one artefact. The separation of e-health content (as structured documents) from workflow enables workflow to be managed more appropriately by services and allows the resulting clinical documents to be re-used in different workflow contexts. There is also less need to have a separate message for every possible step in an interaction
- A structured document implies that e-health information can be more easily rendered in a human readable form than it is in a message. One reason that the PIT format has persisted despite the existence of HL7 v2 pathology messages is because PIT enables information to be more easily presented in a human readable form;
- Messages predominantly support asynchronous point-to-point request/response interactions and multicasting whereas services allow the flexibility to consider other modes of interaction (e.g. synchronous/asynchronous interactions, point-to-point vs. publish/subscribe, stateless vs. stateful interactions, and orchestration vs. choreography, etc)

As indicated at the start of this section, the preferred approach is one based on a combination of services and structured documents. Given that HL7 v2.x messages are widely used at the moment, it is expected that both messaging and a document/services based approach will co-exist for some time.

### 7.2.5 XML vs. Compact Message Size

There is a tension between the requirement for a compact interchange format (such as HL7 v2's vertical bar format) and NEHTA's recommendation that future information interchange be based on XML to leverage industry-standard approaches. The underlying cause of this tension is that message sizes based on XML are much larger than an equivalent message expressed in a traditional HL7 v2 format.

However, NEHTA does not regard the size of XML message size is not viewed to be a serious problem for a number of reasons:

- Message size alone is not the sole requirement for recommending a standard. Message size is one of many requirements considered in the analysis and has to be factored into the final ratings;
- The design-time benefit of access to productivity enhancing tooling based on XML is considered to outweigh the cost of a more verbose run-time XML format. In the XML space there is significant support for parsers, validating parsers, schema languages, query languages, links, path languages, editors, transformation and formatting languages, integrated development environments, etc;
- Of similar size to XML, big XHTML documents are used on a large scale every day and the current Internet has more than enough capacity to share XML documents of similar size and complexity of a HL7 v3 document. For example, most web pages, such as those provided by rich sites like Yahoo, MSN, Amazon, etc are served as XHTML documents, and have a comparable size and complexity to many XML based formats, such as the ones provided for HL7v2.x, HL7 v3 and openEHR.
- In the next 2 years, the performance of networks is likely to increase further to cope with the requirements for on demand video. Broadband is widely available and higher speed networks using ADSL 2+ is starting to become more widely available. Similarly, the size of storage capacity is increasing. Consumers now can purchase more than a terabyte of disk at relatively cheap prices. In the next two years, a terabyte of storage again will be more common place; and

- Compression of XML content can be used to further lower the band width requirements (if that is a serious issue for the specific scenario).

## 7.2.6 Semantic Interoperability

It is important to position how semantic interoperability is defined in this document. There are a number of definitions of semantic interoperability and surprisingly little agreement about what it is. For example:

- ISO TS 18308 defines semantic interoperability as "*the ability for data shared by systems to be understood at the level of formally defined domain concepts*";
- The IEEE standard glossary defines interoperability as the "*Ability of two or more systems or components to exchange information and to use the information that has been exchanged.*"<sup>3</sup>
- HL7 CDA defines semantic interoperability as: "*the ability of two applications to share data, with no prior negotiations, such that decision support within each application continues to function reliably when processed against the received data*";
- The HL7 EHR Working Group provides three definitions :
  - *Technical interoperability is the ability for two or more systems or components to exchange information when and where needed and to use the information that has been exchanged [based on the IEEE standard definition];*
  - *Semantic interoperability assures the clear and persistent communication of meaning by providing the correct context and exact meaning of the shared information; and*
  - *Process interoperability is the well-led, coordinated and timely delivery of patient care that is safe, efficient, cost effective and reflects best practice*

For the purposes of this document, the ISO 18308 definition doesn't really get close to the requirements around semantic interoperability, because it does not address the need for data to be shared in such a way that it can be compared.

The IEEE definition is closer to the needs of this report, but does not fully express the core need of connected clinical systems.

The HL7 CDA definition is inappropriate for two reasons. First, it sets an unreasonably high expectation, which is that two systems should be able to interoperate without prior negotiation. In the real world, there is always negotiation and either it happens between two or more transacting partners as part of a contractual arrangement or it happens in a standards development committee. Second, the CDA definition is too narrow, as there are requirements for things other than decision support to function. For example, it is important that we can transmit clinical information from one system to another in such a way that:

1. An EHR can store information from a remote source such that the EHR can be searched to find related information. For example:
  - (a) *Find all available chest X-Ray reports for this individual;*
2. An interface engine or clinical work flow management system can act upon information from remote sources and divert it to the appropriate recipient. For example:

<sup>3</sup> IEEE Standard Computer Dictionary: A Compilation of IEEE Standard Computer Glossaries, IEEE, 1990

- (a) *A radiology report indicating pulmonary tuberculosis may need to be sent to the team responsible for public health as well as to the clinician who requested the test*
3. A decision support system can act upon from remote sources and provide meaningful advice to a clinician. Examples may include:
- (a) *A decision support system can flag that a similar radiology request has been requested elsewhere recently and warn the clinician that they are about to, potentially, unnecessarily repeat the same test*
- (b) *A decision support system flagging potential drug interactions during prescribing*
4. A secondary uses application can use the data as part of an analysis. Example of such uses could include:
- (a) *A population health researcher may be interested in track the prevalence of various types of diseases within a certain community segment*
- (b) *A hospital needs data to feed a case mix analysis tool in order to extract DRG codes as part of the funding process with the insurers and government.*

The definitions from the HL7 EHR Working group are considered closer to the mark. However, they are too prescriptive about requiring accurate interpretation. For example, simply matching concepts based on string comparisons (a technique that is done in many applications today), may be sufficient to perhaps find all the X-Rays in an EHR, flag a potentially inappropriate test request and send a copy of a test result to a registry. Such forms of weak matching in many cases are considered sufficient in the clinical work force today. For example, large numbers clinicians are quite happy to search Medline, Pub Med or Google, using nothing more than a keyword matching algorithms which can leverage thesauri. However, such a weak form of matching and the high risk of false negatives would not be tolerated for supporting a decision support requirement around detecting potential drug interactions and would present the risk of unwanted statistical bias in a secondary uses.

One way of reducing the risk of false positives and negatives during the matching process would be to use a terminology, like ICD-10, for coding diagnosis and procedure related information. Such an approach would be sufficient perhaps for some secondary uses needs around claiming or a researcher looking for some high level statistics, but would be insufficient to support a more demanding researcher or a more demanding case for decision support.

The definition of *semantic interoperability* followed in this report is based on that in Wikipedia:

*"the ability of two or more computer systems to exchange information and have the meaning of that information automatically interpreted by the receiving system within acceptable tolerances for the specific use case"*

NEHTA considers that it is possible to address a reasonable number of use cases in the short term, by focusing on the development of key SNOMED CT reference sets, a way of sharing structured documents and a constraint language. This will allow the community at large to continue moving forward.

The debate within the community therefore needs to focus on specific use cases and addressing issues with specific reference sets, weaknesses in constraint languages, whether or not a sufficient level quality in the matching process is possible, and the business case for achieving that level of semantic interoperability. Given that the number of use cases is likely to be unending

as people start seeing more opportunities, this process will be an ongoing journey.

The purpose of this report is to make recommendations that support arriving at the first point, so that we can then proceed on the journey required to support the ongoing outcomes of debates within the second point.

In terms of setting a direction on the specific use cases worth exploring, NEHTA's benefits realisation plan will assist with the identification of the most viable path forwards.

### **7.2.7 Standards for EHR storage**

The approach taken in this document is to recommend standards for specifying interoperable structured documents and services rather than recommending the use of a full EHR architecture (similar to that implied by full adoption of the ISO TS 18303, the *openEHR* specifications or storage-specific elements of EN 13606).

This has been a deliberate decision, with the aim of limiting the requirements for standards to manage and structure content to the minimum needed for general e-health information interchange – while providing a means for services to be defined that permit to be versioning and query of clinical documents. The assessment therefore does not seek to go as far as some record architecture standards, which also seek to standardise the common object model to be used for EHR storage, thereby greatly constraining available database design and information storage strategies available to systems participating in standardized e-health information interchange.

While there are advantages in supporting EHR storage standards, such as reducing risks of error due to transformations between the external interoperability interface and the internal database, this document cannot support imposing such models onto vendors as many of these vendors have mature and stable systems that are not easily amenable to the retrofitting of such a model onto their existing systems without significant extra cost.

Having an approach that goes beyond just electronic health records is an essential part of the goals of this document because it is concerned with more than just moving EHR Extracts from one system to another and needs to also cover areas such as referrals, discharge summaries, prescriptions, pathology and diagnostic imaging. The implication of this is the requirements within this document are broader than the previous Shared EHR Standards review.

Notwithstanding the arguments against adopting requirements for full standardization of EHR extracts and storage, many other requirements within this document are based on ISO TS 18308 and its realisation in various environments including *openEHR*, HL7 and EN 13606. Furthermore, any risk of not specifying a full record architecture is mitigated through integration testing which ensures that potential issues around inconsistent approaches to versioning or incorrect transformations are identified and rectified.

## 8 Transition strategy

Activities to be undertaken in Australia to move forward with the recommended approach need to take into account and be aligned with current global work aimed at improving the HL7 v3 standards and addressing issues that arose during initial large-scale implementations, specifically those that were identified within the NHS in the UK. Aspects needing to be investigated and resolved for the longer-term Australian implementation include:

- Likely progress of work within HL7 on templates, harmonised data types, new ITS specifications and tools, CDA R2 and use of clinical terminology;
- The best means of representing NEHTA Data Groups and other detailed clinical information within standardised HL7 v3 and CDA R2 documents – taking into account global work on harmonised data types, refinement of HL7 v3 templates and use of formal clinical terminology within HL7 v 3 information structures;
- Further definition of how the HSSP services environment is to be deployed in Australia within the context of the NEHTA Interoperability Framework;
- Agreeing with Standards Australia and local stakeholders the standardization and compliance work needed to provide the standards and conformance infrastructure for implementation of the proposed approach;
- How to ensure the availability of adequate resources and capabilities within Australia to implement the chosen strategy; and
- More detailed mapping of the steps on the migration path from the current HL7 v2 environment to the future document/services-centric approach.

### 8.1 Major implementation activities

The following activities are proposed by NEHTA to move forward with the longer-term vision outlined above:

- Identify the best means of applying HL7v3 CDA R2, templates and clinical terminology to represent its Data Groups and other clinical content and to clarify technical and strategic issues to be addressed.
- Work with the standards community to ensure that pragmatic approaches and solutions are developed.
- Establish a collaborative program of work with stakeholders and the standards community to facilitate adoption of the document/services-centric approach, to include:
  - Fast-tracking the selection and/or development of the initial set of standards needed to implement this approach; and
  - Publishing specifications for representation of existing data groups in the form of structured documents for referral, discharge, prescribing and dispensing.
- Supporting the progressive extension of the suite of available standards – this is expected to include specifications based on HSSP and CDA R2 templates for areas such as prescribing, dispensing, pathology, radiology, referral, discharge and shared health profile.
- Strengthening Australian collaboration with other nations implementing interoperability strategies based on HL7 v3 and services, particularly the UK and Canada and US government agencies, such as VHA.

- Supporting ongoing work on the application of services-oriented architectures, particularly through HSSP.
- Continuing to foster harmonisation of HL7 v3 with EN 13606 and *openEHR* – particularly in the areas of data types, constraints, clinical models and services architecture.
- Building capabilities in relevant technologies to realise the preferred approach in a consistent, reliable and repeatable manner – through NEHTA engagement with HL7 Australia, Standards Australia, health jurisdictions, the e-health vendor community, and relevant e-health experts.
- Undertaking further planning needed to organise, produce, maintain and disseminate relevant specifications for implementation of the proposed approach.

## 8.2 Standards Development

NEHTA will work with Standards Australia on development of standards which support both the short-term and longer-term directions.

### 8.2.1 Short-term direction

NEHTA will fund the fast track development of standards work identified as being needed in the short term and make the outcomes available for input into the Standards Australia processes. Before undertaking the development of these specifications it will be necessary to understand how best the proposed changes will fit with Standards Australia's work program.

### 8.2.2 Longer-term direction

In terms of supporting the longer-term direction, NEHTA will investigate in detail the technical and strategic issues arising in standardising a document- and service- centric approach to HL7 v3 within the Australian environment and make recommendations for progressing the approach. This study will develop some key examples of specifications using the approach, such as a discharge summary, referral and shared health profile, in order to help understand the related issues in detail.

The study will also explore which specific features of CDA should be supported. Australia needs to obtain maximum leverage from the work of others to learn lessons from the development of technical policies, tooling, documentation, application interfaces and other aspects needed for implementation. Therefore, NEHTA will closely follow HL7 v3 implementation conventions adopted within the largest markets for international vendors, namely within the UK and the US.

## 8.3 Governance

### 8.3.1 E-health governance within Australia

Within Australia, Standards Australia (through Committee IT-014 Health Informatics) is the peak body responsible for e-health standards development and this report proposes that this continue. However, in the short-term, NEHTA will fund the preparation appropriate pre-standards and release them into Standards Australia's processes for review and, where appropriate, publication as Australian Standards.

### 8.3.2 International e-health standards governance

It is clear that Australia will need to continue working in a highly strategic and targeted fashion to ensure that its specific needs are addressed through the International HL7 processes. Standards Australia is an important stakeholder in helping to address this issue, as it is currently responsible for producing localisations of HL7 specifications, implementation guides and working with HL7 processes on behalf of Australia. Therefore, NEHTA will continue to collaborate with Standards Australia on addressing issues that will arise as a result of the adopting the standards approach recommended in this document.

## 8.4 Adoption

Vendors and healthcare providers with existing systems, or who are planning to procure new systems in the near future, should continue using present HL7 v2.x standards.

Once standards become available to support the short term direction, owners of systems or organisations planning to procure a system can start planning to adopt either the new short-term standards or work toward adoption of the longer-term approach. To help facilitate this adoption:

- NEHTA will work with the Jurisdictions on helping them specify standards required to be implemented as part of new systems or enhancements to existing systems they may be procuring in the near future;
- In order to facilitate migration planning at the local level, the specifications for short-term and longer-term standards will include guidelines for how the current standards can be mapped or migrated; and
- As part of NEHTA's engagement role with the community, NEHTA will provide, on a limited basis, advice on implementation issues that may arise at the local level as a result of its recommendations.

Funding arrangements for adoption of the short-term measures will remain the same as at present (i.e. funding responsibility sits with the system owner, such as the jurisdiction, the private sector or the vendors themselves).

Lessons learnt from implementation of the short-term recommendations will help drive implementation planning, models for change management, migration plans and certification requirements for the Shared EHR.

## 8.5 Capacity building

While many of the members of the Australian e-health community have had experience with those standards recommended in the short-term direction, very few have experience with the standards supporting the longer-term direction. Although the capacity building that is required extends beyond NEHTA, NEHTA's contribution will include:

- Developing a strategic working relationship with the NHS in the area of HL7 v3 to help facilitate the flow of knowledge and implementation experience back to Australia;
- In conjunction with Standards Australia, engaging with organisations such as HL7 Australia, to start educating the Australian community on both the short-term and long-term directions; and
- In conjunction with Standards Australia, working with organisations such as HL7 Australia to develop demonstrations of the recommended standards.

## 8.6 Tools

In terms of tooling, NEHTA will:

- Collaborate with NHS on use and further development of existing tools to help facilitate the development of HL7 specifications within Australia;
- Join in collaboration between NHS, Eclipse and others on tooling; and
- Engage with potential vendors of relevant software tools to support specification development within Australia

# Appendix A: References

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