	Results of Investigating the Transformability Between HL7 V3, *open*EHR and EN/ISO 13606			
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1	NPFIT-SHR-QMS-PRP-0015	Glossary of Terms Consolidated.doc	13.0

Glossary of Terms:

List any new terms created in this document. Mail the NPO Quality Manager to have these included in the master glossary above [1].

Term	Acronym	Definition
Archetype		In the context of EN/ISO 13606 and *open*EHR technical specifications, it is a re-usable clinical information model of record content.
European Committee for Standardization (Comité Européen de Normalisation)	CEN	A group representing European member states that produces standards for mandate by the European Commission.
European Standard	EN	A document representing a consensus agreement of the European Committee for Standardization.
Extensible Markup Language	XML	A general-purpose specification for creating custom sets of annotations to text that describe how text is to be structured, laid out, or formatted.
Extensible Markup Language schemas	XML schemas	A means for defining the structure, content and semantics of XML documents in detail.
Extensible Stylesheet Language Transformations	XSLT	An XML-based language used for the transformation of XML documents into other XML or "human-readable" documents.
Health Level Seven Clinical Document Architecture Release Two	HL7 CDA R2	A model of clinical documents for application-to-application information exchange.
Health Level Seven Model Interchange Format	HL7 MIF	A set of inter-related XML schemas that define the set of primary artifacts that may be developed or exchanged as part of HL7 V3.
Health Level Seven template	HL7 template	A data structure, based on the HL7 Reference Information Model, that expresses the data content needed in a specific clinical or administrative context.
Health Level Seven Version Three	HL7 V3	A standard for exchanging messages among information systems that implement healthcare applications.
International Organization for Standardization	ISO	The world's largest developer and publisher of international standards. It is a network of the national standards institutes of 157 countries.
European and ISO standard for Health informatics – Electronic health record communication	EN/ISO 13606	A 5-part standard, with parts at various stages of international approval (including, for example, full approval for part 1 by CEN and ISO in 2007). Part 1: Reference Model Part 2: Archetypes Interchange Specification Part 3: Reference Archetypes and Term Lists Part 4: Security Part 5: Exchange Models
The *open*EHR Foundation	*open*EHR	An international open collaborative that creates technical specifications, open source software and tools for a shared health computing platform.
*open*EHR template	*open*EHR template	A locally-produced constraint specification describing how archetypes should be implemented in a screen form or message specification.

Contents

1 Executive Summary

The project investigated whether equivalence could be established between clinical content models expressed using EN/ISO 13606 or *open*EHR and those expressed using Health Level Seven (HL7) Version 3 (V3). Mappings between example instances were used as a basis for this evaluation, which also builds on the broad experience of the contributing authors.

The project considered the use of *open*EHR archetypes and templates against the EN/ISO 13606 reference model, and found that a bidirectional transformation of clinical model content between HL7 CDA and EN/ISO 13606 formalisms is only feasible if modelling constraints are applied and some work is done on the harmonisation of the classifying vocabularies (HL7 V3 structural codes, the EN/ISO 13606 part 3 code lists, and the corresponding code lists in *open*EHR).

It was noted that being able to transform between the formalisms does not mean that models independently developed in each formalism for the same purpose may be mapped without loss of precision. Using a set of equivalent formalisms will not itself deliver a set of coherent models for the NHS, nor will it ensure that those models are consistent with the clinical models developed by standards organisations outside the NHS.

It is recommended that NHS Connecting for Health (NHS CFH) adopt a single interoperability framework, both for the specification of user interfaces and for application interoperability, using one set of datatypes and reference model. Where this is not possible, management and technical processes should be developed to ensure that clinical content inconsistencies are not introduced as different frameworks are maintained.

2 About this document

2.1 Purpose

This report summarises the results of investigations into the feasibility of creating an automated transform between clinical content models expressed in the EN/ISO 13606 and *open*EHR formalisms and those expressed in the HL7 Version 3 formalism.

2.2 Audience

The intended audience for this document includes NHS CFH, members of the NHS CFH Electronic Health Record Content Technical Advisory Group (EHR Content TAG), and, for some recommendations, HL7, the EN/ISO 13606 project team and the *open*EHR community.

2.3 Content

This document is comprised of the following sections:

- Project objectives
- Project method
- Summary of results, including
  - o An overview of findings
  - o Specific issues encountered
  - o Conclusions in relation to the project objectives
- Summary of recommendations, including to
  - o NHS CFH
  - o HL7, Inc.
  - o The *open*EHR Foundation
  - o The EN/ISO 13606 project team

3 Project context

Project context is described in this section in terms of the business context for transforming between model formalisms and the business requirements and success criteria for transformation.

3.1 Business context for transforming between formalisms

The business context for transforming between formalisms is described in terms of the current interests and activities of NHS CFH, as well as some general principles for prioritising model content transformations of clinical data.

3.1.1 Why transforming between formalisms is of interest to NHS CFH

This project fits into a wider evaluation of the use of ISO/EN 13606 and *open*EHR standards and technologies by NHS CFH. These investigations have focused on the use of *open*EHR tooling and models for documenting data constraints within user interface design. Since NHS CFH already has an investment in the use of HL7 V3 standards for application communications, the ability to assert the relationships between these specifications (i.e. between *open*EHR for user interface data capture and HL7 V3 machine interface data sharing) is required to promote consistency in data created and shared across NHS applications implemented according to both these specifications.

The exercise of creating transformations between the formalisms for expressing data capture requirements, and the formalisms for expressing an interoperability specification will help to inform decisions as to whether common tooling can be created to support the production of both HL7 implementation guides and *open*EHR data capture models, maintaining data consistency and coherence between specifications of both types.

The EN/ISO 13606 standard, because of a shared history with *open*EHR specifications, has many similarities with *open*EHR, particularly with respect to their reference models and archetype model specifications. 13606 is now a European, and will soon be an ISO, standard for the communication of the information content of EHR systems. Its use within a national programme will frequently be alongside the use of HL7 V3 messages and documents in which there may be substantial ongoing investment, as in the case of the NHS. Recognising this potential co-deployment, the NHS has elected to contribute strongly to a global ISO/CEN/HL7 effort to develop business rules and mapping transformations between these representations, and to champion a future convergence pathway.

Thus, NHS CFH is interested from a data models development perspective in establishing a single formal representation of requirements across different project and application design specifications. From an applications user and procurement perspective, it is noted that reducing any discordance between application design specifications should also mitigate any requirement to transform clinical data in implemented systems in future.

3.1.2 Principles for prioritising content for transform

In order to prioritise what data could be transformed across formalisms, the NHS CFH EHR Content TAG provided the project team with the following guiding principles:

- Patient safety requirements are the highest priority

    o This implies that the data transform requirement within the overall NHS clinical information architecture should be minimised, to reduce the potential for errors arising from transformations.

- Detailed mapping requirements should be driven by business requirements for data sharing

- Query requirements should be driven by clinical semantic requirements

- o There is much data that is collected and used within a single application, and for which there is no sharing requirement.
- o This will prioritise what needs to be preserved, and may indicate what (e.g. infrastructure detail) may reasonably be implemented in different ways in different systems.
- o The identity of units of clinical information should be preserved
- o Identifying the appropriate units may be challenging – the inputs for this will need to be both business and technical

- Other information governance requirements need to be identified (e.g. versioning, currency)

Implication:

For end-to-end transforms, the clinical query business requirement should be identified first using a framework that provides the required technical input, and mappings to HL7 V3, EN/ISO 13606 and *open*EHR where needed should be based on this requirement.

3.2 Business requirements and success criteria for transformations

NHS CFH requires different transformations to be defined for different business purposes.

Level 1: Knowledge level transformation.

NHS CFH is currently developing clinical data structure specifications across a wide range of clinical domains, using *open*EHR/ EN 13606 archetypes and *open*EHR templates. It has historically invested in data structure specifications represented as the HL7-based NHS CFH Message Implementation Manual (MIM) templates. Various suppliers to NHS CFH are using the Message Implementation Manual (MIM) templates, and it is also recognised that additional HL7 templates developed elsewhere may prove useful to the NHS. Suppliers may in future be able to exploit archetypes and templates directly, for example by importing their knowledge content into their internal configuration components to influence screens, queries and reports. In order to capitalise on the major effort that is invested within clinical communities in gathering and systematising technical constraints for these data structures, whichever formalism is used to represent the result, NHS CFH wishes to ensure that a bi-directional semantically equivalent transformation is possible and can be implemented through tools to enable these knowledge specifications to be available in both formalisms. The success criterion for this transformation is that the full set of NHS approved data structure specifications (EHR content models) can be published as archetypes and templates using the *open*EHR and EN/ISO 13606 reference models and datatype specifications and as instances of HL7 Clinical Document Architecture Release Two (CDA R2) documents using MIM templates (and possibly HL7 templates). They should be designed to support semantically equivalent EHR instances.

Such transformations serve as a way to document the relationship between different knowledge models, and so can be used to provide traceability between user interface specifications and application interoperability specifications.

They can be used to document conformance assertions to standardised knowledge models. For this purpose, it is important that the transformations make explicit where direct mappings are not possible.

This traceability benefit is relevant when working across the HL7, *open*EHR, and EN/ISO 13606 formalisms, but is dependant on there being similar traceability between versions and related models within each formalism.

This traceability function is successfully delivered if it is possible to author and maintain the mappings between models in a reliable and cost effective way that leads to a reduction in model diversity.

Work towards this level of transformation was demonstrated in this project through a small number of worked examples.

Level 2: Semantically equivalent instance transformation.

It is recognised that EHR data will in practice exist in multiple representations: those unique to each supplier's product and repository, different interoperability messages used to communicate clinical data for specific business purposes or generically, the NHS Care Record Service repository, and any future NHS CFH logical record architecture. A physical transformation of EHR instances may not prove necessary between every one of these representations (because data might not actually be exchanged between all of them), but NHS CFH needs to ascertain that each reference model used nationally for EHR instances is capable of representing semantically equivalent data, such that any future standardised queries, algorithms and business rules for the processing of data can be specified once and be applied across all of the representations faithfully.

For example, it will be essential that a query to extract certain data pertaining to the treatment of a particular condition can be specified in a singular form, be mapped into and executed across all of the relevant systems by suitable (vendor-specific) components, and that the result-sets can be provided by each system in a single nominated standardised form. (Note: the implementation of the necessary transformations will be the responsibility of different product suppliers, but NHS CFH should be able to verify a level of interoperability based on its centrally-specified representations.) Semantically equivalent instance transformation therefore requires that the domain of possible instances corresponding to any given clinical data structure can all be represented faithfully by each kind of reference/instance model in use within the NHS. It does not, for example, require that full version history information can be communicated but only that, for example, each model can meet requirements for version management such that only current information is included in the result sets.

The success criterion for this transformation is that NHS-wide queries and reports can be distributed in a singular form (to be determined) and imported and executed across heterogeneous systems by different suppliers and provide consistent result sets. Working towards this level of transformation was the main focus of this project, since this level of transformation was considered to be achievable in practice and

would be appropriate to prioritise given the NHS CFH EHR Content TAG's guiding principles as specified in Section 3.1.2.

Level 3: Full interoperability transformation.

This kind of transformation requires that all of the clinical and medico-legal information included within an EHR instance in one representation can be transformed into another. This includes, for example, details of version history, authorship, provenance, attestation etc. Although this is the ideal "gold standard" for EHR instance transformations, the business case to exploit this depth of transformation across the NHS is not clear. (It is therefore premature to specify success criteria.) Full interoperability transformation was therefore not included in the scope of the empirical work reported here. However, some observations of the feasibility of achieving this are provided. A small number of model inconsistencies were identified that would limit the completeness of such a transformation, and these are described in Appendix C.

4 Project objectives

The primary objectives of this investigation included:

- Testing whether a useful bi-directional automated transform is possible between NHS clinical content specifications defined using the *open*EHR archetype and template formalisms and those defined by NHS CFH using the HL7 V3 formalism (i.e. Level 2 transformation as defined in Section 3.2 above)

- Reporting on areas of either of these specifications that should change in order to accommodate bi-directional automated transformations

- Providing input towards design guidelines for the maintenance of these specifications that would better accommodate bi-directional transformations.

Other objectives included:

- Testing whether a useful bi-directional XML transform is generally possible between content defined using EN/ISO 13606 and HL7 V3

- Recommending changes to the specifications of NHS CFH, EN/ISO 13606, *open*EHR or HL7 V3 that would better accommodate automated clinical content model 'translations' or transformations.

5 Project method

At a high level, the investigation followed a four-step process:

1. Identify business context and specific requirements for transforming between formalisms

2. Choose representative use case examples

3. Develop hand-crafted transforms

4. Develop demonstration tools for any successful transforms.

Throughout this process, issues were recorded as they arose.

The work undertaken in this project examined the feasibility and quality of representing the same EHR instance data in two reference models: HL7 V3 CDA R2 and EN/ISO 13606 reference model. This was undertaken through worked examples for discharge summary and for childhood vaccination. In both cases clinical data structure models were used to define the specific class pattern adopted within each reference model to represent the example data, i.e. for

- HL7 CDA R2: the NHS CFH MIM Version 7.1 template corresponding to each example

- EN/ISO 13606: one or more *open*EHR archetypes per example.

Because the goal was to achieve semantically equivalent representations for each example, it was necessary first to have semantically equivalent knowledge representations (i.e. to have knowledge instances that conform to Level 1 transformations as defined in Section 3.2).

For pragmatic reasons the MIM template version in each case was used as the clinical design basis and a set of corresponding *open*EHR archetypes was authored.

The clinical data content of the CDA instance examples was then represented within EN/ISO 13606, noting any difficulties or areas of ambiguity.

The work was undertaken using Extensible Markup Language (XML) representations, with the limitation that a formal XML schema has not yet been published for EN/ISO 13606[1] and the project team therefore constructed a limited subset of such a schema to meet the needs of the chosen examples.

A separate challenge addressed by this project was to identify if the mappings, once defined, could be represented within an XML translation tool and thereby translated in an automated way.

5.1 Example models chosen

The clinical examples chosen for this investigation were drawn from a small set of those known *a priori* to conform to one of the target instance representations (i.e. to either the HL7 CDA R2 or to EN/ISO 13606) and to conform to a clinical content model in one of the target knowledge representations (NHS CFH MIM or *open*EHR archetype/template). They were selected on the grounds that they illustrated examples of clinical data that are commonly and usefully communicated in current practice, and needed to be communicated safely.

5.1.1 Selection criteria

Models were selected on the following grounds:

- They had been developed in the formalisms under investigation (i.e. HL7 V3 or *open*EHR archetypes and templates)

- They had been developed to meet identified clinical needs in England

- They had been developed with substantial input from NHS CFH modellers

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[1] Work on this Schema is now at an advanced stage but was not available in time for the work undertaken in this investigation

- There was a reasonable prospect of both the HL7 V3 and the *open*EHR technical artefacts being used by those implementing systems in the NHS.

5.1.2 Description of examples, including how they meet criteria

The clinical models chosen for this investigation were drawn from the NHS CFH MIM Version 7.1 and the set of *open*EHR templates and archetypes developed for the LORENZO 3.5 application design for the North, Midlands, and East Programme for Information Technology (NMEPfIT) or for the London Programme for Information Technology (LPfIT).

The **immunisation** models had been developed in October 2007 for London, in the context of an immediate implementation requirement. The requirement was to support the communication of immunisation information using HL7 templates for CDA documents to a London shared immunisation record. The models included SNOMED Clinical Terms bindings and were provided in both HL7 V3 and *open*EHR forms.

The **discharge summary** example was selected because generic discharge summary clinical models had been defined in both the NHS CFH MIM and in the Lorenzo pilot work, so there was an opportunity to explore the mapping between two clinical content models that had been developed to meet the same requirement, i.e. to be a framework for discharge summaries.

Since the objective of this exercise was to evaluate the ability to transform between the formalisms, and not to harmonise independently modelled content, a set of *open*EHR archetypes were developed that included equivalent information items at the same granularity as the NHS CFH MIM models.

Taking the example instance from the NHS CFH MIM, an instance was then created that conformed to the *open*EHR archetypes and templates formalisms. The mapping exercise was done in this direction because independently authored examples of instance data that conformed to the openEHR archetypes and templates were not available in late 2007 during the discovery phase of the project.

5.2 Types of model mapping examined

The immunisation mapping was done between the clinical content models – i.e. between the *open*EHR archetype and the HL7 V3 static model. Issues relating to the underlying reference models and datatypes were not explored in this part of the work. The focus was on looking at the information items specified in the *open*EHR archetype, and establishing where in the HL7 V3 static model that information would be represented.

When doing the immunisation mapping the investigators noted that many of the information items specified and constrained in the draft HL7 static model for immunisation did not have corresponding nodes in the archetype. They are included in the *open*EHR reference model, but are not exposed in the archetype for constraint or review. Usually this has been a deliberate design choice, and is a feature of archetypes that allows for more clinical focus in design. Such a feature of *open*EHR tools could usefully be implemented in the context of HL7 V3 static models (and indeed any modelling environment that relies on an underlying reference model).

At the time that the project started, the investigators were unable to obtain an XML schema for instances of patient data that conform to *open*EHR templates or

archetypes that reflected the constraints of the reference model and those of the archetype and template. Had such a schema and corresponding example instances been available, they would have been used.

For the discharge summary mapping, mapping was done between instances using the same example data. This helped to focus attention on the sorts of mapping issues that would be most relevant in practice, and allowed the implicit reference model nodes not visible in the archetypes to be considered in the mapping process.

When creating the instance against the *open*EHR template and archetypes for the discharge summary we chose to use the EN/ISO 13606 reference model. This allowed the opportunity to meet the secondary objective of exploring compatibility with EN/ISO 13606 while still using the *open*EHR tooling and formalisms for the definition of the archetypes and templates. However, for datatypes, *open*EHR datatype definitions were used, since there are known issues with the current datatypes for EN/ISO 13606, and the current datatypes will be replaced by an implementation of the ISO health datatypes once they are finalised.

The rationale for wanting to use the EN/ISO 13606 model as a basis for the archetype-defined instance is that it is the reference model for archetypes that has been standardised at ISO and in Europe. Also it has been designed and reviewed specifically for the exchange of clinical information between different EHR systems, rather than for the slightly different objective of being the reference model for the implementation of an EHR system, as is the case for the *open*EHR model.

In the limited testing that was done within this project this approach did not introduce any changes in the meaning of the template or archetype, but it is recognised that the creation, maintenance and use of the archetypes and related templates should be done using a single reference model, and that a choice should be made for this purpose.

The scope of the project did not extend to a detailed comparison and evaluation of the EN/ISO 13606 and *open*EHR reference models.

As the NMEPfIT data capture models were not provided with example patient data, the initial discharge mapping was done using the example discharge letter from the NHS CFH MIM Version 7.1 This provided a useful basis to identify and illustrate a set of issues, though clearly a larger evidence base would be useful to validate and extend the findings reported here.

5.3 Tools used

Tests have been made in which mappings between EN/ISO 13606 and HL7 V3 are captured in machine-readable form and are used to generate bi-directional Extensible Stylesheet Language Transformation (XSLT) translations of instances between the two forms. The only example for which this has been done so far is the Immunisation example, using hand-crafted instances in ISO/EN 13606 and HL7 V3. This is a very simple example which does not contain areas of complexity in terminology-binding that have been identified by the NHS CFH EHR Content TAG in other work (such as term co-ordination). It has proved possible to capture and display the mappings, and to generate correct XSLT translations in both directions from the mappings.

The mapping framework used for these tests includes a tool previously developed for mapping any non-HL7 V3 data format onto HL7 V3 (this framework has previously been used as the basis of the HL7 V2-V3 mapping tool).
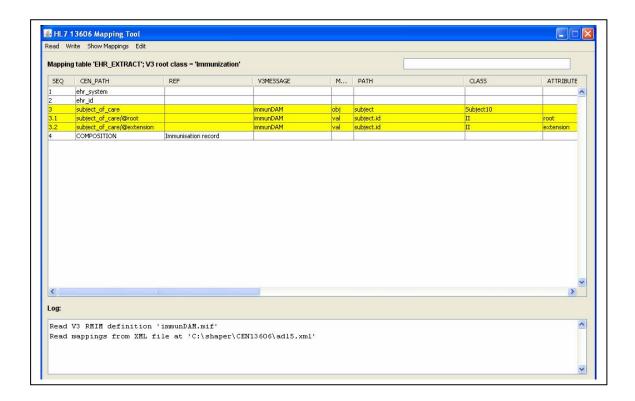
Most approaches to mapping and translation between different data representations (such as XML instances) use an approach of structure-to-structure mapping, and then attempt to create automatic translations based on these mappings. For instance, the Microsoft BizTalk Mapper and many other commercial mapping tools work in this way. However, the *raison d'etre* of translating instances between different structures is to preserve and carry across the semantics of the instances. A basic weakness of the structure-mapping approach is that mapping structures to structures does not convey enough about the semantics of the instances (e.g. how the structures represent associations in the semantic model), and so any automatic translation based only on structure-to-structure mapping is expected to be weak. If the semantics are not captured in the mappings, translations based on the mappings will tend to lose the semantics. Generally such translations have to be supplemented by large amounts of hand-crafted XSLT or other code.

The approach used here does not use structure-to-structure mapping of EN/ISO 13606 to HL7. Instead, it maps both structures onto a common semantic model, and generates translations (XSLT) from the semantic mappings. Wherever the semantics of both structures can be mapped onto the model, the translation will not lose or distort any semantics. Equally, where one structure maps onto a semantic feature but the other does not, the translation is bound to lose information – in a way which can be anticipated from the mappings, but follows from the limitations of the structures, not of the mapping method.

There are several possible semantic models onto which the structures can be mapped. For this demonstration, we mapped the two structures (EN/ISO 13606 and HL7) onto the HL7-based semantic model. However, we believe that similar results could have been obtained by mapping the structures onto any other adequate semantic model, such as a logical record architecture for the NHS. The need to map many different data structures onto one common semantic model emphasises the importance of having a single primary interoperability framework, which provides the semantic model.

The mapping tool first captures the structure of a non-HL7 V3 data instance (in this case, EN/ISO 13606 with constraints specified as one or more *open*EHR archetypes represented in Archetype Definition Language or ADL), and can then display that structure in tabular form. Archetype nodes are identified by their archetype id, and there is one table per archetype. The tool captures the structure of the HL7 V3 instance mapping target, from a HL7 Model Interchange Format (MIF) Version 1.0 file.

It is then possible to map any node in the EN/ISO 13606 structure to any node in the HL7 V3 semantic model by making one menu selection per mapping. The menus navigate the HL7 V3 class model structure. An example of these mappings is shown in the screenshot below.

Here the rows of one table are the descendants of one node in the EN/ISO 13606 structure (in this case, its root node). Some of these nodes (the yellow rows) are mapped to nodes of the HL7 V3 class model structure; the content of the row defines which HL7 V3 node is mapped to the row. Therefore the mappings are captured in a tabular form which can be viewed either in the mapping tool or in a browser (as XML, with a stylesheet that gives a tabular view of the mappings)

The mappings are then output to another tool which automatically converts them into XSLT to translate the instances in either direction. Through this mechanism one of the objectives of the project (automatic translation between EN/ISO 13606 and HL7 V3) has been demonstrated, albeit in a very simple case which does not yet embody many of the practical difficulties which are expected to occur in more complex examples. However, addressing those difficulties is not constrained by the toolset, and it is hoped to carry out further tests to explore the nature of those challenges.

The example instances, the XML form of the mappings (with a stylesheet for tabular display in a browser) and the XSLT translations are available as a separate downloadable file [20].

6 Summary of results

Results from this investigation are summarised in terms of general findings, specific issues encountered, and conclusions related to the project objectives.

6.1 An overview of findings

It was found that all of the clinical data in the HL7 CDA R2 instance examples could be represented within the EN/ISO 13606 reference model. A reference to an illustrative extract of the examples is given in Appendix A.

It was found that mapping user interface specifications and application interoperability specifications that had been independently authored for the same purpose resulted in a loss of precision that could be avoided with a more holistic design approach. The models had often adopted different nomenclature, different fine grained structures, different levels of precision and different bindings to terminology to represent clinically-equivalent record entries. The differences are attributable to independent decisions made on the part of the model designers.

At times, a particular convention or business rule was defined in order to ensure that both examples (and any future examples) would be mapped consistently. These conventions include:

- The elimination of association names from XML paths to avoid excessive containment hierarchies within the data (Note: there are two places in the EN/ISO 13606 reference model where this convention is insufficient, in each case because two associations exist between a pair of classes, and additional work is needed to ratify a suitable approach to defining the relevant paths)

- The use of the EN/ISO 13606 name and meaning attributes in the case of data conforming to archetypes (i.e. in situations where an archetype identifier is present)

- The extension of the *open*EHR archetype identifier by its internal path in order to provide the EN/ISO 13606 archetype identifier to record components internal to an archetype root node

- The use of the EN/ISO 13606 attested view property to represent the rendered text of a HL7 CDA R2 document.

A summary of these business rules is given in Appendix B. It is recommended that further work be undertaken to validate these business rules, after which they should be published to optimise the interoperability of future transformation activities. Implementable transformations, e.g. as XSLT, would further reduce the risk of error or inconsistent mapping.

When considering Level 3 transformation, some differences in modelling approach were identified. These modelling issues include:

- A difficulty in finding an appropriate EN/ISO 13606 mapping target for the HL7 CDA Encompassing Encounter class

- The convention to use an internal path syntax for classes below the level of Entry to meet the requirement in EN/ISO 13606 for every Record Component down to the Element node to have a unique instance identifier for which no corresponding requirement or instance values existed in the HL7-based instance representations or in *open*EHR instances

- Differences in the approach of labelling successive versions of a Clinical Document or Record Component, which questions the utility of the CDA increment number in a distributed computing environment

- Mapping the individual properties (and value domains) of the EN/ISO 13606 Functional Role class, which corresponds most closely to the HL7 Participation class

- A difficulty in finding an appropriate EN/ISO 13606 mapping target for the HL7 CDA Document Custodian

- The inability of the EN/ISO 13606 demographics package to support the identification of a healthcare party acting in a specific role, if that party can assume more than one role within the scope of a single EHR Extract.

A detailed description of these modelling issues is given in Appendix C. Recommendations as to how these differences can be addressed are provided in Section 7.

6.2 Conclusions in relation to the project objectives

This section describes general conclusions with respect to transformability, based on the findings described above.

6.2.1 Is a bi-directional automated transform possible between NHS models based on *open*EHR and HL7 CDA R2 specifications?

It was found that bi-directional transformation between the *open*EHR and HL7 V3 clinical model formalisms is only possible if there are some guidelines on modelling approaches, and harmonisation of categorisations required by the respective frameworks.

It was seen that the independent authoring of clinical models for the same purpose in *open*EHR and HL7 V3 structures, as in the case of the discharge summary, did not result in directly equivalent representations.

Therefore, it is not reasonable to expect that an automated transformation between *open*EHR and HL7 CDA R2 profiles would be possible without coordination in the model design process. There are recommendations in this report which address how coordination in the model design process could be achieved.

6.2.2 Is a useful bi-directional XML transform generally possible between content defined using EN/ISO 13606 and HL7 V3?

It was seen that while the formalisms are functionally consistent, there is a need to harmonise the categorisations (HL7 act specialisations, and HL7 structural codes with the EN/ISO 13606 part 3 term lists and equivalent vocabularies in *open*EHR) required by the modelling frameworks, and to establish mechanisms for co-ordinating the model design process if bi-directional transforms are to be produced without substantial manual effort, and some loss of machine readability in the content.

While such transformations are useful as ways to express the relationship between the specifications, the need for such transformations in implementations should be minimised by establishing a single framework for clinical model development across all specifications.

Direct support for more than one independently maintained framework introduces both a mapping cost and the risks that inconsistencies will be introduced as the frameworks evolve.

7   Summary of Recommendations

This section includes recommendations for changes, directed to different specifications developers, as well as recommendations to NHS CFH about model design guidelines development.

7.1   Recommendations for specifications changes

7.1.1   Recommendations for NHS CFH

Note that a bidirectional transformation of clinical model content between HL7 CDA R2 and EN/ISO 13606 formalisms is possible within a framework of business rules and agreed categories. If and when there is a commitment by HL7, CEN and ISO to maintain the specifications within such a framework, such mappings may be relied upon to be stable over time.

Note that those parts of the mapping process defined through the study examples were capable of being represented within a conversion tool and of being replicated in an automated way, using XSLT.

Adopt a single interoperability framework for the specification of user interfaces and application interoperability. As part of defining that framework, a decision needs to be made between the following alternatives that could provide the prime underpinning of the information model:

- HL7 V3 clinical statement, and CDA R2
- EN/ISO 13606
- *open*EHR
- A locally defined and maintained hybrid committed to be consistent with two or more of these
- An independently defined and maintained framework

It is beyond the scope of this study to recommend what should be used, or to establish the criteria and method to be used to reach a decision. However, the choice of which information model to use as a basis for the interoperability framework needs to take into account controlling the cost and ease of implementation and of the reuse of content models within and beyond the NHS, as well the cost of creating and maintaining those specifications.

If the use of a single framework is not possible immediately then further work should be done to elaborate the details of the transformation as a formal and complete mapping. This should be done through additional examples and a generic complete walk-through of the models. Further work should also elaborate and validate the initial set of business rules identified by this report.

Develop requirements capture, specification and governance processes to maximise the consistency of knowledge artefacts (including but not limited to data structure

content models and their terminology bindings) as these will be developed by different clinical groups across the NHS.

Endorse the approach of defining business rules for the consistent use of properties within any interoperability reference model used. These would need to take into account a closely related NHS CFH process that is defining business rules for the binding of SNOMED CT to clinical models.)

Communicate the set of defined business rules to the relevant SDOs, their Joint Interoperability Council, and to the *open*EHR Foundation, and to encourage these bodies to undertake a wider scrutiny and authoritative publication of such business rules to facilitate better-harmonised interoperability.

Endorse the initial set of modelling issues identified in this report and act to deal with those that fall within the remit of NHS CFH.

Foster efforts through HL7, CEN, ISO, the Joint HL7/ISO/CEN Interoperability Council, the *open*EHR Foundation and NHS CFH system suppliers towards a future convergence pathway for an information architecture for EHR interoperability, including reference models, content modelling formalisms, service specifications and implementation specifications.

Detailed technical recommendations are documented in Appendix C. The key items are summarised here.

- Datatype flavors should be used to constrain the complex ISO datatypes, and support for this should be added to the tooling used to define clinical models

- The NHS' intended use of encompassingEncounter in CDA should be clarified.

- The NHS should review the way that sections are included in CDA mark-up.

- The NHS should clarify the requirements for and implementation of document version identifiers.

- The HL7 templateId should be used to convey the document static model, as is done in balloted implementation guides.

7.1.2 Recommendations for the joint HL7/ISO/CEN initiative

Consistent Clinical Content

It is recommended that a joint HL7/ISO/CEN project be established (with resource support from organisations such as NHS CFH) to agree a set of common clinical models and associated terminology bindings with a similar scope to the templates defined in the HL7 Continuity of Care Document and the NHS CFH MIM. This work should be done together with other national initiatives. Establishing a common approach would dramatically reduce the costs and risks for those organisations committed to the use of these clinical models. This process, however, will take some time to deliver and so needs to be undertaken in parallel with the establishment and use of a national framework for clinical specifications.

Clinically Relevant Constraint Mechanism

Building on the earlier work and the recommendations for a unified NHS approach to content modelling, establish a common approach to machine- and human-readable

expressions of a clinical constraint view of information models, and promote the use of such a view for detailed clinical models developed at NHS CFH, HL7 and CEN.

Structural classification alignment

The structural classifications (i.e. value sets for non-clinical attributes within each model) used in HL7 V3 and EN/ISO 13606 are under-documented and inconsistent. Detailed work should be done to analyse why the differences exist, and to see whether a single value set can be established for each distinct model property, for future adoption.

Reference Model Alignment

Upon completion of the above recommendations, it is anticipated that the material will be available to resolve any remaining differences in the reference models. The value to the purchasers, suppliers, and users of having a single infrastructure underpinning NHS, CEN, HL7 and ISO specifications for healthcare data should be enough to drive through demands for a single approach.

7.1.3   Recommendations for HL7 CDA development

The use of encompassingEncounter should be clarified, so that it can be used in a consistent manner. A set of examples should be maintained for a range of documents created in different clinical settings.

CDA should be structured so that the rendering is separated from the coded entries, so that the CDA mark-up is extended to include SECTION. This extended mark-up is included in the ISO datatypes document.

Provide implementation guidance on the use of document.versionNumber.

The linking between the narrative block text and the entries be enhanced so that the identifier of the entry can be embedded in the narrative, or the use of globally unique identifiers be encouraged where the narrative block is likely to form part of a wider EHR architecture, and not simply exist in the context of an isolated document.

A proposal for the way that originalText can be conveyed alongside a reference to the rendering of an entry in the CDA narrative be developed. This may have impact on CDA R3 and/or ISO datatypes.

7.1.4   Recommendations for EN/ISO 13606 development

Provide guidance on how CDA-style text mark-up should be represented, with a combination of attested views and Entries, and how the links between the two should be asserted. This would promote consistency across EN/ISO 13606 implementations.

FUNCTIONAL_ROLE/performer should be a reference to a role rather than an entity (person or organisation).

association names should be singular. The association from EHR_EXTRACT to COMPOSITION should be called "composition" not "all_compositions" since that later is not a suitable name for each instance of the association.

7.1.5   Recommendations for *open*EHR specifications development

*open*EHR tooling for archetypes should in future support the optional use of an agreed set of specialisations of the ISO data types.

The valuesets for attributes that are not exposed for constraint in the archetypes should be defined in a document that is directly referenced by the reference model.

Distinguish between "User Interface" archetypes and templates (which have nodes that correspond directly to slots on a form or report) and interoperability archetypes and templates (which have nodes that correspond to a commonly agreed granularity). Whether this distinction is not made or not, a mechanism is needed for establishing equivalence between nodes that express a common meaning in different contexts and different granularities.

7.2 Inputs towards NHS CFH model design guidelines and tooling development

7.2.1 Reference Model and datatypes

Many properties of the underlying EHR reference model are not considered during the development of the archetypes, where the analyst is limited by current *open*EHR tools to expressing constraints on only the clinically relevant part of the model. However, assumptions are also made about the other properties of the underlying reference model, and it does not make sense to use a different model to underpin the expression of user interfaces from that used in application-to-application information exchange specifications.

It is recommended that the same reference model and datatypes be used for interoperability and user interface specification.

Note that this is not recommending that all EHR implementations have to use this reference model and set of datatypes. There are sound engineering reasons why EHR systems may choose to use their own reference structures.

In the short term, a consistent approach could be achieved by using manually mapped archetypes as described in the next section.

If different reference models and datatypes are to be considered for use then it is recommended that further work be done to establish the business case for this, and to establish management processes to ensure that inconsistencies are not introduced in the maintenance of these frameworks.

7.2.2 Adoption of the ISO datatypes

It is recommended that NHS CFH develop a plan for the adoption of the ISO datatypes within NHS CFH specifications. This should be a phased approach, with the pre-adoption of features that are required, followed by full adoption when appropriate. The adoption plan should address what criteria should be used by future NHS CFH projects when choosing which datatypes specification to support. It should also address whether NHS CFH will actively monitor or promote the wider use of the specification. A constrained sub-set of the full datatype specification is likely to be sufficient for EHR data, and NHS CFH is recommended to facilitate the development of this.

7.2.3 Harmonised archetype and MIM development

It is recommended that the benefit of being able to maintain and constrain the clinical knowledge component of the specifications be applied to the HL7 V3 specifications as well as to the *open*EHR user interface specifications. It was noted that the

practice of only exposing some parts of the reference model for constraint and review in the *open*EHR templates improves the accessibility of the specifications. It is recommended that this approach be explored for specifying HL7 V3 templates. This is similar to a process for developing form designs using Clinical Statement Flavours as described in [17] and [18], and to the tabular data item specifications work done by William Goossen [14].

It is recommended that a set of base archetypes be defined that represent the clinically relevant content of the current NHS CFH MIM templates. The meaning of the information in these archetypes will need to be exactly the same as the definitions for them in the NHS CFH MIM, and it needs to be assumed that the MIM datatypes and datatype flavors are being used in the definitions.

In order to support the development of specifications for screens and outputs that are more granular than the single code phrase in a document or message clinical statement specification, it is recommended that a constraint editor tool be built that allows detailed archetypes to be defined, at a suitable granularity for user interface design. Tooling would include a terminology server to guide the constraint author to the facets of the code phrase that could usefully be separately displayed, collected, or constrained. Tooling would also include a mapping between the base archetype and the more granular archetype being created.

A Transform example artefacts

The source and target instances for the discharge summary mappings are available at [20].

B Details of transform demonstration tool

Examples of the automated transformation work is available at [19].

C Detailed technical analysis

C.1 Mapping issues

C.1.1 Coded data and Text

In the template definitions there was some confusion as to whether the *open*EHR datatype TEXT was for recording free text data only (as implied by the user interface view in the Ocean Informatics tool), or could also be used for recording coded data. The *open*EHR datatype specification allows for codes or text, but the tooling interface makes it look like text only is permitted. Once the definition of DV_TEXT was looked at, it is clear that it has facets that need not be supported for this use case, such as formatting and hyperlink. It also provides for any number of code mappings for the textual data and the ability to specify a different encoding.

It is noted that the template used openEHR-EHR-OBSERVATION.placeholder.v1 for the clinical finding, rather than openEHR-EHR-OBSERVATION.finding.v1draft which defines a more structured way to represent findings, including bindings to SNOMED codes. It may be that this was not available at the time that the template was authored. These reference valueset defining ELEMENT archetypes, that do constrain the valueset, but that do not put any further constraints on the expressivity of the *open*EHR DV_TEXT datatype.

NHS CFH has previously established the need to tightly constrain the datatypes so as to reduce the cost of testing and implementation during the development of the MIM specifications,and it is recommended that similar levels of constraint would be valuable in the screen definition.

There is a risk associated with defining different sets of constraints on common datatypes, and reusing these constraints. Even without authoring local constraints, there are differences in the permitted values for strings between *open*EHR and HL7 V3. The DV_TEXT value attribute is constrained so as not to include carriage returns or line feeds, but the equivalent attribute in HL7 V3 and the NHS CFH MIM (CD.displayName or CD.originalText) does not have this constraint. This sort of inconsistency is likely to cause confusion and incompatibility, although this specific example inconsistency is understood to be in the process of resolution.

Given that the constraints on the datatypes are critical in the gathering of requirements, it would be useful to have a set of reusable constrained datatypes supported in the requirements-gathering tooling and documentation to avoid this sort of uncertainty.

RECOMMENDATION (NHS CFH, *open*EHR, CEN, HL7): The set of datatype flavor names being proposed in the ISO datatypes be used to express the most refined possible datatype in the model. This is particularly recommended for the datatypes that include codes, translations, or enumerations such as CD, TEXT, PQ, and ED. The possibility of defining some further named constraints to cover the NHS CFH business rules over which coding systems may be sent as translations should also be considered. There may then be further constraints expressed in narrative or machine readable constraint languages, and the realisation of the named flavors may be different in different underlying datatype specifications, but this approach will allow the clinical models to be consistently interpreted across technologies.

RECOMMENDATION (NHS CFH, *open*EHR, CEN, HL7): A constrained sub-set of the ISO data types be defined that meet the requirements for the representation of EHR data values, the clinical model tooling be modified so that this subset be directly supported. and those developing and reviewing requirements be encouraged to check that the datatypes are constrained to only allow the required information items.

C.1.2 Encompassing Encounter

ISSUE: What is the difference between the encompassing encounter and the composition? Is there any guidance in when the identifier from each should be used? Can the encompassingEncounter have a broader scope than the document (such as being the inpatient spell for an operation note?)?

ISSUE: Does the session.time come from the encompassing encounter?

These concrete questions are related to the diversity of usage of the words "encounter" and "episode" in the NHS and healthcare more generally.

RECOMMENDATION (NHS CFH) The MIM maintenance team should consider extending the CDA Implementation guide [4] in section 15 to state that for any document that is to be used to populate an EHR, the document should be taken to be a description of the full encompassing Encounter. In particular the encompassingEncounter.effectivetime should be taken to be the time span that the document describes. Thus an operation note should have the operation as the encompassing encounter, and a discharge note should have the full hospital stay as the encompassing encounter.

RECOMMENDATION (NHS CFH and HL7): The use of encompassingEncounter should be clarified, so that it can be used in a consistent manner. A set of examples should be maintained for a range of documents created in different clinical settings.

C.1.3 Attested view / CDA Body

There are a significant number of information items in the NHS CFH section mark-up that classify sections of the markup (templateId, contentId), and HL7 structural codes on component and section. In developing the transformation it was not clear whether these added any value and if they should be preserved in the EN/ISO 13606 attested view.

There is a requirement to provide an identifier for each section in the markup in the MIM message, and it is not clear what these identifiers should be used for.   It is possible that they are included for consistency with other HL7 organiser classes that do need to be identified. If this is the case then identifiers could be generated as part of a transformation process and need not be retained by the sending or receiving

systems.   Alternatively it may be that the identifiers are to be supported as a way to reference sections alongside or instead of using a path notation.

For consistency these have all been removed in the EN/ISO 13606 example attested view, with the mark-up following the pattern of that used in the example in the HL7 CDA specification document.

The component/section pair includes an extra layer of nesting that would not be needed if the section tag was part of the rendering mark-up, rather than HL7 Reference Information Model (RIM) mark-up that allows for the inclusion of embedded entries within the section.

RECOMMENDATION (NHS CFH): The additional mark-up in the NHS CFH example is deprecated, so that the XML is easier to read and use. Were the classifying markup and section identifiers are retained the intended use for the classifications and identifiers should be described to assist with maintenance of the specifications, and with design of the applications (including transformations) that implement the specifications.

RECOMMENDATION (HL7): CDA be structured so that the rendering is separated from the coded entries, so that the CDA mark-up is extended to include SECTION. This extended mark-up is included in the ISO datatypes document so that it is available for easy use in the CEN specification.

RECOMMENDATION (13606): Provide guidance on how CDA-style text mark-up should be represented, with a combination of attested views and Entries, and how the links between the two should be asserted. This would promote consistency across 13606 implementations

C.1.4 ClinicalDocument.versionNumber

EN/ISO 13606 intentionally does not support an integer version number. If the NHS requires this, then a change request will need to be submitted to CEN and ISO. Sequential version numbering is challenging to maintain in a distributed environment, whereas maintaining a list of setId values, with one for each previous version of the document allows common history of different revisions of a document or extract to be established.

RECOMMENDATION (NHS CFH): Clarify the requirement for integer version number alongside the version set identifier. Submit specification for its use in a distributed environment and any relevant change proposals if this does remain a requirement.

RECOMMENDATION (HL7): Provide implementation guidance on the use of document.versionNumber.

C.1.5 Functional role and ClinicalDocument.Author

The functional role class contains a function code, and a performer, but does not provide for a scoping party for the function.   If the demographic package as provided with EN/ISO 13606 is used, then the performer would be a reference to a person, rather than to a person playing a role in the context of an organisation, which is typically what is required.

The function attribute is optional, and EN/ISO 13606 part 3 does not provide a term list for it, so it is unclear how this attribute would be used.

EN/ISO 13606 FUNCTIONAL_ROLE appears to be the equivalent to the participation class in HL7, with the FUNCTIONAL_ROLE.function attribute determining the function of the FUNCTIONAL_ROLE.performer in this specific composition. In particular since FUNCTIONAL_ROLE does not carry an identifier it is not suited for conveying an identifiable role, which is performed by the performer under the authority of a specific organisation.

While *open*EHR does support the participation of both entities and roles, the codes for role and participation types is not defined in the reference model, and are not constrained by the archetype, but these would need to be specified and maintained if the openEHR reference modle were to be used.

RECOMMENDATION (CEN): FUNCTIONAL_ROLE/performer should be a reference to a role rather than an entity (person or organisation).

RECOMMENDATION (NHS CFH): Where SDS identifiers cannot be used for FUNCTIONAL_ROLE/performer, the EN/ISO 13606 demographics package should not be used to model performers, but these should be modelled as roles.

RECOMMENDATION (*open*EHR): Where coded values are permitted in attributes of the reference model that are not constrained by the archetypes and templates, there should be a document that is the equivalent of EN/ISO 13606 part 3, defining the vocabularies to be used.

C.1.6 ClinicalDocument.custodian

The custodian of a CDA document is responsible for maintaining the integrity of the update process (see separate discussion on versionNumber). The EN/ISO 13606 model does not have the concept of an information custodian, with the business rules governing stewardship being addressed elsewhere.   The closest mapping for this would be found in 13606 part 5 that addresses the exchange of EN/ISO 13606 record extracts.

C.1.7 RECORD_COMPONENT/name and RECORD_COMPONENT/meaning

In EN/ISO 13606 the name and meaning properties serve similar purposes, the former to be a local label for the node (provided by the exporting system) and the latter to be the systematised (interoperable) label - for example the archetype node label, or a SNOMED CT code to which the node itself is mapped (as opposed to its value). The meaning attribute is optional, and in particular might be omitted if an archetype_id value is supplied. The *open*EHR approach is to only allow the archetypeId in the instance, with the "meaning" being made available in the archetype definition.

This use of the name and meaning is complicated in situations where an Element name and its data_value are represented in combination as a single SNOMED CT Concept. This issue has been documented in the Terminfo DSTU, since it is equivalent to the actCode and actValue combination problem: a similar business rule approach is recommended for the use of ISO/EN13606 in these situations.

C.1.8 Many archetype elements to one SNOMED Expression

The approach described here assumes that there is a 1-1 mapping from EN/ISO 13606 record components to HL7 clinical statements. Given the similarity that exists in the models and in the purposes for which they are intended, this is reasonable.

However it is clear from the terminology binding work that there are numerous occasions where combinations of record components in the archetypes that have been created to express clinical requirements correspond to a single SNOMED expression.

This happens where the code for the leaf record component is dependant upon parent nodes. In this case the granularity of the mapping is not affected, and it may make sense to preserve the containing Record Components as Organisers in the clinical statement model.

However when a SNOMED term is created by combining information that is expressed in two sibling nodes in the requirements archetype, it may make sense to provide a mapping to an "interoperability archetype" that has a clean 1-1 mapping to the Clinical Statement model as used with Terminfo rules.

User interface clinical models (templates) need to have data points that correspond to each field on a document, report, or data entry form, whereas for interoperability archetypes need to have a set of coherent and attributable Record Units (Clinical Statements or Record Components) that correspond in granularity to that of the terminology in use.

RECOMMENDATION (NHS CFH): Distinguish between user interface templates that may be more unrolled than interoperability archetypes.

C.1.9 Many archetype elements to one act class

In the finding archetype there are separate elements for "FindingCode", "FindingValue", and "InterpretationCode".   In the MIM template these all share a common GUID identifier as a single act. In the EN/ISO 13606 standard it is required that they have separate rc_id values, expressed using the II datatype.

Given that there is an rc_id on the Entry, it seems reasonable that using the entry.rc_id and then a path expression to the component of the entry can indirectly identify these components. This avoids the excessive use of II (and therefore of ISO OIDs), and means that unique OIDs are created and used within HL7 V3 and EN/ISO 13606 only for corresponding class nodes. The creation of "synthetic" IIs purely for mapping conformance purposes are therefore avoided.

C.1.10 OriginalText references as URL fragment identifiers

In the context of HL7 CDA where there is only a single rendering included in the document using fragment identifiers (references starting with "#") is fine. However as soon as the documents are combined into a larger document, or there are multiple renderings provided for a set of statements, this form of referencing breaks down.

RECOMMENDATION (HL7): The linking between the narrative block text and the entries be enhanced so that the identifier of the entry can be embedded in the narrative, or the use of globally unique identifiers be encouraged where the narrative block is likely to form part of a wider EHR architecture, and not simply exist in the context of an isolated document.

C.1.11 Entry mappings

The entry mappings did not fit into the archetypes used in the *open*EHR template, since these were free-text placeholders for treatment and findings, and the statements in the CDA document included codes.

The detailed content modelled in the archetype for discharge summary was not appropriate for the example provided in the MIM.

Since all of the content of the *open*EHR template was optional there was not a problem of not having particular data values. However it would have been a frustratingly large screen to scroll through if used as a user interface specification.

C.1.12 Medication mapping issues

There are substantial issues around mapping the medication items, and this is something to be addressed in the next version of this document. These appear primarily to be due to differences in the clinical content models obtained from the source formalism authors rather than a difference in the capability of each formalism to represent the example's data content.

There was no place for medication code in the archetype

The entry in the MIM example does not have the ability to represent structured dosage instructions; these can only be represented in the narrative block (I suspect that this is an error in the example).

The example contained drug dosage as a text string, and there was no slot for this in the archetype. (Some legacy systems will only have records of drug doses in an unstructured form, so this is a reasonable requirement).

RECOMMENDATION (NHS CFH): Review medication archetypes against MIM to validate them.

C.2 Observations on CDA example

C.2.1 Clinical and Technical validity

The text in section 7.1 of the MIM states that the examples have been technically and clinically validated. The comment in the examples contradicts this. One or other assertion should be corrected.

C.2.2 SchemaLocation

There is a schemaLocation attribute in the example on the ClinicalDocument node. While this is useful when creating examples using XML tools, and may be useful to some of those viewing the example, schemaLocations should not be included in production instances, and so a comment should be added to indicate this

RECOMMENDATION (NHS CFH): Add a comment to all examples stating that he schemaLocation should not be included in production implementations

C.2.3 Npfitlc:messageType

This is used to convey the document type. In the HL7 balloted implementation guides (e.g. [1], [3]) this information is conveyed using ClinicalDocument/templateId

RECOMMENDATION (NHS CFH): templateId be used to convey the document static model, as is done in balloted implementation guides. Alternatively the CDA Implementation document [4] should be updated to explain that this attribute is equivalent to ClinicalDocument/templateId in HL7 approved implementation guides.

C.2.4 displayName and originalText

The guidance in section 12 of [4] states that displayName should be used to convey the text from the picklist shown to the user. DisplayName is intended as a means to convey the text associated with the code in the code system, rather than specifically the text that was presented to the user, which may have been locally authored. This is made clear in the documentation for datatypes R2 [5]. While this was not stated clearly in the datatypes R1 specification [6], it is stated that the primary purpose for using displayName is to support debugging of messages (not for conveying text that is clinically useful). Where the originalText seen by the user needs to be transferred this should be done in originalText. Since originalText is used to convey the reference to the part of the CDA narrative that is used to convey the statement there is an issue that needs to be resolved

RECOMMENDATION (HL7): A proposal for the way that originalText can be conveyed alongside a reference to the rendering of an entry in the CDA narrative be developed. This may have impact on CDA R3 and/or ISO datatypes.

C.2.5 CREtype categorisation

This requirement to be able to categorise entries is a generic one, that is currently addressed in a number of different ways in HL7 models.

While the requirement to categorise is generic, the reasons for requiring categorisation information in communication instances vary, and are not always made explicit. HL7, CEN and *open*EHR all have categorisations built into the reference models directly, or through structural vocabularies, that overlap with the functions of the NHS CFH CRE types.

RECOMMENDATION (HL7): This approach to categorisation be promoted within HL7 and a single solution to representing categories be included in the core properties of HL7 V3 models document that is being drafted for HL7 ballot [8].

RECOMMENDATION (NHS CFH, HL7, CEN, *open*EHR): Categorisations of information are a significant barrier to interoperability of data. Currently the specifications do not have a consistent set of categories, nor do the requirements for categorisation across the different specifications fit into a consistent framework. It is recommended that a focused piece of harmonisation work look at what categorisations are used and why, and propose a detailed set of changes.

C.2.6 13606 XML serialisation issues

In order to provide example instances for the 13606/*open*EHR templates it was necessary to establish a set of rules for the XML representation of the instances.

This ITS (Implementation Technology Specification) has been devised for the purpose of example instances only. While the ITS has not been separately documented, this section of the report discusses issues encountered while choosing the XML representation.

C.2.7 Association names

Association names have not been used in the EN/ISO 13606 instance. The class name has been used for the XML element name. For most classes this is not an issue, since there is only a single relationship between any two classes. However

FUNCTIONAL_ROLE can be either a "composer" or "other_participants" in the context of a COMPOSITION.

The alternative of using the association name would have obscured the SECTION/ENTRY/CLUSTER/ELEMENT hierarchy, but would be consistent with the ITS used by *open*EHR [16]

RECOMMENDATION (CEN, ISO): association names should be singular. The association from EHR_EXTRACT to COMPOSITION should be called "composition" not "all_compositions" since that later is not a suitable name for each instance of the association.

C.2.8 Tree structures

It is not clear how to name the nodes within Entries. Using the Class or association name in the reference model as has been done in this case is the most generic approach, and is ideally suited to processing based on the reference model. If implementations are to process based on the archetypes, then it may be simpler to use the names provided in the archetype for the XML element names.

D References

[1] HL7 Implementation Guide for CDA Release 2: Healthcare Associated Infection Reports, Release 1
http://www.hl7.org/documentcenter/ballots/2008JAN/downloads/CDAR2_IG_HAIRPT_R1_D2_2007JAN.zip

[2] CCD draft
http://www.hl7.org/documentcenter/ballots/2007JAN/downloads/CDAR2_IMPL_CCD_I2_2007JAN.zip

[3] CCD (final) http://www.hl7.org/library/General/HL7_CCD_final.zip

[4] NPFIT-FNT-TO-DPM-0737   NPFIT-ELIBR-AREL-P1R2-0178 Technical Guidance for Implementation of Templated CDA Domains v1.1 dated 3/12/07

[5] http://www.hl7.org/v3ballot/html/infrastructure/datatypes_r2/datatypes_r2.htm#dt-CD

[6] http://www.hl7.org/v3ballot/html/infrastructure/datatypes/datatypes.htm#dt-CD

[7] MIM 7.1.0
http://www.hl7.org.uk/repository/version.asp?sectionid=229&documentId=613&versionId=705&version=1

[8] http://informatics.mayo.edu/wiki/index.php/Core_Properties_of_V3_Models

[9] EhrExtract Walkthrough v0.1 (www reference needed)

[10] *open*EHR discharge letter template used to define target content for the mapping. http://www.openehr.org/svn/knowledge/TAGS/dev-uk-nhs/Lorenzo_3.5/pub/ContentRelease-3.1.0/templates/gen/html/ENTDischarge.v3.html and http://www.openehr.org/svn/knowledge/TAGS/dev-uk-nhs/Lorenzo_3.5/pub/ContentRelease-3.1.0/templates/xml/openehr/ehr/composition/ENTDischarge.v3.oet

[11] Example of Discharge Letter CDA document POCD_MT150001UK06 for "Mary" taken from the NHS CFH MIM [12]

[12] 7.1.0 NHS CFH MIM (Message Implementation Manual) http://www.hl7.org.uk/repository/version.asp?sectionid=229&documentid=613&versionid=705&version=1

[13] CDA Release 2 specification http://www.hl7.org/v3ballot/html/infrastructure/cda/cda.htm

[14] William Goossen Presentation http://www.hl7.org/library/committees/patientcare/GoossenPatientCare%26ClinicalSIGsgroups3May2007%2Epdf

[15] http://www.openehr.org/svn/specification/TAGS/Release-1.0.1/publishing/architecture/am/archetype_principles.pdf

[16] http://www.openehr.org/releases/1.0.1/its/XML-schema/index.html

[17] http://www.ramseysystems.co.uk/rsMIFeditor/rsMIFeditor_ppt.zip [18] http://www.ramseysystems.co.uk/dmsp/DMSPTechnicalReportv0r1.doc

[19] http://www.ehr.chime.ucl.ac.uk/download/attachments/3375121/WobertWordenTAGInputs.zip

[20] http://www.ehr.chime.ucl.ac.uk/download/attachments/3375121/hl713606TAGFeb2008examples.zip