nehta

# An Evaluation of Standards Supporting Interoperability in E-Health

## Shared EHR Design Initiative

Version 1.8 - 25 January 2007

Confidential - Draft

National E-Health Transition Authority

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# Executive Summary

## Introduction

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 Electronic Health Records (EHR).

### Background

In 2005, NEHTA commissioned DH4 Pty Limited (DH4) to carry out a consultancy to review Shared EHR standards then being developed around the world, to assess the utility of these standards and their potential impact on Australian developments (including their ability to support other NEHTA specifications) and to recommend the most appropriate standards for sharing EHR information in the Australian context.

In brief, the DH4 review's main 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 the content and logical structure of Shared EHR information and its relationship to clinical concepts;
- Initially, to use specified HL7v2.x messages to interchange Shared EHR information; and
- In the longer term, to progressively introduce either HL7 CDA release 2 or an XML serialisation of EN13606 as the preferred means of interchanging Shared EHR information.

The DH4 review noted that the standards selected for introduction in the longer term would depend on global developments in e-health standards and their ability to support clinical terminology, constraints (archetypes and templates) and moves toward structured documents and service-oriented technologies.

Since the report was written, there has been feedback from stakeholders, lessons have been learnt from e-health standards development and implementation around the world and NEHTA has continued to progress on a range of initiatives that affect the standards needed for information interchange and interoperability throughout the Australian health sector.

This report considers what e-health standards approach should now be adopted for the longer-term in light of these recent developments.

### Drivers for Change

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.

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.

Service oriented approaches are starting to be taken more seriously with HL7 working with the Object Management Group (OMG) to define a new generation of services-oriented specifications for information interchange through the healthcare Services Specification Project (HSSP).

The need for rigorous application of clinical terminology as the foundation of semantic interoperability for clinical information is now generally accepted and SNOMED CT is being released for widespread use at reasonable cost throughout the world. In parallel to this 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 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 for e-health standards now emerging in Australia, particularly formal clinical terminology, structured documents and services-oriented architectures. Meeting the requirements will involve the adoption of many new standards and the replacement and update of some existing standards.

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The expanded standards portfolio must meet the needs for Shared Electronic Health Records (Shared EHR) for a comprehensive, uniform standards approach that will enable a wide range of clinical information to be specified and seamlessly represented for interchange between applications. 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.

As the national approach to Shared EHR moves closer to submitting its business case to COAG; 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.

# Evaluation of Alternatives

Recommending a standards approach to address the business needs described above is extremely difficult. The challenge in making a decision stems from the alternatives having quite different mixes of strengths and weaknesses. Therefore, this review has tried to identify an approach which "on balance" best supports the different requirements and then make recommendations on how to address any potential weaknesses. The review also examines the implications of adopting a recommended approach and the activities needed to move forward and reach the goal.

## Method

In making a recommendation, NEHTA's approach has used the following steps:

1. A set of requirements were constructed by reviewing existing statements of requirements (such ISO TS 18308, HL7 EHR Functional Requirements), needs emerging from the NEHTA work program, lessons learned from implementing the various standards, and by comparing features of the standards that are currently available. The requirements

were then categorised into separate logical groupings under the broad headings:

a. Features;

b. Ease of implementation; and

c. Community support.

2. The following standards approaches were identified as potential candidates for assessment:

a. A *HL7 v2 approach* which uses HL7 v2.x discharge/referral, prescribing, pathology and diagnostic imaging messages, potentially extended to carry clinical information represented using openEHR or EN 13606 archetypes;

b. A *Document/Service-Centric HL7 v3 approach* which focuses on services for document sharing using CDA R2, Templates and HSSP, rather than adopting the full suite of specifications within the HL7 v3 standard. This approach will also seek to leverage enhancements to the HL7 v3 specifications that have been made as a result of international implementation experience with in the UK, US and Canada, in particular, proposed refinements to the Data Types, ~~XML~~ ITS, ~~UML ITS,~~ TermInfo, Templates, Clinical Statements and Continuity of Care Document (CCD);

c. An *EN 13606 approach* that assumes all 5 parts of the EN 13606 standards are completed and an archetype knowledge framework is available; and

d. An *openEHR approach* which uses the specifications currently available on the *open*EHR website

3. The alternative approaches were reviewed against the requirements, strengths and weakness were identified and the ability of each candidate to meet the requirements requirement was then rated on a common 5 point scale, where 5 represents fit for purpose and 1 represents a standard that is not fit for purpose and even with substantial work and major compromises or concessions it is unlikely to result in a satisfactory outcome.

4. The aggregated ratings were then subjected to a sensitivity analysis which examined the effect on the totals of varying the scoring weights under several different scenarios, including scenarios which heavily bias features, ease of implementation and community support; and

5. A recommendation is now being made on a basis of selecting the approach which consistently remained the top-scoring candidate throughout the sensitivity analysis.

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**Commented [GG3]:** Overall this approach carries some technical risk, in that we do not yet know how the OMG side of the process will go. It's not necessary for that process to succeed, but it's certainly a significant enough technical risk – and will be perceived as such by the Australia community – that it's worth a paragraph discussing this in the executive summary, and a little more depth further into the document (I will comment there too)

## Results

After undertaking a sensitivity analysis, a service- and document-centric approach to HL7 v3 consistently remains the stronger candidate in all scenarios, including the overall case, features bias case, ease of implementation bias case and a community support bias case.

| | Overall | Features Bias | Ease of Implementation Bias | Community Support Bias |
|---|---|---|---|---|
| HL7 v2 approach | 3.0 | 2.8 | 2.9 | 3.3 |
| Document- and Service centric HL7 v3 approach | 3.2 | 3.3 | 3.2 | 3.3 |
| EN 13606 approach | 3.0 | 3.1 | 2.9 | 2.9 |
| *open*EHR approach | 3.0 | 3.2 | 3.0 | 2.9 |

When considering the differences in ratings, clearly there is no "perfect" solution which meets all requirements. If there was, it would have had a considerably higher overall rating. The low differences in ratings, indicates that at this point in time there is little to be gained by moving from the current HL7 v2 standards to a new standard in the short term. However, the closeness of ratings also indicates that despite the strength of 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. In the longer term a document- and service-centric HL7 v3 approach is likely to be the front runner, for the following reasons:

- *Features:* HL7 v3 is currently the only framework that can support the development of a multitude of different kinds of specifications, including specifications for prescribing, referrals, discharge summaries, and other artefacts required for interoperability in e-health. Furthermore, HL7 v3 has growing support for a service-based approach and SNOMED CT;
- *Community Support:* The HL7 community has the largest participant base internationally, which will further assist with the longer term adoption and sustainability of the standard. Furthermore, the heavy investment of the UK NHS in HL7 v3 has demonstrated that it can be made to work on a national scale and has led large international vendors to start building support for v3. HL7 v3's strengths will continue to be enhanced as other countries, for example as Canada's Infoway Program and the US invest more heavily in HL7 v3.

Before a document- and service- centric HL7 v3 approach can emerge as the dominant method, technical barriers need to be addressed around improving the support for templates and terminologies and providing better tools for aiding specification development and simplifying the complexity of implementation.

In the longer term, the other approaches are likely to have challenges keeping pace with a document- and service- centric HL7 v3 method for the following reasons:

- The HL7 v2 approach would requires reworking of its underlying model to provide a more unified framework that supports contemporary development practices;

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- EN 13606 would needs to become more inclusive of sharing information beyond just EHR content. The availability of tooling needs to improve significantly, the standards community around it needs to increase in size to become more self sustaining and it currently lacks a contestable market of major suppliers; and
- The *open*EHR approach, while having technical advantages in a number of different areas at the moment, would needs to become more inclusive of sharing information beyond just EHR content, currently lacks a contestable market of major suppliers and currently is not supported by an accredited standards setting organisation.

# Recommendations

## Strategic Direction

Based on the evaluation of the alternatives, it is clear that HL7 v2 should continue to be supported in the short to medium term. In the longer term, it is likely that a service-and document-centric HL7 v3 approach, subject to additional work being undertaken at an international level, will become a stronger alternative than the current approach.

Therefore, it is recommended that NEHTA that adoption proceed in the following stages:

- *Current:* Existing standards, including HL7 v2.3.1 and HL7 v2.4 should continue to be supported;
- *Short-Term Direction:* In the next 9-12 months a set of HL7 v2.x messaging standards should be developed which have been enhanced to be more compliant with NEHTA's recommendations for clinical information data groups, SNOMED CT, unique health identifiers, and a transport layer specification based on web services. This activity will take HL7 v2 forward within the limits of what is technically feasible within HL7 v2; and
- *Longer-Term Direction:* An initial program of work to assess in detail some of the technical and strategic issues associated with adopting a services- and document-centric approach to HL7 v3. If the barriers to adoption can be addressed, a program of work should be put into place to fast-track the establishment of the initial set of standards, tools and skills needed to implement the recommended approach (subject to the barriers to adoption described above being addressed). The suite of standards is expected to include services based on HSSP and CDA R2 templates for areas such as prescribing, dispensing, pathology, radiology, referral, discharge and shared health profile.

Australian adoption of the European EN13606 standard on EHR Communication to represent clinical information for Shared EHR, at this stage, is no longer recommended. This decision aligns with Standards Australia's recent recommendation to not provide a full standard for EN 13606 and to support it as a technical report instead.

## Benefits

The key benefits of the recommendations are:

- the proposed short term direction will:
  - provide a straight forward migration path for owners of existing systems; and
  - leverage the existing support for HL7 within the Australian and International community;
- the proposed longer term direction will allow:

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**Commented [GG7]:** Is this practical? To me, this seems sufficiently unrealistic to make people wonder about the sense behind the document? If it's not unrealistic, some comment about why?

**Commented [GG8]:** Worth adding that it will allow Australian vendors more access to international markets by following the major path of adoption?

- a new suite of standards to be developed in a more unified and coherent fashion with support for richer features, such as better support for services, terminology, templating, structured documents, etc, than are presently supported within current standards; and
- Australia to leverage the implementation experience and standards arising from major national integration programs in the UK NHS's Connecting for Health and Canada's Infoway programs.

## Risks

The risks inherent in adopting the longer term direction are there are presently a number of unresolved issues within HL7 v3 that adversely affect its suitability for adoption now. These issues are complex and 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. Therefore it is essential that such risks 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 (tools | authoring | feedback from implementation)
- Fostering harmonisation of HL7 v3 with EN 13606 and *open*EHR; and
- Collaboration with other implementing nations such as the UK and Canada.
- Supporting the collaboration between HL7 and OMG

Finally, if the recommended long term direction proves to be too difficult to standardise, other strategies can be explored based on the other standards considered in this document.

## Consultation

Information within this report was prepared on following consultation with a number of parties:

- All material was circulated within NEHTA for comment
- The material was reviewed by DH4, who undertook the original review
- Substantive feedback from the Jurisdictions and Standards Australia received from the previous review report was incorporated into the review

In preparation for adoption of the proposed direction, it will be necessary to consult with key stakeholders. This includes the Jurisdictions, Standards Community and Vendors. Sessions with the respective groups will need to be conducted.

## Standards Development

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

*Support for 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.

**Commented [GG9]:** It would be interesting to see whether a joint group of UK & Australians, from both within and without the government programs, can actually come up with a report summarising the implementation experience – that could prove tricky to get agreement on anything substantial and worthwhile. I don't think this document should say anything different, but thought I'd comment anyway

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**Commented [GG11]:** Given the sensitivities of various involved players, it may be wise to pay more lip service to advance consultation with the technical committees about the planned work (rather than just "understanding").

*Support for Longer-Term Direction*

In terms of supporting the longer-term direction, NEHTA will fund an exploratory study, which 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 should 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 need to explore which specific elements of HL7 v3 should be supported. As Australia is a late entrant to the HL7 v3 field, it would be unwise to try and take policy decisions on HL7 v3 that put Australia ahead of, or out of step with, the likely changes underway internationally. Australia needs to obtain maximum leverage from the work of others to avoid re-working technical policies, tooling, documentation, application interfaces and other aspects needed for implementation. Therefore, Australia should closely follow HL7 v3 implementation conventions adopted within the largest markets for international vendors, namely within the UK and the US.

**Commented [GG12]:** Should propose that government support of healthcare standards development should be aligned with these goals (if that's possible). In particular, funding of attendance to HL7 WGMs should be linked to the longer term goals, rather than the ad-hoc yes/no each time.

Maybe this is a comment about the governance section too

## Governance

*Governance within the Australian Community*

Within Australia, Standards Australia should remain as the peak body responsible for e-health standards development. In the short-term, NEHTA will, as part of its transition role, release appropriate specifications into Standards Australia processes for review and, where appropriate, publication as Australian Standards. More details about this proposed relationship will be defined in a document titled "NEHTA and Standards Australia: Working Together". The agreement is currently being negotiated with Standards Australia, and once completed will be made available on the NEHTA website.

In the longer-term, business cases, including the national approach to Shared EHR, may result in a change of governance arrangements for e-health in general; however, Standards Australia is expected to continue having a significant role as the peak standards development organisation for Australia.

*Governance Internationally*

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 need to understand how it can collaborate with Standards Australia on addressing issues that will arise as a result of the adopting the standards approach recommended in this document.

## Adoption

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

Once standards become available to support the short term direction, owners of systems or organisations planning to procure a system can, at their discretion, 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 learned 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.

### 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. Therefore it will be essential to consider the following:

- NEHTA should develop 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;
- NEHTA, in conjunction with Standards Australia, should engage with organisations, such as HL7 Australia, to start educating the Australian community on both the short-term and long-term directions; and
- NEHTA, in conjunction with Standards Australia, work with organisations such as HL7 Australia to develop demonstrations of the recommended standards.

### Tools

In terms of tooling, NEHTA should:

- Obtain access to existing tools from the NHS to help facilitate the development of HL7 specifications within Australia; and
- Participate with the HL7 tooling collaborative; and
- Look at how it can effectively engage with potential vendors of relevant software tools to support specification development within Australia

**Commented [GG13]:** NHS tools are somewhat corrupt because they do not entirely follow hl7 v3. It would probably be a mistake for Australia to pursue the same non-compliant path when it could be compliant. For this reason, rather than "obtain access", I would recommend wording along the lines of "Collaborate with NHS on use and further development of existing tools". I guess there's been some discussions about this, so that wording might be a problem, but it would be beneficial if the wording acknowledged the background problem that the tools as is mightn't lead Australia in the quite the direction it wants to go

## Next Steps

On the basis of the recommendation, the next steps after this report should be to:

- Consult on this document with stakeholders;
- Work with Standards Australia on incorporating the short-term and long-term directions into the standards development plan;
- Provide some certainty to the community in terms of continuity of direction;
- Procure services to help fast track the development of standards to support the short-term direction;
- Procure services to help explore in detail the technical and strategic issues involved in adopting the longer-term direction;
- Commence working with implementers and procurers to encourage adoption of the recommended standards;

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**Commented [GG14]:** I know, really, that this is too hard to address; but it would be good for the document to push in this direction, even if in the end it's only lip service

- Build capacity within the Australian community for the short and long term direction; and
- Establish a better understanding of requirements for tooling to support the recommended approach.

# 1 Introduction

## 1.1 Purpose

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 Electronic Health Records (EHR).

## 1.2 Intended Audience

Initially this document is intended for:

- NEHTA Staff;
- Jurisdictions; and
- NEHTA Reference Groups

In time the document will be circulated more widely within the Australian Standards community and public for comment.

This document assumes the reader is familiar with the Shared EHR Standards Review.

## 1.3 Background

### 1.3.1 Review of Shared EHR Standards

In 2005, NEHTA commissioned DH4 Pty Limited (DH4) to carry out a consultancy to review Shared EHR standards then being developed around the world, to assess the utility of these standards and their potential impact on Australian developments (including their ability to support other NEHTA specifications) and to recommend the most appropriate standards for sharing EHR information in the Australian context.

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- In the longer term, to progressively introduce either HL7 CDA release 2 or an XML serialisation of EN13606 as the preferred means of interchanging Shared EHR information.

The DH4 review noted that the standards selected for introduction in the longer term would depend on global developments in e-health standards and their ability to support clinical terminology, constraints (archetypes and templates) and moves toward structured documents and service-oriented technologies.

Since the report was written, there has been feedback from stakeholders, lessons have been learnt from e-health standards development and implementation around the world and NEHTA has continued to progress on a range of initiatives that affect the standards needed for information interchange and interoperability throughout the Australian health sector.

This report considers what e-health standards approach should now be adopted for the longer-term in light of these recent developments.

### 1.3.2 Feedback Received on the Review

The report was circulated to a number of different groups for review, including: the Jurisdictions and the public.

#### 1.3.2.1 Jurisdictional Feedback

The Jurisdictions were generally supportive of the paper. While the Jurisdictions did not indicate a strong preference for any specific alternative going forward, they indicated their preference for something that is:

- More likely to be supported by Commercial Off the Shelf (COTS) solutions used within the Jurisdictions (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.

#### 1.3.2.2 Public Feedback

Organisations and individuals associated with Standards Australia Committee IT-014 (Health informatics) also provided a substantial amount of feedback on the document. 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) needed to be made more clearly;
- The distinction between the document-oriented aspects of EHR content and some of the action-related aspects handled by messages (e.g. request, response, acknowledgement, cancel, replace, etc) needed to be made clearer. Furthermore, it was felt 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 and IHE) and Shared EHR standards needs to be discussed in more detail;
- Standards for data storage should have been discussed;
- Issues around unstructured documents and human readability need to be discussed;
- Concerns were raised about the risk of recommending a standard which is divergent from the standards, like HL7 v3 , starting to be supported by vendors within the UK and USA;
- In contrast to the previous point, concerns where 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 made clearer

### 1.3.3 Changes Since the Review Was Issued

#### 1.3.3.1 Progress within NEHTA

Since the development of the Shared EHR Standards review paper by DH4, a number of work items have been progressed within NEHTA. Items that are of specific relevance include:

- The NEHTA Shared EHR Design Initiative has developed a suite of Business Processes, Functional Requirements, Information Requirements and Technical Requirements
- The NEHTA Secure Messaging Initiative has affirmed that secure messaging should be based on Service Oriented Architecture (SOA), Web Services and XML.
- With the support of Jurisdictions, the NEHTA Clinical Terminologies Initiative has committed Australia to SNOMED CT as its primary clinical terminology, and is getting closer to forming an international SNOMED SDO and releasing a Medicines terminology. The proposed standards approach must be capable of effectively and reliably integrating with multiple clinical terminologies, specifically SNOMED CT and the locally specified medicines terminology.
- The NEHTA Clinical Information Initiative has developed a specification for discharge summaries
- In 2006, NEHTA commissioned Deloitte Consulting to conduct an "E-Health Profile Study", which reviewed the current e-health capabilities of the Jurisdictions and their readiness to adopt NEHTA recommendations. While, the broader outcomes of that piece of work are not within the scope of this document to discuss, it is clear that, while some Jurisdictions have direct control and implementation teams to support changes within some core systems, most Jurisdictions are, in general, highly dependent on their preferred vendors being able to support changes in standards. This finding confirmed the feedback from the Jurisdictions, which was that any choice going forward must be supportable by COTS products. The report also identified a reasonable level of interest in the Jurisdictions in using web services and SNOMED CT in future implementations of systems, but further work needed to be done on understanding the appropriate staging of implementation.

#### 1.3.3.2 Progress within Standards Development Organisations

On a national basis the following progress has been made by Standards Australia of the following standards:

- *Referrals:*
  - HL7 V2.4 Referral (for discharge summary and referral) messaging specification completed
  - HL7 V2.4 Referral message implementation guide development in progress
  - HL7 V2.5 Referral messaging specification development commenced
- *Pharmacy:* HL7 V2.4 Pharmacy messaging specification completed
- *Pathology and Radiology:* HL7 V2.4 Pathology and Radiology messaging specification development – in progress
- *Immunisations:* HL7 V2.4 Immunisation messaging specification in progress
- *CDA implementation of Referral message:* progress has slowed in the last 12 months due to non-availability of key team members. Progress is expected to resume in 2007.

On an international basis the following progress has been made on relevant standards:

- The International SDO for terminology is in its formative stages;
- The NHS has adopted CDA R2 for its national summary care record and will be releasing some of its specifications into the HL7 processes.

- Very little progress has been made within EN 13606
- HL7 is considering, balloting or in the process of publishing new versions of:
  - Data Types (guided by efforts to harmonise EN 13606, *open*EHR and HL7 data types);
  - ~~UML~~ ITS (guided by implementation experience within the UK);
  - Templates Specification (guided by implementation experience within the UK and elsewhere);
  - CCD (Continuity of Care Document) is an implementation of the Continuity of Care Record (CCR), which is statutorily required for patient referrals in the US, in CDA R2. Ballot cycle two opened.
  - HL7 Services Specification Project (HSSP) has started work on engaging with the OMG to develop standards
- Among many other relevant activities, ISO TC215 (Health Informatics):
  - 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).
  - Is collaborating with HL7 on a joint publication of the datatypes

**Commented [GG15]:** Worth mentioning that part 5 has been drafted?

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## 1.4 Drivers for Change

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.

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.

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

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 for e-health standards now emerging in Australia, particularly formal clinical terminology, structured documents and services-oriented architectures. Meeting the requirements will involve the adoption of many new standards and the replacement and update of some existing standards.

The expanded standards portfolio must meet the needs for Shared Electronic Health Records (Shared EHR) for a comprehensive, uniform standards approach that will enable a wide range of clinical information to be specified and seamlessly represented for interchange between applications. This approach also needs to facilitate use of the same information in other e-health applications, including: referrals, discharge summaries, administration, finance, 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.

As the national approach to Shared EHR moves closer to submitting its business case to COAG; 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.

It is anticipated that such a suite of standards will need to be able to provide a contemporary approach which:

- Includes a unified standards development framework that:
  - addresses the broad spectrum of e-health content, including e-prescriptions, referrals, discharge summaries, diagnostic service requests and reports, as well as Shared EHR information;
  - provides proven information models, data types and flexibility needed to represent the full range of users' requirements for e-health content in a comprehensive and unambiguous form;
  - uses formal, consistent approaches for developing standards and for specifying lower level e-health content in accordance with those standards;
  - provides repeatable processes to derive practical, consistent specifications for reliable information interchange and enable semantic interoperability;
  - enables e-health information to be represented and used interchangeably as structured documents or as messages;
  - is well supported by automated tooling for capturing and modelling e-health information content and for expressing this in both human-readable and machine-readable forms;
  - supports the proper use of clinical terminologies (including SNOMED CT);
  - provides multi-level constraint structures to enable simplified specification and control of clinical content; and
  - has a means of specifying and capturing various types of static and dynamic linkages to other e-health content.
  - Provides a well understood path that leads to application implementation
- Is geared for use with contemporary services-oriented architectures (SOA) for e-health interoperability;
- Is easy to implement in a reliable manner (relative to other approaches); and

**Commented [GG16]:** Repeating note made in executive summary – should be a paragraph or two detail why HL7 V2 doesn't meet these requirements

**Commented [GG17]:** Because information is constantly leaking in both directions between admin & clinical domains in healthcare applications

**Commented [GG18]:** It seems clear to me now that there is no such thing as simplified. The problem is hard ("Wicked") and all we can do is move the deckchairs on the titanic. But there does seem to be more appropriate and less appropriate arrangements, and we want to achieve the best balance between specification and implementation complexity

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**Commented [GG19]:** I wonder whether this is a sub point of an implementable bullet, along with the SOA point. But maybe they are different. Still , implcmentation should be in this list, it seems to me

- Has engaged a large, open community of standards users (including government programs), vendors and contributors.

# 2 Approach

## 2.1 Introduction

Recommending a standards approach to address the business needs described above is extremely difficult. The challenge in making a decision stems from the alternatives having quite different mixes of strengths and weaknesses. Therefore, this review has tried to identify an approach which "on balance" best supports the different requirements and then make recommendations on how to address any potential weaknesses. The review also examines the implications of adopting a recommended approach and the activities needed to move forward and reach the goal.

## 2.2 Scope

The scope of recommendations in this document is to cover electronic sharing of clinical information between different organisation, and covers areas such as:

- Referrals;
- Discharge summaries;
- Diagnostic test results (including Pathology and Radiology);
- Prescriptions; and
- Shared EHR

The recommendation is also likely to have implications for standards for other systems, such as: registries, patient administration systems, claiming, supply chain, etc. While desirable, discussion of standards to support these areas is not within the scope of this document.

**Commented [GG20]:** In practice, I don't see why registries, admin, and claiming are out of the scope. They include some clinical info, and the clinical info includes demographics and some financial info. I don't know whether Australia plans to leverage SPL or not, and whether this has supply chain implications. But, well, you have to draw the limit somewhere. Perhaps there could a paragraph noting the leakage – or maybe that is covered enough in the comment a couple of pages up?

## 2.3 Method

In making a recommendation, NEHTA's approach has used the following steps:

1. A set of requirements were constructed by reviewing existing statements of requirements (such ISO TS 18308, HL7 EHR Functional Requirements), needs emerging from the NEHTA work program, lessons learned from implementing the various standards, and by comparing features of the standards that are currently available. The requirements were then categorised into separate logical groupings under the broad headings:
    a. Features;
    b. Ease of implementation; and
    c. Community support.
2. The following standards approaches were identified as potential candidates for assessment:
    a. A *HL7 v2 approach* which uses HL7 v2.x discharge/referral, prescribing, pathology and diagnostic imaging messages, potentially extended to carry clinical information represented using openEHR or EN 13606 archetypes;
    b. A *Document/Service-Centric HL7 v3 approach* which focuses on services for document sharing using CDA R2, Templates and HSSP, rather than adopting the full suite of specifications within the HL7 v3 standard. This approach will also seek to leverage enhancements to the HL7 v3 specifications that have been made

as a result of international implementation experience with in the UK, US and Canada, in particular, proposed refinements to the Data Types, ~~XML~~ ITS, ~~UML ITS,~~ TermInfo, Templates, Clinical Statements and Continuity of Care Document (CCD);

c. An *EN 13606 approach* that assumes all 5 parts of the EN 13606 standards are completed and an archetype knowledge framework is available; and

d. An *openEHR approach* which uses the specifications currently available on the *open*EHR website

3. The alternative approaches were reviewed against the requirements, strengths and weakness were identified and the ability of each candidate to meet the requirements requirement was then rated on a common 5 point scale, where 5 represents fit for purpose and 1 represents a standard that is not fit for purpose and even with substantial work and major compromises or concessions it is unlikely to result in a satisfactory outcome.
4. The aggregated ratings were then subjected to a sensitivity analysis which examined the effect on the totals of varying the scoring weights under several different scenarios, including scenarios which heavily bias features, ease of implementation and community support; and
5. A recommendation is now being made on a basis of selecting the approach which consistently remained the top-scoring candidate throughout the sensitivity analysis.

## 2.4 Rating the Approaches

To assist in assessing the fit of each standards approach to requirements, the following rating system was developed, with a view to obtaining an organised picture of major differences for comparative purposes.

The rating system works by ranking each standard against a 5 level scale, based on the amount of effort / time required to progress the standard to being fit for purpose as well as the amount of compromises or concessions that may need to be made to adopt it. The higher the ranking the more easy it will be to make the standard fit for purpose.

| Rating | Definition |
|---|---|
| 1 | The standard is not fit for purpose and even with substantial work and major compromises or concessions it is unlikely to result in a satisfactory outcome |
| 2 | The standard requires substantial work or it might be necessary to make a serious number of compromises and concessions in order to adopt the standard |
| 3 | The standard requires a moderate amount of work to tailor it to meet the requirements or only a moderate number of compromises or concessions will be needed in order to adopt the standard |
| 4 | The standard is generally fit for purpose and requires some work to tailor it to meet the requirements or only a few compromises or concessions are needed to adopt the standard |
| 5 | The standard is fit for purpose |

In situations where an approach has been enhanced by assuming the availability of features in the future, consideration is also given to the time and work needed to realise the enhancement.

# 3 Overview of Requirements

## 3.1 Introduction

This section provides an overview of the requirements for a standard and a discussion of some of the implications of the requirements themselves.

## 3.2 Requirements

The requirements have been grouped into three major categories around: features, ease of implementation and community support. Each of these categories will be discussed below.

The full suite of the requirements can be found in Appendix A.

### 3.2.1 Features

In order to support the drivers described in section 1.4, the kinds of features this review looked for within the set of candidates included:

- *Specification Development Framework:* In developing specifications to be put through the standards processes it is essential to have a common framework that ensures a consistent approach to developing standards. Such a framework requires an explicitly defined approach which can handle a wide number of cases, whilst ensuring a consistent approach to structure and semantics, sound clinical design and separation of responsibilities. The framework should also help the standards developer understand how tradeoffs are balanced, provide support for different implementation approaches, extensibility, localisation and promote a formal approach. Ideally the framework should also conform to the NEHTA Interoperability Framework Support;
- *Structured Documents:* The framework should provide structured documents as a mechanism for sharing clinical content. The structured document should support the general properties of a document oriented approach, promote versioning, include a structured approach to breaking up the document with sections and data groups and support attachments. In addition to this the structured documents should be capable of supporting the NEHTA CII event summary and data group specifications;
- *Data Types:* Within the body of a structured document, the kinds of data that should be able to be captured include text, quantities, dates and times, encapsulated content, links and identifiers. In addition to this the data types should be able to support the NEHTA specifications for CII Data Types and Unique Health Identifiers;
- *Terminology Support:* Content within a structured document should be able to be coded using a terminology. This requires terminology data types, a vocabulary for codes within the structured document and guidelines provided on how to handle the interface between structure and terminology;
- *Constraints Support:* In order to ensure that structured documents are used appropriately within different contexts it will be necessary to provide a constraint language that defines the context in which the constraint should be used, constraints on structure, constraints on terminology usage, bindings to terminologies and supports composability and reuse of constraints;
- *Interchange Format:* The content within the structured document should be parsable using industry standard parsers, provided in a format that is simple to build a parser for and provide a compact message size. The

**Commented [GG21]:** I worry about this word. In as much as everything that can say anything is a language, it's the right technical word, but "constraint language" seems to imply something like OCL or ADL, where as this is kind of approach is not necessarily indicated by the requirements. So I wonder whether the word "constraint framework" would be more appropriate

interchange format should also support the NEHTA Secure Messaging recommendation for XML;

- *Services Support:* The structured documents should be sharable using services. These services should support the desirable properties of a Service Oriented Architecture and provide support for functional areas such as identification, structured document management and clinical process management. The recommended services should support the NEHTA recommendations for web services; and
- *Security:* Services which access structured documents should ensure that the client is appropriately authenticated, the client is only allowed to access material they are authorised to access, the confidentiality of communications is preserved through encrypted connections and non-repudiation mechanisms such as audit trails and digital signatures are supported.
- *Localisation and Extensibility:* The framework should be based on recognised international standards. The standards need to provide a way to constrain the content to support the other requirements detailed here, and in addition, it needs to provide a recognised way to express extensions to the content that is outside the scope of the standard itself.

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**Commented [GG22]:** Something like this. Obviously there is more detailed discussion proposed below

### 3.2.2 Ease of Implementation

Ease of implementation is an important factor in selecting an appropriate standard. As developer time and testing time is a highly expensive resource, the easier the implementation, the more likely these costs can be contained. The kinds of desirable properties for ease of implementation this review considered included:

- *Low Complexity of Implementation:* Complex implementation issues can easily confound developers and create issues for tester. Therefore it is essential the standard has clear documentation, uses simple design patterns, have a minimal impact on the internals of existing systems and facilitate reuse;
- *Limited Opportunities for Variance:* Variances in implementation of a standard can create serious issues during integration testing phases. Opportunities for variance can be limited by providing implementation guides, conformance specifications, limiting the use of text fields for sharing structured information, cutting back on optional fields and features and avoiding the use of modal design patterns;
- *Clear Migration Path:* Very few standards are introduced in a green field situation and the need for a clear migration path that developers can leverage is essential. Facilitating a clear migration path requires a specification of mappings from existing specifications, support for backwards compatibility between different releases of standards and a staged or levelled implementation approach that lets procurers select a level of complexity required to support their needs.
- *Tool Support for Implementation and Migration:* Developer productivity is dependent of having access to tools that simplify their task. This includes have a choice of development platform and not being limited to a single language, having access to computer processable specifications that can be used to generate code from or interpreted at run time, having access to open source libraries that are supported by an active community, access to modules for interface engines to simplify migration and access to testing suites and online testing services to test their implementations against.
- *Tool Support for Specification Development:* In order to have fast turn around on the development of standards, tools that support the specification development process are critical. This requires access to

**Commented [GG23]:** Can be limited by standardising business practices – but don't know whether this is in the scope of this document or not.

tools that faithfully implement the standard and access to editors and libraries of existing specifications for producing specifications.

### 3.2.3 Community Support

The final area the review considered was community support for the candidate as such support means that ongoing development of the standard is more likely to be self sustaining in the future. The elements of community support considered included:

- *Governance:* The candidate standard must be managed by a body recognised as a standards development organisation. If the standard is an international standard, Australia must be able to participate in processes and produce localisations for the Australian market. The processes behind the development of the standard must be consensus and quality driven. Finally, adoption of the standard should not create international trade barriers.
- *Australian Community Support:* The candidate standard should be supported by the Australian standards community and local vendor community and ideally the ongoing development of the standard should have minimal dependence on key individuals; and
- *International Community Support:* The candidate standard should be supported by the International standards community and international vendor community and ideally the ongoing development of the standard should have minimal dependence on key individuals.

## 3.3 Discussion of the Requirements

### 3.3.1 Introduction

There are a number of issues that inevitably arise when producing the requirements for evaluating standards. This section will attempt to shed some light on the thinking behind the requirements and the trade offs that are being made. Aspects covered include:

- Record Architectures vs. Frameworks;
- Messages vs. Structured Documents and Services;
- XML vs. Compact Message Size; ~~and~~
- Semantic interoperability; and~~.~~
- Extensibility and localisation.

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### 3.3.2 Record Architectures vs. Specification Development Framework

The approach taken in this document is to recommend the use of a framework for specification development rather than recommend the use of a full record architecture. Before describing the motivation behind that choice, it is first worth discussing the differences.

The similarities and differences between the two approaches are summarised below:

| Specification Development Framework | Record Architecture |
|---|---|
| Can be applied to the development of a wide range of specifications for sharing information in e-health | Applicable only to Electronic Health Records |

**Commented [GG24]:** This is actually the differences between openEHR and HL7 V3. more generally, neither a specification development framework nor a record architecture need to be limited or scoped the way that these have been. For instance, a record architecture could choose to provide a record architecture for patient administration. I'm not sure how to handle this, whether the whole section should be recast as a discussion of openEHR vs HL7 V3, or whether it should be left as an abstract discussion, and the differences scaled back. Or whether it should be noted that the two different conceptual approaches have found champions in openEHR & HL7 V3 and that they will be used as the basis for comparison of the differences between the practical outcomes of pursuing the two different approaches.

I have refrained from making more comments throughout the comparison until the general approach is clear; then I can comment further

| | |
|---|---|
| Covers only the sharing of information | Covers the storage and sharing of electronic health records |
| Ensures a consistent approach to structure and semantics | Ensures a consistent approach to structure and semantics |
| Promotes Sound Clinical Design | Promotes Sound Clinical Design |
| Promotes Separation of Responsibilities | Promotes Separation of Responsibilities |
| Describes Trade Offs | Describes Trade Offs |
| Supports Pluggable Implementation Approaches | Supports Pluggable Implementation Approaches |
| Supports Extensibility | Supports Extensibility |
| Supports Localisation | Support Localisation |
| Promotes a Formal Approach | Promotes a Formal Approach |

As one can see there are a large number of similarities between the two approaches, the main differences are ones of scope. A record architecture is focussed more on electronic health records and covers sharing of information between electronic health records and storage of information within electronic health records, whereas a specification development framework supports the sharing of health information in a broad number of areas, beyond just electronic health records, and is not directly concerned with storage.

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.

In terms of storage, whilst this document recommends versioning of structured documents, defining an object model which governs the logical design of the storage model for an EHR, as is done within a record architecture, is going one step too far.

The motivation for wanting a record architecture to govern the logical storage model comes from two sources:

- A standardized approach to storage reduces the risk of inconsistent approaches to versioning being implemented by different vendors; and
- Having a common approach to both storage and communication removes the risks around potentially error prone transformations that may occur between interfaces and the underlying database structure

While there are advantages in supporting a full record architecture, this document cannot support imposing a logical storage model onto vendors as many of these vendors have mature and stable systems that are not easily amenable to retrofitting such a model on top of their existing systems without risking destabilising their product. Furthermore, from an international product management perspective, an international vendor is unlikely to make such an expensive and risky change to their product for the purposes of the Australian market place.

However, it is important not to throw the baby out with the bath water and ~~recognizing~~ recognize that there are still many useful ideas within a record architecture. Many of the requirements within this document are based on the ISO 18308 requirements. Furthermore, it is important to recognise the

risk of not using a full record architecture must be mitigated through integration testing which ensures that potential issues around inconsistent approaches to versioning or incorrect transformations are identified and rectified.

### 3.3.3 Messages vs. Structured Documents and Services

This document prefers an approach based on structured documents and services over a pure messaging based approach for a number of reasons:

- The current clinical environment is predominantly a document driven world and the usage of structured documents is likely to make the mapping of real world requirements to structured documents easier than it is to map them to a set of messages;
- A structured document implies that it is presented in a form that is more amenable to rendered in a human readable form than a message is. For example, PIT has persisted despite HL7 v2 pathology messages because PIT is more easily presented in a human readable form;
- Messages conflate control flow and content within the body of the one item. By separating services (i.e. control flow) from the content (i.e. structured documents), it promotes reuse of services in other contexts and starts to eliminate the issue of having a separate message for every possible step in an interaction; and
- Messages only support a single mode of interaction (asynchronous request/response style interactions between 2 points), 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, orchestrations vs. choreographies, etc)

As indicated at the start of this section, the preferred approach is one based on services and structured documents. Given that HL7 v2 messages are in use in the environment at the moment, the implication of this approach is that both messaging and a structured document / service based approach will need to co-exist for some time to come.

**Commented [GG25]:** A similar comment to the last section. What's the difference between messages and docs/services – I think there's flavour of difference. They both approach the same outcome from different directions. But increasingly the difference in HL7 is characterised by early vs late binding of content and function calls. In fact, it appears that in the end, HL7 will gracefully migrate to a point where no one can tell the difference any more.

Again, this section is actually comparing the V3 dynamic model as it is with documents and services as it might be. The fundamental advantage of docs is CDA itself – a stable reusable format – which also happens to be it's primary downfall – one size doesn't fit all (back to the issue of the balance of complexity between specification and implementation).

Again, I think this section should note the basis of the comparison. Once the overall direction is resolved, I will make further detailed comment

**Commented [GG26]:** This is not true; there is support for multicast too

### 3.3.4 XML vs. Compact Message Size

There is a tension between the requirement for a compact interchange format and NEHTA's recommendation for XML. The implication of this is that message sizes based on XML, compared to the average HL7 v2 message, are likely to be larger.

However, the 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 benefit of access to productivity enhancing tooling based on XML is considered to outweigh the cost of a more verbose 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;
- XML itself is used on a large scale basis 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 by HL7v2.x, HL7 v3 and *open*EHR.

- 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).

### 3.3.5 Semantic Interoperability

Commented [GG27]: I wasn't going to generally comment on things that were done well. But this is a very nicely written section indeed

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 18308 defines semantic interoperability as "the ability for data shared by systems to be understood at the level of formally defined domain concepts";
- 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;
  - Semantic interoperability assures the clear and persistent communication if 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
- Wikipedia defines semantic interoperability as: "the ability of two or more computer systems to exchange information and have the meaning of that information accurately and automatically interpreted by the receiving system"

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 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 standard 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:
    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; and
    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 definition from the HL7 EHR Working group and Wikipedia is closer to the mark. However, it is 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 (as in use case 1a), flag a potentially inappropriate test request (as in use case 3a), send a copy of a test result to a registry (use case 2a). 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 (use case 3b) and would present the risk of unwanted statistical bias in a secondary uses (use cases 4a and 4b).

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 (use case 3b) or a researcher looking for some high level statistics (perhaps use case 3a), but would be insufficient to support a more demanding researcher or a more demanding case for decision support (such as use case 3b).

Therefore definition of semantic interoperability used in this document will be one which is a variant of the one from the 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"*

In the standards world, the concept of "semantic interoperability" is usually used as a pejorative. For example: "the competitor's standard does not support semantic interoperability". However, as one can see, is not really a productive form of argument as simple keyword matching is capable of supporting a number of use cases. A more constructive argument should be around specific use cases, the desired quality of matching (e.g. level of false

negatives and positives) that is tolerable and the business case for achieving that level of semantic interoperability.

The implication of this style of thinking is two fold:

- A reasonable number of use cases will be possible right now if we can settle at least on some key SNOMED CT reference sets, a way of sharing structured documents and a constraint language. Making this step will at least allow the community at large to continue moving forward in the interim; and
- The debate needs to shift to more specific use cases and focus on 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 are likely to be unending as people start seeing more opportunities and devils in the detail will pose problems in the quality of matching, this process will be a journey, rather than an overnight journey to the single destination of "semantic interoperability nirvana".

The purpose of this document is to make a recommendation to support 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, the shared EHR benefits realisation plan, when it becomes available, is intended to recommend specific use cases that need to be focussed upon.

### 3.3.6 Proposed new section: Extensibility and Localisation

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Commented [GG28]: This is just a draft placeholder. I'll be very happy for you to take to it with a knife

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, 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 a lot of optionality open to the implementor. 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 optionality and extensibility.

Given the diverse business and clinical practices throughout the world, international standards necessarily allow for a degree of optionality. The standard needs to provide a framework for expressing how this optionality is 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 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 judiciously is better than not being able to deliver the features that are required.

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

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# ~~5~~4 Comparison of Standards against Requirements

## ~~5.1~~4.1 Introduction

In this section, four options for a standards approach are assessed against the requirements outlined in the previous section. The approaches assessed are:

- HL7 v2 approach (potentially enhanced with archetypes),
- Document-centric HL7 v3 approach,
- EN 13606 approach, and
- *open*EHR approach.

## ~~5.2~~4.2 HL7 v2

### ~~5.2.1~~4.2.1 Introduction

HL7 version 2 has been around for around for at least 19 years. It defines message structures for health information, and has generally been used for messages whose structure can be defined in advance, such as pathology results. More recently, messages have been defined in Australia for referral and discharge, which try to cater for more dynamically created messages. In 'original' HL7 version 2 messages, including the version used in Australia, the messages consist of text fields separated by the bar character ('|'); a working group at HL7 have specified how messages can be expressed in XML.

The core HL7 version 2.x standard is further defined for use in Australia through implementation guides prepared by Standards Australia Committee IT-014 (Health Informatics) and published in the following standards:

- AS4700.1-2005 - Patient Administration; v2.4
- AS4700.2-2004 - Pathology orders and results; v2.3.1 (under review)
- AS4700.3-2002 - Drug prescription messages; v2.3.1
- AS4700.4-2005 - Pharmacy messages v2.4 (pre-publication)
- AS4700.5-2002 - Immunisation messages v2.3.1 (v2.4 pre-publication)
- AS4700.6-2004 - Referral and discharge summary v2.3.1, with work in progress for v2.4
- AS4700.7-2005 – Diagnostic imaging orders and results v2.3.1 (pre-publication)
- DR_00048 - Implementation of Health Level Seven (HL7), Version 2.3.1. - Part 4: Pathology results for registries
- DR_03288 - Implementation of Health Level Seven (HL7) Version 2.4 - Part 1: Patient administration
- HB262-2002- Pathology electronic messaging - Guidelines for pathology messaging between pathology providers and health service providers - Implementation guide

Internationally, HL7 v2 is used extensively, mainly to interconnect information systems used in delivering secondary and tertiary health care services. Within Australia, there is widespread acceptance of clinical messaging based on HL7v2 with implementations, on the whole, operating successfully. Use of HL7v2 is supported by the Australian Standard implementation guides listed above and an accumulation of local expertise, products and services.

Use of HL7 v2 messages is steadily increasing within Australia, with primary uses including:

- Pathology messaging inside and outside hospitals for communication of results;
- Communication of some results from laboratories to notifiable disease registries;
- Use within hospitals for:
  - Communication regarding admissions, transfers and discharges;
  - Some tentative usage in pharmacy;
  - Some tentative usage in discharge summaries
  - Some usage of scheduling messages for Theatre, Outpatients and Radiology.

### ~~5.2.2~~4.2.2 Approach Considered

This section considers an approach to implementing HL7 v2 based on the following combination of specifications:

- HL7 v2.x Ref message for supporting referrals, discharges and other event summaries to be stored within the Shared EHR.
- Other HL7 v2.x standards to support other requirements (e.g. identifier management);
- XML Serialisation of message content and web services would be used for transmitting message content; and
- HL7 v2 archetype based extensions are also considered.

### ~~5.2.3~~4.2.3 Lessons Learned from Implementation

HL7 v2 has been a success story both locally and internationally. HL7 v2 is probably the suite of standards in the widest use at the moment. There are a number of reasons for the success of HL7 v2:

- In the early days of HL7 a few key vendors founded HL7 because it would allow their applications to integrate with other applications and compete with the larger vendors who offered a more complete solution. Procurers loved this story as it allowed them to build a best of breed solution and reduced the risk of single vendor lock in;
- One of the main reasons for the success of HL7 v2 is that it provided an open specification for a killer application: Patient Administration System (PAS). As PASs are a core system required by almost all every medium to large scale hospital to operate effectively, the success of HL7 was almost a guaranteed by procurers hungry to purchase best of breed solutions.
- As the HL7 organisation's membership grew it invested a significantly amount of resources into building its brand, marketing, attracting large vendors, lobbying at government levels, lobbying at other standards organizations, training of newcomers, providing special interest groups to cater for the newly emerging class of e-Health experts; and
- Finally, HL7 v2, the specification, made the important technical choice by using a simple file format. The file format meant that the implementation of HL7 v2 was accessible to most vendors who use a variety of programming languages, ranging from mainframe programmers, to UNIX programmers, and Windows based developers. Furthermore, they did not mandate any preferred mechanism for file transfer and permitted any solution ranging from shared file systems, FTP, TCP/IP sockets, email, HTTP and now web services to be used.

Compared to industry's experience with proprietary interfaces, HL7 v2 substantially reduced implementation times and costs. However, these costs and times varied considerably by vendor. HL7 v2 failed to meet this requirement because of the high degree of variance in the implementation of the HL7 v2 standards for a few key reasons:

- A large amount of the intent or rationale for message design is lost in the HL7 v2 message development processes;
- HL7 v2 relies on simple tools such as MS Word for specification development, which makes it difficult to ensure that specifications are prepared in a consistent fashion and it cannot be leveraged for code generation;
- The HL7 v2 file format is too simplistic and lacks a consistent and regular underlying structure, leading to numerous irregularities between implementations;
- The HL7 v2 reference model does not contain any useful tools for expressing containment or references, leading to a multitude of different approaches to this problem;
- The HL7 v2 specifications themselves contain a substantial amount of optionality and poorly specified free text descriptions of interfaces in HL7 v2 which make it difficult to specify precise contract terms for HL7 interfaces;
- There is no consistent set of terminologies for use with HL7 v2, which makes it difficult to integrate information from heterogeneous information sources;
- Despite the availability of specifications like HL7 v2 pathology specification, PIT based content attachments have continued to co-exist as an attachment to the v2 message because PIT has a more document oriented feel that ensures a guaranteed rendering of the pathology result for the clinician. This problem is likely to get exacerbated in the future as vendors will need~~ing~~ to produce reports with a more modern look and feel and embedded multimedia content in their reports which can accommodate the newer types of diagnostic tools; and
- Making enhancements to the HL7 v2 standard is getting increasingly difficult as some of the earlier design choices and subsequent band aids are really starting to take their toll;

This combination of elements has lead to unrealistic expectations that have hurt vendors and procurers equally.

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### ~~5.2.4~~4.2.4 Fit to Requirements

| Requirement | Support |
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| Specification Development Framework | • *Explicit Specification Development Framework:* The HL7 v2.x development process is entirely ad hoc and there is no explicit methodology (rating: 1)<br>• *Generality:* HL7 v2 has already been adapted for a number of different uses including: patient administration, pathology, discharge referral, Immunisation, diabetes, diagnostic imaging and claims. (rating: 4)<br>• *Consistent approach to structure and semantics:* While there is some consistency between specifications, there is no common model that ensures consistency (rating: 2)<br>• *Promotes Sound Clinical Design:* Members |

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| | receive no formal guidance in constructing messages, nor is there a simple way of referencing clinical evidence (rating: 1)<br>• *Separation of Responsibilities:* There is no clear separation of responsibilities (rating: 1)<br>• *Balances Trade Offs:* There does not seem to be any clear thinking about how the trade offs are balanced (rating: 1)<br>• *Pluggable Implementation Approaches:* There is some support for different implementation approaches, but it is done on an ad-hoc basis (rating: 2)<br>• *Extensibility:* Some research has been done on supporting extensibility and reuse within HL7 v2 by adding archetypes (rating: 3)<br>• *Localisation:* Localisation is possible within HL7 v2 through the use of the infamous "Z segments". (rating: 2)<br>• *Formalisation:* There is no formalisation of the framework underlying HL7 v2. (rating: 1)<br>• *NEHTA Interoperability Framework Support:* HL7v2 does not break down its approach in accordance with the Interoperability Framework (rating: 1)<br>Average Rating: 1.7 |
| Structured Documents | • *Document Oriented Approach:* HL7 v2 does not support the characteristics of a structured document. (rating: 2)<br>• *Versioning:* HL7 v2 does support versioning, but it is confusing to implement as changes to versions of messages are published in a variety of different ways (rating: 3)<br>• *Document Body:* HL7 v2 does not directly support the concept of structured documents. The whole message is similar to a document, but it does not really support a document oriented paradigm. (rating: 2).<br>• *Sections:* HL7 v2 does not support sections (rating: 1).<br>• *Data Groups:* A HL7 V2 segment is similar to a data group, but its support is fairly weak. Originally HL7 v2 was designed to support administrative requests and reports and is starting to face some significant challenges in representing complex structures required to support clinical content. There have been work arounds developed in this area, but it is acknowledged that this is an ongoing challenge for HL7 v2. There is no clean ontological separation of concepts at the data group level (rating: 1).<br>• *Attachments:* HL7 v2 supports attachments; however there are some restrictions on size. |

**Commented [GG29]:** Some research has been done, but it's hardly mature and established. I, for one, don't like the whole approach. I think it rates a 2 ("requires serious work, possibility of compromise")

**Commented [GG30]:** Although everyone hates them (and they've been misused), they've been proven again and again as a viable and mature approach when you have to use them. I think this should score more highly. And I think that extensibility and localisation are actually backwards here and through the rest of the document; localisation is the ability to take the standard as is and express local variance within he scope of the standard, and extensibility is the ability to extend the standard itself

**Commented [GG31]:** Actually, it's quite formal: mssages, segments, fields, components, subcomponents, and tables. Nice and solid – but completely at the wrong layer to be useful as a formalisation at the level desired. I'd express it a little differently

**Commented [GG32]:** Really? That's not my experience. Optionality and variance between different interfaces are pains, but switching between versions has always been solid and easy. And it's always published as a marked up word document with all the changes listed. I'd give it a 5 myself ;-)

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| | (rating: 4)<br>• *NEHTA CII Event Summaries:* HL7v2 supports some similar content to the CII event summaries (e.g. referral and discharge), however, it is not able to easily support some of the more complex event summaries that will appear in time (rating: 2)<br>• *NEHTA CII Data Groups:* From a NEHTA perspective, many of the message segments provided by HL7v2 are quite different from the data groups recommended by the NEHTA CII initiative and significant work will need to be done in harmonisation and many compromises are likely to need to be made. (rating: 2)<br>Average Rating: 2.1 |
| Data Types | • *Text:* HL7 v2 provides support for alpha numeric data. Structured text is supported by embedding HTML in fields (although the fields are not typed as HTML). No harmonization with other standards has been performed (rating: 2)<br>• *Quantities:* HL7 v2 provides support for numeric values. Some support is provided for units, percentages, ranges, etc, but this is not always structured in a uniform approach. No harmonization with other standards has been performed (rating: 2)<br>• *Dates and times:* HL7 v2 provides support for date time values and time series, although there are not necessarily consistent approaches to handing partial dates and times. No harmonization with other standards has been performed (rating: 2)<br>• *Encapsulated Content:* HL7 v2 provides support for MIME embedded content. No harmonization with other standards has been performed (rating: 3)<br>• *Links:* HL7 v2 has recently added support for links, but it does not support links to external structured documents (rating: 2)<br>• *Identification:* HL7 v2 provides support for identifiers. No harmonization with other standards has been performed (rating: 3)<br>• *NEHTA CII Data Types:* HL7 v2 provides support for many of the CII data types requirements. No harmonization with other standards has been performed (rating: 3)<br>• *NEHTA Identifiers:* HL7 v2 provides support for many of the requirements for NEHTA identifiers, but further alignment is required. No harmonization with other standards has been performed (rating: 3) |

**Commented [GG33]:** So?
This is a common refrain here, but since it applies to all standards (and it's work in progess), what does saying it achieve?

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| | Average Rating: 2.5 |
| Terminology | • *Terminology Data Types:* HL7 v2 supports terminology data (rating: 4)<br>• *Clearly Defined Vocabulary:* The vocabulary underlying HL7 v2 has been defined, but no description of how terms from other terminologies can be substituted has been defined. (rating: 3)<br>• *Interface Between Terminology and Structure:* Very little guidance is provided on how to address this issue within HL7 v2. (rating: 2)<br>• *NEHTA recommendations for SNOMED CT:* HL7 v2 permits SNOMED CT content, but provides no real recommendations for how SNOMED CT can be used within HL7 v2. (rating: 1)<br>Average Rating: 2.5 |
| Constraints | • *Constraint Metadata:* Some experimentation has been done on using to HL7 in conjunction with v2 *open*EHR style archetypes, although the standard has yet to be published (rating: 2)<br>• *Structural Constraints:* Some experimentation has been done on using to HL7 in conjunction with v2 *open*EHR style archetypes, although the standard has yet to be published (rating: 2)<br>• *Terminology Bindings:* Some experimentation has been done on using to HL7 in conjunction with v2 *open*EHR style archetypes, although the standard has yet to be published (rating: 2)<br>• *Composability and Reuse:* Some experimentation has been done on using to HL7 in conjunction with v2 *open*EHR style archetypes, although the standard has yet to be published The *open*EHR style archetype does not support effective levelling of archetypes (rating: 2)<br>• *Validation Algorithms:* No validation algorithm has been published (rating: 2)<br>Average Rating: 2 |
| Interchange Format | • *Industry Standard Parsers:* HL7 v2 supports an XML format as well as a more compact ER7-like format (i.e. the vertical '\|' bars). There is no industry standard parser for the ER7-like format (rating: 3)<br>• *Simplicity:* The format is simple to build a parser for, but the irregularities in the implementations make building parsers that handle different vendors implementations quite hard (rating: 2)<br>• *Message size:* HL7 v2 supports a more compact ER7-like format. However, HL7 v2 |

**Commented [GG34]:** This is a common refrain for this criteria, but I don't know what it means. I don't know what else HL7 could say about how terms from other terminologies can be substituted – it seems well understood to me

**Commented [GG35]:** ? huh? You want a terminfo for v2? I have no idea why this would be required?

**Commented [GG36]:** I think archetypes is irrelevant here. HL7 has defined profiles, and you can use these to constrain the content of the message in all sorts of interesting ways (though they don't support Composability and Reuse (though the eclipse toolkit for v2 does!)

**Commented [GG37]:** What about AHML? They do a good job…

**Commented [GG38]:** So are the rest of the ratings based on XML or ER/7? I think ER/7, so why not XML?

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| | traditionally has a size limit in messages of 64 Kb, as that is the maximum size piece of content that can be sent as a single message over a socket. However, work has been done on lifting this limit to over 2MB in HL7 2.5. (rating: 4).<br>• *NEHTA Secure Messaging:* XML is supported by HL7 v2, but the support for an alternative ER7 format may create confusion (rating: 4).<br>Average Rating: 3.3 |
| Services | • *Service Oriented Architecture:* HL7 v2 supports some of the service requirements, but the dominant assumption is a messaging approach which isn't easily tailored for use in an SOA environment (rating: 2)<br>• *Identification Services:* HL7 V2 does have messages that support the requirements for identification, but most of them are described as messaging specifications (rating: 3)<br>• *Structured Document Management Services:* HL7 v2 does not messages that support the requirements (rating: 2)<br>• *Clinical Process Management Services:* HL7 v2 has messages that support many of the requirements, but most of them are described as messaging specifications (rating: 3)<br>• *NEHTA Web Services Recommendation Support:* There has been some work done within IHE community on sharing HL7 v2 messages via web services, however, the IHE stack is based on a different Web Service stack than the one recommended by NEHTA (rating: 2)<br>Average Rating: 2.4 |
| Security | • *Authentication:* Nothing within HL7 v2 prohibits this requirement from being supported (rating : 5)<br>• *Authorisation:* HL7 v2 does not presently support a uniform approach to labelling of data at the segment level (rating: 2)<br>• *Confidentiality:* Nothing within HL7 v2 prohibits this requirement from being supported (rating : 5)<br>• *Non-Repudiation:* Nothing within HL7 v2 prohibits this requirement from being supported (rating : 5)<br>Average Rating: 4.3 |
| Low Complexity of Implementation | • *Clear Documentation:* The specifications require a reasonable degree of expertise from a developer to implement (rating: 3)<br>• *Simple Design Patterns:* The specifications |

**Commented [GG39]:** Actually, this isn't really true, except in a couple of interactions (will be fixed in v2.6). It may be true of many implementations, I cannot say

**Commented [GG40]:** It's not clear to me why HL7 V2 is different to the other standards in this regard. Why not a 5?

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| | do not use any complex design patterns. However, if archetypes are included, then the complexity will increase significantly. (rating: 3)<br>• *Minimal System Impact:* The specifications do not require vendors use specific components from third parties or to make internal changes to their system (rating: 4)<br>• *Facilitates Reuse:* Segments are reused in many messages and message definitions are reused for many trigger events. However, in order to accommodate this extensive reuse, most data fields are optional, making reuse quite complicated. (rating: 2)<br>Average Rating: 3.0 |
| Limited Opportunities for Variance | • *Implementation Guides:* A number of implementation guides have been developed for HL7 v2 specifications (rating: 4)<br>• *Conformance Specifications:* Some work has been started on conformance specifications, but more work is required (rating: 3)<br>• *Limited Use of Text Fields for sharing Structured Information:* HL7 v2 uses a large number of text fields for sharing structured information (rating: 2)<br>• *Limited optional fields and features:* Substantial optionality in HL7 v2 makes it difficult to specify precise contract terms for HL7 interfaces. (rating: 2)<br>• *Limited use of modal design patterns:* There are some modal fields, but they are not very common (rating: 3)<br>Average Rating: 2.8 |
| Clear Migration Path | • *Straight Forward Mappings From Existing Specifications:* There is a strong relationship between earlier versions of the HL7 v2 specifications and the later versions (rating: 4)<br>• *Backwards Compatibility:* There are a number of recommendations provided for HL7 v2 to ensure backwards compatibility, but the degree of variance in the specifications makes the backwards compatibility difficult to control (rating: 3)<br>• *Levelled Implementation Approach:* There is no support for a levelled implementation approach within HL7 v2 (rating: 1).<br>Average Rating: 2.7 |
| Tool Support for Implementation and Migration | • *Platform Independence:* HL7 v2 messages can be implemented in a number of programming languages, but (rating: 3)<br>• *Computer Processable Specifications:* HL7 v2 specifications are provided entirely in natural language and require the |

**Commented [GG41]:** What more is required? Other than a wiki page of my own questions as an actual implementor of conformance tools, I don't know of any outstanding issues

**Commented [GG42]:** See note in appendix. Not clear that this is important

**Commented [GG43]:** I don't agree. This is one of the best parts of v2 for me (speaking as an implementor). Sure, variance is a pain, but it's basically orthogonal to version in most cases, and switching versions is trivial

**Commented [GG44]:** Sentence is incomplete

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| | implementer to interpret the specifications (rating: 1)<br>• *Open Source Libraries:* There are a number of open source tools supporting HL7 v2. However, the quality and the activity within the community supporting these tools is highly variable. (rating: 3)<br>• *Interface Engine Support:* There is a large market of interface engine vendors who support HL7 v2 messages (rating: 5)<br>• *Testing Services:* Some third party vendors provide testing services, however given the weakness of the specifications it is quite difficult to do strong conformance testing (rating: 3)<br>Average Rating: 3.0 |
| Tool Support for Specification Development | • *Faithfulness to the Specification Development Framework:* As there is no formal framework for HL7 v2, it is very difficult to build tools which faithfully implement the framework. (rating: 1)<br>• *Specification Editors:* As there is no formal specification development framework for HL7 v2, it is very difficult to build tools which faithfully implement the specification development framework. (rating: 1)<br>• *Specification Libraries:* As there is no formal specification development framework for HL7 v2, it is very difficult to build a library service to support the specifications (rating: 1).<br>Average Rating: 1 |
| Governance | • *Recognized Body:* HL7 v2 is currently supported by a recognized standards body, Standards Australia (rating: 5)<br>• *Australian Participation in Processes:* Changes to HL7 v2 by Australia can also be taken into the international standards community for HL7 v2 (rating: 4)<br>• *Support for Australian Localisations:* The governance process does allow Australia to create its own localisations. (rating: 5)<br>• *Consensus and Quality Driven Release Process:* The release process is consensus driven, but in the past, coherence between different specifications has not been formally monitored. In the future, Standards Australia is starting to take a stronger role in ensuring greater cross standard coherence. (rating: 3)<br>• *Creates No International Trade Barriers:* The standard does not create any barriers. (rating: 5)<br>Average Rating: 4.4 |

**Commented [GG45]:** This is not true. Access databases are available, along with a number of derived products, as are conformance profiles, which include infrastructure for derived processing. I think this should score more highly

**Commented [GG46]:** It's possible, it's not difficult, the tools are good and free. More to the point, no one bothers – I think this conveys a quite different message about the relevance of this. I hope it scores little

**Commented [GG47]:** Same comment as above; there is a formal framework, and you can build tools to it (I've done It many times). But it's not the level of framework or tool that you are looking for. Ditto for the next to comments too. Have you looked a Message Workbench?

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| Australian Community Support | • *Australian Standards Community Support:* The Australian e-health standards already has significant support for HL7v2 (rating: 4)<br>• *Minimal Dependence on Key Individuals:* Although the pool individuals is small, there is no dependence on key individuals. (rating: 4)<br>• *Vendor community support:* The Australian vendor already has significant support for HL7v2 (rating: 4)<br>Average Rating: 4.0 |
| International Community Support | • *Australian Standards Community Support:* The International e-health standards and vendor communities already has significant support for HL7v2. (rating: 4)<br>• *Minimal Dependence on Key Individuals:* Although the pool individuals is small, there is no dependence on key individuals. (rating: 4)<br>• *Vendor community support:* The International vendor already has significant support for HL7v2 (rating: 4)<br>Average Rating: 4.0 |

### ~~5.2.5~~4.2.5 Strengths and Weaknesses

The pros of adopting HL7 v2 as the preferred approach are:

- The Australian and International e-health standards and vendor communities already has significant support for HL7v2;
- HL7 v2 has already been adapted for a number of different uses including: patient administration, pathology, discharge referral, Immunisation, diabetes, diagnostic imaging and claims;
- The migration path from existing widely implemented HL7 V2.3 specifications is relatively clear;
- HL7 v2 is currently supported by a recognized standards body, Standards Australia; and
- Internationally, Standards Australia has been quite successful in ensuring that Australia's needs are supported by the HL7 V2 specifications.

The cons of adopting HL7 v2 as the preferred approach are:

- HL7 v2 does not provide a well defined specification development framework;
- HL7 v2 does not provide support for structured documents and has limited support for complex clinical information;
- HL7 v2 does not provide openly defined support for services or integrate with other existing approaches; and
- As a result of a poorly defined specification development framework, HL7 v2 has weak tool support.

## ~~5.3~~4.3 Document/Service Centric HL7 v3 approach

Commented [GG48]: Generally this section is hard to follow, because it's always hard to know whether v3 means "dynamic model with messages" or "CDA with services". Officially it claims to be CDA with services, and I have based my comments on this

### ~~5.3.1~~4.3.1 Introduction

HL7 Version 3 is a fundamentally different approach to HL7 v2, and was designed from the ground to support more precise usage of messages (and later documents) to support effective interoperability across organisations, regions and countries, as well as addressing shortcomings in HL7 v2. Whilst originally intended to replace HL7 v2, it is now accepted that the two different approaches achieve different objectives. HL7 v3 seeks to provide stronger support for:

- Top-down message development emphasizing reuse across multiple contexts while retaining semantic interoperability;
- Representation of complex relationships;
- Formalisms for vocabulary support;
- Support for large scale integration;
- Solving re-use and interoperability across multiple domain contexts;
- A uniform set of models;
- Expanded scope to include community medicine, epidemiology, veterinary medicine, clinical genomics, security, etc.

The key element of the HL7 v3 approach is that all HL7 v3 ~~messages~~ content ~~are~~ is based on a common base model, known as the Reference Information Model (RIM). The RIM and a range of structures derived from it express the data content needed in a specific clinical or administrative domain and provide representations that reflect the connections between the information carried in the various fields of HL7 messages relating to that domain.

The HL7 Development Framework (HDF) focuses on the RIM as a basic building block and then uses a process of documenting processes, actors, rules, artefacts and the gradual refinement of the RIM to a domain specific purpose, from which message and document specifications can be developed. The initial version of the HDF standard primarily supports messaging specifications, but ~~in the future~~ it is currently~~will~~ being expanded to better support for structured documents, services and context management.

HL7 CDA is a part of the HL7 suite of specifications and allows clinical documents to be produced as XML documents that are easily rendered in a human readable form, are machine interpretable and can be carried as a payload in both services and messages.

Needs a paragraph here about HSSP, and then services with CDA documents

In the international community, the largest adopter of HL7 v3 is the NHS Connecting for Health (CfH) program in the UK. CfH has used HL v3 in a number of contexts, including personal demographics, electronic booking, electronic prescribing and will soon undertake deployment of a large scale system based on CDA and templates for its Shared EHR program of work. Outside of the UK, v3, as either messages or CDA, is recommended for use by Infoway in Canada, NICTIZ in the Netherlands and it has been heavily used within Germany. Within the US, ~~d~~ a number of the Regional Health Information Organisations (RHIOs) make use of CDA and CDA has been selected by the US Government Consolidated Health Informatics (CHI) initiative as the recommended standard for representing all clinical reports in an electronic form (including clinical reports from the DHHS, Medicare, Medicaid, the FDA and Veteran Affairs). CDA has also been adopted as the standard for all clinical records in NATO and many other nations in Europe are actively investigating CDA based solutions.

Within the Australian context, Standards Australia has been closely monitoring developments within HL7 v3, building capacity and providing input into the

development of HL7 v3. Medicare Australia has also trialled HL7 v3 within one of its claiming applications.

Commented [GG49]: Politics, I know, but I don't think it got that far advanced to say that

### ~~5.3.2~~4.3.2 Approach Considered

The HL7 v3 approach considered here is a service and document-centric one based heavily on adoption of CDA R2 structured documents, Templates and HSSP. This approach will also leverage~~s~~ the RIM, HDF, Terminfo, Clinical Statements~~, UML ITS~~ and the ~~XML~~ ITS. This approach will also seek to leverage enhancements to the HL7 v3 specifications that have been made as a result of international implementation experience with in the UK, US and Canada. Examples include the Data Types, ~~XML~~ ITS, ~~UML ITS,~~ Term Info, Templates, Clinical Statements and Continuity of Care Document (CCD).

### ~~5.3.3~~4.3.3 Lessons Learned from Implementation

HL7 v3 has been adopted in a number of different places, and in most cases the motivation for adoption in all of these cases has been quite similar:

- HL7 v3 supports a wide variety of domains, which will give the adopting community the opportunity to incrementally add new specifications as they need them
- HL7 v3 provides a relatively comprehensive framework which supports:
  - A structured top-down approach to message development which emphasizes collection of the original requirements and reuse across multiple contexts
  - Representation of complex relationships
  - Strengthened vocabulary support and creation of more uniform messaging models, which in turn address some of the problems with the high degrees of variance in implementation, optionality and free text within HL7 v2 have been reduced
  - A contemporary implementation approach based on object orientation, UML and XML
- In the area of clinical documents, CDA has been received fairly positively because:
  - In the eyes of clinicians, CDA is easy to sell as most of healthcare is document oriented and not message oriented. For example, a reports, referrals, discharge summaries, assessments and care plans are all documents.
  - It is relatively easy to ensure that rendering a CDA document for display will ensure that the layout the clinician is expecting will be preserved
  - CDA offered different levels that projects could choose to support, ranging from unstructured text documents through to highly structured text documents. The allowed projects to decide what was most appropriate for their situation and get started.
  - CDA provides a single stable wire format that can be re-used in a number of different applications

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In adopting HL7 v3, however, a number of different lessons have been learned:

- In 2005, Infoway in Canada released a recommendation that HL7 v3 was the preferred set of standards. There was a reasonable amount of resistance from some of the Jurisdictions to the HL7 v3 recommendation. Their view was that, while they support the technical motivations for adopting HL7 v3, they argued that they didn't want to undertake the risk of being an early adopter and preferred to keep

working with HL7 v2. As a result, Infoway has become more flexible about its recommendation for HL7 v3, allowing Jurisdictions to keep on using HL7 v2 in existing implementations, while it continues on working on making the HL7 v3 specifications more mature.

- The NHS CfH program has widely implemented HL7 v3 in a number of areas including their Personal Demographics Service, ePrescribing Service and Choose and Book. These services are large scale applications, supporting thousands of users and millions of patients.

  The CfH team for their Shared EHR implementation is proposing using CDA R2 and templates. The Patient Summary Information Service (PSIS) is expected to be operational in 2007.

  ~~The CfH team for their Shared EHR implementation is proposing using CDA R2 and templates. The Patient Summary Information Service (PSIS) is expected to be operational in 2007.~~

  - The messages are very complex in structure and contain many extra XML elements that do not contribute at all to the message data, though they are required to support some methods of processing the message. As the messages grow more semantically complex, the ratio drops.
  - The models upon which the wire format is based are not implementable directly from a UML model. If they were, this would provide the added benefits of enabling analysts, modellers, architects and software developers to work with the message content and formats in many more ways, more aligned with their normal development processes.
  - Semantic consistency and interoperability can be at risk as two different instances of the same data conforming to different constraints may have different wire formats.

  The NHS has raised these issues with the HL7 Board and is currently pursuing a strategy to address these issues, but it is unclear whether these issues will be able to be addressed, which has strengthened the interest in CDA.

- Within the US, HL7 v3 has been under competitive pressure from the ASTM standards community. In parallel to the development of CDA release 2, ASTM, who had traditionally worked on claiming, had been busily consulting with peak bodies of clinicians to come up with a standard pro-forma, the Continuity of Care Record (CCR), which described a patient's background health history and could be used for improving continuity of care of patients as they moved between multiple providers.

  The benefit of CCR was self evident to implementers, such as the some of the US based RHIOs, as it provided a single document with well defined fields that could help facilitate sharing of care, rather than having a generic document, like CDA which could support a wider variety of use cases, but with less clear guidance on what needed to be provided.

  CCR caught the HL7 community somewhat by surprise and is viewed as a serious challenge to HL7 CDA as the ASTM community has been lobbying with the US government to have CCR adopted as the preferred standard. More recently, HL7 has started working with the ASTM community to develop a common standard which brings together CDA and CCR, called the "Continuity of Care Document (CCD)".

- Also in parallel with the development of HL7 v3 CDA, a group of vendors within the US and Europe had gotten together within the Integrating the Health Enterprise (IHE) umbrella to develop a suite of specifications,

**Commented [GG50]:** Moved it, then put it back here

known as IHE Cross Document Sharing (XDS), that would allow CDA documents stored in multiple locations to be located and retrieved using web services. A number of the RHIOs within the US have adopted the IHE XDS model.

The vendor community was drawn to the model because it is straight forward to implement, and the IHE community provides a forum called a "Connect-athon" which would allow vendors to come together to demonstrate that their products can interoperate.

The HL7 organisation has become aware of the strength of the model and has started to work with the IHE and the OMG to develop a set of specifications for Services with HL7 under the HSSP banner. The RLUS specification, which is the most advanced HSSP product, is a service that could be used to implement an XDS like framework and take advantage of a full SOA environment.

### ~~5.3.4~~4.3.4 Fit to Requirements

| Requirement | Support |
|---|---|
| Specification Development Framework | • *Explicit Specification Development Framework:* Through HDF, HL7 v3 provides a well defined framework for the development of specifications (rating: 4)<br>• *Generality:* The HDF and RIM-based models have been applied to a broad spectrum of domains ranging from patient administration and supply chain messages to clinical orders and reporting to the human genome (rating: 5)<br>• *Consistent approach to structure and semantics:* The HDF does promote a consistent approach to structure and semantics through the usage of the RIM. However significant manual work is required to ensure that specifications are appropriately levelled, consistent, non-overlapping and intelligently interlinked (rating: 3)<br>• *Promotes Sound Clinical Design:* While the RIM ensures that a some elements of the clinical design are sound, much of the approach to sound clinical design is dependent upon the modeller. There is no consistent way of referencing clinical evidence (rating: 2)<br>• *Separation of Responsibilities:* The HDF does provide some separation of responsibilities (rating: 4)<br>• *Balances Trades Offs:* How tradeoffs are balanced is not described explicitly in the documentation. However, some of the discussion of the tradeoffs can be found within the discussion forums. (rating: 2)<br>• *Pluggable Implementation Approaches* HL7 v3 and HDF support pluggable implementation approaches including support for approaches based on different transport layers and modelling technologies |

**Commented [GG51]:** I worry about this. Are we talking about V3 or CDA? V3 is lovely and broad, but CDA is rather narrower. It seems a little inconsistent to be evaluating CDA with services, and commenting about the breadth of V3 generally. I know this is commenting in the specification development framework, but it still seems inconsistent to me

**Commented [GG52]:** Same comment as above. Does this matter, given that the information model is CDA not all of V3?

**Commented [GG53]:** Same again. CDA is a small group, with much more consistency, but on the other hand, more is delegated to the end user in templates

**Commented [GG54]:** This is a general V3 comment. For CDA + Services, the picture is somewhat different

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| | (rating: 4)<br>• *Extensibility:* Some support for extensibility is available, but more work is required on templates (rating: 3)<br>• *Localisation:* The HDF provides support for localisation, but HL7's rules for localisation can be confusing, with each country (realm) potentially ending up with a different variety of their own ~~messages~~formats. More work needs to be applied to global management of HL7 v3 to ensure that localisation does not result in a fractious set of implementations (rating: 3)<br>• *Formalisation:* The HDF does have an underlying model, but it could be more soundly engineered (rating: 3)<br>Average Rating: 3.3 |
| Structured Documents | • *Document Oriented Approach:* CDA R2 is able to support all of the requirements. (rating: 5)<br>• *Versioning:* CDA supports a versioning model, but the semantics of versioning should be made clearer (rating: 3)<br>• *Document Body:* CDA R2 is able to support structured documents, however it supports it as an act rather than as a document class (rating: 4)<br>• *Sections:* CDA R2 is able to support sections, however it supports it as an act, rather than as a section class. (rating: 4)<br>• *Data Groups:* CDA R2 is able to support data groups. However, there are some concerns over the ontological basis of the RIM. The RIM itself does not distinguish between whether it is an "ontology of reality" (i.e. a description of things in the real world, like SNOMED CT is) or an "ontology of information" (i.e. an information model designed for recording things that happen in the real world). For example, it is not clear whether the RIM should be recording "acts of observation" (reality based modelling) or "observations" (information based modelling). While these philosophical objections are interesting, they do not prevent the production of implementable specifications. The HL7 organisation is aware of the issue and is working towards a resolution. (rating: 4)<br>• *Attachments:* CDA documents can be attached to other CDA documents as encapsulated content. (rating: 5)<br>• *NEHTA CII Event Summaries:* Most of the CII event summaries should be supportable by the HL7 v3 CDA, clinical statements, template and TermInfo specification. In |

**Commented [GG55]:** Again, I think the definitions are around the wrong way. Templates are close, I think, and now it's just tools that are required. I think the score should be higher

**Commented [GG56]:** I don't understand this. That's the point of localisation. The layered approach – which is otherwise good – will always lead to this problem if not used judiciously.

**Commented [GG57]:** But at least it's possible. This is important – HL7 has a framework for doing this, unlike 13606/openEHR. I think the score should be higher

**Commented [GG58]:** Umm, so? I know the religious argument, but does it matter anyhow here?

**Commented [GG59]:** Same. Does this matter in any fashion?

**Commented [GG60]:** Hmm. What are data groups? Does this have anything to do with the academics of the RIM as an ontological basis for the combined theory of the universe?

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| | 2004, the Health*Connect* Clinical Information Program (CIP), managed to demonstrate that the majority of the discharge summary fields (the forerunner of the modern NEHTA CII work) could be mapped to CDA. (rating: 3)<br>• *NEHTA CII Data Groups:* Some or most of the CII data groups should be supportable by the HL7 v3 CDA, clinical statements, template and TermInfo specification. However, it is highly likely that some compromises will be necessary (rating: 3)<br>Average Rating: 3.9 |
| Data Types | • *Text:* HL7 v3 provides support for textual data, although some further harmonization work is required. (rating: 4)<br>• *Quantities:* HL7 v3 provides support for quantities, although some further harmonization work is required (rating: 4)<br>• *Dates and times:* HL7 v2 provides support for date time values and time series, although some further harmonization work is required. (rating: 4)<br>• *Encapsulated Content:* HL7 v3 provides support for embedded content, although some further harmonization work is required. (rating: 4)<br>• *Links:* It is not clear how HL7 v3 supports links (rating: 3)<br>• *Identification:* HL7 v3 provides support for identifiers, although some further harmonization work is required (rating: 4)<br>• *NEHTA CII Data Types:* HL7 v3 provides support for many of the CII data types requirements (rating: 5)<br>• *NEHTA Identifiers:* HL7 v3 provides support for many of the requirements for NEHTA identifiers, but there are still some discrepancies (rating: 4)<br>Average Rating: 4.0 |
| Terminology | • *Terminology Data Types:* HL7 v3 supports sharing of terminological data (rating: 5)<br>• *Clearly Defined Vocabulary:* The vocabulary underlying HL7 v3 has been defined, but no description of how terms from other terminologies can be substituted has been defined. (rating: 3)<br>• *Interface Between Terminology and Data Structures:* HL7 v3 has specific recommendations on addressing this interface through its TermInfo specification; however, considerable work is needed to get a balance that can be relied upon in clinical decision support (rating: 2) |

**Commented [GG61]:** Not sure quite what this means or why it's significant in this evaluation

**Commented [GG62]:** I'm not sure why. It's clear to me – though I am the editor, so I might not know what isn't clear to the insiders

**Commented [GG63]:** Again, I don't know what this means. But it's said in all 4 cases, so maybe it should just be dropped

**Commented [GG64]:** No fair. HL7 V3 should get the highest score here for doing termInfo, especially since terminfo is mentioned in the pro's for V3. The general topic is not otherwise addressed in the other cases though I goes the terminfo reasoning applies to the other ones as well.

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| | • *Support for NEHTA SNOMED CT Recommendation:* HL7 v3 ~~supports~~ has specific recommendations on how to use SNOMED CT, however additional work is likely to be still required on how SNOMED CT should be used in different situations (rating: 3)<br>Average Rating: 3.3 |
| Constraints | • *Constraint Metadata:* Much work has been done on templates, constraints and constraint languages but it has yet to be fully realised. (rating: 2)<br>• *Structural Constraints:* Much work has been done on templates, constraints and constraint languages but it has yet to be fully realised, with more work and implementation trials needed (rating: 3)<br>• *Terminology Bindings:* It is not clear how terminology bindings will be supported (rating: 3)<br>• *Composability and Reuse:* Some work has been done in the templates and constraints area on constraint languages, however the specification needs further work. No work has been done on levelling of constraints (rating: 2)<br>• *Validation Algorithms:* No work has been done on validation algorithms. It is assumed that schematron will support the validation requirements. Dependence on a technically specific approach is not desirable (rating: 2)<br>Average Rating: 2.4 |
| Interchange Format | • *Industry Standard Parsers:* HL7 v3 supports XML (rating: 5)<br>• *Simplicity:* ~~The message structure~~CDA is complex. No statements have been made about it being context free, although it is relatively strongly typed through the use of XML (rating: 3)<br>• *Message Size:* ~~HL7 v3 messages~~CDA documents tend to be very verbose, compared to HL7v2 messages. (rating: 2)<br>• *NEHTA Secure Messaging:* CDA is an XML ~~is supported by HL7 v3~~format (rating: 5).<br>Average Rating: 3.8 |
| Services | • *Service Oriented Architecture:* There has been some work done on supporting SOA within HL7 v3, including a web services ITS, work with IHE and now work within the OMG under HSSP (rating: 4)<br>• *Identification Services:* The EIS specification supports most of the recommendations for these services. (rating: 4) |

**Commented [GG65]:** Not sure why it isn't clear

**Commented [GG66]:** What's that?

**Commented [GG67]:** Maybe it's just because that's my baby, but I would've though we'd qualify for a 3 here ;-)

**Commented [GG68]:** No fair. There is now 3 known ways to do template validation, each with different strengths:
•Schematron
•Transform to schema
•Direct evaluation by HTC funded Eclipse code
Obviously(!) the last approach is the best

So it's not true that no work has been done. Nor does it depend on a specific approach.

Should score more highly here.

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| | • *Structured Document Management Services:* The RLUS specification support most of the requirements for this service (rating: 4)<br>• *Clinical Process Management Services:* HL7 v3 provides a number of different specifications for supporting these requirements, but they are specified as messages and not as services (rating: 2)<br>Average Rating: 3.5 |
| Security | • *Authentication:* Nothing within CDA prohibits this requirement from being supported (rating : 5)<br>• *Authorisation:* Nothing within CDA prohibits this requirement from being supported (rating : 5)<br>• *Confidentiality:* Nothing within CDA prohibits this requirement from being supported (rating : 5)<br>• *Non-Repudiation:* Nothing within CDA prohibits this requirement from being supported (rating : 5)<br>• Average Rating: 5.0 |
| Low Complexity of Implementation | • *Clear Documentation:* Compared to documentation in most projects, implementers of v3 have found the documentation relatively complete, particularly with CDA. ~~However, there is a learning curve to be climbed before a developer is ready to start implementing~~ (rating: 2)<br>• *Simple Design Patterns:* HL7 v3 messages, because of the RIM, tend to be complex to implement. This complexity comes from two sources, one is having a specification development framework that supports a broad scope and second is from a number of historical decisions that are difficult to undo. The first is going to be difficult to get around unless the requirement for a broad scope is removed. The second can be improved with time (rating: 2)<br>• *Minimal System Impact:* The ~~v3~~ CDA approach allows Vendors to take an arms length approach to implementations. Most of the impact comes from interfacing requirements, not from internal system requirements (rating: 4)<br>• *Facilitates Reuse:* ~~More work is required to ensure that HL7 v3 can support more reuse between implementations~~CDA supports reuse (rating: 3)<br>Average Rating: 2.8 |
| Limited Opportunities for Variance | • *Implementation Guides:* Some work has been done on implementation guides within the NHS, but significantly more needs to be |

**Commented [GG69]:** Delete because CDA is easier. I think!

**Commented [GG70]:** Again, this is not about CDA. CDA is a single design pattern, with templates, a single schema. Should score more highly

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**Commented [GG71]:** And therefore should score better

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| | done (rating: 3)<br>• *Conformance Specifications:* The HL7 v3 approach is driven very strongly around the preparation of conformance specifications for each of its specifications. However, this promise is still not well supported and further work within the HL7 community needs to be done on this area (rating: 2)<br>• *Limited Use of Text Fields for Sharing Structured Information:* Has potential for a significantly more structured approach to sharing information but flexibility still needs to be externally controlled when using CDA documents as central element (rating: 4)<br>• *Limited Optional Fields and Features:* One of the premises for v3 was that it reduced the number of optional fields over v2. While we are not entirely sure that has been achieved in CDA, the introduction of templates should reduce the opportunities for variance. (rating: 3)<br>• *Limited Use of Modal Design Patterns:* The mood code and other coded fields in the RIM create a risk of modal classes, but the HDF approach of refinement is designed to drive the risk of variance out (rating: 3)<br>Average Rating: 3.0 |
| Clear Migration Path | • *Straight Forward Mappings From Existing Specifications:* There is some relationship between the earlier HL7 v2 specifications and ~~HL7 v3~~CDA and some proprietary mappings have been developed within implementation sites, but these mappings are not yet shared (rating: 3)<br>• *Backwards Compatibility:* ~~More work needs to be done to ensure better backwards compatibility of HL7 v3 specifications~~CDA has a formal framework for ensuring backwards compatibility based on transforms (rating: 4~~3~~)<br>• *Levelled Implementation Approach:* CDA provides a levelled implementation approach using templates (rating: 4).<br>Average Rating: 3.~~3~~6 |
| Tool Support for Implementation and Migration | • *Platform Independence:* ~~HL7 v3 messages~~CDA documents can be implemented in a number of programming languages (rating: 5)<br>• *Computer Processable Specifications:* ~~Many of the current specifications are available as~~There is a schema and a MIF file for CDA. ~~XML Schemas and t~~There is work being undertaken on ~~making this much more repeatable and reliable and~~ providing stronger UML support (rating: 4)<br>• *Open Source Libraries:* The HL7 Home base |

**Commented [GG72]:** Again, not a CDA based comment

**Commented [GG73]:** See note in appendix; not clear that this relevant

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| | project and source forge provides a suite of HL7 v3 open source tools. In addition to this the Open Healthcare Framework for Eclipse funded by ~~IBM~~ NHS and others is progressing on developing tools in this space under the H3ET project through the HL7 Tooling Collaborative (HTC). (rating: 3)<br>• *Interface Engine Support:* Some vendors of interface engines within the UK and the US are starting to support HL7 v3 (rating: 3)<br>• *Testing Services:* The NHS has done some work on developing testing services. Similarly, CDA is used increasingly in IHE circles (rating: 3)<br>Average Rating: 3.6 |
| Tool Support for Specification Development | • *Faithfulness to the Framework:* Within the HL7 v3 community, the standards and derived specifications are maintained with a suite of tools. The degree of conformance of these tools to the specification development framework needs more work and has led to requests for fundamental changes to the underlying standards to ensure that they can be reliably and economically supported by new tooling (rating: 3)<br>• *Specification Editors:* Within the HL7 v3 community, the specifications are maintained with a suite of tools. However, the existing Visio editor is not particularly user friendly and only runs on an non-recent version of Visio.<br>~~IBM and the~~The NHS, through the HTC, is funding the development of HL7 tools using the Eclipse framework which should result in the development of better tools~~. In addition to this, a tooling collaborative has also been set up to further the development of HL7 tools~~. (rating: 2)<br>• *Specification Library:* Some work has started on developing specification libraries for v3 (rating: 2)<br>Average Rating: 2.3 |
| Governance | • *Recognised Body:* HL7 is an ANSI-accredited standards setting body, also recognised by ISO TC215 and its main products have been accorded international standards status. Currently there is some interest within Standards Australia on undertaking some work on HL7 v3 and/or CDA but little established capability. (rating: 4)<br>• *Australian Participation in Processes:* On an international basis, Australia is currently participating in the international HL7 processes for v3. Australia has a few key representatives who participate in strategic areas. However, the community is quite large and the body of existing work is also |

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| | very large and getting changes through can be quite challenging. It is clear that Australia will need to continue working in a highly strategic and targeted fashion to ensure that specific needs are addressed through the HL7 processes. When Australia does work in a highly strategic fashion it has a good track record in getting its changes through (rating: 4)<br>• *Support for Australian Localisations:* The recognition of "realm" variations and rules for localization of specification development framework behind HL7 v3 allow for Australia to create its own localisations; however, this process does not seem capable of retaining any interoperability or economies of implementation between realms. The more Australia focuses on templates instead of localisations of domain models, the less likely this will be an issue (rating: 3)<br>• *Consensus and Quality Driven Release Process:* The standards development process and the specification development framework behind HL7 v3 aims to ensure a reasonable degree of consensus and coherence between v3 standards and specifications but these processes are often challenged by the broad scope of HL7 activity. (rating: 3)<br>• *Creates No Trade Barriers:* The adoption of v3 would not create such a barrier, other than to the extent it would need strong localization in its current form. (rating: 5)<br>Average Rating: 3.8 |
| Australian Community Support | • *Australian Standards Community Support:* There are a number of individuals and companies within Australia that have participated for a very long period of time in the development of HL7 v3. (rating: 3)<br>• *Minimal Dependence on Key Individuals:* There is still some strong dependencies on key individuals in Australia, but with effort this base is able to be grown (rating: 2)<br>• *Support by Local Vendors:* No products in Australia currently support HL7 v3, although some vendors have been experimenting with HL7 v3 (rating: 2)<br>Average Rating: 2.3 |
| International Community Support | • *International Standards Community Support:* The HL7 v3 standards community is the largest e-health standards community in the world. The UK, Netherlands and Canada all have adopted HL7 v3. Germany is also a heavy user of the specifications. (rating: 5)<br>• *Dependence on Key Individuals:* In the past HL7 v3 and CDA were~~as~~ dependent on key |

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| | individuals, but these days the dependence is less so. However, some of this dependence still exists (rating: 3)<br>• *Support by Vendors:* Three of the major vendors which supply systems in the NHS and here in Australia support HL7 v3 and will soon support CDA R2. (rating: 3)<br>Average Rating: 3.7 |

### ~~5.3.5~~4.3.5 Strengths and Weaknesses

Some of the advantages of adopting a Service and Document Centric HL7 v3 approach are:

- HL7 v3 has a specification development framework that can support requirements for standards and specification across a broad range of areas, including Shared EHR, ePrescribing, Referrals, Registries and other areas requiring e-health interoperability;
- HL7 v3 is evolving to support services and has growing levels of resources working in the services space;
- HL7 v3 is the only specification development framework that has specific recommendations on how to use SNOMED CT;
- HL7 v3 has tooling support which is being updated and made more usable by the NHS, has tooling support. This tooling support will, in time, only get stronger as groups like ~~IBM's~~ Eclipse ~~team~~ OHF take more interest in it;
- HL7 v3 & CDA are now being used in large scale applications within the NHS;
- HL7 v3 has been implemented by a two large international vendors, who have products installed in every Jurisdiction in Australia;
- There are opportunities to collaborate internationally with other countries, like the UK and Canada, on the development of specifications and standards; and
- HL7 has an integrated localisation and extensibility framework that can support real requirements in a timely fashion while standards change in their own timeframe
- The HL7 community has the largest participant base internationally, which further aids with the sustainability of the recommendation

On the negative side:

- The communication of health information in HL7v3 tends to be very verbose compared to HL7 v2;
- CDA & HL7 v3 interchange specifications, because of the generic nature of the RIM and inherited characteristics of the methodology used to derive class models from it can be complex to understand and implement;
- In representing the NEHTA CII data groups using the HL7 v3 methodology, it is likely that a number of compromises will need to be made; and
- One of the problems with a large community supporting a specification, is that from a governance point, it can be difficult to move such a large community when decisions need to be made. It is clear that Australia will need to continue working in a highly strategic and targeted fashion to ensure that specific needs are addressed through the HL7 processes.

**Commented [GG74]:** But some of this is not in CDA. I guess that really we are envisaging one or two other documents as well

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# ~~5.4~~4.4 EN 13606

## ~~5.4.1~~4.4.1 Introduction

EN 13606 defines a model of an EHR Extract which is to be used by EHR systems in Europe for communicating parts or all of an EHR to another system. An EN 13606 Extract can contain multiple Compositions, up to and including an entire EHR, including multiple current or previous versions; it also contains sufficient demographic and other reference data for a receiver to make sense of the extract. The parts of the standard are:

- *Part 1:* Reference model;
- *Part 2:* Archetype interchange specification;
- *Part 3:* Reference archetypes and term lists;
- *Part 4:* Security requirements and distribution rules; and
- *Part 5:* Exchange models.

**Commented [GG75]:** Should acknowledge that some of these parts are not yet finalised

In 2005, an "Archetype Knowledge Framework" was proposed to provide a stronger ontological basis for using EN 13606, including the structure and guidelines for an internationally shared library of archetypes. This specification is likely to cover:

- *Part 1:* Archetype Ontology
- *Part 2:* Domain Base Concept Model (DBCM)
- *Part 3:* Term Binding Rules
- *Part 4:* Archetype Library
- *Part 5:* Mapping Guidance

An earlier ENV 13606 pre-standard was finalised in 1999/2000 and was implemented on a trial basis by several European countries, including Norway, which is still using it.

The new 5-part EN 13606 differs significantly from the earlier pre-standard; having incorporated the notion of archetypes as originally implemented in *open*EHR. On of the key attractions of the new EN 13606 is its promise to provide an internationally-endorsed means of sharing clinical information using archetypes; however, this benefit is challenged by a few emerging differences between the EN 13606 standards and existing implementations, which use *open*EHR archetypes.

Several European countries have trial sites which are intending to use the new EN 13606 standard. Within the UK, iSoft and BT are currently experimenting with it, but not using it in a production capacity. Within Australia, Standards Australia has a committee (IT-14-9) working on parts of the EN 13606 standard as it proceeds through ballot for acceptance as an international standard in parallel with based on earlier requirements emerging from Health*Connect*; but there are currently no vendors implementing it.

## ~~5.4.2~~4.4.2 Approach Considered

This section considers an approach which assumes a fully completed suite of CEN 13606 specifications. The potential of enhancing EN 13606 using the archetype knowledge framework was also considered.

## ~~5.4.3~~4.4.3 Lessons Learned from Implementation

As there are no significant implementations of EN 13606, little can be inferred about lessons learned from implementation.

### ~~5.4.4~~4.4.4 Fit to Requirements

| Requirement | Support |
|---|---|
| Specification Development Framework | • *Explicit Specification Development Framework:* There is no separate framework for application of EN 13606. However, it would be possible to generalize some of the elements within EN 13606 to produce a framework (rating: 3)<br>• *Generality:* EN 13606 is primarily designed to support the sharing of EHR Extracts. It was never designed to support transactions for referrals, prescriptions/ dispensing or identifier management. While in theory, EN 13606 could be adapted to be broader, there are some concerns from within the CEN community that would resist its use to manage documentation of transactions outside the shared EHR context as they have other standards based on different frameworks for handling such matters. (rating: 2)<br>• *Consistent approach to structure and semantics:* EN 13606, when used with appropriate archetype repositories and tools , does promote a consistent approach to structure and semantics but the archetype development framework has yet to be defined to automate these processes. In particular, more emphasis needs to be placed on ensuring that archetypes are appropriately levelled, consistent, non-overlapping and intelligently interlinked (rating: 2)<br>• *Promotes Sound Clinical Design:* EN 13606 does not provide any detailed rules or guidance for designing archetypes and the archetype method does not provide 'built-in' quality assurance or semantic consistency checks. Presumably the Archetype Knowledge Framework is intended to promote~~s~~ sound clinical design of artefacts like structured documents. At present there is no consistent way of referencing clinical evidence (rating: 2)<br>• *Separation of Responsibilities:* The original EN 13606 specifications followed a stronger ODP style approach in separating responsibilities. This strength of separation seems to have been lost in recent years. (rating: 4)<br>• *Balances Trade Offs:* No discussion of how trade offs are balanced is provided. (rating: 1).<br>• *Pluggable Implementation Approach:* Nothing in EN 13606 prohibits pluggable implementation approaches, but there is no direct support for it either. (rating: 3)<br>• *Extensibility:* EN 13606 supports extensibility and reuse via archetypes (rating: 5)<br>• *Localisation:* EN 13606 does not provide any guidance on localisation. Presumably this is handled through the forthcoming archetype |

**Commented [GG76]:** Again, I have an issue with the definitions of extensibility and localisation. 13606 supports a degree of localisation by constraint using archetypes, but has no support for extensibility outside what is expected

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| | knowledge framework. Insufficient work has been done on archetype governance to help minimize fractious sets of archetypes evolving that may hamper interoperability and make it difficult to deploy products in an international context (rating: 2)<br>• *Formalisation:* The archetype approach strongly formalises how the approach works. (rating: 4)<br>Average Rating: 2.8 |
| Structured Documents | • *Document Oriented Approach:* All requirements are supported, with the exception of human readability, which requires more work. Also, compositions in EN 13606 cannot be exchanged separately without an EHR Extract (rating: 4)<br>• *Versioning:* EN 13606 composition support versioning, but the semantics are not well defined. (rating: 3)<br>• *Document Body:* All requirements are supported (rating: 5)<br>• *Sections:* All requirements are supported (rating: 5)<br>• *Data Groups:* Most of the requirements are supported, however the EN 13606 model does not provide adequate ontological separation of concepts within the reference model at the data group level (rating: 3)<br>• *Attachments:* EN 13606 Compositions do not support attaching other compositions directly. Instead they must be supported by links to other compositions within an EHR Extract (rating: 4)<br>• *NEHTA CII Event Summaries:* Archetypes can be used to support most if not all CII requirements (rating: 5)<br>• *NEHTA CII Data Groups:* Archetypes can be used to support most if not all CII requirements (rating: 5)<br>Average Rating: 4.3 |
| Data Types | • *Text:* EN 13606 provides support for textual data, although some further harmonization work is required. (rating: 4)<br>• *Quantities:* EN 13606 provides support for quantities, although some further harmonization work is required. (rating: 4)<br>• *Dates and times:* EN 13606 provides support for date time values and time series, although some further harmonization work is required. (rating: 4)<br>• *Encapsulated Content:* EN 13606 provides support for embedded content, although some further harmonization work is required. (rating: 4) |

**Commented [GG77]:** Does this matter?

**Commented [GG78]:** Attachments may be something other than compositions? EN 13606 has support for binary attachments in the datatypes

**Commented [GG79]:** It strongly appears that 13606 is in a mess with datatypes. I accept some responsibility here, but it's a result of history; the existing draft is based on an ugly rehash of the hl7 datatypes spec that creates more problems that it solves; no one is happy with it. If now appears that CEN 13606 will adopt the ISO datatypes I am working on, but that is not at all clear. I recommended that CfH support the use of openEHR datatypes with 13606, but Dipak tells me this is not possible at the CEN level. So the current status is rather confused, and I think the scores are too high.

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| | • *Links:* It is not clear how links are supported within EN 13606 (rating: 3)<br>• *Identification:* EN 13606 provides support for identifiers, although some further harmonization work is required. (rating: 4)<br>• *NEHTA CII Data Types:* EN 13606 provides support for many of the CII data types requirements (rating: 5)<br>• *NEHTA Identifiers:* EN 13606 provides support for some of the requirements for NEHTA identifiers, but the demographic model has much to be desired (rating: 2)<br>Average Rating: 3.8 |
| Terminology | • *Terminology Data Types:* EN 13606 supports most of the requirements for terminology, although some further harmonization is required (rating: 4)<br>• *Clearly Defined Vocabulary:* Key elements of the vocabulary underlying EN 13606 are in the term lists in Part 3. Terms from various terminologies can be introduced into archetyped items. Better guidance on use of this functionality is needed. No description of how terms from other terminologies can be substituted has been defined. (rating: 3)<br>• *Interface between terminology and data structure:* While EN 13606 can support terminologies, and the "Archetype Knowledge Framework" is intended to provide guidance on terminology usage within data structures, this specification has yet to be developed (rating: 1)<br>• *Support for NEHTA SNOMED CT recommendation:* EN 13606 supports SNOMED CT, but it currently provides very little guidance on how to support SNOMED CT (rating: 3)<br>Average Rating: 2.8 |
| Constraints | • *Constraint Metadata:* EN 13606 will have a constraint language based on the *open*EHR archetypes approach, which can meet the requirements (rating: 5)<br>• *Constraint Language:* EN 13606 will have a constraint language based on the *open*EHR archetypes approach, which can meet the requirements (rating: 5)<br>• *Terminology Bindings:* EN 13606 will have support for terminology bindings based on the *open*EHR archetypes approach, which can meet the requirements. (rating: 5)<br>• *Composability and Reuse:* EN 13606 will have a constraint language based on the *open*EHR archetypes approach, which can meet most of the requirements, however, it is weak in the area of levelling and constraints below the level of entry cannot be reused in other contexts |

**Commented [GG80]:** Again, I don't know what this means. But it's said in all 4 cases, so maybe it should just be dropped

**Commented [GG81]:** Oh? I hadn't noticed that?

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| | (rating: 3)<br>• *Validation Algorithms:* A full and tested algorithm for validation has yet to be published, but should be straight forward (rating: 3)<br>Average Rating: 4.2 |
| Interchange Format | • *Industry Standard Parsers:* There are several proposed interchange formats for of EN 13606 including a generic XML format but none with official endorsement as a standard. Some preliminary work has also been done on a HL7 v3 based format. Archetype issues still need to be considered (rating: 3)<br>• *Simplicity:* There are several possible interchange formats for of EN 13606 including a generic XML format but none with official endorsement as a standard. Some preliminary work has also been done on a HL7 v3 based format. Most formats need some understanding of archetypes to implement (rating: 3)<br>• *Message Size:* There are several proposed interchange formats for of EN 13606 including a generic XML format but none with official endorsement as a standard. Some preliminary work has also been done on a HL7 v3 based format (rating: 3)<br>• *NEHTA Secure Messaging:* There are several proposed interchange formats for of EN 13606 including a generic XML format but none with official endorsement as a standard. Some preliminary work has also been done on a HL7 v3 based format (rating: 3)<br>Average Rating: 3.0 |
| Services | • *Service Oriented Architecture:* Some very preliminary work has been done on services specifications within the CEN community (rating: 3)<br>• *Identification Services:* No work is available on this topic within the EN 13606 community which has an EHRA focus (rating: 1)<br>• *Document Management Services:* Part 5 will define computational viewpoint of services interfaces. There has also been some work done by the IHE and HSSP communities on providing web services for EN 13606 (rating: 3)<br>• *Clinical Process Support Services:* No work is available on this topic (rating: 1)<br>• *NEHTA Secure Messaging:* Part 5 will define computational viewpoint of services interfaces. There has also been some work done by the IHE and HSSP communities on providing web services for EN 13606. IHE and HSSP are not compliant with the Web Service stack recommended by NEHTA (rating: 2)<br>Average Rating: 2.5 |

**Commented [GG82]:** Is this really true? Dipak claimed otherwise a couple of weeks ago (personal conversation)

**Commented [GG83]:** Doesn't get around to addressing the issue. Because the terminology bindings are carried in the instance instead of the archetype (different to openEHR extracts), the message size is going to be greater – possibly even more than CDA. Should be ranked lower

**Commented [GG84]:** Again doesn't get to the point. All are xml based, and would be expected to work with proposed NEHTA infrastructure?

**Commented [GG85]:** Well, there's HISA, which is a services specification, and is hardly preliminary. But in the scope of 13606, there is only a draft (part 5). The draft is fairly high level, which means that it will fit to SOA, but there will be many ways to do that

**Commented [GG86]:** HSSP isn't? Isn't it too early to say this?

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| Security | • *Authentication:* Nothing within EN 13606 prohibits this requirement from being supported (rating : 5)<br>• *Authorisation:* Nothing within EN 13606 prohibits this requirement from being supported (rating : 5)<br>• *Confidentiality:* Nothing within EN 13606 prohibits this requirement from being supported (rating : 5)<br>• *Non-Repudiation:* Nothing within EN 13606 prohibits this requirement from being supported (rating : 5)<br>Average Rating: 5.0 |
| Low Complexity of Implementation | • *Clear Documentation:* Compared to other specifications, the CEN material is less voluminous and easier to assimilate. Although since no one has actually used this material in implementations, it is difficult to know what issues remain within the documents (rating: 3)<br>• *Simple Design Patterns:* Implementation of two level modelling approaches is possible, but non-trivial. (rating: 3)<br>• *Minimal System Impact:* Nothing within the specification indicates an issue with system impact (rating: 4)<br>• *Facilitates Reuse:* The archetyping approach facilitates a high level of reuse (rating: 4)<br>Average Rating: 3.5 |
| Limited Opportunities for Variance | • *Implementation Guides:* At present limited implementation guidance is available within Parts 3 and 4. (rating: 2)<br>• *Conformance Specifications:* No work has been done on providing conformance specifications (rating: 1)<br>• *Limited Use of Text Fields for Sharing Structured Information:* EN 13606 does not encourage this kind of approach (rating: 4)<br>• *Limited Optional Fields and Features:* While large numbers of the fields are optional, they can be constrained using archetypes (rating: 4)<br>• *Limited use of modal design patterns:* The model itself does contain a large number of modal fields at the lower levels, but these can be constrained using archetypes (rating: 4)<br>Average Rating: 3.0 |
| Clear Migration Path | • *Straight Forward Mappings From Existing Specifications:* There is a very weak relationship between earlier versions of the HL7 v2 specifications and the EN 13606 specifications (rating: 2)<br>• *Backwards Compatibility:* More work needs to be done to ensure better backwards compatibility of specifications (rating: 3) |

**Commented [GG87]:** That's up the archetype isn't it?

**Commented [GG88]:** Compared to V3, this comment is less favourable but the score is higher. Huh?

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| | • *Levelled Implementation Approach:* There is no support for a levelled implementation approach within EN 13606 (rating: 1).<br>Average Rating: 2.0 |
| Tool Support for Implementation and Migration | • *Platform Independence:* Nothing within the specification indicates dependence on a specific platform (rating: 4)<br>• *Computer Processable Specifications:* The specifications for EN 13606 are available in UML and the archetypes are available in ADL. ADL as a format is hard to implement because it is not context free. (rating: 3)<br>• *Open Source Libraries:* There are no significant open source initiatives supporting EH 13606 at present; however, some *open*EHR tools are directly adaptable (rating: 2)<br>• *Interface Engine Support:* No interface engines support EN 13606 at present (rating: 1)<br>• *Testing Services:* No testing services are available at present (rating: 1)<br>Average Rating: 2.2 |
| Tool Support for Specification Development | • *Faithfulness to the Framework:* While there has been some work done on archetype editors for supporting *open*EHR, very little work has been done on a EN 13606 specific support features within those archetype editors (rating: 3)<br>• *Specification Editors:* While there has been some work done on archetype editors for supporting *open*EHR, very little work has been done on a EN 13606 specific support features within those archetype editors (rating: 3)<br>• *Specification Libraries:* No work has been done on EN 13606 archetype libraries although much of the work on *open*EHR archetypes would be useable directly or with trivial modification (rating: 2)<br>Average Rating: 2.7 |
| Governance | • *Recognised Body:* The EN 13606 specifications are primarily under the control of European Union members who participate in the CEN processes. The CEN community has made the specifications more internationally applicable by submitting the specifications into ISO. Standards Australia currently has a subcommittee whose work program includes Australia's contribution to EN 13606. At this stage it does not intend to make it a full Australian Standard. Instead, the intention is to make the EN13606 content locally available through a technical report (rating: 4)<br>• *Australian Participation in Processes: :* Australia, while not able to participate as a formal member of CEN ballots, has ample opportunity at both CEN and ISO to give detailed feedback to the committees |

**Commented [GG89]:** Though this hasn't happened yet

**Commented [GG90]:** Funny scoring here. First 2 seem like less favourable comments than the third, but score more highly

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| | responsible for EN 13606 (rating: 3)<br>• *Support for Australian Localisations:* This is presumably handled through the archetypes (rating: 4)<br>• *Consensus and Quality Driven Release Management Processes:* The EN 13606 processes are consensus and quality driven, however there has been little breadth of participation in recent years (rating: 3).<br>• *Creates No International Trade Barriers:* If EN 13606 becomes an ISO specification, then it should not create any issues. (rating: 4)<br>Average Rating: 3.6 |
| Australian Community Support | • *Australian Standards Community Support:* Outside of a small group of standards community members, there is limited detailed knowledge about EN 13606 in the broader standards community. Within the Australian community a significant amount of effort has been expended by some individuals and companies in marketing similar concepts from *open*EHR and generating interest within the Australian e-health community in concepts like record architectures and archetypes. (rating: 3)<br>• *Minimal Dependence on Key Individuals:* There are only a few key individuals who are presently capable of supporting this standard, but this can grow in time. (rating: 2)<br>• *Support by Local Vendors:* While some vendors in Australia have an interest in *open*EHR, very few have an interest in EN 13606 at present (except perhaps to "legitimise" the use of archetypes). (rating: 2).<br>Average Rating: 2.3 |
| International Community Support | • *International Standards Community Support:* There is interest in the UK and Europe, with some countries being prepared to adopt, when approved by CEN (but this will also depend on the directions adopted by current pan-Europe e-health initiatives). There is no support for this standard from the USA. (rating: 3)<br>• *Minimal Dependence on Key Individuals:* The EN 13606 specifications at the moment are looked after by a very small core of individuals. (rating: 2)<br>• *International Vendor Support:* While there is some interest ~~in~~, many vendors simply used the EN 13606 material as input into their requirements for their product, rather than something they are formally compliant with. Within the UK, iSoft and BT are currently experimenting with it, but it is not used in a production capacity (rating: 2)<br>Average Rating: 2.3 |

**Commented [GG91]:** Though note my comments above

**Commented [GG92]:** Though is there any prospect that it would otherwise be taken up outside Europe? The dismissal seems a little bit glib here

### ~~5.4.5~~4.4.5 Strengths and Weaknesses

The advantages of adopting EN 13606 as the preferred approach are:

- Between the EN 13606 reference model and archetypes there is a basis for a relatively complete approach to requirements for Shared EHR. The only addition required would be finalisation of Part 5 exchange models and other activities adding support for services.
- EN 13606 Archetypes can be directly applied to support most of the CII information requirements.
- It has an iconic position that is enabling it to benefit from further *open*EHR developments and from collaborative activity with HL7 (in the areas of archetypes/templates and data types) and with HSSP and IHE in relation to application of services concepts to Shared EHR.

The disadvantages of adopting EN 13606 as the preferred approach are:

- EN 13606 is really only designed to support EHR Extracts, and not to the broader needs of a more general purpose framework for standards and specification development. This means that additional frameworks are likely to be required for information moving in and out of the shared EHR environment (e.g. e-prescriptions);
- The work program on EH 13606 has been delayed on many occasions with most parts still in the pipeline for final endorsement and publication at both CEN and ISO. Until finally approved, its standing as an international standard cannot be guaranteed – particularly given the small contributor base;
- More work is needed on supporting EN 13606 with services – the computational viewpoint in Part 5 is still to be resubmitted as a full draft compatible with HISA specifications;
- Little is known about the ease of implementation of EN 13606. Only indirect experiences from *open*EHR and GEHR implementations can be used to infer anything about the ease of implementation of EN 13606;
- There is presently very little tooling support available for EN 13606, other than tooling which is adaptable from use with *open*EHR;
- The standard has been heavily influenced by the needs of the European Union, although it is also being progressed as an international standard via ISO;
- There is a risky degree of dependence of this standard on a few key individuals; and
- Very few, if any vendors, locally or internationally support EN 13606 as yet.

## ~~5.5~~4.5 *open*EHR Approach

### ~~5.5.1~~4.5.1 Introduction

The *open*EHR Foundation is an international not-for-profit foundation, working towards making the interoperable, life-long electronic health record a reality and improving health care in the information society. The Foundation achieves this by:

- Developing open specifications, open-source software and knowledge resources;
- Engaging in clinical implementation projects;
- Participating in international standards development; and
- Supporting health informatics education

The *open*EHR Foundation works in an open manner, where membership is freely available to anyone who registers on the *open*EHR website. The *open*EHR Foundation works in two broad activity areas: the "technical" (governed by the Architecture Review Board (ARB)) and the "clinical" (governed by the Clinical Review Board (CRB)). The technical area is where engineering work is done, including specifications, implementations, testing and conformance. The clinical area is where healthcare domain professionals and organisations engage with *open*EHR, including on the development and deployment of ontologies, archetypes, templates, guidelines, and clinical education and training.

The *open*EHR model is based heavily on the much older Good European Health Record (GEHR) model. Since then *open*EHR has had a number of innovations added to it, including the archetypes, and has been influenced by and influenced the development of HL7 v3.

*open*EHR formalises the EHR in terms of:

- *Reference model:* This is described as a model for effective structuring of a medico legally sound health record and not the clinical data that is contained within it (this is supported via a second level of specifications – the archetypes)
- *Archetypes and Templates Model:* Archetypes are descriptions of valid Entries, Sections and Compositions. These are expressed in a formal manner which enables them to be shared between systems. A blood pressure archetype represents a description of all the information a clinician might want to report about a blood pressure measurement, and may include some aspects which are mandatory. *open*EHR Templates are logical models of user forms - and are described in terms of choices of archetypes whose data are captured on a particular form.
- *Service Model:* This is the computational viewpoint of the *open*EHR architecture. The service model consists of service definitions for the major services in the EHR computing environment. These are largely derived from existing work in OMG Corbamed, CEN HISA and implementation experience.
- *Terminology and other Ontologies:* Underpinning archetype-enabled health record systems are knowledge resources such as vocabularies, terminologies and ontologies, which define the semantics of terms and concepts referenced in the health record. Archetypes enable multiple terminologies to be used, and in any natural language in which they are available.

The *open*EHR model has been implemented by a small group of vendors within Europe, Australia and the US, and is currently deployed in small scale implementation sites in either an alpha or beta test mode. Probably the most significant of these sites in Europe is a Dutch Health Record product built by Zorg Gemak, which is currently in an alpha test mode. Within the UK, iSoft and BT are currently experimenting with it, but it is not used in a production capacity. Within Australia, *open*EHR has been successfully deployed by two vendors: Ocean Informatics and Extensia Solutions. Queensland Health also is currently trailing an *open*EHR based repository as a core part of it's new service oriented architecture. The current status of usage of *open*EHR within the US is currently unknown.

### ~~5.5.2~~4.5.2 Approach Considered

The approach considered involved the available specifications for *open*EHR 1.0.

### ~~5.5.3~~4.5.3 Lessons Learned from Implementation

The lessons learned in implementation for *open*EHR, stretch back to the original Good European Health Record (GEHR) experiences. The GEHR story is interesting in the sense that for the first time, a group of experts got together to try and bring a number of different concepts from record management, terminologies and data exchange formats together into the one framework. GEHR itself was based on an implementation of the HEALTH.*one* EHR developed by Alain Maskens, a Belgian oncologist. The GEHR model was trialled within a trial site based in inner London, lead by Dr Sam Heard, supporting general practitioners. The implementation hit a number of stumbling blocks with implementation related to the lack of rigorous specification behind the original GEHR model.

After the GEHR project, some of the early participants continued working on it came up with an inspired solution to the unimplementable parts of GEHR, based on using an object oriented reference model and a second level constraint model called "archetypes". This came to be known as the Good Electronic Health Record (GEHR).

To further simplify the implementation issues for vendors, it was proposed that an open source GEHR Kernel written in Eiffel which stored EHR content in an object oriented database (Matisse) and shared information using CORBA, be developed. The theory being that if every vendor replaced the core of their system with the GEHR Kernel, they would then have solved all their interoperability issues. The GPCG funded the exercise, but the GEHR Kernel was never ever completely implemented, not because of issues with the unimplementability of GEHR, but more to do with Eiffel not supporting Microsoft's COM interface properly. The project was eventually salvaged by using another approach based on sharing of health record information using GEHR compliant XML based file format.

At the same time as the GEHR kernel was being developed, the kernel concept was being floated with some of the major vendors as a form of achieving health record interoperability. Unfortunately, the vendors received the idea very coldly because they had little interest in undertaking a major reimplementation of their application based on the GEHR Kernel. This outcome indicating a clear preference amongst vendors to work with file formats and specifications of interfaces, rather than being forced to introduce a foreign software component into the core of their product.

In time, GEHR evolved into a much better branded approach called *open*EHR. Some of the concepts from HL7 v3 and CDA where included with the original concepts from GEHR and a newer *open*EHR reference model emerged. In addition to this, the concepts behind archetypes evolved to the next level of maturity and it became much clearer about what the nature of archetypes exactly was. The *open*EHR archetype is a method of specifying constraints on how a reference model should be used in a given context. When information is shared using the *open*EHR approach, all content is exchanged in a common generic model and higher order tools are required to enforce that the archetypes are properly used in that context. Content in *open*EHR cannot be safely interpreted without referring to the archetype, as the archetype provides the definitions of the content and bindings to terminologies.

The benefit of the archetype approach is you can develop a single piece of software that can handle a large variety of contexts. The benefit of the cloning approach is you can give a set of well defined messages to a vendor to implement.

**Commented [GG93]:** This paragraph probably needs an extra sentence explaining why this is relevant. Or that may belong a couple of paragraphs down – but few readers will pick up on the implications of what is being discussed here

In environments where archetypes have been trialled, such as the Brisbane Southside Health*Connect* Trial, many of the participants and consultants involved, just didn't get the concept of archetypes and simply asked for the XML-Schema for a specific event summary. When it was explained that it wasn't that simple, that they needed to implement a two level model, it proved to be a difficult proposition to explain and they preferred to work from

some pre-filled in example XML instances that they could copy and paste from and be provided with a test suite to test their system against.

It turns out that in retrospect, after talking to staff from the NHS who have been experimenting with similar ideas to archetypes with HL7 templates, that some vendors prefer to work with a more generic format and a constraint framework and others prefer to work with a simpler file format, examples XML instances and test tools. It depends on the nature of the implementer and the capabilities of their programmers and the system they implement.

One of the chief success stories within *open*EHR has been the archetype editor. The provision of a simple tool that lets users construct their own archetypes and be less dependent on a few experts in the standards community has led the way for helping sell the *open*EHR concept. Recent workshops within the NHS have shown that is relatively straight forward to convert requirements into archetypes. The process is somewhat simpler than the existing process for preparing HL7 v3 templates. However, some of the learnings from that exercises was that there is still a high degree of skill required to design sound archetypes which are both clinically sound and safely reusable in a number of different contexts. This example invites the importance of separating archetypes into those which represent core reference concepts like diagnosis or medication which need to be designed by an expert, from *open*EHR templates (different from HL7 templates), which show how different archetypes can be bound together for different contexts and can be designed by a more naive user.

### ~~5.5.4~~4.5.4 Fit To Requirements

| Requirement | Support |
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| Specification Development Framework | • *Explicit Specification Development Framework:* There is no separate specification of a framework for *open*EHR which defines the process for how requirements are translated into a variety of different specifications. However, it would be possible to generalize some of the elements within *open*EHR to produce such a framework (rating: 3)<br>• *Generality: open*EHR is primarily designed to support a record architecture for an EHR. It was never designed to support discharge summaries, referrals or prescriptions/dispensing between non-EHR applications. However, nothing within the *open*EHR approach prohibits it from being adapted to be broader. (rating: 3)<br>• *Consistent approach to structure and semantics:* The *open*EHR approach does promote a consistent approach to structure and semantics. However, more guidance on the design of archetypes would be required to ensure further consistency in the design of archetypes. In particular more emphasis needs to be placed on ensuring that archetypes are appropriately levelled, consistent, non-overlapping and intelligently interlinked (rating: 2)<br>• *Promotes Sound Clinical Design:* While the *open*EHR reference model partially promotes this, there is still quite an art form involved in good archetype design. The *open*EHR material |

**Commented [GG94]:** Worth mentioning that It would be nice to clarify the relationship between the proposed CEN archetype standards and openEHR?

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| | provides very little guidance on what constitutes good clinical design. Presumably this will be addressed in time. At present there is no consistent way of referencing clinical evidence at levels lower than the entry level archetype (rating: 3)<br>• *Separation of Responsibilities: open*EHR does separate the responsibilities relatively clearly (rating: 4)<br>• *Balances Trade Offs:* The discussion of how trade offs and design decisions are balanced is not formally documented and is only available by searching through the discussion boards (rating: 2).<br>• *Pluggable Implementation Approach:* Some discussion on pluggable implementation approaches has been provided, but the specifications still need more maturity (rating: 3)<br>• *Extensibility: open*EHR supports extensibility and reuse via archetypes (rating: 5)<br>• *Localisation: open*EHR does not provide any guidance on localisation. Presumably this is handled through the archetypes. However, insufficient work has been done on archetype governance to help minimize fractious sets of archetypes evolving that may hamper interoperability and make it difficult to deploy products in an international context (rating: 2)<br>• *Formalisation:* The archetype approach strongly formalises how the approach works. (rating: 4)<br>Average Rating: 3.1 |
| Structured Documents | • *Document Oriented Approach:* All requirements are supported (rating: 5)<br>• *Versioning: open*EHR provides a well defined versioning model. (rating: 5)<br>• *Document Body:* Many of the requirements are supported. However, in *open*EHR a composition does not contain details like name, date of birth, gender, etc and a compositions in *open*EHR cannot be safely passed around without wrapping them in an EHR Extract, as the EHR extract provides the demographic details of the individual involved. (rating: 4)<br>• *Sections:* All requirements are supported (rating: 5)<br>• *Data Groups:* All requirements are supported. However, it should be noted that the ontological separation is not as good as it could be as it is not entirely clear when the observation, evaluation and instruction classes should be applied (rating: 4)<br>• *Attachments:* Compositions cannot directly be attached within other compositions. However, |

**Commented [GG95]:** Same comments as for 13606

**Commented [GG96]:** Again, like with 13606 – is this a problem?

**Commented [GG97]:** Same comment as for 13606

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| | links within an EHR Extract can be used (rating: 4).<br>• *NEHTA CII Event Summaries:* Archetypes can be used to support most if not all CII requirements (rating: 5)<br>• *NEHTA CII Data Groups:* Archetypes can be used to support most if not all CII requirements (rating: 5)<br>Average Rating: 4.6 |
| Data Types | • *Text: open*EHR provides support for textual data. (rating: 5)<br>• *Quantities: open*EHR provides support for quantities. (rating: 5)<br>• *Dates and times: open*EHR provides support for date time values and time series. (rating: 5)<br>• *Encapsulated Content: open*EHR provides support for embedded content. (rating: 5)<br>• *Links:* The *open*EHR model does support links, but not as a data type (rating: 4)<br>• *Identification: open*EHR provides support for identifiers. (rating: 5)<br>• *NEHTA CII Data Types: open*EHR provides support for many of the CII data types requirements (rating: 5)<br>• *NEHTA Identifiers: open*EHR provides support for some of the requirements for NEHTA identifiers, but the demographic model requires more work to become consistent (rating: 3)<br>Average Rating: 4.6 |
| Terminology | • *Terminology Data Types: open*EHR supports the data type requirements for terminology (rating: 5)<br>• *Clearly Defined Vocabulary:* The vocabulary underlying *open*EHR has been defined, but no description of how terms from other terminologies, such as SNOMED CT, can be substituted has been defined. (rating: 4)<br>• *Interface between terminology and data structure:* While *open*EHR can support terminologies limited guidance on terminology usage within data structures and their interplay has been provided. This specification has yet to be developed (rating: 3)<br>• *Support for NEHTA SNOMED CT recommendation:* *open*EHR is capable of supporting SNOMED CT, but it provides little guidance in the form of an implementation guide on how to support SNOMED CT (rating: 4)<br>Average Rating: 4.0 |
| Constraints | • *Constraint Metadata: open*EHR provides a relatively rich constraint language that supports all the metadata requirements |

**Commented [GG98]:** I can think of several ways, including in the datatypes – though maybe it's a little ambiguous what "link" means

**Commented [GG99]:** Since it's archetyped, not sure what this comment means?

**Commented [GG100]:** Everything else got a 3 for this. I don't know why openEHR scores more highly than the others.

**Commented [GG101]:** Why does this score more highly than 13606? I don't think they are different in this regard.

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| | (rating: 5)<br>• *Structural Constraints: open*EHR provides a relatively rich constraint language (rating: 5)<br>• *Terminology Bindings: open*EHR archetypes will have support for terminology bindings (rating: 5)<br>• *Composability and Reuse:* The *open*EHR approach does support some degree of composability and re-use of archetypes, but it does not descend below the entry level. There is no guidance on how archetypes can be levelled to promote more effective re-use and consistency between archetypes (rating: 3)<br>• *Validation Algorithms:* A partial algorithm for validation has been published, but hasn't been fully tested for all the features supported by ADL (rating: 3)<br>Average Rating: 4.2 |
| Interchange Format | • *Industry Standard Parsers: open*EHR provides an interchange format based on XML, however, to implement parsing correctly the implementer still needs to consider issues around archetypes (rating: 3)<br>• *Simplicity:* The format is not self standing and requires a strong understanding of archetypes to implement (rating: 3)<br>• *Message Size: open*EHR messages in XML can be quite verbose (rating: 2)<br>• *NEHTA Secure Messaging: open*EHR provides an interchange format based on XML (rating: 5)<br>Average Rating: 3.3 |
| Services | • *Service Oriented Architecture:* Much of the thinking within the *open*EHR community is service oriented and supports many of the properties required. However, some of the thinking is somewhat behind where other standards bodies are at in this area (rating: 3)<br>• *Identification Services:* Some limited work has been done on identification services, but it needs further work (rating: 2)<br>• *Document Management Services:* There has been a reasonable amount of work on document management services within the *open*EHR community, but the specifications are still forthcoming (rating: 3)<br>• *Clinical Process Support Services:* No description of how these services are supported has been provided (rating: 1)<br>• *NEHTA Secure Messaging:* No work has been done on developing services based on the Web Service stack recommended by NEHTA (rating: 2) |

**Commented [GG102]:** So this isn't about slots? What is it about?

**Commented [GG103]:** It can't be many features that aren't supported – surely 3 is a bit of a harsh rating here?

**Commented [GG104]:** Given the discussion above, 3 seems like a funny score here – it's not simple, and that's not going to change

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| | Average Rating: 2.2 |
| Security | • *Authentication:* Nothing within EN 13606 prohibits this requirement from being supported (rating : 5)<br>• *Authorisation:* Nothing within EN 13606 prohibits this requirement from being supported (rating : 5)<br>• *Confidentiality:* Nothing within EN 13606 prohibits this requirement from being supported (rating : 5)<br>• *Non-Repudiation:* Nothing within EN 13606 prohibits this requirement from being supported (rating : 5)<br>Average Rating: 5 |
| Low Complexity of Implementation | • *Clear Documentation:* The *open*EHR material is voluminous and can be difficult to assimilate. Some key parts of the documents have been used in implementations and the documentation is starting to improve. Many clinicians working with the documentation for archetypes find it relatively straight forward to follow (rating: 3)<br>• *Simple Design Patterns:* Implementation of two level modelling approaches is possible, but non-trivial. (rating: 2)<br>• *Minimal System Impact:* The record architecture approach, if taken seriously, can have a profound impact on the internals of systems. However, it is still possible to wrap a system and provide *open*EHR style interfaces (rating: 3)<br>• *Facilitates Reuse:* The archetype approach facilitates a high level of reuse (rating: 4)<br>Average Rating: 3.0 |
| Limited Opportunities for Variance | • *Implementation Guides:* At present no separate implementation guides are available for using *open*EHR purely for e-health information interchange. Much of the implementation guidance is buried within specifications or forum discussions (rating: 3)<br>• *Conformance Specifications:* No work has been done on providing conformance specifications (rating: 1)<br>• *Limited Use of Text Fields for Sharing Structured Information:* *open*EHR does not encourage this kind of approach (rating: 4)<br>• *Limited Optional Fields and Features:* While large numbers of the fields are optional, they can be constrained using archetypes (rating: 4)<br>• *Limited use of modal design patterns:* The model itself does contain a large number of modal fields at the lower levels, but these can be constrained using archetypes (rating: 4) |

**Commented [GG105]:** Same comment as for 13606

**Commented [GG106]:** Compared to HL7 v3, this comment is less favourable but the score is higher. Huh?

| | |
|---|---|
| | Average Rating: 3.2 |
| Clear Migration Path | • *Straight Forward Mappings From Existing Specifications:* There is a very weak relationship between earlier versions of the HL7 v2 specifications and the *open*EHR specifications (rating: 2)<br>• *Backwards Compatibility:* More work needs to be done to ensure better backwards compatibility of specifications (rating: 3)<br>• *Levelled Implementation Approach:* There is no support for a levelled implementation approach within *open*EHR. (rating: 2).<br>Average Rating: 2.3 |
| Tool Support for Implementation and Migration | • *Platform Independence:* The documentation has a clear preference for Eiffel as an implementation language and for defining the semantics. However, this does not limit the implementer to using other languages (rating: 3)<br>• *Computer Processable Specifications:* The specifications for *open*EHR are available in UML and XMI and the archetypes are available in ADL. ADL as a format can be hard to implement because it is not context free. (rating: 4)<br>• *Open Source Libraries:* There are a number of different open source tools available for *open*EHR, with varying degrees of quality and active community support (rating: 3)<br>• *Interface Engine Support:* Some work has been done on adding interface engines support for *open*EHR within a project within Queensland Health (rating: 2)<br>• *Testing Services:* No testing services are available at present (rating: 1)<br>Average Rating: 2.6 |
| Tool Support for Specification Development | • *Faithfulness to the Framework:* While there has been some work done on archetype editors for supporting *open*EHR, more work has to be done to ensure the editors are faithful to the *open*EHR specifications (rating: 3)<br>• *Specification Editors:* A reasonable amount of work has been some work done on archetype editors for supporting *open*EHR. However, the tools still need more work on being made more mature (rating: 4)<br>• *Specification Libraries:* Some work has been done on archetype libraries (rating: 3)<br>Average Rating: 3.3 |
| Governance | • *Recognised Body:* The *open*EHR specifications are primarily under the control of the *open*EHR Foundation, which is not recognised as an accredited standards development organisation. Work would need to be done on |

| | |
|---|---|
| | bringing it into a form that works for the Australian Government, such as within Standards Australia (rating: 2)<br>• *Australian Participation in Processes:* Australia can submit changes into the *open*EHR processes. However, the processes themselves are still entirely controlled by one or two individuals (rating: 3)<br>• *Support for Australian Localisations:* This is presumably handled through the archetypes (rating: 4)<br>• *Consensus and Quality Driven Release Management Processes:* The *open*EHR processes are quality driven, however the role of consensus in these processes is somewhat unclear (rating: 2).<br>• *Creates No International Trade Barriers:* *open*EHR as it is currently defined may create potential trade barriers (rating: 2)<br>Average Rating: 3.0 |
| Local Community Support | • *Australian Standards Community Support:* Outside of a small group of ~~standards community~~foundation members, there is limited detailed knowledge about *open*EHR in the broader standards community. Within the Australian community a significant amount of effort has been expended by some individuals and companies in marketing *open*EHR and generating interest within the Australian e-health community in concepts like record architectures and archetypes. (rating: 3)<br>• *Minimal Dependence on Key Individuals:* There are only a few key individuals who are presently capable of supporting this standard, but this can grow in time. (rating: 2)<br>• *Support by Local Vendors:* A few small vendors in Australia have an interest in *open*EHR. None of the large vendors have an interest (rating: 2).<br>Average Rating: 2.3 |
| International Community Support | • *International Standards Community Support:* While there are some research prototypes of *open*EHR being built on an international basis, there is no formal government or standards support for it in any country. (rating: 1)<br>• *Minimal Dependence on Key Individuals:* The *open*EHR specifications at the moment are looked after by a very small core of individuals. (rating: 2)<br>• *International Vendor Support:* While there is some interest in *open*EHR, no major international vendors implement it in a production capacity. Within the UK, iSoft and BT are currently experimenting with it, but it is not used in a production capacity. Similarly it is being experimented within in Holland (rating: |

**Commented [GG107]:** It's not clear whether this would lead to any different outcome than the 13606 experience – a snapshot is frozen and hacked to get through the standards process

| | |
|---|---|
| | 3)<br>Average Rating: 2.0 |

### ~~5.5.5~~4.5.5 Strengths and Weaknesses

The main advantages of an *open*EHR approach are that:

- *open*EHR offers a technically rich approach which has reasonably strong support for structured documents, data types, terminology and constraints.
- The *open*EHR approach to archetypes facilitates a stronger approach to semantic interoperability
- The *open*EHR community actively promotes an open source approach, which, in the longer term, subject to the availability of high quality open source libraries, may make it easier for implementers.

The key weaknesses of the *open*EHR approach are:

- Compared to other approaches, its international vendor community support is weaker and it is not supported by an accredited standards development organisation

**Commented [GG108]:** Some of the other key weaknesses of the 13606 solution are also weaknesses of openEHR too

# ~~6~~5 Ratings Results

## ~~6.1~~5.1 Introduction

This section presents the results of the rating process. It starts by describing how the different elements were weighted, describes the aggregate ratings and then analysis the results.

## ~~6.2~~5.2 Weightings

In computing the aggregate rating, a weighting has been applied to each of the requirements. The higher the weighting, the more important the overall requirement is. The weightings are based on the following breakdown:

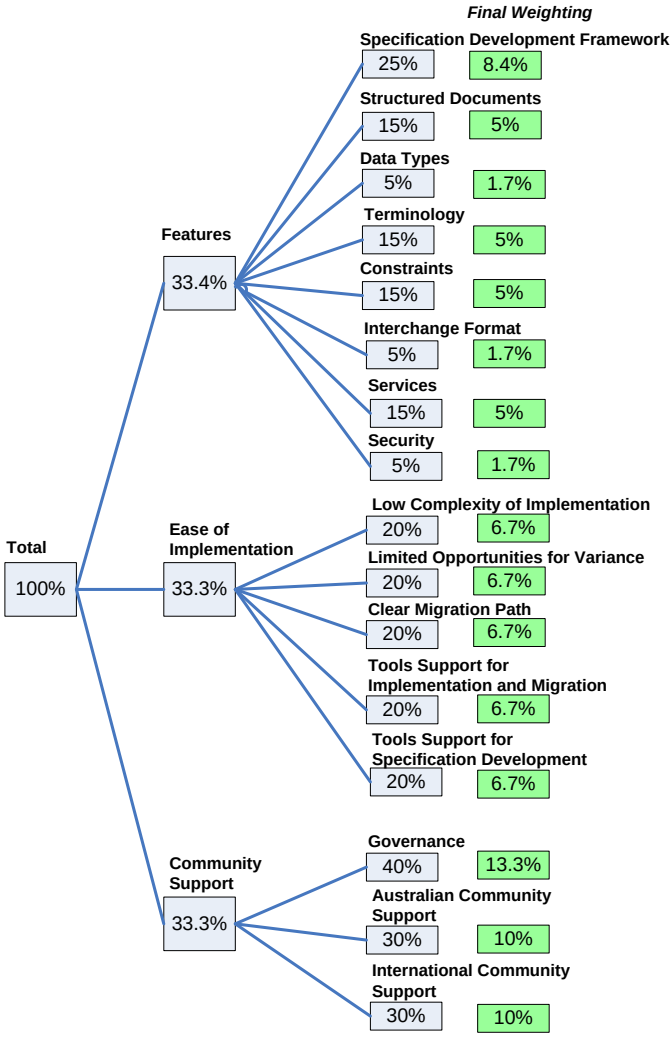


Figure 1: Weightings

## ~~6.3~~5.3 Results

Based on the rating system, the following results are obtained:

| | Weighting | HL7 v2 | Weighted Rating | Document/ Service Centric HL7 v3 Approach | Weighted Rating | EN 13606 | Weighted Rating | openEHR | Weighted Rating |
|---|---|---|---|---|---|---|---|---|---|
| **Features** | | | | | | | | | |
| *Framework* | 8.4% | 1.7 | 0.14 | 3.3 | 0.28 | 2.8 | 0.23 | 3.1 | 0.26 |
| *Structured Documents* | 5.0% | 2.1 | 0.11 | 3.9 | 0.20 | 4.3 | 0.22 | 4.6 | 0.23 |
| *Data Types* | 1.7% | 2.5 | 0.04 | 3.9 | 0.07 | 3.8 | 0.06 | 4.6 | 0.08 |
| *Terminology* | 5.0% | 2.5 | 0.13 | 3.3 | 0.17 | 2.8 | 0.14 | 4.0 | 0.20 |
| *Constraints* | 5.0% | 2.0 | 0.10 | 2.4 | 0.12 | 4.2 | 0.21 | 4.2 | 0.21 |
| *Interchange Format* | 1.7% | 3.3 | 0.06 | 3.8 | 0.06 | 3.0 | 0.05 | 3.3 | 0.06 |
| *Services* | 5.0% | 2.4 | 0.12 | 3.5 | 0.18 | 2.5 | 0.13 | 2.2 | 0.11 |
| *Security* | 1.7% | 4.3 | 0.07 | 5.0 | 0.08 | 5.0 | 0.08 | 5.0 | 0.08 |
| **Ease of Implementation** | | | | | | | | | |
| *Low Complexity of Implementation* | 6.7% | 3.0 | 0.20 | 2.8 | 0.19 | 3.5 | 0.23 | 3.0 | 0.20 |
| *Limited Opportunities for Variance* | 6.7% | 2.8 | 0.19 | 3.0 | 0.20 | 3.0 | 0.20 | 3.2 | 0.21 |
| *Clear Migration Path* | 6.7% | 2.7 | 0.18 | 3.3 | 0.22 | 2.0 | 0.13 | 2.3 | 0.15 |
| *Tool Support for Implementation and Migration* | 6.7% | 3.0 | 0.20 | 3.6 | 0.24 | 2.7 | 0.18 | 2.6 | 0.17 |
| *Tool Support for Specification Development* | 6.7% | 1.0 | 0.07 | 2.3 | 0.15 | 2.3 | 0.15 | 3.3 | 0.22 |
| **Community Support** | | | | | | | | | |
| *Governance* | 13.3% | 4.4 | 0.59 | 3.8 | 0.51 | 3.6 | 0.48 | 3.0 | 0.40 |
| *Australian Community Support* | 10.0% | 4.0 | 0.40 | 2.3 | 0.23 | 2.3 | 0.23 | 2.3 | 0.23 |
| *International Community Support* | 10.0% | 4.0 | 0.40 | 3.7 | 0.37 | 2.3 | 0.23 | 2.0 | 0.20 |
| **Un-weighted Average Rating** | | **2.9** | | **3.4** | | **3.1** | | **3.3** | |
| **Weighted Average Rating** | | | **3.0** | | **3.2** | | **3.0** | | **3.0** |

## ~~6.4~~5.4 Analysis

### ~~6.4.1~~5.4.1 Approach to Analysis

The analytical approach in this section is to undertake a sensitivity analysis based on a number of different scenarios which re-weighted certain aspects of the requirements, and then selecting the standard that consistently remained the preferred approach. Therefore, the result is a result, which independently of weighting, is capable of being the best candidate for supporting the requirements.

### ~~6.4.2~~5.4.2 Analysis from a Weighted Average Perspective

Based on the rating system, the order from best fit to worst fit is:

| **Weighted Average Rating** | |
|---|---|
| Document/Service Centric HL7 v3 | 3.2 |
| HL7 v2 and<br>EN 13606<br>*open*EHR | 3.0 |

### ~~6.4.3~~5.4.3 Strength in Requirement Group

When analysing the strongest and weakest candidates in each area, it can be seen that each of the standards have different strengths and weaknesses. This reflects again why they decision is not easy to make.

| **Requirement** | **Strongest** | **Weakest** |
|---|---|---|
| Framework | Document/Service Centric HL7 v3 | HL7 v2 |
| Structured Documents | *open*EHR | HL7 v2 |
| Data Types | *open*EHR | HL7 v2 |
| Terminology | Document/Service Centric HL7 v3 | HL7 v2 |
| Constraints | EN 13606 and<br>*open*EHR | HL7 v2 |
| Interchange Format | Document/Service Centric HL7 v3 | EN 13606 |
| Services | Document/Service Centric HL7 v3 | *open*EHR |
| Security | Document/Service Centric HL7 v3<br>EN 13606 and<br>*open*EHR | HL7 v2 |
| Low Complexity of Implementation | EN 13606 | Document/Service Centric HL7 v3 |
| Limited Opportunities for Variance | *open*EHR | HL7 v2 |

| | | |
|---|---|---|
| Clear Migration Path | Document/Service Centric HL7 v3 | EN 13606 |
| Tool Support for Implementation and Migration | Document/Service Centric HL7 v3 | EN 13606 |
| Tool Support for Specification Development | *open*EHR | HL7 v2 |
| Governance | HL7 v2 | *open*EHR |
| Australian Community Support | HL7 v2 | Document/Service Centric HL7 v3<br>EN 13606 and<br>*open*EHR |
| International Community Support | HL7 v2 | EN 13606 |

## ~~6.4.4~~5.4.4 Sensitivity Analysis

### ~~6.4.4.1~~5.4.4.1 Unweighted Average Rating

If the bias provided by the weightings is excluded, and consider the un-weighted average rating, the standards remain in the same order:

| **Un-Weighted Average Rating** | |
|---|---|
| Document/Service Centric HL7 v3 | 3.4 |
| *open*EHR | 3.3 |
| EN 13606 | 3.1 |
| HL7 v2 | 2.9 |

It should be noted that this specific method of analysis does is not likely to yield a different result from the features bias as the number of feature related groups of requirements outweigh the other groups of requirements.

### ~~6.4.4.2~~5.4.4.2 Features Bias

If the ratings model deliberately biases features (i.e. weight = 50%), and the community support and ease of implementation factors are made a lower priority (i.e. weight = 25% each), the ordering stays the same as the original rating model:

| **Features Bias** | |
|---|---|
| Document/Service Centric HL7 v3 | 3.3 |
| *open*EHR | 3.2 |
| EN 13606 | 3.1 |
| HL7 v2 | 2.8 |

#### ~~6.4.4.3~~5.4.4.3 Ease of Implementation Bias

If the model is biased towards ease of implementation (i.e. weight = 50%) and all other factors are made a lower priority (i.e. weight = 25% each), a similar ordering is retained:

| **Ease of Implementation Bias** | |
|---|---|
| Document/Service Centric HL7 v3 | 3.2 |
| *open*EHR | 3.0 |
| HL7 v2 and<br>EN 13606 | 2.9 |

#### ~~6.4.4.4~~5.4.4.4 Community Bias

If the model is biased towards community support (i.e. weight = 50%) and the other factors are made a lower priority (i.e. weight = 25% each), HL7 v3 still remains the main candidate:

| **Community Bias** | |
|---|---|
| HL7 v2<br>Document/Service Centric HL7 v3 | 3.3 |
| EN 13606 and<br>*open*EHR | 2.9 |

## ~~6.5~~5.5 Results

After undertaking a sensitivity analysis, a service- and document-centric approach to HL7 v3 consistently remains the stronger candidate in all scenarios, including the overall case, features bias case, ease of implementation bias case and a community support bias case.

| | **Overall** | **Features Bias** | **Ease of Implementation Bias** | **Community Support Bias** |
|---|---|---|---|---|
| HL7 v2 approach | 3.0 | 2.8 | 2.9 | 3.3 |
| Document- and Service- centric HL7 v3 approach | 3.2 | 3.3 | 3.2 | 3.3 |
| EN 13606 approach | 3.0 | 3.1 | 2.9 | 2.9 |
| *open*EHR approach | 3.0 | 3.2 | 3.0 | 2.9 |

When considering the differences in ratings, clearly there is no "perfect" solution which meets all requirements. If there was, it would have had a considerably higher overall rating. The low differences in ratings, indicates that at this point in time there is little to be gained by moving from the current HL7 v2 standards to a new standard in the short term. However, the closeness of ratings also indicates that despite the strength of 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. In the longer term a document- and service-centric HL7 v3 approach is likely to be the front runner, for the following reasons:

- *Features:* HL7 v3 is currently the only framework that can support the development of a multitude of different kinds of specifications, including specifications for prescribing, referrals, discharge summaries, and other artefacts required for interoperability in e-health. Furthermore, HL7 v3 has growing support for a service-based approach and SNOMED CT;
- *Community Support:* The HL7 community has the largest participant base internationally, which will further assist with the longer term adoption and sustainability of the standard. Furthermore, the heavy investment of the UK NHS in HL7 v3 has demonstrated that it can be made to work on a national scale and has led large international vendors to start building support for v3. HL7 v3's strengths will continue to be enhanced as other countries, for example as Canada's Infoway Program and the US invest more heavily in HL7 v3.

Before a document- and service- centric HL7 v3 approach can emerge as the dominant method, technical barriers need to be addressed around improving the support for templates and terminologies and providing better tools for aiding specification development and simplifying the complexity of implementation.

In the longer term, the other approaches are likely to have challenges keeping pace with a document- and service- centric HL7 v3 method for the following reasons:

- The HL7 v2 approach requires reworking of its underlying model to provide a more unified framework that supports contemporary development practices;
- EN 13606 needs to become more inclusive of sharing information beyond just EHR content. The availability of tooling need to improve significantly, the standards community around it needs to increase in size to become more self sustaining and it currently lacks a contestable market of major suppliers; and
- The *open*EHR approach, while having technical advantages in a number of different areas at the moment, needs to become more inclusive of sharing information beyond just EHR content, currently lacks a contestable market of major suppliers and currently is not supported by an accredited standards setting organisation.

# ~~7~~6 Recommendations

## ~~7.1~~6.1 Strategic Direction

Based on the evaluation of the alternatives, it is clear that HL7 v2 should continue to be supported in the short to medium term. In the longer term, it is likely that a service-and document-centric HL7 v3 approach, subject to additional work being undertaken at an international level, will become a stronger alternative than the current approach.

Therefore, it is recommended that NEHTA that adoption proceed in the following stages:

- *Current:* Existing standards, including HL7 v2.3.1 and HL7 v2.4 should continue to be supported;
- *Short-Term Direction:* In the next 9-12 months a set of HL7 v2.x messaging standards should be developed which have been enhanced to be more compliant with NEHTA's recommendations for clinical information data groups, SNOMED CT, unique health identifiers, and a transport layer specification based on web services. This activity will take HL7 v2 forward within the limits of what is technically feasible within HL7 v2; and
- *Longer-Term Direction:* An initial program of work to assess in detail some of the technical and strategic issues associated with adopting a services- and document-centric approach to HL7 v3. If the barriers to adoption can be addressed, a program of work should be put into place to fast-track the establishment of the initial set of standards, tools and skills needed to implement the recommended approach (subject to the barriers to adoption described above being addressed). The suite of standards is expected to include services based on HSSP and CDA R2 templates for areas such as prescribing, dispensing, pathology, radiology, referral, discharge and shared health profile.

Australian adoption of the European EN13606 standard on EHR Communication to represent clinical information for Shared EHR, at this stage, is no longer recommended. This decision aligns with Standards Australia's recent recommendation to not provide a full standard for EN 13606 and to support it as a technical report instead.

**Commented [GG109]:** What does it mean to support them? Does this mean that actual NEHTA services will have to support v2? If it doesn't mean this, is it worth saying anything? If it does mean this, doesn't this remove a big plank of the v3/document thing: since we'd have to figure out how to make v2 work, which is part of the reason not to support v2

**Commented [GG110]:** Really continuing the last comment – is this a good idea? What will it achieve? If it allows applications to get "NEHTA-ready" in advance, I guess there's some point, though things would have to be backwards compatible (?). if it means that NEHTA has to support v2, then, same as above

## ~~7.2~~6.2 Benefits

The key benefits of the recommendations are:

- the proposed short term direction will:
  - provide a straight forward migration path for owners of existing systems; and
  - leverage the existing support for HL7 within the Australian and International community~~;~~.
- the proposed longer term direction will allow:
  - a new suite of standards to be developed in a more unified and coherent fashion with support for richer features, such as better support for services, terminology, templating, structured documents, etc, than are presently supported within current standards; and
  - Australia to leverage the implementation experience and standards arising from major national integration programs in the UK NHS's Connecting for Health and Canada's Infoway programs.

## ~~7.3~~6.3 Risks

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 now. These issues are complex and 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. Therefore it is essential that such risks be mitigated through:

- Undertaking an exploratory project to examine in detail the technical issues prior to further standards development;
- Fostering ongoing harmonisation of HL7 v3, EN 13606 and *open*EHR; and
- Collaboration with other implementing nations such as the UK and Canada.

Finally, if the recommended long term direction proves to be too difficult to standardise, other strategies can be explored such as making further enhancements to HL7 v2 or using *open*EHR.

## ~~7.4~~6.4 Consultation

Information within this report was prepared on following consultation with a number of parties:

- All material was circulated within NEHTA for comment
- The material was reviewed by DH4, who undertook the original review
- Substantive feedback from the Jurisdictions and Standards Australia received from the previous review report was incorporated into the review

Finally, if the recommended long term direction proves to be too difficult to standardise, other strategies can be explored based on the other standards considered in this document.

## ~~7.5~~6.5 Standards Development

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

### ~~7.5.1~~6.5.1 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.

### ~~7.5.2~~6.5.2 Long Term Direction

In terms of supporting the longer-term direction, NEHTA will fund an exploratory study, which 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 should 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 need to explore which specific ~~elements~~ features of ~~HL7 v3~~ CDA should be supported. As Australia is a late entrant to the ~~HL7 v3~~ CDA

field, it would be ~~un~~wise to ~~try and take policy decisions on HL7 v3 that put Australia ahead of, or out of step with, the likely changes underway internationally~~act consistently with other implementing jurisdictions. Australia needs to obtain maximum leverage from the work of others to avoid re-working technical policies, tooling, documentation, application interfaces and other aspects needed for implementation. Therefore, Australia should closely follow HL7 v3 implementation conventions adopted within the largest markets for international vendors, namely within the UK and the US.

**Commented [GG111]:** This wording is not quite appropriate for CDA/Services rather than HL7 V3 messaging.

## ~~7.6~~6.6 Governance

### ~~7.6.1~~6.6.1 Governance within the Australian Community

Within Australia, Standards Australia should remain as the peak body responsible for e-health standards development. In the short-term, NEHTA will, as part of its transition role, release appropriate specifications into Standards Australia processes for review and, where appropriate, publication as Australian Standards. More details about this proposed relationship will be defined in a document titled "NEHTA and Standards Australia: Working Together". The agreement is currently being negotiated with Standards Australia, and once completed will be made available on the NEHTA website.

In the longer-term, business cases, including the national approach to Shared EHR, may result in a change of governance arrangements for e-health in general; however, Standards Australia is expected to continue having a significant role as the peak standards development organisation for Australia.

### ~~7.6.2~~6.6.2 Governance Internationally

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 need to understand how it can collaborate with Standards Australia on addressing issues that will arise as a result of the adopting the standards approach recommended in this document.

## ~~7.7~~6.7 Adoption

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

Once standards become available to support the short term direction, owners of systems or organisations planning to procure a system can, at their discretion, 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 learned 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.

## ~~7.8~~6.8 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. Therefore it will be essential to consider the following:

- NEHTA should develop 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;
- NEHTA, in conjunction with Standards Australia, should engage with organisations, such as HL7 Australia, to start educating the Australian community on both the short-term and long-term directions; and
- NEHTA, in conjunction with Standards Australia, should work with organisations such as HL7 Australia to develop demonstrations of the recommended standards.

## ~~7.9~~6.9 Tools

In terms of tooling, NEHTA should:

- Obtain access to existing tools from the NHS to help facilitate the development of HL7 specifications within Australia; and
- Participate with the HL7 tooling collaborative; and
- Look at how it can effectively engage with potential vendors of relevant software tools to support specification development within Australia

**Commented [GG112]:** See note in executive summary on this subject

**Commented [GG113]:** Maybe this should be a little less specific – "join in the collaboration between NHS, Eclipse and others"

## ~~7.10~~6.10 Next Steps

On the basis of the recommendation, the next steps after this report should be to:

- Consult on this document with stakeholders;
- Work with Standards Australia on incorporating the short-term and long-term directions into the standards development plan;
- Procure services to help fast track the development of standards to support the short-term direction;
- Procure services to help explore in detail the technical and strategic issues involved in adopting the longer-term direction;
- Commence working with implementers and procurers to encourage adoption of the recommended standards;
- Build capacity within the Australian community for the short and long term direction; and
- Establish a better understanding of requirements for tooling to support the recommended approach.
- Build capacity within the Australian community for the short and long term direction; and
- Start establishing a better understanding of requirements for tooling.

# Appendix A: Requirements

## A.1 Features

### A.1.1 Specification Development Framework

| | |
|---|---|
| **Area** | Specification Development Framework |
| **Description** | The standards approach requires a framework which can be used for translating requirements into standards and specifications. The framework also simplifies the task of creating specifications by allowing the author to create new specifications from existing components within other specifications. The specification development framework needs to promote sound design from a clinical perspective, separation of responsibilities, allow for different implementation approaches, support extensibility, reuse and localisation.<br><br>Of all the elements of the specification development framework, the localisation element is possibly the most important element of the framework for Australia's needs, as it allows Australia to take standards that have been implemented successfully overseas and localise them for the Australian context. |
| **General Requirements** | • *Explicit Framework:* The approach must provide an explicit specification development framework for translating requirements into specifications.<br>• *Generality:* The same specification development framework should be equally applicable to developing a range of specifications for sharing clinical content in different but related contexts . For example, it could be used for equally defining specifications for sharing EHR, referrals, discharge summaries and prescriptions/dispensing.<br><br>It is desirable that the same specification development framework can be applied in some areas related to patient administration, such as requesting a individual's identifier and demographic information.<br><br>Support for areas such as claiming and supply chain, would be desirable but non-essential.<br>• *Consistent approach to structure and semantics:* The specification development framework should ensure that a homogenous approach to the structure and semantics of clinical content is supported. This is essential because:<br>– Information within the Shared EHR is often extracted from other clinical |

**Commented [GG114]:** Should be rephrased in terms of extensibility and localisation. Agree with the importance

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| | documents and communications<br>– Information with clinical documents and communications is often extracted and placed into the Shared EHR<br>– The Shared EHR can contain a variety of different kinds of clinical documents, which contain similar information (e.g. diagnosis, alerts, allergies, etc), which needs to be query-able in a reliable fashion<br>• *Promotes Sound Clinical Design:* The approach must promote sound clinical document design. In particular the framework should foster safe medico legal documentation practices and should ensure that the information collected is connected to evidence and best practice recommended by peak clinical bodies;<br>• *Separation of Responsibilities:* Promoting a clear separation of responsibilities, including:<br>– Clear separation between requirements, design and implementation<br>– Clear separation between structured documents, services and terminologies<br>– The specification development framework needs to respect needs to respect boundaries and try not to be everything to every one. In particular, it should not try to cross over into general enterprise computing requirements, such as security, identity management, directories, etc.<br>• *Balances Trade Offs:* There are many different ways of developing specifications, some of which can have adverse effects on issues such as ease of implementation, reuse, extensibility and generality. Where these trade offs have been made should be clearly documented.<br>• *Pluggable Implementation Approaches:* The specification development framework must be independent of implementation approach and be able to support the addition of new implementation approaches<br>• *Extensibility:* The specification development framework must support creating new and more structured document types and services and promote the reuse of existing components;<br>• *Localisation:* The specification development framework must support the ability to tailor existing structured document types and services for local purposes;<br>• *Formalisation:* The meta-model underlying the specification development framework |

**Commented [GG115]:** These definitions are ok, though apparently at odds with some of the interpretations above; but the definitions should be meshed with the discussion section about extensibility added above

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| | needs to be soundly engineered |
| **Conformance with Existing NEHTA Recommendations and Specifications** | • *NEHTA Interoperability Framework Support:* The specification development framework must support a clear separation of perspectives from an organisational, informational and technical perspective, as per the NEHTA interoperability framework |
| **Notes** | • In formalizing the specification development framework, it isn't necessary for all requirements to be supported to a highly detailed level. A clean and practical approach to some elements should be favoured in the short term over spending years getting the details behind a comprehensive framework correct. |

### A.1.2 Structured Documents

| **Area** | Structured Documents |
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| **Description** | The specification development framework must support the creation of new types of structured documents for the exchange of clinical information.<br><br>Structured documents can originate from a variety of clinical settings, including general practices, specialist clinics, hospitals, pathology labs, imaging services, pharmacies, community health workers and allied health clinicians.<br><br>Structured Documents contain information relevant to clinical decision making and may cover a single treatment (e.g. a consultation), a number of treatments related to an episode of care (e.g. discharge summary), or a history of events (e.g. an individual's health history).<br><br>Many structured documents, such as referrals or test results, are usually created for the purpose of a specific piece of correspondence. Some structured documents may also contain a subset or a summary of the more detailed local record. They can, however, sometimes provide detailed information to facilitate the shared care of an individual.<br><br>A structured document can contain sections. A section ~~contains~~ containing clinical information within a Structured Document belongs under one clinical heading, usually reflecting the flow of information gathering during a clinical encounter, or structured for the benefit of future human readership. A section consists of a set of data groups.<br><br>A data group is an structured information package that can be used to structure clinical information such as one observation, one clinical finding, one interpretation, one intervention, or one intervention. Each can be represented as an entry in a structured document. Contextually related data groups can be grouped together to form |

**Commented [GG116]:** ? looks like this would be right

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| | clinical statements within a structured document. |
| **General Requirements** | • *Document Oriented Approach:* In order to support a document oriented approach, a structured document needs to support the following characteristics:<br>– Persistence: A structured document continues to exist in an unaltered state, for a time period defined by local and regulatory requirements.<br>– Stewardship: A structured document is maintained by an organization entrusted with its care.<br>– Potential for authentication: A structured document is an assemblage of information that is intended to be legally authenticated.<br>– Context: A structured document establishes the context for its contents.<br>– Wholeness: Authentication of a structured document applies to the whole and does not apply to portions of the document without the full context of the document.<br>– Human readability: A structured document is readily amenable to being processed to being human readable.<br>• *Versioning:* The approach to supporting structured document should support persistence by promoting a version management strategy for structured documents in which structured documents are only amended and never deleted.<br>• *Document Body:* A structured document should support:<br>– A structured document should have a header, which:<br>• identifies the structured document,<br>• identifies the Subject (e.g. name, identifier, date of birth, sex),<br>• identifies the responsible clinician (e.g. name, provider identifier, organisation, organisation identifier),<br>• Times (i.e. when the event happened vs. when the information was recorded),<br>• Document type (e.g. referral, discharge summary, etc),<br>• Sensitivity Label(s) controlling the confidentiality level of the document,<br>• Document status (e.g. draft or |

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| | final)<br>• Versioning information (e.g. is this a document a replacement for another document)<br>– An ordered set of Sections and/or data groups. Note that while section headings are totally optional, ~~but~~ a structured document should contain at least one data group.<br>• *Sections:* The structured document should support sections, which:<br>– Sections can contain subsections and data groups<br>– Sections must support an ordered hierarchy of subsections<br>– A section does not change the meaning of a data group. A section is a convenient way of structuring a document for ease of reading.<br>• *Data Groups:* Data groups should<br>– Metadata about data groups should include:<br>• There must be a unique way of identifying data groups<br>• Identifiers for the subject (if different from the subject of the structured document)<br>• Identifiers for the author (if different from the author of the structured document)<br>• The data group shall support the recording of time at a given instant, an elapsed time since a particular event, and as a duration.<br>• The data group shall support the recording of the time-zone in which the recording took place.<br>• Each data group must have a sensitivity label<br>– Content with data groups should support structured content which is appropriately typed. The kinds of structures supported include:<br>• The data groups shall enable storage of data as lists such that the order of the data is preserved when the data is displayed.<br>• The data groups shall enable storage of data in tables such that the relationships of the data with the row and column headings are preserved. |

**Commented [GG117]:** This is grammatically difficult, not sure how to reword it

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| | • The data group shall enable storage of data in hierarchies such that the relationship between the node parents and children are preserved.<br>• The data group shall enable storage of data such that simple name / value pairing is preserved.<br>• The data group shall enable the storage of multiple values of the same measurement taken at closely proximate times at the same contact, or at different contacts and at different locations. The context of these measurements shall be preserved – such as who took the measurement, what method was used etc. These values should be able to be returned in a query and ordered in different ways<br>• The data group shall support the inclusion of comments within the data stored – enabling the clinician to qualify structured information appropriately. Comments shall be able to be linked to specific data attributes.<br>– A data group should be relatively self contained to facilitate safe querying. For example, a section heading like "presenting complaints" should not change the meaning of a diagnosis data group. The diagnosis data group itself should indicate that the diagnosis is a presenting complaint.<br>– The data group shall support the inclusion of comments within the data stored – enabling the clinician to qualify structured information appropriately. Comments shall be able to be linked to specific data attributes.<br>– A data group should have subtypes that support a clean ontological separation of concepts and facilitates safe modelling of clinical content.<br>• *Attachments:* The structured document shall permit other structured documents or encapsulated content to be attached to the structured document. |
| **Conformance with Existing NEHTA Recommendations and Specifications** | • *NEHTA CII Event Summaries:* Structured documents should be able to support the event summary definitions provided by the NEHTA Clinical Information Initiative (CII)<br>• *NEHTA CII Data Groups:* The data groups must be able to support data structures |

**Commented [GG118]:** This is difficult – it fosters duplication at best. How would you specify a condition? The link wouls say, "condition of", then the data group would say ("asthma condition") and condition is duplicated. Seems like a problem to me – certainly doesn't support clean ontological separation of concepts

**Commented [GG119]:** Worrying too – what is the acceptable scope of "qualify"? I guess this is reasonable, but I worry that the qualification will be too great. We already have this issue with coded elements in HL7

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| | conformant with those data structures recommended by the NEHTA Clinical Information Initiative (CII) |
| **Notes** | • It is likely that there will be a difference between the way the NEHTA CII data groups structure information and the way certain standards structure information at the data group level. Picking one or the other is not necessarily the right answer. While some degree of harmonisation on a case by case basis will be necessary, it should be noted that specific Australian requirements will result in divergence from International standards. This is no different from other countries, where they have diverged from international standards in order to support specific local requirements. The localisation processes within the specification development framework should help address some of these issues. |

### A.1.3 Data Types

| **Area** | Data Types |
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| **Description** | Standardised data types are used within e-health information interchange to ensure the structure of the type of content is appropriately identified and can be processed independently of the internal data types within any given application language. |
| **General Requirements** | • *Text:*<br>– The data types shall support the inclusion of narrative free text.<br>– The data types shall support the inclusion of structured text within the unstructured data (for example, the inclusion of a table or an image within a block of text).<br>– The data types shall support formatting of rich text (e.g. italics, bold, underlining, dot points, etc)<br>• *Quantities:*<br>– The data types shall support the definition of the logical structure of numeric and quantifiable data, including the handling of units.<br>– Quantities should include a measure of precision related to the method of measurement.<br>– Percentages shall be able to be expressed as quantities.<br>– The data group shall support the definition of the logical structure of ranges – that is high and low values.<br>– The data group shall support the definition of the logical structure of |

**Commented [GG120]:** Some of these requirements refer to "Data group" rather than data type. I appreciate why this is, since different standards scope datatypes differently. But it seems like some explicit acknowledgement of the fact would be appropriate, rather than burying this inside the "data types" section. There's a comment at the foot of the notes where this could be best commented on

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| | quantity ratios (i.e. x of a per y of b).<br>• *Dates and times:*<br>– The data types shall support the definition of the logical structure of dates and times.<br>– The data types shall support recording of time in all units down to milliseconds.<br>– The data group shall support approximate, partial, and fuzzy dates and times such as: approximate dates/times: e.g. sometime yesterday, last week; partial dates : e.g. ??/May/1997, ??/ ??/1928.<br>– The data group shall support the recording of future planned events or actions such as: periods of day or time: e.g. morning, afternoon, evening, shifts (day, evening, night), while awake; approximate points of date/time: e.g. upon awakening, at mealtime (breakfast, lunch, dinner), at bedtime; relative points of day or time: e.g. before breakfast, after lunch, before bedtime, two days post discharge, one week after last dose; alternating and patterned dates/times: e.g. alternate every 8 hours, alternate every 3 days, every Monday/Wednesday/Friday, every Sunday, every third Tuesday.<br>• *Encapsulated Content:*<br>– The data types shall allow for the incorporation of data types defined elsewhere, such as HTML, PDF, DICOM, MIME, etc<br>• *Links:*<br>– The data types shall support links to internal content within the structured document and to content within other structured documents.<br>• *Identification:*<br>– The data types shall support standards for information which enable the unambiguous identification of the subject of care and third parties such as next of kin<br>– The data types shall support standards for information which enable the unambiguous identification of the clinicians involved in care (including their role and context of care), the location of care and non-clinical contacts.<br>– The data types shall support standards |

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| | for information which enable the unambiguous identification of the Provider Organisations involved in care (including their role and context of care), the location of care and non-clinical contacts. |
| **Conformance with Existing NEHTA Recommendations and Specifications** | • *NEHTA CII:* The NEHTA CII work provides requirements for data types<br>• *NEHTA Identifiers:* Individuals will be identified within structured document header and data groups using their IHI (Individual Health Identifier – as defined by NEHTA). Providers and their organisations will be identified within structured document header and data groups using their HPI (Healthcare Provider Identifier – as defined by NEHTA) |
| **Notes** | • Data types also need to support terminology. This is discussed in another section<br>• Some reviewer have pointed out that the data types really belong inside the section on structured document requirements. However, when that was done, other reviewers then complained it should be separated out. To solve this issue we will separate it out and then weight it more lowly in the ranking process. |

### A.1.4 Terminology

| **Area** | Terminology |
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| **Description** | Terminologies are one of the key building blocks of semantic interoperability as they ensure that information from different sources can be compared in a reliable fashion. In order to do this, the data groups and the underlying data types must support exchange of information coded using terminologies in a clear and consistent fashion. This means that the interface between terminology and the data groups must be clear and consistent. |
| **General Requirements** | • *Terminology Data Types:* The data types shall support:<br>– Data types shall support multiple coding systems (entry or interface terminologies, reference terminologies and classifications).<br>– The data types shall support the capture of the code, the coding scheme (e.g., coding/classification system), version, preferred terms, original text provided by the clinician, and original codes (if the term was translated from another terminology).<br>– The data types shall enable storage of data from terminologies and preserve |

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| | the information about the terminology set from which it was chosen.<br>• *Clearly Defined Vocabulary:* The vocabulary underlying many of the fields within the structured document, sections and entries, need to be defined and where codes from terminologies, like SNOMED CT, can be substituted needs to be identified.<br>• *Interface between terminology and data structure:* The interface between the data groups and types and terminology should ensure that when the data structure and terminology perform similar or overlapping functions there are clear guidelines on how the terminology should be used in this case and how certain fields in the data structure may modify the meaning of terms. |
| **Conformance with Existing NEHTA Recommendations and Specifications** | • *NEHTA SNOMED CT Recommendation Support:* Data within data groups and types will be coded using the SNOMED CT terminology reference sets identified by the NEHTA Clinical Terminologies project |
| **Notes** | • Trying to solve the entire suite of issues around the interface between structure and terminologies is a large and complex task and may take years to resolve. Therefore in the interim, it will be necessary to make some pragmatic short term decisions until a long term solution can be found. This will mean that in the short term the focus should be on developing a small collection of reference sets and providing a limited set of data groups where the interface between the data group and reference set is clear (e.g. for medications, problem/diagnosis, procedure, adverse reaction / alert, etc).<br>• The question around how much pre and post coordination should be supported is non-trivial and probably can only be answered on a case by case basis. For example, the degree of pre and post coordination required for medications is probably different from that for adverse reactions and alerts. |

### A.1.5 Constraints

| **Area** | Constraints |
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| **Description** | The foundation of interoperability is in ensuring that potential ambiguities that may arise from a combination of generic concepts in the structured document, data type or terminology are constrained and rules are provided for their use in specific contexts.<br>In the past, constraints on how a standard should be used in a certain context were typically in the form of an "implementation guide", and the implementers were responsible for ensuring that |

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| | their system fulfilled the constraints appropriately. By supporting constraints more formally, the risk of variances in implementation and multiple interpretations of the implementation guide are substantively reduced. |
| **General Requirements** | • *Constraint Meta data:* Each constraint should define:<br>– Globally unique identifier for the constraint<br>– Identification of the body governing and recommending the constraint<br>– Date of creation<br>– Version<br>– Publication state (e.g. test, draft, draft for trial use, production, deprecated, etc)<br>– A definition of the context in which the constraint is applicable, including the overall clinical scope<br>• *Structural Constraints:* Constraints on the use of structured documents should be defined in terms of:<br>– Sections that must be included<br>– Data groups that must be used<br>– The typing of data fields or slots to restrict the type of data e.g. dates, numbers, quantities, text, etc.<br>• *Terminology Bindings:* Constraints should be able to be put on how terminologies should be used in specific contexts.<br>• *Composability and Reuse:* The constraint language must promote compensability and reuse of constraints in different contexts. The approach to reuse should promote a levelled approach which separates common building block level constraints from higher order constraints that reuse more basic building block level constraints. The governance on the lower level building block constraints needs to be tightly controlled to ensure that such constraints are safely reusable in different contexts.<br>• *Validation algorithms:* Algorithms need to be provided to show how the constraint language can be used to ensure that the content of structured documents, data types and terminologies are used appropriately in different contexts. |
| **Conformance with Existing NEHTA Recommendations and Specifications** | • None Required |
| **Notes** | • None noted |

### A.1.6 Interchange Format

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| **Area** | Interchange Format |
| **Description** | The interchange format provides a way for sharing structured documents / event summaries across the network. |
| **General Requirements** | • *Industry Standard Parsers:* The interchange format needs to be parse-able using widely available industry standard parsers<br>• *Simplicity:* Ideally the interchange format needs to be as strongly typed and as context free as possible, in order to reduce the possibility of programmer errors<br>• *Message Size:* The interchange format needs to be compact in order to minimize band width requirements. It should also support sharing of large amounts of content (if required) |
| **Conformance with Existing NEHTA Recommendations and Specifications** | • *NEHTA Secure Messaging:* NEHTA's secure messaging initiative currently recommends XML as the underlying syntax of the interchange format and the use of XML Schema to describe the format. The model behind the XML Schema itself is governed by the requirements from Structured Documents section above. |
| **Notes** | • None. |

### A.1.7 Services

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| **Area** | Services |
| **Description** | The specification development framework should promote the sharing of structured documents using a service oriented architecture (SOA) approach. |
| **General Requirements** | • *Service Oriented Architecture:* The specification development framework should promote a service oriented architecture (SOA) approach. In particular:<br>– The services should support the requirements of business processes<br>– The services should promote loose coupling by ensuring that dependencies between services are minimized<br>– Interfaces exposed by services should operate on a formally defined contract.<br>– The interfaces should support strong encapsulation and hide the internal details of implementation<br>– The service should promote statelessness by minimizing the need the need to retain state information between invocations |

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| | – Services should promote reuse and composition<br>– Services should be discoverable<br>– Concerns between content, transmission oriented infrastructure and invocation patterns should be separated out<br>– Invocation patterns should not be limited to simple messaging style interactions and support other types of interaction<br>• *Identification Services:* The approach should provide services for:<br>– Probabilistic matching of identifiers based on demographic details<br>– Directory services for searching the demographic details of individuals, providers, organisations, etc<br>• *Structured Document Management Services:* The approach should support a variety of services for managing structured documents, including services for:<br>– Record management of shared EHRs (i.e. creation, activation/deactivation, merging, splitting, archival, etc)<br>– Lifecycle management of structured documents (creation, amendment, etc)<br>– Retrieval, Viewing, Reporting and Notifications<br>– Access control to shared EHRs and structured documents<br>• *Clinical Process Management Services:* The approach should provide a variety of services for:<br>– Referrals<br>– Diagnostic Testing<br>– Prescriptions<br>– Notifications to Registries<br>– etc |
| **Conformance with Existing NEHTA Recommendations and Specifications** | • *NEHTA Web Services Recommendation:* The services for managing structured documents must conform to NEHTA's Secure Messaging recommendations for web services |
| **Notes** | • The services discussed here do not include interfaces for supporting configuration management (e.g. managing support for different types of structured documents), system administration (e.g. backing up the Shared EHR service) and participation management (e.g. invitations to participate). Such interfaces are internal interfaces that a Shared EHR Service system administration |

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| | tool or participation management tool will need and not interfaces that are exposed to clients like GP desk tops, CISs, etc. Therefore, they have been excluded from the scope of this requirement. |

### A.1.8 Security

| **Area** | Security |
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| **Description** | Services which access structured documents should ensure that the client is appropriately authenticated, the client is only allowed to access material they are authorised to access, the confidentiality of communications is preserved through encrypted connections and non-repudiation mechanisms such as audit trails and digital signatures are supported. |
| **General Requirements** | • *Authentication:* Services which access structured documents should ensure that the client is appropriately authenticated. While it is not necessary for the standard to specify in detail the nature of authentication required, the services supported by the preferred standard should be able to be run within an authentication framework provided by an underlying infrastructure such as WS-Security.<br>• *Authorisation:* Services which access structured documents should ensure the client is only allowed to access material they are authorised to access. While it is not necessary for the standard to specify in detail the nature of authorisation required, the services should be able to work with an access control scheme based on labelling data at the structured document and data groups level with a sensitivity level and having an authorisation module make access control decisions is the preferred approach.<br>• *Confidentiality:* Services which access structures should ensure that the confidentiality of communications is preserved through encrypted connections. While it is not necessary for the standard to specify in detail the nature of confidentiality required, the services supported by the preferred standard should be able to be run within a confidentiality framework provided by an underlying infrastructure such as WS-Security.<br>• *Non-Repudiation:* Services which access structures should ensure that non-repudiation mechanisms such as audit trails and digital signatures are supported where appropriate. While it is not necessary for the standard to specify in detail the nature of non-repudiation required, the services supported by the preferred standard should |

**Commented [GG121]:** I wonder whether this is properly factored – all the options were given the same score for this, but I'm not sure that all of hem have properly clarified how a digital signature would be applied to the document being exchanged.

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| | be able to be run within a security framework provided by an underlying infrastructure for digital signatures such as WS-Security. Also the services should be able to work with an external auditing framework. |
| **Conformance with Existing NEHTA Recommendations and Specifications** | • *NEHTA Secure Messaging:* The services should support security requirements recommended by NEHTA's Secure Messaging Initiative<br>• *NEHTA User Authentication Initiative:* The services should support authentication of clients using policies recommended by NEHTA's user authentication initiative. |
| **Notes** | • At this stage insufficient information is available on user authentication within NEHTA. More information should be available in time. |

## A.2 Ease of Implementation

### A.2.1 Low Implementation Complexity

| **Area** | Low Implementation Complexity |
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| **Description** | Complexity of implementation is one of the primary factors affecting the cost of uptake of standards for e-health information interchange. The greater the complexity of implementation, the more the cost of uptake increases as more time is spent by programmers understanding the specifications, implementing and unit testing. |
| **General Requirements** | • *Clear Documentation:* The specifications need to be fairly self explanatory, so that an average programmer can implement them without the need to attend unnecessarily long training sessions or rely on a handful of specialist consultants to explain it to them<br>• *Simple Design Patterns:* The specifications should not use design patterns that result in complex and convoluted implementations that are difficult to implement, test and maintain<br>• *Minimal System Impact:* The specifications should be developed in a way that favors a high degree of encapsulation and loose coupling. For example, the specifications should not explicitly force the vendor to unnecessarily expose the internal states of processes within their application, incorporate third party components or build a high degree of dependence on external services. Similarly, the specifications should not cause vendors to have to radically restructure the internals of their application to support the specification. Such an approach will mean that vendors will have a |

**Commented [GG122]:** This should be require. Any implementor can produce complex convoluted implementations no matter how easy the specification patterns are

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| | reasonable amount of control in how they choose to implement a specification to best fit with their product.<br>• *Facilitates Reuse:* The specifications should facilitate reuse by vendors, meaning that as new specifications are implemented it should be possible for a vendor to reuse components from the previous implementation |
| **Conformance with Existing NEHTA Recommendations and Specifications** | • In time NEHTA will be developing a set of certification criteria for systems. These criteria may have an impact on the implementation |
| **Notes** | • Note that in some cases, design choices in the specification development framework, such as certain patterns to improve extensibility while trading off against complexity of implementation. |

### A.2.2 Limited Opportunities for Variance

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| **Area** | Limited Opportunities for Variance |
| **Description** | Nothing affects interoperability more than variance in implementations. If vendors implement specifications in different ways then the chance of achieving interoperability is significantly reduced and more time is spent in integration testing. |
| **General Requirements** | • *Implementation Guides:* Implementation guidance can significantly aid implementers understand the specific details required to be implemented to support a certain context.<br>• *Conformance Specifications:* The specifications need to be sufficiently clear to be used as a basis for procurement of systems and testing by an independent party. Such specifications need to clarify flows of information expected to be shared in response to certain events, client roles and responsibilities and server roles and responsibilities.<br>• *Limited Use of Text Fields for Sharing Structured Information:* Text fields which contain structured information can easily be abused by different implementers and result in a large number of integration problems.<br>• *Limited Optional Fields and Features:* By restricting the availability optional fields and features, the risk of variance in implementation is substantially reduced.<br>• *Limited use of modal design patterns:* By using design patterns that change the meaning of classes through the setting of modes, the risk of implementation variance is increased. |

**Commented [GG123]:** I don't see why model design patterns is linked to variance. If it's not documented clearly, sure, but the alternative is to clone related concepts, and then you can get variance in both the standard and the implementation. I'm not necessarily in favour of model patterns, but I think this is creating a problem here. Also, the scoring for this one didn't seem to make sense

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| **Conformance with Existing NEHTA Recommendations and Specifications** | • None noted. |
| **Notes** | • Note that in some cases, design choices in the specification development framework, such as certain patterns to improve generality, extensibility, and reusability can result in more opportunities for variance because to support extensibility or reusability, optional features and modal design patterns may need to be used. However, some of this risk can be offset by introducing a constraint language constraining misuse of optional fields and modal design patterns. Naturally, the introduction of a constraint language then in turn increases the complexity of implementation. |

### A.2.3 Clear Migration Path

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| **Area** | Clear Migration Path |
| **Description** | In adopting the new standards approach there must be a clear migration path for moving from implementations of various existing standards and specifications and also for seamlessly moving between different versions of the standards that form part of the approach. |
| **General Requirements** | • *Straight Forward Mappings from Existing Specifications:* The process of converting information in existing standards, such as HL7 v2.3, to the new standard should be straight forward.<br>• *Backwards Compatibility:* When new versions of specifications are introduced, it is desirable that they should be backwards compatible with previous versions and minimize the need for special case handing rules being introduced to support the different versions<br>• *Levelled implementation approach:* The approach should support a levelled implementation approach which allows vendors to implement just enough complexity to support their current set of requirements |
| **Conformance with Existing NEHTA Recommendations and Specifications** | • None noted. |
| **Notes** | • Note that straight forward mappings and backwards compatibility may not be possible if the previously used specifications do not fit current information sharing requirements and did not share the appropriate |

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| | information |

### A.2.4 Tool Support for Implementation and Migration

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| **Area** | Tool Support for Implementation and Migration |
| **Description** | As time spent implementing software is one of the key determinants in the actual cost of software, tool support for aiding implementation and migration activities is an important way to help reduce turn around times by developers. |
| **General Requirements** | • *Platform Independence:* The standard must be implementable in a variety of programming languages currently in use by a number of vendors (e.g. Java, C#, C/C++, Visual Basic, Delphi, etc) on a variety of different operating systems (e.g. Windows, Linux, AIX, Solaris, etc).<br>• *Computer Processable Specifications:* The specifications should be available in a form (e.g. XMI or XML Schema) that code generation tools can process to support programmers getting started within implementation.<br>• *Open Source Libraries:* A wide range of open source libraries should be available to help implementers start developing their solutions. The libraries should have a relatively high quality, completeness and an active community supporting it.<br>• *Interface Engine Support:* There ~~must~~ should be third party interface engine products that are likely to support conversion of the existing standards currently in use to the newly proposed standard.<br>• *Testing Services:* Services should be available to allow vendors to test examples of structured documents they have implemented within their product prior to integration testing |
| **Conformance with Existing NEHTA Recommendations and Specifications** | • No specific requirements. |
| **Notes** | • Note that in some cases, design choices in the specification development framework, such as certain patterns to improve extensibility or semantic interoperability, can adversely affect ease of implementation. Without tooling to support developers this can be a serious challenge. However, waiting lengthy amounts of time for tooling to be developed is also equally undesirable. Therefore, some pragmatic decisions will need to be made in this space. |

**Commented [GG124]:** To be consistent with other requirements – no particular reason why this is more required than others, specially since most interface engines do XML stuff at the least

**Commented [GG125]:** And services

### A.2.5 Tools Support for Specification Development

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| **Area** | Tools For Specification Development |
| **Description** | The specification development framework needs to be supported by a tool chain which supports a number of different functions, such as creating new specifications, and managing existing specifications |
| **General Requirements** | • *Faithfulness to the Specification Development Framework:* The approach must provide tools that faithfully implement the underlying formal models of the specification development framework<br>• *Specification Editors:* In supporting the specification development framework, the tools should provide:<br>– Structured Document Type and Constraint Editing<br>– Integration with terminology tools<br>– Documentation Generation<br>– Structured Document Example Creation Tool<br>– Generation of computer processable specifications (e.g. in XML Schemas or XMI)<br>– Sample Form Generation<br>• *Specification Library:* The tools should provide a library of reusable specifications for Structured Document Types, Constraints, etc |
| **Conformance with Existing NEHTA Recommendations and Specifications** | • No specific requirements. |
| **Notes** | • High degrees of tools support is probably difficult to expect for standards that are still evolving. |

## A.3 Community Support

### A.3.1 Governance

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| **Area** | Governance |
| **Description** | In order to ensure that Australia's need to develop an advanced nation's technical infrastructure for e-health is supported, a strong influence on the governance of standards used by that infrastructure will be required |
| **General Requirements** | • *Recognised Body:* The approach to standards needs to be undertaken by a body that is recognized as an accredited standards development organisation.<br>• *Australian Participation in Processes:* If the |

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| | approach is based on an international standard, then it will be necessary to ensure that there is a way that Australian representatives can participate in the standards development process and ensure that Australian e-health priorities and policies are not precluded by international standards activities.<br>• *Support for Australian Localisations:* The governance approach will need to ensure that the development of new specifications (or localisation of international standards) aligns with Australian Health priorities and policies, in the areas of e-health and quality and safety in health care.<br>• *Consensus and Quality Driven Release Process:* The governance approach must ensure that clear quality assurance points are in place for delivery of standards. This includes quality assurance steps for developing drafts, trial use versions and versions ready for production use. The release process needs to be driven by community consensus and by quality assurance controls to ensure that the collective suite of standards are coherent as a whole and resolve any inconsistencies between standards (or previous versions of standards)<br>• *Create No International Trade Barriers:* The standards development process should be aligned with the Code of Good Practice for the Preparation, Adoption and Application of Standards annexed to the World Trade Organisation (WTO) Agreement on Technical Barriers to Trade[1]. This means that:<br>– Standards are not prepared, adopted or applied with a view to, or the effect of, creating unnecessary obstacles to international trade;<br>– Where international standards exist or their completion is imminent, they shall be used, or the relevant parts of them, except where such international standards or relevant parts would be ineffective or inappropriate;<br>– With a view to harmonising standards on as wide a basis as possible, the standardising body shall, in an appropriate way, play a full part, within the limits of its resources, in the preparation by relevant international standardising bodies of international standards regarding subject matter for which it either has adopted, or expects |

[1] World Trade Organisation. (1994). *Agreement on Technical Barriers to Trade, Annex 1*, p. 115-119 accessed 26 May 2006, http://www.standardsinfo.net/isoiec/inttrade.html

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| | to adopt, standards;<br>– Once the standard has been adopted, it shall be promptly published or otherwise made available in such a manner as to enable interested parties to become acquainted with them; and<br>– A reasonable interval should be allowed between the publication of technical regulations and their entry into force in order to allow time from producers to adapt their products to the requirements. |
| **Conformance with Existing NEHTA Recommendations and Specifications** | • No requirements. |
| **Notes** | • Note that some of the requirements listed above will not be possible until more work has been done on a longer term governance solution or until the case for Shared EHR is funded. |

### A.3.2 Australian Community Support

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| **Area** | Australian Community Support |
| **Description** | In order for a recommendation to have a chance of being adopted, a close and co-operative working relationship between local standards bodies, local vendor community and Jurisdictional IT departments is essential. |
| **General Requirements** | • *Australian Standards Community Support:* Support for the recommendation within the Australian Standards Community is important as it ensures that the standard is more likely to be consensus based<br>• *Minimal dependence on key individuals:* The specification should not be highly dependent on one or two key individuals within the Australian standards community. If those members move on, there is a risk the specification will no longer be supported.<br>• *Support by Local Vendors:* The recommended approach must be likely to be adopted by local vendors |
| **Conformance with Existing NEHTA Recommendations and Specifications** | • No specific requirements |
| **Notes** | • Making any decisions in this area can be extremely challenging as nearly all participants in the community have a conflict of interest of one form or another. For example, many consultants differentiate themselves by being experts in specific standards, some vendors have limited |

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| | resources and supporting new standards competes with their existing product development plans, and project managers having their scope, budgets or timelines affected by a change in standard.<br>• There is some debate over to what degree local community support is necessary. Given that localisation of any standard to support Shared EHR specific requirements will mean that implementations will not be able to easily leverage much of what has been done before in other implementations, some may argue that this requirement is not as strong as it could be. However this argument does not hold for one main reason: Vendors are more likely to build a higher implementation risk premium into their price for a specification that they have no experience with, than for one that they already have some experience with. |

**Commented [GG126]:** Risk premium needs to be factored into NEHTA planning too, since NEHTA (or government generally) recruits from the same market, and is also capable of pursuing dead ends at both strategic and technical levels. Greater experience in and out of Australia will amortize this risk

### A.3.3 International Community Support

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| **Area** | International Community Support |
| **Description** | In recognizing that many Australian healthcare providers purchase products that come from the international market place, and that some Australian vendors sell their products internationally, it is important to ensure that Australia's needs are supported by standards implemented by vendors in the international market place. |
| **General Requirements** | • *International Standards Community Support:* Active participation by within the International Standards Community in supporting of the recommended standards approach is important as it ensures that the related standards are more likely to be based on broad international consensus.<br>• *Minimal Dependence on Key Individuals:* The specification should not be highly dependent on one or two key individuals within the international standards community. If those members move on, there is a risk the specification will no longer be supported.<br>• *International Vendor Support:* The recommended approach must be likely to be adopted by international vendors as many Jurisdictions purchase products from international vendors |
| **Conformance with Existing NEHTA Recommendations and Specifications** | • None noted. |
| **Notes** | • There is some debate over to what degree international community support is |

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| | necessary. Given that localisation of any international standard to support Australian requirements will mean that implementations will not be able to easily leverage much of what has been done before in other countries, some may argue that this requirement is not as strong as it could be. However this argument does not hold for a couple of reasons:<br>– International vendors are more likely to build a higher implementation risk premium into their price for a specification that they have no experience with, than for one that they already have some experience with.<br>– The adoption of a common set of standards internationally means that there is likely to be greater interest in creating tools to support the standard. The tools themselves can result in productivity gains for Vendors and Standards Bodies alike |