	Investigating implementing CEN 13606 with HL7 V3 and SNOMED CT			
NHS Connecting for Health	**Programme**	NPFIT	**Document Record ID Key**	
	Sub-Prog / Project	Technology Office	<Insert Document Record ID Key>	
	Prog. Director	P. Jones	Status	Final
	Owner	K. Lunn	Version	1.0
	Author	L. Sato	Version Date	2006-12-20

Investigating implementing CEN 13606 with HL7 V3 and SNOMED CT – Final Report

Amendment History:

Version	Date	Amendment History
0.1	2006-12-01	First draft for project team comment
0.2	2006-12-11	Draft for project review group comment (edits from project team comments and further contributions and revisions from investigation leads)
0.3	2006-12-18	Edit suggestions received from D. Kalra, C. McCay, J. Whatling, M. Shafarman, J. Cox, C. Flashman, R. Smithies; additional content from L. Sato.
1.0	2006-12-20	Edits suggested by R. Dixon and based on Project Board discussion.

Approvals:

This document must be approved by the following:

Name	Title / Responsibility	Date Approved	Version
K. Lunn	Head, Data Standards & Products and Communications & Messaging	2006-12-20	1.0
M. Severs	Chair, Information Standards Board	2006-12-20	1.0
J. Thorp	Director, Business Requirements	2006-12-20	1.0

Distribution:

Internal to NHS CFH, to those participating in the project, and to relevant standards communities.

Contents

1 Project background

1.1 Programme context

This project was sponsored by the NHS CFH Communications & Messaging (C&M) and Data Services & Products (DS&P) departments, the NHS Information Standards Board (ISB) and the NHS Care Record Service (CRS). Key motivators for this project included:

- The progression of the 13606 standard in European[1] and ISO standards approvals

- Interest expressed in implementing the 13606 standard (and/or related *open*EHR specifications) by other home countries within the UK and by some key NHS NPfIT suppliers[2]

- Difficulties to date in establishing an NHS CFH approach for defining, validating and approving detailed clinical information models (to a greater potential clinical detail than standard HL7 V3 models provide[3]) and/or a common record architecture to provide mechanisms to support NHS-wide clinical semantic interoperability.

1.2 Objectives

The objective was to evaluate the feasibility of adopting CEN 13606 within NHS NPfIT in terms of its utility in:

- Expressing clinical information business requirements for electronic communications

- Producing and maintaining a common record architecture[4] to facilitate the safe, unambiguous recording, viewing and communication of current and planned care between both human and machine users. This includes:

  o Providing the record structures and safe communication that enables the Care Pathway driven distributed care envisioned by the NHS NPfIT.

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[1] The NHS is required by European regulation to adopt CEN [Comité Européen de Normalisation] standards.

[2] By coincidence, a British Computer Society report, *The Way Forward for NHS Health Informatics* (15 December 2006) recommended that 13606/*open*EHR specifications be used as "starting points" for establishing a patient record architecture and the representation of content, "especially clinical content".

[3] This would often correspond to model detail at the level of HL7 V3 Templates, the modelling technique for which is still under development at HL7. As a matter of policy, models that highly constrain clinical expression are not standardised internationally by HL7.

[4] "Common record architecture" meaning a model which is capable of recording the clinical process as exemplified by history taking, examination, diagnosis/formulation and planning next steps, together with documentation of any communications about this care process. Such a model must enable the unambiguous recording and communication of the care process between human and machine agents.

- o Providing the record structures with consistent unambiguous semantics common to all implementations which enable the provision of consistent Decision Support as required by NHS NPfIT, and also improve quality of data for secondary use purposes.

- Producing and maintaining common machine representations and approaches for processing grammatically constrained clinical phrases that can be realised in the current and planned NHS NPFIT architecture

While not primary objectives for the project, communicating the results is expected to achieve secondary benefits with respect to international standards development. For example, a summary of evaluation results from this project should be influential in upcoming UK votes related to 13606 as it progresses through the European and ISO standards approval processes. In addition, international indications suggest that NHS CFH input would be welcomed in the context of new initiatives related to 'harmonising' the CEN/ISO 13606 standards in development with HL7 Version 3.

1.3 Scope

Key project deliverables:

- An evaluation of CEN 13606 from key potential NHS CFH use perspectives

- Recommendations for how NHS CFH could adopt CEN 13606

- A summary of high-level change recommendations for CEN 13606, SNOMED CT, and HL7 V3

1.4 Exclusions

This project was not intended to investigate all alternatives to CEN 13606, but was focused on assessing the feasibility of adopting this developing European standard in the NHS NPfIT environment.

Although the project recognises issues related to the 'governability' of CEN 13606 artefacts, it is out of scope for it to recommend a specific potential governance structure and process for NHS adoption.

Given its limitations in time and other resources, this project has identified issues that are recommended for further NHS CFH investigation.

1.5 Evaluation focus

This project focused on evaluating the potential NHS use of the following parts of CEN/ISO 13606:

- 13606-1 – Reference model

- 13606-2 – Archetype interchange specification

The terms "archetype" and "reference model" are used throughout this report. As a key feature of 13606, an **archetype** is described in 13606-1 as "a formal expression of a distinct, domain-level concept, expressed in the form of constraints on data whose instances conform to the reference model". 13606-1 describes the **reference**

model as representing "the global characteristics of health record components, how they are aggregated, and the context of information required to meet ethical, legal and provenance requirements".

Note: Although potentially relevant to some of the findings of this brief study, time was not available to evaluate aspects of 13606-3 (Reference archetypes and term lists) in detail.

A short glossary of terms may be found in Appendix A.

1.6 Evaluation approach

Within this short-term project[5], a number of small-scale evaluation exercises were conducted. In summary, the exercises were as follows:

- Conduct a 13606 archetype design workshop with clinicians, business analysts and message modellers, using the *open*EHR Archetype Editor to create test artefacts based on clinician input, as well as NHS specifications from the Data Dictionary and the Message Implementation Manual. Example related archetypes from the *open*EHR Foundation were also reviewed. (*led by D. Kalra, UCL*)

- Analyse and identify the issues related to implementing archetypes at a national scale for the purposes of expressing shared clinical information requirements and / or a logical clinical record architecture. (*led by L. Sato, NHS CFH*)

- Map the concepts expressed in the test archetypes to SNOMED CT terms. (*led by E. Cheetham, NHS CFH*)

- Analyse and identify issues related to potentially interoperating between archetypes and HL7 Version 3 (*led by C. McCay, Ramsey Systems, with key input from G. Grieve, Jiva Medical*)

- Map the test archetypes to an existing local logical data model (*led by L. Pelley, BT*)

- Analyse the potential for archetypes to support the design of common user interfaces (*led by J. Whatling and N. Jones, BT*)

2 Summary of findings

This section describes the main findings from the evaluation exercises and links them with general NHS requirements.

2.1 Expressing clinical communication business requirements

NHS CFH currently defines communication business requirements in the form of UML (Unified Modelling Language) models representing participants, interactions

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[5] The evaluation period for the project lasted one month (Nov. 2006), and all project team members were part-time.

and information classes. To date, UML's support for the expression of re-usable and detailed clinical information requirements (including complex constraints on clinical expression) is unproven. It has also been historically difficult, given the available formalisms and documentation formats, to support detailed reviews and discussions between business analysts and clinicians and/or clinical terminologists to refine and validate the requirements models, particularly at a distance. Thus, NHS CFH has a requirement that is not currently being met for a machine formalism that will support both clinician and clinical terminologist engagement in defining detailed semantic models that are easy to understand, easy to provide detailed comments upon, and are appropriately generic for re-use across many NHS IT projects.

Issues and general requirements from a standards interoperability perspective (with respect to archetypes as expressions of business requirements that are 'passed on' to the HL7 messaging technology) are discussed in Section 2.2.2.

2.1.1 Archetypes design method and current tooling

CEN/ISO 13606-2 defines a method for constructing 'archetypes' as re-usable information constraint patterns (e.g. for recorded allergy information) on a given reference model. CEN/ISO 13606-1 provides a reference model deemed suitable for personal health record structures (i.e. as organising features within a logical clinical record).

13606 has not been widely implemented. The *open*EHR Foundation has pioneered much of the standard's content, including developing the constraint formalism, Archetype Definition Language (ADL). Some of *open*EHR's current formalisms differ significantly from 13606, particularly with respect to extensions in the reference model, changes to the data types, and extensions to the archetype design method.

For the purposes of this investigation, these key technical differences were noted prior to reviewing archetype outputs from the *open*EHR tools (designed within a test group) and before giving project team members an opportunity to independently experiment with them.

Key findings:

Human-level communication

- Clinicians and information modellers in the project team generally found reading, discussing and designing archetypes relatively straightforward. The terms used in the 13606 and *open*EHR reference models are accessible and easily mapped to general clinical recording practice.

Consistency and mechanisms for re-use

- Neither 13606 nor *open*EHR currently provides detailed rules or guidance for designing archetypes. As the basic archetypes design method does not provide 'built-in' quality assurance or semantic consistency checks, current practice relies mainly on the clinical and logical modelling knowledge of individual designers.

- General and flexible (as to detail) mechanisms to support indexing and re-using archetypes are provided within 13606-2.

The reference model

- As noted above, the 13606 reference model is easily understood by clinicians in the context of high-level structures (e.g. sections) related to recording clinical data.

- In the construction of clinical archetypes, the key difference between the *open*EHR and 13606 reference models is that *open*EHR includes sub-classes for (record) Entry (e.g. Observation, Evaluation). Casual use of the available Archetypes Editor seemed to indicate that some types of data may be ambiguous whether they are, for instance, observations or evaluations. While a rigorous technique for disambiguating these classifications given a particular 'edge' case may be available within *open*EHR research or modelling, it was not immediately clear or intuitive to the project team how to differentiate between these Entry sub-classes at all times.

  - Similar issues related to the difficulties in rigorously categorising clinical information have been identified and addressed to some extent in other health informatics standards, notably the SNOMED CT (SCT) Concept Model and the ISO TS 22789 (Conceptual framework for patient findings and problems in terminologies). An exploration into using the SCT Concept Model as a basic semantic framework to define reference archetypes is described in Section 2.3.1.1.)

Semantic richness

- Current archetypes design practice relies on semantic models known implicitly within individual designers or review groups. The generic structures within 13606 are capable of expressing varying levels of detail within an individual archetype, but the depth and breadth of this semantic detail is completely dictated by the archetype authors. The formalism does not in itself provide strong support for semantic linkages across archetypes.[6]

- It is currently not possible to reference clinical evidence or other information at the archetype 'node' (element) level.

The constraint formalism

- Although not tested within this project, the ADL constraint formalism is reported to technically support NHS business requirements. Some of the more complex constraints expressions (e.g. for conditional and correlational constraints on values) are available, but have not been implemented and may require some tools modification for easier use.

- It should be noted that current *open*EHR tools allow for XML expressions of archetypes, in addition to output in the ADL format.

Tooling

- No tooling currently exists for implementing the CEN 13606 reference model, although *open*EHR tools have implemented a reference model that is

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[6] It should be noted that this type of semantic weakness is a general characteristic of reference information models, and not peculiar to CEN 13606 or *open*EHR.

extended from 13606 and have also implemented the constraint language, ADL.[7]

- Different *open*EHR Archetypes editors should be reviewed (e.g. in addition to the Ocean Informatics Archetypes Editor, a Java-based archetypes editor has been developed in Sweden and is capable of importing and exporting archetypes in different formats, e.g. in XML).

- Within CEN, the strategic direction of travel is currently towards harmonising with *open*EHR and HL7 V3 data types (within the auspices of an ISO work item). Given this, it may be pragmatic from a standards conformance perspective to use the *open*EHR data types currently implemented within the *open*EHR archetype design tools. Further discussion on data types may be found in Section 2.2.2.1.

- It is also reported that *open*EHR tools may be extended to output in XMI (i.e. readable to UML-based tools), although some information loss in the translation towards a UML graphic is likely. Translating to UML may be desirable only in the context of allowing a graphical reference to, and summary depiction of, an archetype within a larger business requirements model.

2.1.2 Considerations for implementing at a national scale

Although 13606 formalisms may be applied to non-clinical types of health record data, it is likely that any archetypes for NHS-wide use, at least initially, should focus on clinical data. Providing high-level structures for clinical data modelling is 13606's strength, particularly in terms of clinician and potential clinical terminologist engagement.

As noted above, it is not technically difficult to produce archetypes; the challenge of archetypes is in creating consistent, non-overlapping, and intelligently inter-linked models. Methods to date suggest that the 'coherence' within an archetype repository is maintained through the efforts and skills of individual archetype designers. It is likely that better support methods (for both human and machine inspection) will be needed in order for a national repository to avoid semantic redundancies and conflicts. One validation mechanism may be to semantically map archetypes against existing clinical information models (such as those reviewed and approved by the HL7 V3 community) and/or existing clinical semantic frameworks. Developing more rigorous technical methods for providing some level of quality assurance in archetypes design is a current work item of the *open*EHR Clinical Review Board and with collaborating universities. Some related issues and possible options for further exploration are discussed in Section 2.3.1.

Should the potential of archetypes for re-use across different IT implementation projects be realised, the benefit to the NHS in terms of reducing redundant effort and potentially conflicting clinical information requirements specification and modelling should be significant. Semantic coherence across NHS information specifications would enable suppliers to develop systems that support more than one national data

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[7] Communications with an *open*EHR tools developer indicates that adapting *open*EHR tools to support particular aspects of 13606 may be relatively easily done.

specification at the same time. Also, reducing the design effort in documenting clinical information requirements models is particularly important given the relatively scarce resources of clinician and clinical terminologist expertise available per NHS IT project.

National considerations such as distribution and governance are discussed in Section 2.3.1.4.

2.1.3 Summary of strengths and weaknesses

Potential benefits for using CEN 13606 to record and communicate clinical information requirements include:

- A reference model based on common concepts related to record structures (sections, entries, etc.) that clinicians generally find intuitively simple to understand and use.

- Open source tools available that have at least partially adopted CEN 13606.

- Tabular output that may be adapted to document detailed mapping findings (to terminologies or other data models) and queries/answers about archetypes design.

Current weaknesses include:

- The 13606 reference model cannot in itself provide a full basis for semantic interoperability. For stronger semantic integrity, it will need to function in association with a model that provides structures for detailed clinical semantics and the formalism may need to be extended to more strongly support 'inter-node' (cross concept) linkage. Issues related to associating a clinical conceptual framework with 13606 are further explored in Section 2.3.1.1.

Further development is required for tools (and tools specifications) that support:

- Implementing the 13606 reference model

- Providing graphical views of archetypes (ideally compatible with UML-based tools, for interoperability with other UML-based business requirements modelling – even if such interoperability may be limited in terms of the depth of information translated, this may be useful to refer to archetypes within larger business requirements modelling).

- An extended ADL formalism (or to augment it with another formalism) to enable more complex machine-interpretable constraints expression[8].

2.2 13606 interoperability with SCT and HL7 V3

NHS CFH is currently committed to implementing various international interoperability standards within NHS NPfIT. The ones with most potential technical overlap with CEN 13606 are SNOMED CT (SCT) and HL7 Version 3 (V3).

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[8] Informal communication indicates that ADL already supports complex conditional constraints, but it is unclear how well current tooling supports the use of these extensions.

From a practical perspective, adopting 13606 would depend on its amenability for interoperating within the same architecture as SCT and HL7 V3.

2.2.1 SCT mapping

Most observations made during this review could be applicable to the terminology component of any clinical requirements gathering and detailed representation method.

Summary impressions:

- For requirements management, the archetype approach is superior to tabular, paper-based (e.g. MS Word) representations.

- For representation of an ultimate technical solution, the current archetype approach risks concentrating solutions on the 'models of use' that were in the minds of the developers. Support for 'reference/semantic archetypes' and 'implementation archetypes' may help manage the differentiation between core meaning and usage patterns.

- Clear agreement on the semantic contribution of each archetype and/or the terminology it references must be agreed for meaningful analysis

- Many of the problems identified in the context of terminology binding are present in any technical solution, not specifically the archetype-based approach.

2.2.1.1 Requirements elicitation, capture, and negotiation

As a general impression, the discipline of capturing and negotiating vocabulary requirements in the available archetype development tools was useful[9].

The test approach of 'late' binding first draft archetypes to SNOMED CT (i.e. a clinical terminology specialist received value sets enumerated or in narrative form in the draft archetype and was asked to map to SCT) performed similarly to previous tabular requirements for the first iteration, but did allow (with some document customisation) more fruitful dialogue and negotiation – in particular, a clear framework for referencing different conceptual elements.

The discipline of value set identification (by the requirements engineers and clinical specialists) was broadly comparable to previous experience – perhaps improved by the enlightened nature of the participants and workshop leads.

A frequent problem with previous requirements gathering exercises within NHS NPfIT has been the identification of 'suitable' SNOMED CT content during the requirements engineering stage ('early binding'). A hazard of this is that such content will automatically be considered part of the solution, even if it is either drawn from inappropriate concept types in SNOMED CT, or includes nuances that would better be represented in either the information model or other terminology-coded elements. The approach taken in the project workshop was to blind the developers to existing

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[9] A comparison with the features of Enterprise Architect was not possible in the timescale of the project, but when compared with pure tabular documentation (with no indication of depth, nesting or dependency) the archetype approach faired favourably.

SNOMED CT content, which protected against this problem, but has some dis-benefits:

- Forcing developers to provide suitable terminology content 'de novo' (even if they had contributed to previous terminology development exercises that were now included in SNOMED CT).

- Preventing access to existing content which might provide cues to lexical conventions (which would need to be clarified at any rate upon terminological review).

A suggested option (not pursued in this exercise) was to make SNOMED CT available during the requirements gathering stage, on the understanding that content identified would not automatically be included in the solution. Using each archetype as a negotiation tool should allow this pattern of modification.

The structure of the 'ELEMENT & value' representation within each archetype had similarities with previous tabular representations of the message development 'W5s' and clinical dataset development projects. Each of these approaches risks reinforcing the 'data collection form' model of use representation – the main problem of which is compounding the arbitrary terminology split between what is represented in the 'prompt' and what is represented in the 'value' (in part the HL7-discussed 'code/value' debate).

2.2.1.2 Semantic distribution

The requirements archetype analysis and negotiation performed within this study highlighted a number of important issues regarding both 'what' semantics were expressed in the archetype and, if present, 'where' the semantics would be represented.

'What' semantics - Implicit and explicit representation

Detailed analysis of the 'allergy' archetype revealed that there was no automatic terminology representation of the 'allergy' notion[10] – this was stated in the name of the archetype but not repeated in the suggested terminology-coded elements.

'Where' semantics – terminology and information model overlap

Detailed analysis of the 'allergy' archetype revealed several elements that specified concepts that were (according to the SNOMED CT concept model and post-coordination rules) natural properties of other SNOMED CT concepts (for example the 'severity of a reaction' is a property of the reaction). Risks and benefits of a post-coordinated documentation approach are explored below. It is perhaps a reflection of the differences between the 13606 and HL7 V3 reference models that very little overlap was encountered between the SNOMED CT model and the 13606 model, whilst it is recognised (and being addressed by the TermInfo work) that there are many points of overlap between SNOMED CT and the HL7 V3 RIM.

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[10] This may be a limitation of tools knowledge rather than of the archetyping method. (e.g. A different 'pane' [than that used for other term bindings] within the Ocean Informatics Archetype Editor allows binding a term to an archetype 'root' concept.)

2.2.1.3 Analytical substrate

Re-stating the observation that the notion of 'allergy' was not terminologically explicit in the first test draft 'allergy' archetype, there was some concern that the archetypes themselves would provide a proportion of the semantics (in order to test for the presence of an allergy in a record one would need to identify the 'allergy archetype', e.g. through its name and identifier, in a given implementation). Reworking the allergy example was relatively straightforward, but ensuring all relevant semantics are in an appropriate form could be a potentially complex 'standardisation' stage of archetype development.

2.2.1.4 Models of use v. model of meaning

The principle of supporting both 'semantic brokerage' and 'in-use design' is explored elsewhere in this report. It is reasonable to say that as currently conceived, 13606 archetypes do not automatically support or manage the distinction between these differing requirements, but it is equally fair to say that a development approach that could produce suites of archetypes (addressing these differing perspectives on each domain in an integrated fashion) could be achieved.

2.2.1.5 Legacy data problems

A well recognised problem in the construction of detailed clinical models is the tension between 'greenfield' specifications (that can constrain all future instances regardless of earlier solutions) and 'brownfield' specifications (where previous representations have to be considered). Whilst not a primary design intention, archetypes may be able to specify alternative representations for the same information, which could then support both the creation of new instances (conformant with a preferred representation) and old instances (based, perhaps, on sub-optimal representations). If complex uni- or bi-directional mappings are required (to support other forms of legacy management) then archetypes would not, on their own, provide a mechanism for their support.

2.2.1.6 Pre and post-coordinated expressions

Much concern has been expressed regarding aspects of SNOMED Clinical Terms (SCT) post-coordination. Some of this concern is well-founded, but must be managed with any compositional terminology.

It is a reasonable criticism of the SCT product that no mechanism is provided for instructing qualifier or refinement cardinalities. Expanding pre-coordinated (into post-coordinated) properties within the structure of an archetype would provide access to suitable constraint machinery, but is only a partial solution. Note, for instance, that if the elements of a SCT post-coordinated expression are distributed in this way, the SCT mechanisms for equivalence detection (expression normalisation and comparison) cannot be easily invoked.

Two complementary approaches can be usefully applied to address this issue:

- SCT developers are in process to provide a machine-readable formalism for the distribution of both general concept model constraints and more specific value set constraints.

- Consider an approach that supports archetype-based constraint specifications (which if directly implemented would result in base post-coordinated expressions), along with rules for transforming or coercing the expression thus created into a SCT-conformant post-coordinated expression. This latter object could then be more easily normalised and analysed.

2.2.2 HL7 V3 mapping

13606 is a standard for expressing EHR extracts, which is part of the scope of the HL7 V3 Patient Care, Clinical Document Architecture (CDA) and Clinical Statement Pattern developing standards. The standards and the tools that support them have been developed in different ways, with the focus for HL7 being on achieving consensus amongst healthcare informaticians, and the focus for 13606 being to provide an environment for gathering and responding to clinician requirements.

Despite this difference of focus, there are substantial similarities in the methodology and structures defined in each of these standards.

2.2.2.1 Data Types Harmonization between HL7 V3 and CEN 13606

CEN 13606 and HL7 V3 are both based on reference models. These are simple object-orientated information structures where the attributes of the models use a set of predefined specifications known as data types. The data types are a set of information structures that include and build upon generally defined data types such as Booleans, Numbers and Strings to provide a richer set of data types suitable for use in healthcare systems.

Work arising out of a revision to the UML rendition of the HL7 V3 data types has suggested that there is a new prospect for progress in data types standards convergence, and both CEN and ISO are currently receptive to considering the HL7 V3 UML ITS data types (in progress and developed with *open*EHR data types as a key input) as a basis for a common set of data types.

2.2.2.2 Mapping difficulties

During the investigation, mappings to and from 13606 instances were attempted. A number of issues were identified when 13606 was used to define information items without regard to the requirement to be able to express the information items in an HL7 V3 environment

Meaning implied by sibling and containment structures – Within 13606 entries, clinical information is expressed using list and tree structures, the meaning of which is determined by the archetype identified for that entry.   When mapping to HL7 V3 (or any implementation architecture) the relationships need to be mapped to the corresponding relationships in the target information model. Whether or not all plausible archetype expressions may be mapped to HL7 V3 is disputed and requires further investigation. It has been suggested that the challenge is mainly in making explicit the structural attributes and relationships that are implicit within archetypes, to support HL7 V3 mapping.

The value of HL7 V3 static models – Many HL7 V3 static models represent significant domain expert knowledge. The consensus reached and actively maintained over the appropriate clinical information items to exchange in HL7 V3 messaging and

documents is a valuable resource that would not be used if 13606 archetypes modelling was entirely uninformed by V3 models.

Consistency – Without some governance and consistency management, the use of the 13606 reference model and archetypes would not provide a scalable approach. The use of stable reference archetypes that are then constrained to express particular requirements should provide stability for implementations, and could be done in a way that was consistent with appropriate HL7 V3 information structures.

2.2.2.3 13606-HL7 V3 model mapping approach

In 'waterfall mapping', requirements models using 13606 would be passed to message modellers to create the appropriate HL7 V3 structures. This would mimic the sequential approach to requirements and message modelling currently used within NHS CFH. One of the lessons learned from using this approach to date is that it is sometimes difficult to reconcile business/clinical with messaging and terminology 'requirements' within one information structure. Another lesson learned is that it is difficult to engage clinicians and clinical terminologists appropriately within this process, given limited expert resources available to a number of concurrent NHS IT projects. As some negotiation across these major interests and types of expertise will always be required, it is recommended that the formalisms of 13606, SCT and HL7 V3 be harmonised as much as possible within the requirements modelling (i.e. at the outset of the design process).

Recommendation

It is recommended that if 13606 is to be adopted by NHS CFH, the possibility of constraining either or both 13606 and HL7 V3 within the NHS should be explored as a way to optimise translations between them. Such constraints could be defined in a set of high-level archetypes. For instance, a set of archetypes could be identified that are equivalent to the clinical statement models as used in HL7 Clinical Document Architecture (with the informal extensions identified by IHE that are required to track more recent developments to the HL7 V3 Clinical Statement). It is also recommended that an iterative design approach is taken for the design of all archetypes, including those representing any top-level constraints against 13606 and HL7 V3.

2.3 Building a common logical record architecture

Logical models define the entities, attributes, key groups, rules, relationships, and definitions of the information of interest, structured to suit particular business requirements.

It is important to note the scope of 13606, which focuses on the communication of Electronic Health Record (EHR) extracts of information. This information, given the traditional users of EHRs, primarily focuses on information of clinical interest and needs also to support other requirements of patient records, including those that are medico-legal in nature.

Within the context of the NHS NPfIT information architecture, EHR extracts of clinical (or medico-legal) interest form a component of a larger business information scope. Although much progress has been made in defining methods and formalisms to

describe clinical semantics, no strict formalism or wide-spread process for clinical record 'content' modelling has been applied within NHS NPfIT to date.

NHS operational requirements for a common logical record architecture include:

- Support for patient safety (in terms of the reliability, validity and consistency of information interpretation)

- Support for the Common User Interface (in terms of provision of the distinctions that enable CUI views to be created and manipulated)

- A consistent way of realising archetypes using SNOMED CT and HL7 V3 to suit NHS NPfIT requirements (this topic is addressed in Section 2.2)

- Consistent and transparent querying for context specific view creation, decision support, electronic care pathway and secondary uses requirements

- Relationship with NHS NPfIT Care Record Elements

- Relationship with other national data models, including PDS and Directory of Services

- Availability of suitable tooling to support authoring and maintenance requirements

- Support for end-to-end semantic interoperability, including:

- Ease of mapping to existing local data stores, as well as to national specifications (i.e. as an interface specification)

2.3.1 Potential archetypes use

This investigation explored the potential use of archetypes with respect to building a clinical information model (to 'broker' semantics across various implementations or information uses), available tools, distribution and governance, a relationship to Care Record Elements, relating to a local logical data model, and designing common content for user interfaces.

2.3.1.1 Providing a 'model of meaning'

A key potential use of 13606 within the NHS is to assist in the design of a 'model of meaning' or 'semantic broker' applicable across various IT projects. In order to avoid structural cross-mapping problems 'downstream' from requirements expression, the analysis within this study suggests that the base semantic structures underlying NHS archetypes (and requirements modelling) should be machine-mappable to the 13606 reference model, the SCT Concept Model and the HL7 V3 EHR-related information models[11]. (For reference, the SCT Concept Model is copied in Appendix B.)

None of these models alone is sufficient in producing base models of clinical meaning that are semantically rich, rigorous and consistent while also being both human- and machine-readable in detail. It is possible that a combination, while not being 'perfect', may at least be an improvement compared with trying to reconcile three independent views of clinical information within individual IT projects.

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[11] From an HL7 V3 perspective, one suggestion is to focus archetypes on the same scope as V3's Clinical Statement Pattern expressions.

In theory, increasing the level of expression constraint within a 'reference' layer of archetypes (as part of the 'model of meaning') should increase the likelihood that any archetypes built from these reference archetypes are semantically interoperable. (It was noted that the test method of negotiating expression constraints with the two other interoperability models (SCT and V3) after designing archetypes based on the 13606 or *open*EHR reference models would not be scalable to a national level given the number of iterations and level of human effort required to make all necessary reconciliations.)

A potential archetypes hierarchy is as follows:

1. **Reference Archetypes** – Based on the 13606 Reference Model (and selected *open*EHR extensions), using the 13606 constraint language (ADL), and structured to align with the SCT concept model and the HL7 V3 Clinical Statement Pattern. These should provide basic concepts and conceptual relationships for the full scope of clinical information. Constraints at this level should target defining unambiguous categories and high-level attributes of clinical concepts. An alignment with the SCT concept model should facilitate mapping to SCT terms in the descendants of these archetypes.

2. **Primitive Archetypes** – Based on Reference Archetypes, these express enterprise-level business constraints as design patterns and organisational design policies (e.g. with respect to decisions related to the use of pre- or post-coordinated SCT terms or the use of the NHS number, etc.).

3. **Implementation Archetypes** – Based on Primitive Archetypes, these express project-level constraints or design patterns based on information use requirements (e.g. messaging, user interface design, storage format, etc.).

Resources to develop a national repository and to support a national governance process must also be in place (high-level requirements for these are discussed in Section 2.3.1.4.).

Both primitive and implementation archetypes must use the underlying national reference archetypes. Implementation archetypes should be registered nationally to encourage their re-use where applicable, but need not be strictly 'governed' by a central authority except to check that they conform with NHS primitives and the reference archetypes.

It is expected that, within a project or at the national level, archetypes will undergo an iterative design process influenced by inputs given potentially at all stages of design through implementation.

Preliminary attempts to create reference and other archetypes within the proposed hierarchy are described in Appendices C and D.

2.3.1.2 Models of Use

It has been suggested[12] that another potentially useful view of implementation archetypes would map them against three tiers of information system requirements:

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[12] M. Shafarman, email communication 2006-12-14.

1. Application – How information is captured and presented to users (e.g. clinicians).

2. Interoperability – How semantics are supported between applications (e.g. messaging).

3. Persistent storage – How clinical data is integrated from many sources (e.g. to support queries or national data collections).

While the first 'tier' (Applications) must achieve strong user (e.g. clinical) communication, the Interoperability and Persistent storage tiers can only support decision support and secondary uses with the computational ability to navigate across equivalent codes and coded expressions. Whether 'reference' or other archetypes can be defined to support such navigation needs to be further investigated.

Although it would need to be further tested, a possible archetypes hierarchy could be defined to reflect the SCT concept domains in the reference layer. For information, the 19 SCT concept domains or term hierarchies are: Clinical finding, Physical force, Procedure, Event, Observable entity, Environments/geographical locations, Body structure, Social context, Organism, Situation with explicit context, Substance, Staging and scales, Pharmaceutical / biologic product, Linkage concept, Specimen, Qualifier value, Special concept, Record artefact, and Physical object.

NHS 'primitive' archetypes should be based on the semantic reference archetypes and could be defined for any constraint pattern considered to be useful at an 'enterprise-wide' level. These may range from the expression of small (e.g. 'NHS number') to large constraint patterns (e.g. a nationally-defined shared clinical document).

A brief summary view of this archetypes hierarchy is in Figure 1.
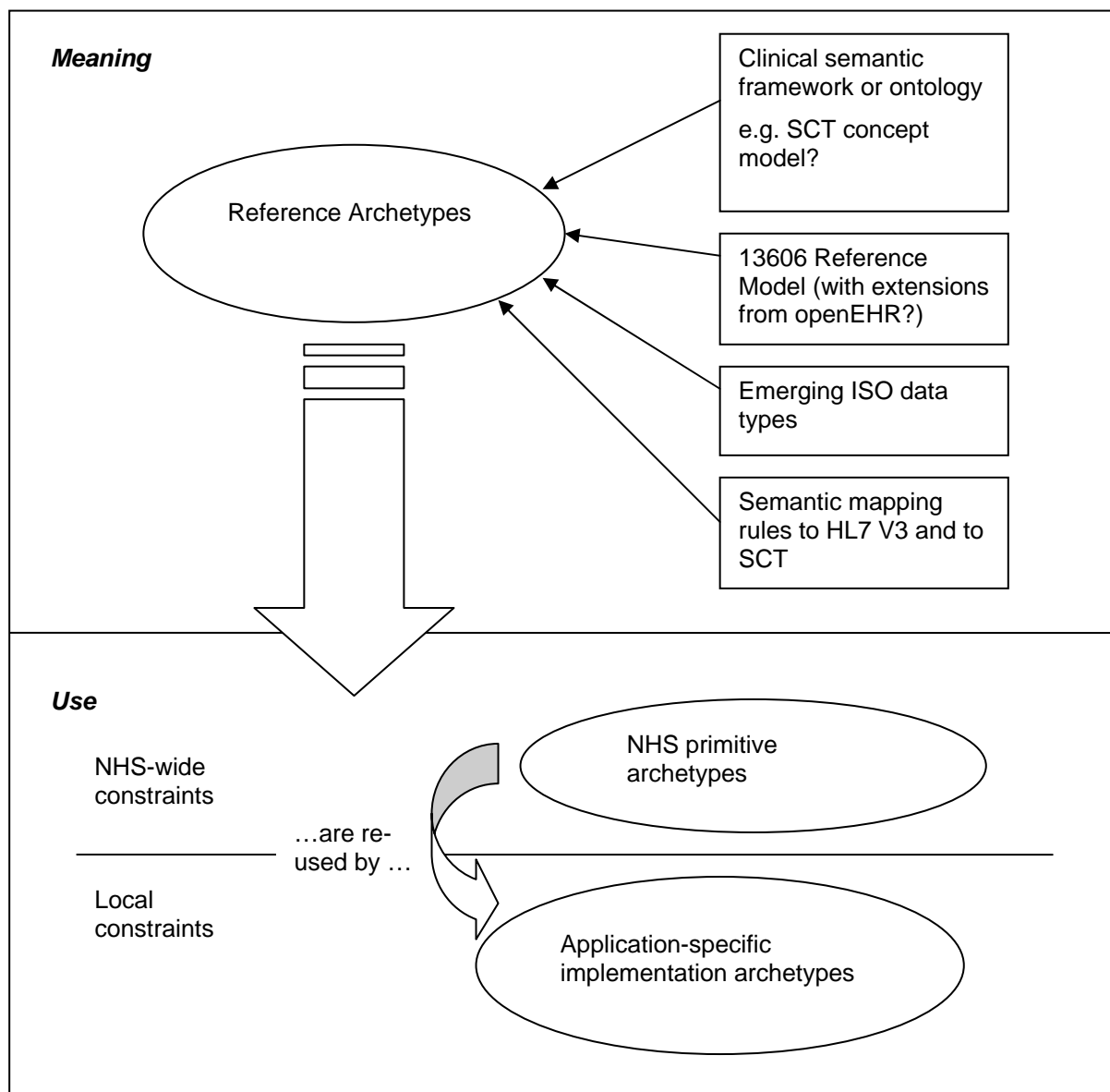
Figure 1. Summary view of a potential archetypes 'hierarchy'

Further investigation would be required to determine the specifics and decisions to enable (or decide against) an NHS CFH approach for:

- Using the SCT concept model (or other clinical semantic framework) in guiding the semantic structure of the highest level reference archetypes.

- HL7 V3 mappings (or additional information required within archetypes for automated mapping) at the Reference and Primitive levels.

- SCT term (or 'group' or 'place holder') bindings at all levels.

- Mappings to other national data specifications at the Reference and Primitive levels (e.g. Care Record Elements, NHS Data Dictionary).

2.3.1.3 Tooling

In addition to archetypes design tooling (discussed to some extent in Section 2.1), an archetypes repository suitable for supporting NHS-wide access, release control and configuration management would be required. This repository would also need to be capable of indexing flexibly and to multiple archetype meta data. A few related features of a national archetypes repository are described in Section 2.3.1.4.

Archetypes meta-data mandated and suggested in CEN 13606-2 are listed in Appendix E.

2.3.1.4 Governance, versioning and distribution

Should a hierarchy of archetypes like that described in Sections 2.3.1.1 and 2.3.1.2 prove to be useful and feasible, a governance process (at both the project and national levels) will be needed to control releases, negotiate between any conflicting views, and to provide general clinical and technical quality assurance for archetypes within the national repository.

It should be noted that release and versioning strategies for both the reference model and for individual archetypes will be needed at a national level.

A national archetypes repository should strictly control the release of approved reference and primitive archetypes, and should also publish project-level archetypes for optional re-use.

Governance

A national governance process will be needed to control releases of reference and primitive archetypes, negotiate between any conflicting technical views on their design, and provide general clinical, terminological and technical quality assurance for archetypes within the national repository.

This suggests that, at an NHS-wide level, the following types of groups would need to be in place to approve the national 'model of meaning' (NHS reference archetypes), as well as some NHS-wide models of 'use' (NHS primitives):

- A clinical review board, to validate archetypes against clinical semantics and recording practice.

- A technical architecture review board, to assure that reference and primitive archetypes are technically sound and rigorous and that they fit appropriately within the larger NHS information infrastructure. This board should also be responsible for approving the reference model, constraint formalism and data types used, as well as publishing technical policies and guidelines for designing NHS archetypes. This group should also be responsible for answering queries about the interpretation of reference and primitive archetypes to support mappings to local NHS data models[13].

- An archetypes administration board, to oversee the archetypes approvals process and to host a national repository, responsible for registering,

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[13] This requirement is briefly discussed in Section 2.3.1.7.

releasing, versioning and configuration managing NHS archetypes at all levels.

It should be noted that groups capable of acting in the roles suggested above may already be in place within the NHS and may be able to extend their current roles to cover archetypes-related responsibilities.

Versioning

Although not looked at in detail within this study, it is noted that archetypes publication will need to support a rigorous process for clearly marking allowed variants as well as successive versions of the same archetype.

A general governance approach for variants may hold both as 'draft' or 'informative' until implementation evidence supplies more guidance about which may be stronger as a 'standard' NHS archetype. Or, allowed variants may be associated with different terminologies on an ongoing basis.

It is also possible that archetype variants may include realisations of the same semantic archetype in different IT formalisms, e.g. as an HL7 V3 Template.

How changes in archetypes should be 'cascaded' technically to all NHS specifications 'depending' on that archetype will need to be addressed. This may mean that the NHS registry of archetypes also records data about national specifications or implementations that 'subscribe' to a given archetype. If an archetype changes, an automated alert to its subscriber stakeholders should be generated from the repository.

2.3.1.5 Relating to Care Record Elements

It is likely that archetypes may be mapped to NHS Care Record Elements (CREs) and this information may be included in the 'metadata' recorded in association with NHS archetypes.

The project did not fully investigate mapping archetypes concepts to NHS CREs, but a preliminary exercise indicated that mapping at the level of an archetype or an element cluster may be appropriate.

It is likely that CRE mapping information could be conveyed within the data associated with an archetype and available within an archetype registry.

2.3.1.6 Relating to other national data models

This project did not have the resources to investigate the possible relationship of archetypes with specific national data models.

2.3.1.7 Relating to local logical data models

An initial mapping between one test archetype and the BT healthcare logical data model indicated that most elements were relatively easily mapped, although some archetype concepts required further elaboration before a definitive mapping was possible.

It is likely that answering queries (e.g. from suppliers or from other NHS organisations) to facilitate mappings to local models will be a NHS (centralised) responsibility in order to support a consistent and wide-spread implementation of NHS archetypes.

2.3.1.8 Designing common content for user interfaces

Within this investigation, the archetype authoring tools seemed attractive to clinicians for expressing their requirements for data capture and sharing. The expression of these requirements, however, did not seem to be adequately constrained. Consequently, as was similarly observed in Section 2.1.1, it would be easy for illogical archetype authoring to take place.

The tools used during this evaluation did not enable an exploration of how archetypes could be linked together within an EHR Extract. Indeed, the purpose of this test was to evaluate the project archetypes and not EHR Extracts. As a further study, it would be valuable to explore an EHR Extract modelled on smaller, reusable, linked archetypes based on a single Entry to represent the adverse reaction or drug prescription archetypes as diagrammed in Figure 2.
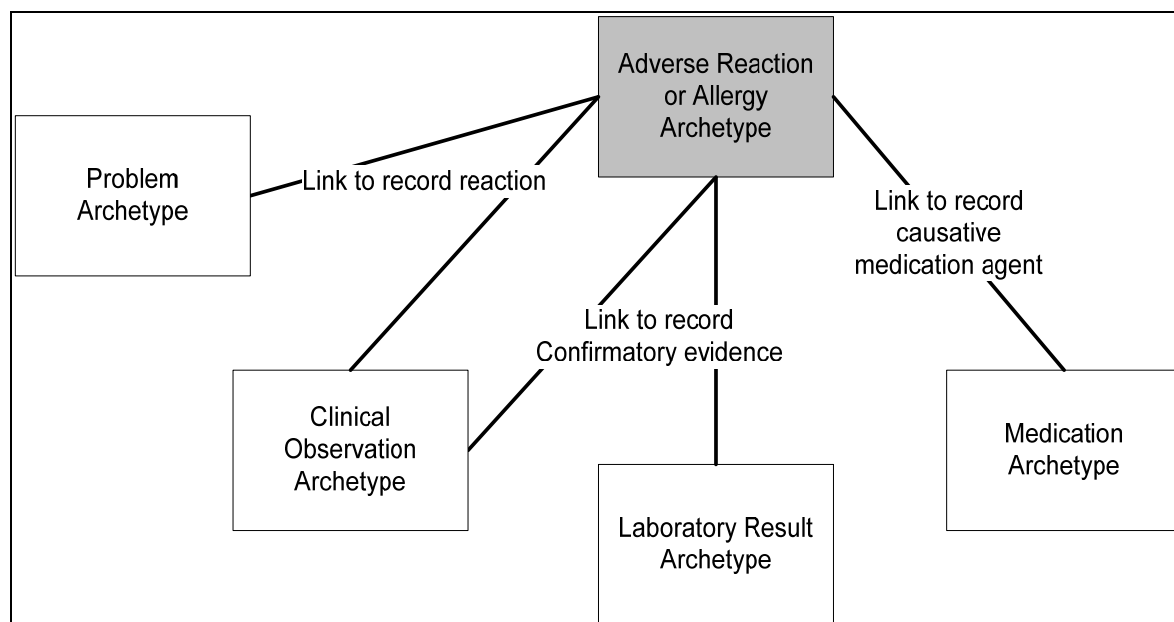
Figure 2. Example modelling of an EHR Extract with linked archetypes

Structuring the EHR Extract in such a way could have advantages for data extraction and storage in the recipient system and a downstream impact on presenting data back to the users or performing functions such as decision support. If the receiving application was a regional shared record it may want to store received data in a more relational way. In this scenario, all problems may be stored as data generated from the same storage archetypes rather than from compiling problems from different sources as 'clinical indications' in data captured using, for example, the medication archetype.

The investigators were confused by the apparent mixing of Observations, Evaluations, Actions and Instructions in the test archetypes. It seems intuitive that this should be avoided and could be resolved using the *open*EHR templating mechanism.

If the receiving system has no way of linking data received through the EHR Extract to any other data then the presentation of the data is limited to those Elements named in the authored Archetypes. However, if the EHR Extract contained smaller linked Archetypes then the application or user could choose what additional information they required at presentation. For example, we may assume that the clinician would only want to see the medication name and route of administration for a drug that caused an adverse reaction and then include those Elements in the Adverse Reaction archetype. However the clinician may have also wanted to see the dose that caused the reaction - the alternative EHR Extract structure could have enabled this. Additionally the link could be to an accompanying Archetype instance in the EHR Extract or could be to data store in the originating application. This is illustrated in Figure 3.
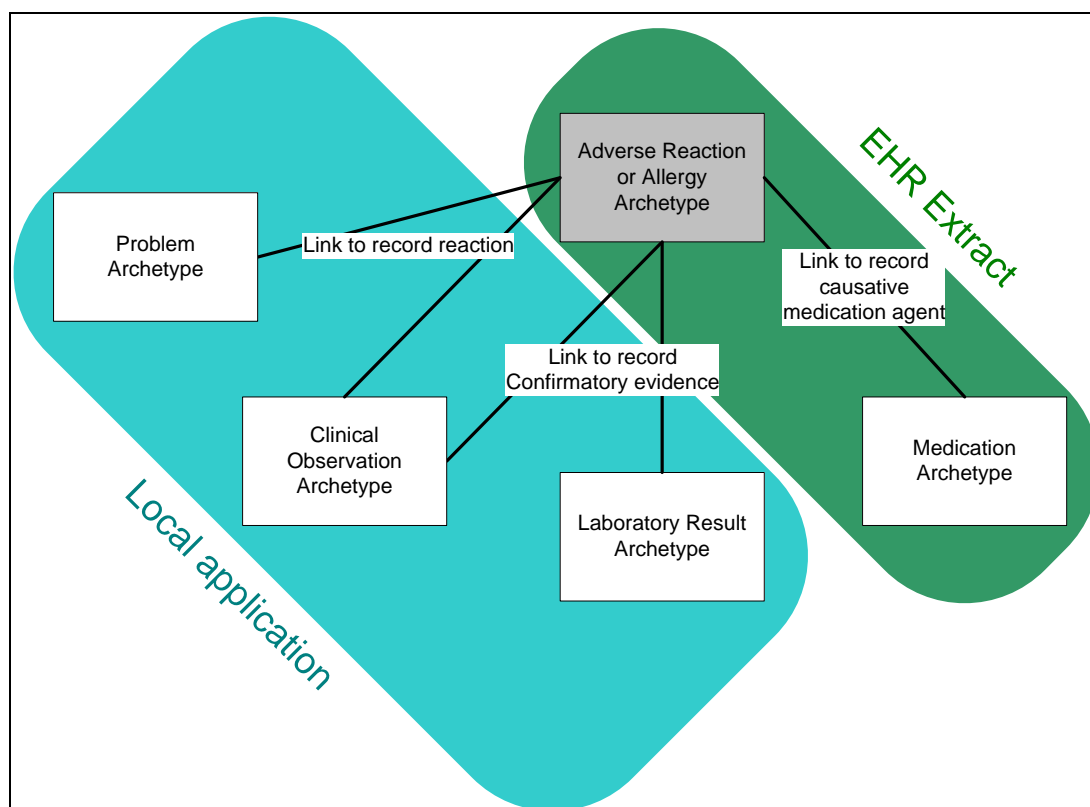
Figure 3. Linking a local archetype instance to the EHR Extract

The purpose of the EHR extract is an important consideration. Perhaps all-encompassing archetypes would work well if there was limited need for data exchange between systems and there was limited ability to align applications data models with that of the EHR Extract. If, however, the purpose is to transmit a major proportion of the patient's care then ideally data should be sent in linked archetype instances.

When representing information from an EPR, the composition structure is required and as such the evaluation should be performed on how this would be achieved using information collected in archetypes.

The issue around how to design the EHR Extract will need further discussion and exploration – perhaps by modelling alternative linked archetypes to represent the

currently authored archetypes. Currently *open*EHR does not provide tools to link items such as Elements and Archetypes together.

Given this, further exploration of the relationship between Entries, Archetype design and the structure of EHR extracts is recommended. Included in this exploration should be an assessment of how existing applications could populate such an EHR Extract and how a receiving system (another application or a Shared Record) could extract and reutilise data from that EHR Extract.

Other conclusions

If data captured using Archetypes is linked together in the EHR Extract then additional data pertaining to the link may need to be captured. Where this is the case, such data would need to be captured as Elements in one of the archetypes. Recording that a medication was indicated for a particular condition with the intention of being preventative, curative, or palliative could be an example of such additional data.

Links between archetypes may need to be constrained. For example, it may be desirable to constrain a medication's clinical indication to a medical problem or to a laboratory result, but not to an administrative note.

During the course of this test, several recommendations for additional Elements within each of the test archetypes were made and are documented in the full investigation report.

Due to the complexity of end-user interfaces needing to draw information together from data obtained from different EHR Extracts, sometimes from different systems, this test was limited in what it could say about the ability of archetypes to fulfil end-user presentation requirements.

The brief exploration of constructing EHR Extracts around smaller archetypes addressing single Entries makes a case that designing archetypes around a single Entry leads to increased reuse of archetypes for different purposes.

The relationship between clinical statements, which are attractive for data presentation, and the EHR Extract needs further exploration. It has been suggested that *open*EHR templates might persist for display purposes and thus could contain the clinical statements as links between items in these templates.

The mechanisms for suppressing Element data in some archetypes for the purposes of confidentiality were not considered here.

3   Key conclusions

Key conclusions are summarised as they relate to the three project objectives.

3.1   Expressing clinical information requirements

Strengths

- Clinicians and information modellers in the project team generally found reading, discussing and designing archetypes relatively straightforward.

- 13606 provides techniques for flexible and multiple indexing of archetypes.

- The 13606 constraint formalism (ADL) is reported to support all identified requirements for information constraints expression (this assertion was not tested within this project, however).

- While tools specific to 13606 do not exist, *open*EHR tools may be relatively easily adapted to conform to 13606 as needed (with limited NHS investment).

Weaknesses

- Neither CEN 13606 nor *open*EHR currently provides detailed rules or guidance for designing archetypes. This has serious implications at the national level with respect to the level of human effort required to assure consistent archetype designs at a high quality. This may be at least partially addressed by establishing a strict hierarchy of archetypes that inherit semantic and technical constraints from a limited set of archetypes. This limited 'top level' set should be designed with a clinical semantic framework and with the requirements for interoperating with other NHS technical standards in mind.

- The use of *open*EHR specialisations of ENTRY (Observation, Evaluation) were found to be useful at times, and confusing at others. This may be an issue of the lack of experience within the project team or the lack of accessible modelling guidelines, or it may be preferable to specialise *open*EHR's GENERIC ENTRY class (which is roughly equivalent to the 13606 ENTRY class) with specialisations left to reference archetypes for further testing (and relating to a comprehensive clinical semantic framework).

- Archetype node-level information (e.g. cross-linking nodes or referencing clinical evidence) is currently not supported by 13606 or *open*EHR.

- Tooling that supports ADL is limited and development is confined to a relatively small community of organisations within *open*EHR. The export of XML expressions of archetypes may allow ADL-based tools to interoperate with a wider set of tools, however. An automated translation to HL7 V3 structures (e.g. to the XML-based HL7 Modelling Interchange Format) may enable interoperation with the small set of existing HL7 V3 tools, but such translations await the convergence of data types and other technical rules for identifying 13606 / *open*EHR / HL7 V3 semantic equivalents.

Recommendations

- A NHS CFH project should be initiated to further test the use of the 13606 Reference Model, the Archetype Definition Language, and NHS-selected extensions from *open*EHR specifications using available (or minorly extended) archetype design tools. The use of *open*EHR data types should be acceptable, at least initially, as the emerging ISO data types work should include a migration path from *open*EHR (as a key contributor to current ISO data types development).

- The Lorenzo 3.5 and other interested NHS NPfIT application development projects (e.g. from BT and other suppliers) should be supported to define data capture and display information requirements in collaboration and accordance with parallel developments in NHS Reference and Primitive archetypes.

- Different *open*EHR Archetypes editors should be assessed for potential NHS CFH adoption and further development. Tools development recommendations include:
  - o Using the emerging ISO healthcare informatics data types. (This should improve the support for automated translations to HL7 V3.)
  - o Referencing a suitable semantic framework model (once / if one has been assessed to be suitable).
  - o Outputting in XMI such that the NHS CFH-preferred business analysis tool, Enterprise Architect, can display an archetype within larger UML diagrams.

3.2 Producing and maintaining a common reference record architecture

Strengths

- Key NHS NPfIT stakeholders have indicated interest in using 13606 / *open*EHR for detailed clinical information modelling in support of their applications development.

- Although not perfect, 13606 / *open*EHR specifications have a potential (pending further testing) to provide an approach for defining a common record architecture and detailed clinical semantic models for NHS CFH.

- 13606 / *open*EHR archetypes are generally more easily understood by clinicians and clinical terminologists than their HL7 V3 equivalents.

- Archetypes have been designed for re-use and support flexible indexing techniques for finding and retrieving them as needed.

Weaknesses

- Neither 13606 nor *open*EHR specifications have been previously implemented at a national-level scale. Also, an international 'starter set' of archetypes (e.g. within the *open*EHR repository) is currently relatively small in scale.

- 13606 / *open*EHR archetypes development must be linked with a rich clinical semantic framework in order to have a level of consistency with respect to semantic 'coherence'. This is only an area of research at this time.

- Developing a hierarchy or network of linked archetypes (as per the general requirements discussed in Section 2.3) is not yet supported. This is also an area of current research.

- See also weaknesses listed in Sections 3.1 and 3.3.

Recommendations

- Should further investigation into archetypes design indicate that national adoption is worthwhile, an NHS CFH project should identify the specific resource and other requirements (including pre-requisites and tooling gaps that need to be addressed) for NHS-wide adoption.

- In order for archetypes to interoperate (and thus be economically feasible to implement) with other interoperability standards in the current NHS architecture, high-level and overarching archetypes that map consistently to SCT and HL7 V3 constructs should be designed and centrally controlled. All project-level NHS archetypes should be 'descendants' of the higher-level (reference and primitive) archetypes. Note, however, that the NHS would be lead researchers, as well as first implementers in this area, should this recommendation be accepted.

- Establishing the correct hierarchy of archetypes for a national architecture has not been done before and requires a cautious further investigation and implementation approach (ideally coupled with breakthrough implementation projects that allow for an incremental build-up of draft archetypes for wider review and potential NHS CFH approval).

- Whether or not or how a national archetypes repository could support complex data queries or clinical decision support needs to be investigated.

- Requirements and specifications for inter-node linkage and the mechanisms for linking and re-using archetypes fragments should be further investigated, leading to further tools refinement as needed. In particular, the linked modelling approach suggested in Section 2.3.1.7 should be further explored.

3.3 Producing and maintaining common machine representations within the NHS NPfIT architecture

Benefits related to 13606 adoption

- Clinical information requirements modelling – The standard (along with *open*EHR extensions and tools) provides for the structured documentation of clinical requirements, and supports their review by clinicians and clinical terminologists.[14]

- Standards clarity – Using structures that have been agreed by ISO, CEN and HL7 will reduce the risk of drift over time in the structures used for clinical information in the EHR.

Technical risks and recommendations

- The introduction of the 13606 way of describing concepts may introduce new complexity for those who are already using HL7 V3 within NHS NPfIT. This could be mitigated by introducing the concepts within the HL7 frame of reference (a process that has been underway for some time), or by maintaining an HL7 expression of the specifications developed in the 13606 framework.

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[14] Note that information requirements modelling is not standardised within the scope of HL7 V3. HL7 has suggested UML diagrams for general requirements capture, but as mentioned in Section 2.1, this type of modelling has not yet produced detailed and semantically re-usable clinical information requirements models.

- (Model) structural vocabularies (e.g. as in 13606-3, HL7 V3, and some aspects of NHS CFH Care Record Element types) must be harmonised. This is something that it was not possible to fully explore in this project, but should be done prior to implementation. 13606-3 has not yet been ratified, and further investigation is needed to identify any areas of technical difficulty. If this is not done, the systems and information that are structured according to the HL7 V3 models or NHS CFH CRE types will not be consistent with the 13606-based specifications.

- The introduction of model structural codes and other constraints in the reference archetypes may increase the perceived complexity for clinicians. The inclusion of these attributes will help to ensure that further technical questions do not need to be asked as the requirements are mapped into HL7 V3 and SCT structures, but such explicit precision may not be needed from a clinical perspective. This may be mitigated by allowing different views of archetypes (or providing V3 equivalents as needed) that may 'hide' any details that are not needed for clinical requirements identification and validation, and expose them for computational interoperability requirements.

- 13606 has not been widely used, so all the risks of early adoption apply, including implementation against a standard that is not used by many others. This may be mitigated somewhat by actively working towards a CEN/HL7/ISO convergence (to 'pool' implementation communities), although it is recognised that the CEN, HL7 V3 and ISO (and SCT) implementation communities are also not very large on a global basis. Working in collaboration with key NHS NPfIT suppliers to enhance the potential for archetypes to assist in their applications development may help mitigate this type of implementation risk.

- Establishing reference archetypes will be crucial in defining the information model into which existing and prospective systems must map. A formal process of wider peer review and critique should be established. The risk associated with limited input may be mitigated by mapping existing clinical models (e.g. from HL7 and from *open*EHR) during the development of reference archetypes, as international models have been developed with extensive input and review.

- Wherever appropriate, national archetypes should be bound to SCT terms and V3 Template expressions of them should also be made available for wide use.

3.4 Overall summary

Overall, although some investment in further investigation, and if successful, further human resource and tools development would be required, the use of 13606 / *open*EHR archetypes to establish clinical information requirements models and a common patient record architecture have the potential to save wide-spread project and application development costs in the longer term (by supporting the potential re-use of clinical semantic models, software, and patient record data).

The successful large-scale implementation of archetypes to form the basis of a common reference clinical record architecture would depend on closely relating

archetypes with a comprehensive clinical semantic model. Further testing is required to prove whether this is possible.

Whether archetypes can support decision support and complex query requirements needs to be determined through further investigation and is unlikely to be possible without extending the archetypes tools to support inter-node semantic linkage.

If technical mapping issues are resolved, archetypes may be design to support the two-way translation between detailed messaging or documents models and conceptual models that are easier for clinicians to understand and validate and also, potentially, easier for clinical terminologists to constrain to precise data values. If technical mapping issues are not resolved, however, it may not be cost-effective to introduce a new modelling formalism (and associated new tools) to the NHS NPfIT interoperability architecture.

4   Recommendations for potential 13606 adoption

Given an already-established interest in using archetypes to assist in clinical engagement in application design, the Lorenzo 3.5 development project may have the appropriate interest and resources (not discounting the potential need for some additional support) to act as a 'breakthrough' archetypes implementation initiative for the NHS.

The following has been proposed as requirements (ideally to be available in January 2007) from the perspective of implementing Lorenzo 3.5[15]:

- Scope the clinical content available to projects as a 'starter set'

- A core set of reference archetypes to which clinicians can readily relate

- Design guidance for separating NHS-wide versus local clinical business rules, workflow, and guidelines appropriately, from an archetype design perspective

- Design guidance on best practice for user interface (e.g. for forms)

- Technical trouble-shooting support

- Access to a robust toolset, including a repository that handles versioning

- Training in archetypes design and tools use

- In the initial stages, some project management support for archetypes design development and use

- Archetypes governance aligned with project timeline requirements

Given the interest in archetypes of at least one major NHS NPfIT applications development (and others may be interested upon further consultation with NHS NPfIT suppliers), it is recommended that NHS CFH conducts further tests (as needed to prove or disprove the preliminary conclusions related to national implementation in Section 3) over the next six months to a year in parallel with assisting and observing

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[15] It should be noted that such requirements may not be exclusive to this project; NHS CFH should actively seek collaborations with other NHS development projects or suppliers with an interest in (and resources to contribute to) collaborating in piloting archetypes design in the near term.

the experience of this (and any other suitable NHS NPfIT applications design) project's trial use of archetypes within the shorter term. Aspects of the longer-term investigation are outlined in Section 5.

5 General pre-requisites for NHS implementation

In order to appropriately support Lorenzo 3.5 and other planned NHS NPfIT applications development and to provide the pre-requisites for full NHS CFH implementation, an NHS CFH project should be established to address (through the identification of people, policies and process and development of tools) the following general areas:

- Reference and primitive archetypes design, and their clinical / patient safety in terms of consistent interpretation

- Governance and distribution

- Project-level archetypes design (working with the Lorenzo 3.5 development team and any other interested NHS NPfIT projects)

- Archetypes integration with NHS CFH business analysis models

- Archetypes integration with SNOMED CT models and terms

- Archetypes integration with NHS CFH message models

Given the timelines, it is recognised that breakthrough implementation projects will need to progress with the methods, tools and archetypes currently available, with a plan (ideally supported by NHS CFH) to allow for a convergence strategy with national archetypes, tools and a repository as they become available (if they prove to be feasible upon further investigation).

6 Recommendations related to international standards development

13606 is currently progressing through both ISO and CEN standards approval.

6.1 UK vote recommendations

For ISO/CEN 13606-1

CEN 13606-1 (reference model) has been approved as a European standard. ISO 13606-1 approval, however, is still in progress. Given the 'direction of travel', ISO 13606-1 should reference the upcoming ISO data types, rather than the CEN data types referenced in CEN 13606-1.

For ISO/CEN 13606-2

13606-2 is still in progress within both ISO and CEN approvals. Editorial comments about the limitations of archetypes use and recommendations for extension could be made based on this project's (or a follow-on NHS project's) findings. In addition, the outcomes of standards harmonisation projects (see Section 6.2) should also inform UK votes on this standard.

For ISO/CEN 13606-3

The process of designing NHS reference archetypes should inform the UK ballot on 13606-3 (not yet approved by CEN or ISO).

6.2 Input to standards harmonisation projects

In October 2006, an agreement was signed by representatives of ISO/TC 215, CEN/TC 251 and HL7, Inc. to work collaboratively to harmonise both standards and standards development workplans.

In November 2006, the HL7 Board of Directors allocated a small amount of funding towards data types harmonisation and also to '13606 harmonisation'. It is likely that the ISO/CEN/HL7 standards bodies would be interested in the results of this project's suggested approach of designing reference and primitive archetypes to pre-constrain clinical information requirements expression in a manner that supports consistent mapping to HL7 V3 (and SCT).

The main specific technical 'standards convergence' issue identified as required within this study is the finalisation of a common set of data types for *open*EHR, CEN, ISO and HL7 adoption. Technical leadership for this is already supported via an HL7 V3 development project funded by Communications & Messaging and this effort should be continued.

In addition, as mentioned in Section 2.2.1.5, this project recommends NHS CFH support for SNOMED's efforts to develop general and specific constraint mechanisms that would improve its potential use in querying recorded data in a semantically reliable manner. The exact requirements for this, however, should be further investigated, as mentioned in Section 3.

In order to aid in standards 'convergence', this report will be shared with the international standards communities, and communications will continue in order to align any ongoing NHS efforts in this area with related standards initiatives.

A Glossary of Terms

Archetype (model) – Information model of the metadata to represent the domain-specific characteristics of electronic health record entries, by specifying values or value constraints for classes and attributes in the electronic health record Reference Model (prEN 13606-2, August 2006 draft)

Model of Meaning - What is known and can be inferred about the instances of a given concept, or … What it is sensible to say or ask about a something, and what is implied by saying it. (A. Rector, *Notes on "Model of Meaning" and "Models of Use"*, October 2005)

Model of Use – When, where and why to use, store, or display a concept or group of concepts, or… When, where or why it is sensible to say or ask something. (A. Rector, *Notes on "Model of Meaning" and "Models of Use"*, October 2005)

(EHR) Reference Model – the global characteristics of health record components, how they are aggregated, and the context of information required to meet ethical, legal and provenance requirements (prEN 13606-1, June 2006 draft)

HL7 V3 Template - an expression of a set of constraints on the RIM which is used to apply additional constraints to a portion of an instance of data which is expressed in terms of some other Static Model. Templates are used to further define and refine these existing models within a narrower and more focused scope. (HL7 V3, Templates Project, January 2007 ballot draft)

B SNOMED Concept Model

C An example reference archetype (D. Kalra)

Approach

As a preliminary step, one example high-level SNOMED-CT concept: Clinical Finding, has been selected as the basis to author a high-level Reference Archetype. A copy of the RTF export representation of this is included at the end of this Appendix.

In authoring the archetype, several important design decisions and issues were encountered.

1. The SNOMED-CT terminology and concept model have been developed in isolation from the development of EHR Reference Models. They therefore include some aspects of context that would (for non-SNOMED-CT entries, such as quantity measurements) be represented by the EHR Reference Model. Some of these, for example the "provider of history other than subject" (also called "finding informer"), have no bearing whatsoever on the clinical concepts being described and are part of the medico-legal context in which particular instances were captured. In designing this Reference Archetype such context has NOT been included in the archetype, since it is represented already by the EHR Reference Model. The NHS will need to consider if it is indeed wise to advocate that SNOMED-CT terms are used for such medico-legal context.

2. Some aspects of the SNOMED-CT context model define high-level linkages from a Clinical Finding to other Clinical Findings or to other high-level concepts. In an EHR these links would normally be between entries, rather than all the information be captured within a single entry. For example, if a clinical finding has occurred after a previous clinical event, that event would normally be represented in a separate entry (which might already exist in the EHR). These kinds of associations would be modelled in an EHR Reference Model via a LINK association. These features have therefore not been included explicitly in the Archetype, but in the case of ISO/EN 13606 the corresponding Link vocabulary term (from Part 3 of the standard) is documented below.

3. The SNOMED-CT association Interprets, and its inverse Has Interpretation, are not described clearly enough in the SNOMED CT User Guide for me to be certain about the corresponding Link terms(s).

4. Clinical Finding has two principal sub-classes: Finding and Disorder. For the purposes of this pilot Reference Archetype, these have not been distinguished, and the archetype contains the full set of Elements needed to represent either. However, to help convey where these two sub-classes differ, a Cluster for Disorder details has been introduced to contain its specialised Elements. No equivalent Cluster is needed for Finding, since its specialised associations can all be represented using Links.

5. It is intended that Reference Archetypes should be composed as constraints on a basic Entry structure, which could be either the 13606 Entry or the *open*EHR GENERIC_ENTRY (due to be added in Specification release version 1.0.1 next month). At present the available archetype editor tools do not support either, and so the simplest form of ENTRY supported by the tools (the *open*EHR EVALUATION) was used for this example.

Comments on the Clinical Finding Reference Archetype design

The following associations have been included explicitly within the Archetype node hierarchy

SCT association	Archetype representation approach
Severity (0..1)	represented as an ELEMENT
Occurrence (0..1)	represented as an ELEMENT
Onset (0..1)	represented as an ELEMENT
Course (0..1)	represented as an ELEMENT
Episodicity (0..1)	represented as an ELEMENT
Finding site (0..n)	since multiplicity is 0..n, and each site may optionally specify a laterality, this has been represented as CLUSTER (0..n)

site laterality	with two ELEMENTS, site (1..1) and laterality (0..1)
Associated morphology 0.n	represented as an ELEMENT with unbounded upper limit to multiplicity
Finding method (0..1)	represented as an ELEMENT
Disorder	represented as a CLUSTER (0..1), for use if the Clinical Finding is a kind of disorder, containing two ELEMENTS:
o Causative agent (0..n)	represented as an ELEMENT with unbounded upper limit to multiplicity
o Pathological process (0..n)	represented as an ELEMENT with unbounded upper limit to multiplicity

The following associations would each be represented as a LINK instance. These do not appear in the archetype

SCT association	13606-3 LINK code	13606-3 Link term
Has definitional manifestation	LINK-C8i	Is manifested by
Associated with	Link-C0	Is related to the same problem or health issue
Due to	LINK-C1i	Is caused by
After	LINK-C9	Is sequel
Interprets	LINK-C1 ? LINK-C2 ? LINK-C3 ?	Is cause (interpretation) Revised interpretation Evidence for
Has interpretation	LINK-C1i ? LINK-C3i ?	Is caused by Is justified by

The following is a pure medico-legal attribute of the Reference Model and is not to be included in an Archetype.

  o Finding informer

Conclusions

It has been shown through this example that in principle a Reference Archetype can be fashioned to reflect the main parts of the SNOMED-CT context model for Clinical Findings. However, when considering the range of kinds of information that might need to be represented in a generic Entry, ISO/EN 13606 distinguishes several categories, reproduced in the table below.

Code	Meaning	Description
IC01	Principal or 'core' value	The CLUSTERS or ELEMENTS that contain the main values that are the subject of the ENTRY

Code	Meaning	Description
IC02	Supplementary/Complementary details about the value	Contextual information that most users would regard as necessary to interpret the core values
IC03	Patient State/Circumstances	Contextual information about the patient's circumstances when an observation is made e.g. fasting, standing
IC04	Method Details	Contextual information about the method of an observation, such as the technique or device used
IC05	Clinical Reasoning	Any explanatory information provided by the author to explain or reference a clinical decision or interpretation
IC06	Protocol/Guideline followed	A description, reference or explanation of any protocol or guideline that informed this ENTRY (e.g. to perform an observation, or initiate a plan)
IC07	Reference to Knowledge source	A reference to any external knowledge source, such as a web site or medical text, that explains or amplifies a clinical decision
IC08	Presentation	Any information about how the values in the ENTRY should be presented, if this is considered important to communicate to an EHR Recipient. Image rendering information is one example of this
IC09	Assertion status	To indicate that this ELEMENT contains a value that indicates the presence/absence,,normality/abnormality of the core values (e.g. if the core value is a questionnaire question, and this ELEMENT contains the yes/no answer)

Although not all of these kinds of data will be needed in a clinical finding entry, it is not clear how some of these, such as the patient's state, an explanation of reasoning or a reference to a guideline would be included in the Clinical Finding archetype as it presently stands. The archetype presently also makes no provision for non-SNOMED-CT data values, such as quantity measurements.

In fact, the current archetype might sensibly be called a Coded Clinical Finding Entry. It remains to be determined if this is the sensible scope for this Reference Archetype, or if it should be extended to incorporate the other kinds of information envisaged by 13606-3. The *open*EHR OBSERVATION also includes a formal model for time series data, and it is also not clear if this kind of data structure should be in scope.

The issue to be considered is not if such an extended archetype can be authored: this is technically feasible; but if the result will be useful as a high-level blueprint for detailed clinical finding archetypes. This will require a more extensive investigation, involving rich samples of knowledge and data structures, and a larger peer group than is possible in this present evaluation.

A more serious issue to be considered is the role of post-co-ordination along with this Archetype. A post-co-ordinated expression has the potential to include the entire context represented in this Clinical Findings tree as a single compound terminological expression. Such an expression would therefore be inconsistent with an alternative representation that used each of these nodes as specified in this Archetype. Furthermore, it is not to date possible to constrain post-co-ordination so as to enforce the optionally or multiplicity constraints specified in this Archetype, or any other rules that might be

specified. This means that instances of a post-co-ordinated term might not even be capable of transformation into a form that conforms to this Archetype.

RFT Export form of the Clinical Finding Archetype

Header

  Concept: SCT Clinical Finding Reference Archetype

Definition

  EVALUATION

  DATA = {

    Structure = TREE

    Items

        Severity (0..1)

       the direct causative agent of a disease

        DataType = Text

        Constraint: Terminology; SCT Severity

       Occurrence (0..1)

       the specific period of life during which a condition first presents

        DataType = Text

        Constraint: Terminology; SCT Occurrence

       Onset (0..1)

       the period of onset or the temporal pattern of presentation e.g. gradual, sudden

        DataType = Text

        Constraint: Terminology; SCT Onset

       Course (0..1)

       the course of a condition, e.g. acute, chronic

        DataType = Text

        Constraint: Terminology; SCT Course

       Episodicity (0..1)

       First episode, new episode, ongoing episode etc.

        DataType = Text

        Constraint: Terminology; SCT Episodicity

       Finding site (0..*)

- The body site affected by the condition

Items

Site (1..1)

Anatomical site, location of prosthesis etc.

DataType = Text

Constraint: Terminology; SCT Site

Laterality (0..1)

Laterality of the site, as specified in the same instance of this CLUSTER

DataType = Text

Constraint: Terminology; SCT Laterality

Associated morphology (0..*)

morphologic changes seen at the tissue or cellular level

DataType = Text

Constraint: Terminology; SCT Associated morphology

Finding method (0..1)

the means by which a clinical finding was determined

DataType = Text

Constraint: Terminology; SCT Finding method

Disorder details (0..1)

- Additional optional details if this Clinical Finding is a kind of Disorder

Items

Causative agent (0..*)

the direct causative agent of a disease

DataType = Text

Constraint: Terminology; SCT Causative agent

Pathological process (0..*)

the underlying pathological process for a disorder that is not structural and not represented by the Associated morphology

DataType = Text

Constraint: Terminology; SCT Pathological process

} -- end Data

D 'Strawman' examples in an archetypes hierarchy (R. Kidd)

This appendix provides examples to illustrate the basic concepts of a possible archetypes hierarchy that contains reference, primitive and project-level archetypes (or templates).

Note that the terminology binding element of this work should be improved through review by expert terminologists.

D.1 Clinical Finding Reference Archetype

Purpose of archetype

The reference archetype has been designed using the SCT concept model as a basis. This provides a strong mapping between the reference archetype itself (the model of meaning) and the terminology that will be used to describe it (SCT).

Part of the rationale for using the SCT model was to reduce the likelihood for debate regarding the semantic meaning of models; constructing a reference archetype with SCT concepts in mind allows base concepts to be bound with a relationship to SCT.

Design Rationale

On the whole, clusters and attributes found in the archetype are taken directly from the SCT model.

Where a linkage concept points to a group of classes (e.g. Onset → Gradual/Sudden onset) a cluster has been used (usually taking the name of the linkage concept) containing attributes which represent the relevant classes.

Disorder has been represented as an optional cluster within Clinical Finding (rather than specialising the archetype). This allows the recording of a clinical finding to be marked as a disorder without having to create another (specialised) archetype, in the interest of keeping the number of reference archetypes as low as possible.

Term bindings have been made from attributes to the top-level concept for that concept – e.g. Severity: 246112005. This is purely to show that in the reference archetype, the Severity attribute is of this type (and this may not be the right thing to do). In the primitive archetype that follows, the NHS may choose to constrain choices to specific severities (or state that the value may be any of the child values of Severities).

Clinical Finding

Entity: EVALUATION

Concept description:	Identification:
A clinical finding reference archetype (evaluation/observation) which corresponds to the SCT concept model	Id: openEHR-EHR-EVALUATION.ClinicalFinding.v1draft Reference model: openEHR_EHR

Data

Structure = TREE

Concept	Description	Constraints	Values
Finding site	'Finding Site' identifies the part of the body affected by the specific clinical finding. For example: 'Injury of cornea' (has) 'finding site' 'Corneal structure'	Cluster 0..*	
Acquired body structure	e.g. Operative site, Scar	**Text** 0..*	Terminology; SCT Acquired body structure: 280115004
Associated with	Any factor associated with the clinical finding	Cluster 0..*	
Substance	e.g. Allergen class, dietary substance	**Text** 0..1	Terminology; SCT Substance: 105590001
Organism	e.g. microorganism	**Text** 0..1	Terminology; SCT Organism: 410607006
Clinical Finding	Refers back to itself recursively (not sure how to model this here)	**Text** 0..1	Terminology; SCT Clinical finding: 404684003
Physical force	e.g. Altitude, Electiricity, Explosion	**Text** 0..1	Terminology; SCT Physical force: 78621006
Physical object	e.g. Device, Domestic, office and garden artefact	**Text** 0..1	Terminology; SCT Physical object: 260787004
Procedure	Procedure by device, General treatment	**Text** 0..1	Terminology; SCT Procedure: 71388002

Concept	Description	Constraints	Values
T **Pharma/bio product**	e.g. Alcohol products, Alternative medicines	**Text** 0..1	Terminology; SCT Pharmaceutical/biological product: 373873005
T **Events**	e.g. Abuse, Accidental event	**Text** 0..1	Terminology; SCT Events: 272379006
After	Any finding or event which preceded this clinical finding	Cluster 0..*	
T **Procedure**	Procedure by device, General treatment	**Text** 0..1	Terminology; SCT Procedure: 71388002
T **Clinical Finding**	Refers back to itself recursively (not sure how to model this here)	**Text** 0..1	Terminology; SCT Clinical finding: 404684003
Due to	Any clinical finding or event which contributes to this clinical finding	Cluster 0..*	
T **Clinical Finding**	Refers back to itself recursively (not sure how to model this here)	**Text** 0..1	Terminology; SCT Clinical finding: 404684003
T **Events**	e.g. Abuse, Accidental event	**Text** 0..1	Terminology; SCT Events: 272379006
T **Course**	The course of a condition, e.g. acute/chronic	**Text** 0..1	Terminology; SCT Course: 260908002
T **Occurrence**	The specific period of life during which a condition first presents	**Text** 0..1	Terminology; SCT Occurrence: 246454002
Onset	The period over which the finding presented - e.g. sudden, gradual	Cluster 0..1	
T **Gradual onset**	Qualifier value	**Text** 0..1	Terminology; SCT Gradual onset: 61751001

Concept	Description	Constraints	Values
T **Sudden onset**	Qualifier value	**Text** 0..1	Terminology; SCT Gradual onset: 61751001
T **Episodicity**	First episode, new episode, ongoing episode etc.	**Text** 0..1	Terminology; SCT Episodicity: 246456000
T **Severity**	The degree of severity of the clinical finding, e.g. mild/fatal	**Text** 0..1	Terminology; SCT Severity: 246112005
T **Associated morphology**	Morphologic changes seen at the tissue or cellular level	**Text** 0..*	Terminology; SCT Morphologically abnormal structure: 49755003
T **Finding by method**	e.g. finding by inspection, finding by palpation	**Text** 0..1	Terminology; SCT Finding by method: 118240005
Disorder	In SCT, a Disorder isA kind of Clinical Finding - these optional attributes allow description	Cluster 0..1	
T **Pathological process**	e.g. autoimmune, iatrogenic	**Text** 0..*	Terminology; SCT Pathological process: 308489006
Causative agent	The agent identified as causing the disorder	Cluster 0..*	
T **Substance**	e.g. Allergen class, dietary substance	**Text** 0..1	Terminology; SCT Substance: 105590001
T **Organism**	e.g. microorganism	**Text** 0..1	Terminology; SCT Organism: 410607006
T **Physical force**	e.g. Altitude, Electiricity, Explosion	**Text** 0..1	Terminology; SCT Physical force: 78621006

Concept	Description	Constraints	Values
T **Physical object**	e.g. Device, Domestic, office and garden artefact	**Text** 0..1	Terminology; SCT Physical object: 260787004
T **Pharma/bio product**	e.g. Alcohol products, Alternative medicines	**Text** 0..1	Terminology; SCT Pharmaceutical/biological product: 373873005

D.2 Clinical Finding (NHS-specific) Primitive Archetype

Purpose of archetype

The purpose of this archetype is to constrain the Model of Meaning Reference Archetype for general NHS purposes, creating a primitive archetype containing business rules suitable for the NHS. Once the primitive archetype has been created it is expected that domains will take it and constrain it further as required, creating Project Archetypes (which could map directly to NHS HL7 V3 Templates).

Disclaimer

This is not a 'fit for use' NHS clinical finding archetype; the business rules stipulated below are purely arbitrary and are for example purposes only. They are intended to show how the archetype hierarchy could work in practice.

Rationale for constraints

Pathological process – constrained out; not necessary for NHS.

Courses – constrained to be 1..1 for NHS Clinical Findings: Business rules for the NHS stipulate that we always need to know the course of a clinical finding (e.g. acute, aggressive, benign, etc).

Severities – constrained to be 1..1 for NHS Clinical Findings: Business rules for the NHS stipulate that we always need to know the severity of a clinical finding (e.g. fatal, mild, etc).

NHS Clinical Finding

Entity: EVALUATION

Concept description:	Identification:
A Primitive Archetype which constrains the Clinical Finding Reference Archetype for NHS purposes. The constraints represented herein are for example purposes only, and aren't intended to be realistic. % after a SCT code indicates that the code or any descendants of the code can be used.	Id: openEHR-EHR-EVALUATION.NHSClinicalFinding.v1draft Reference model: openEHR_EHR

Data

Structure = TREE

Concept	Description	Constraints	Values
Finding site	'Finding Site' identifies the part of the body affected by the specific clinical finding. For example: 'Injury of cornea' (has) 'finding site' 'Corneal structure'	Cluster 0..*	

Concept	Description	Constraints	Values
T **Acquired body structure**	e.g. Operative site, Scar	**Text** 0..*	Terminology; SCT Acquired body structure: 280115004%
Associated with	Any factor associated with the clinical finding	Cluster 0..*	
T **Substance**	e.g. Allergen class, dietary substance	**Text** 0..1	Terminology; SCT Substance: 105590001%
T **Organism**	e.g. microorganism	**Text** 0..1	Terminology; SCT Organism: 410607006%
T **Clinical Finding**	Refers to another Clinical Finding (not sure how to model this recursion here)	**Text** 0..1	Terminology; SCT Clinical finding: 404684003%
T **Physical force**	e.g. Altitude, Electiricity, Explosion	**Text** 0..1	Terminology; SCT Physical force: 78621006%
T **Physical object**	e.g. Device, Domestic, office and garden artefact	**Text** 0..1	Terminology; SCT Physical object: 260787004%
T **Procedure**	Procedure by device, General treatment	**Text** 0..1	Terminology; SCT Procedure: 71388002%
T **Pharma/bio product**	e.g. Alcohol products, Alternative medicines	**Text** 0..1	Terminology; SCT Pharmaceutical/biological product: 373873005%
T **Events**	e.g. Abuse, Accidental event	**Text** 0..1	Terminology; SCT Events: 272379006%

Concept	Description	Constraints	Values
After	Any finding or event which preceded this clinical finding	Cluster 0..*	
Procedure	Procedure by device, General treatment	Text 0..1	Terminology; SCT Procedure: 71388002%
Clinical Finding	Refers to another Clinical Finding (not sure how to model this recursion here)	Text 0..1	Terminology; SCT Clinical finding: 404684003%
Due to	Any clinical finding or event which contributes to this clinical finding	Cluster 0..*	
Clinical Finding	Refers to another Clinical Finding (not sure how to model this recursion here)	Text 0..1	Terminology; SCT Clinical finding: 404684003%
Events	e.g. Abuse, Accidental event	Text 0..1	Terminology; SCT Events: 272379006%
Course	The course of a condition, e.g. acute/chronic	Text 1..1	Terminology; SCT Courses: 288524001%
Occurrence	The specific period of life during which a condition first presents	Text 0..1	Terminology; SCT Occurrences: 272120004%
Onset	The period over which the finding presented - e.g. sudden, gradual	Cluster 0..1	
Gradual onset	Qualifier value which describes the onset of a clinical finding	Text 0..1	Terminology; SCT Gradual onset: 61751001
Sudden onset	Qualifier value which describes the onset of a clinical finding	Text 0..1	Terminology; SCT Sudden onset: 385315009
Episodicity	First episode, new episode, ongoing episode etc.	Text 0..1	Terminology; SCT Episodicities: 288526004%

Concept	Description	Constraints	Values
T **Severity**	The degree of severity of the clinical finding, e.g. mild/fatal	**Text** 1..1	Terminology; SCT Severities: 272141005%
T **Associated morphology**	Morphologic changes seen at the tissue or cellular level	**Text** 0..*	Terminology; SCT Morphologically abnormal structure: 49755003%
T **Finding by method**	e.g. finding by inspection, finding by palpation	**Text** 0..1	Terminology; SCT Finding by method: 118240005%
Disorder	In SCT, a Disorder isA kind of Clinical Finding - these optional attributes allow description	Cluster 0..1	
Causative agent	The agent identified as causing the disorder	Cluster 0..*	
T **Substance**	e.g. Allergen class, dietary substance	**Text** 0..1	Terminology; SCT Substance: 105590001%
T **Organism**	e.g. microorganism	**Text** 0..1	Terminology; SCT Organism: 410607006%
T **Physical force**	e.g. Altitude, Electiricity, Explosion	**Text** 0..1	Terminology; SCT Physical force: 78621006%
T **Physical object**	e.g. Device, Domestic, office and garden artefact	**Text** 0..1	Terminology; SCT Physical object: 260787004%
T **Pharma/bio product**	e.g. Alcohol products, Alternative medicines	**Text** 0..1	Terminology; SCT Pharmaceutical/biological product: 373873005%

D.3 NHS Adverse Reaction Identification

Purpose of template

The purpose of this particular template is to record the existence of an allergy in a patient (e.g. when first identified). This template is NOT for recording specific instances of adverse reaction – there will a separate template for that purpose.

Rationale for Constraints

Finding site – constrained out as this is NOT an archetype to represent an instance of an allergy, rather just to record that an allergy is present (assumes that allergy may present differently each time, esp. concerning contact allergies)

Associated with – constrained out as assumed that the attributes available through Disorder -> causativeAgent.

After/dueTo – constrained out, not relevant to Adverse reactions

Episodicity – constrained out as not relevant to recording a general adverse reaction. More suited to instances.

Finding method – only relevant to instances

Causative agent -> Physical force, physical object – constrained out; not required for adverse reactions

Disorder – constrained to 1..1 – must represent the allergen

Causative agent – constrained to 1..* - must choose one (or more) of the three available attributes

NHS Adverse Reaction ID

Entity: EVALUATION

Concept description:	Identification:
A Template Archetype which is intended to demonstrate how a primitive archetype can be further constrained to create a template archetype. In this case the template is for a basic allergy identification to be stored within a patient's record and brought up for quick review e.g. in case of emergency following hospital admittance. % after a SCT code indicates that the code or any descendants of the code can be used.	Id: openEHR-EHR-EVALUATION.NHSAdvReacID.v1draft Reference model: openEHR_EHR

Data

Structure = TREE

Concept	Description	Constraints	Values

Concept	Description	Constraints	Values
T Course	The course of a condition, e.g. acute/chronic	**Text** 1..1	Terminology; SCT Courses: 288524001%
Onset	The period over which the finding presented - e.g. sudden, gradual	Cluster 0..1	
T Gradual onset	Qualifier value which describes the onset of a clinical finding	**Text** 0..1	Terminology; SCT Gradual onset: 61751001
T Sudden onset	Qualifier value which describes the onset of a clinical finding	**Text** 0..1	Terminology; SCT Sudden onset: 385315009
T Severity	The degree of severity of the clinical finding, e.g. mild/fatal	**Text** 1..1	Terminology; SCT Severities: 272141005%
T Associated morphology	Morphologic changes seen at the tissue or cellular level	**Text** 0..*	Terminology; SCT Morphologically abnormal structure: 49755003%
Disorder	In SCT, a Disorder isA kind of Clinical Finding - these optional attributes allow description	Cluster 1..1	
Causative agent	The agent identified as causing the disorder	Cluster 1..*	
T Substance	e.g. Allergen class, dietary substance	**Text** 0..1	Terminology; SCT Substance: 105590001%
T Organism	e.g. microorganism	**Text** 0..1	Terminology; SCT Organism: 410607006%
T Pharma/bio product	e.g. Alcohol products, Alternative medicines	**Text** 0..1	Terminology; SCT Pharmaceutical/biological product: 373873005%

E Potential NHS archetypes meta data

CEN 13606:2 mandates that each archetype includes the following information:

- A globally-unique archetype identifier.

- The repository identifier or authority responsible for maintaining it. (In the context of this report, this would be the NHS.)

- The concept that best defines the overall clinical scope of instances conforming to this archetype as a whole, expressed as a coded term or as free text in a given natural language. (Note that this concept may be bound to an SCT term.)

- The underlying Reference Model for which this archetype was ideally fashioned. (Note: an archetype might be capable of use with more than one relevant Reference Model within a given health informatics domain, but it is expected that the archetype will be optimised for one.)

- The natural language in which this archetype was originally defined, represented by its ISO 639-code. In the event of imprecise translations, this is the definitive language for interpretation of the archetype. [This may be assumed to be English for the NHS.]

- Its publication state – e.g. test, draft, local, national, preferred, deprecated, and the date when this status was applied.

- The party who approved the archetype's publication.

- Suggested or intended review date.

Of the list of types of information that 13606 notes is possible to record about an archetype, the following may be of use to the NHS:

- The globally-unique identifier for the archetype of which this archetype is a specialisation and to which it shall also conform.

- The globally-unique identifier of the former archetype that this definition replaces, if it is not the first version of an archetype.

- The reason for defining this new version of a pre-existing archetype.

- The identifier of the replacement for this archetype, if it has been superseded.

- One or more description sets, defining its usage and purpose. Multiple versions of this information may be included, represented in different natural languages or to inform different kinds of potential user (e.g. various secondary uses).

- A description, reference or link to the published medical knowledge that has underpinned the definition of this archetype.