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The use of standard content specifications in a national health interoperability framework

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Abstract
The openEHR community has developed a specification that has been taken up by the standards community and has this year been adopted as ISO 13606. The specification offers an engineering and semantic framework for implementing an electronic health record (EHR) service within a service-oriented architecture. The semantic framework provides the means of agreeing the clinical and other content of the EHR independently of the implementation infrastructure. The clinical content is expressed using a formal language, itself part of the ISO standard, which ensures the content specifications provide a single computable source for many key artifacts required for semantic interoperability.

Keywords: semantic interoperability, clinical content, electronic health records, national eHealth programs

1. Introduction

National eHealth programs require standards in order to provide a foundation for distributed and specialised health care without fragmentation, repeated investigations and silos of health information [1]. Offering an alternative to more traditional process-oriented approaches to health informatics standards setting, *open*EHR has grown as a community-driven standard based on interest, research outputs and collaboration [2]. Such a 'grass-roots' movement has been able to establish processes fit for the endeavor and develop governance processes that evolve with uptake and interest. This paper addresses the pathway to interoperability and information sharing using the *open*EHR Framework and standard content specifications. It represents knowledge gained via real life experiences in EHR implementation and content definition for the UK Connecting for Health Programme [3], the Australian[4] and Danish *open*EHR trials[5] and reflects input from many colleagues.

2. Background

The *open*EHR Framework provides a means of creating, validating, communicating and storing personal health information in the manner required for accountable health care while allowing the clinical content to be specified in a just-in-time manner. The content specifications are first expressed in the form of constraint models known as archetypes, which are authored by clinician experts as formal and machine readable expressions [6]. The archetypes, with the bound terminology in context, provide the agreed foundation of clinical semantics. Archetypes are reusable and can be selectively aggregated and refined to meet specific needs in clinical templates. Each template consists of its own collection of archetypes to suit a specific purpose. Thus a template might be created for a discharge summary in one hospital that is laid out quite differently and uses different data points from that in another hospital, but as both are based on the same archetype library the information can be machine processed at the receiving end. Figure 1 shows the relationship of *open*EHR archetypes and templates.

The *open*EHR community has a growing library of high quality authored archetypes for use in clinical care and tools to support their maintenance, governance and release.

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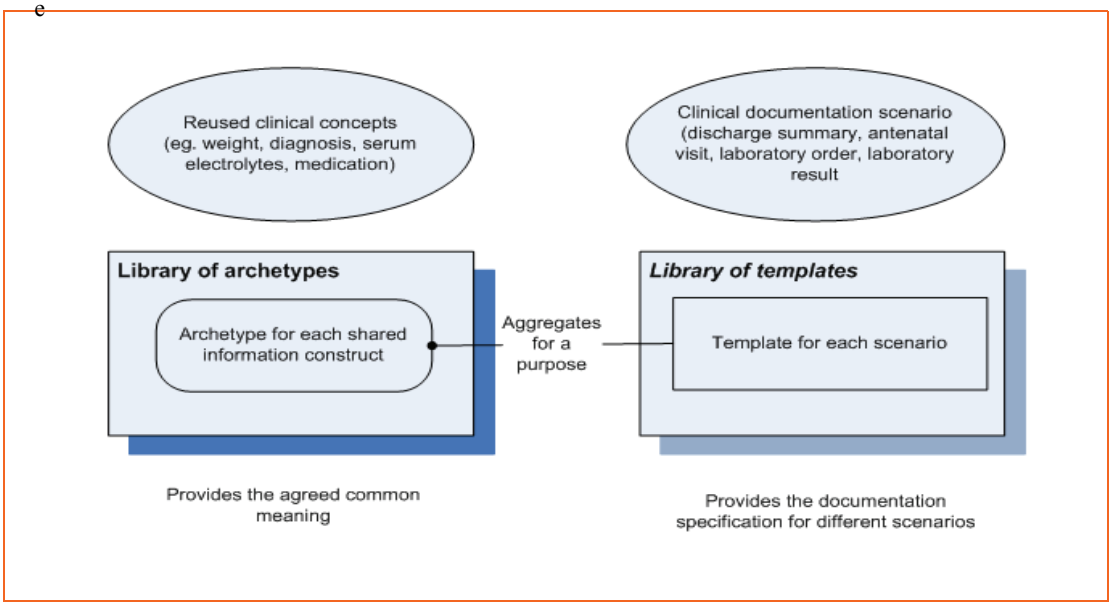

Figure 1: Relationship of openEHR archetypes and templates Standards in health care

3. Standards in health care

Within health care there is a range of data communication standards. The message standard most widespread is HL7 version 2 [6]. UN/EDIFACT and locally agreed XML schemas are also widely used [7]. Some countries have developed HL7 v3 implementations [8]. Document standards in use include HL7 CDA (and its CCD variant), CCR and *open*EHR, with PDF and other image formats in common use for non-computable content representation. The computable forms of the resulting messages and documents all use terminology differently, based on specific vocabularies and code/value sets defined in each of the underlying standards, and have varying ability to exploit standard terminologies such as SNOMED CT.

As *open*EHR has a formal mechanism to author, review, maintain and govern clinical content, it is a candidate for bringing the diverse range of standards into a common semantic framework via the adoption of a formal and well engineered health record architecture and tools. The framework consists of a single information model or schema for all data which provides features to determine responsibility, meaning, layout and other safety and accountability issues. The specification of the content is by way of a standard constraint language [9] which allows expression of clinical content, navigation and metadata to any level of complexity. Most importantly, these specifications can evolve and be updated as managed assets. Having the foundation in place, it is then possible to determine how to use the archetypes – which ones and which parts are relevant – in different settings. This is the template, which itself can be used to define the data for forms, messages, and transformations to other formats. An openEHR template for a discharge summary could have a formal transformation to CDA, CCR, HTML or PDF for example.

Once a jurisdiction has decided to use a message standard like HL7 version 2, 3 or CDA, the work then begins to negotiate the message structure and content. Ideally this will be re-useable in other jurisdictions, but the diversity of health care, language dependencies etc make it very difficult. Each message becomes an end-to-end agreement, which in some cases is viewed as reflecting the commercial interests of vendors rather than the needs of clinical users within the jurisdiction.

A community-based standard like *open*EHR, a shared specification evolving through implementation, allows clinician experts to determine the content specifications and formally express these independently of any particular application or message structure. This is achieved through the separation of archetypes from templates, allowing system developers the freedom to recombine clinician-defined content with no possibility of endangering data interoperability, which is guaranteed at the archetype level. The resulting specifications can be used to consolidate information in *open*EHR based repositories and to specify how specific information will be carried in messages and CDA documents.

3.1. Developing clinical content specifications

Creating the content specifications as archetypes and templates is a task that takes time and some skill. There is now growing international experience of using the *open*EHR Framework for this purpose. One advantage of using *open*EHR is its support for clinical process through the INSTRUCTION and ACTION

classes. While this does not capture the business rules *per se*, it does mean that the pathway steps that might be documented in performing interventions of any kind can be specified.

This content creation process requires specification of value sets, which may be part of the content specification itself or drawn from an external terminology. Binding to an external terminology will usually be done at the time of template design (i.e. for a particular purpose) which allows flexibility in coding for the future.

The process as shown in Figure 2: The specification of clinical content can be applied to establish semantic interoperability of clinical information at various levels of scale, providing a consistent approach which can engage all interest groups. It might be performed by clinical system developers, hospitals, jurisdictions or nations in the same manner using the same tools and services.

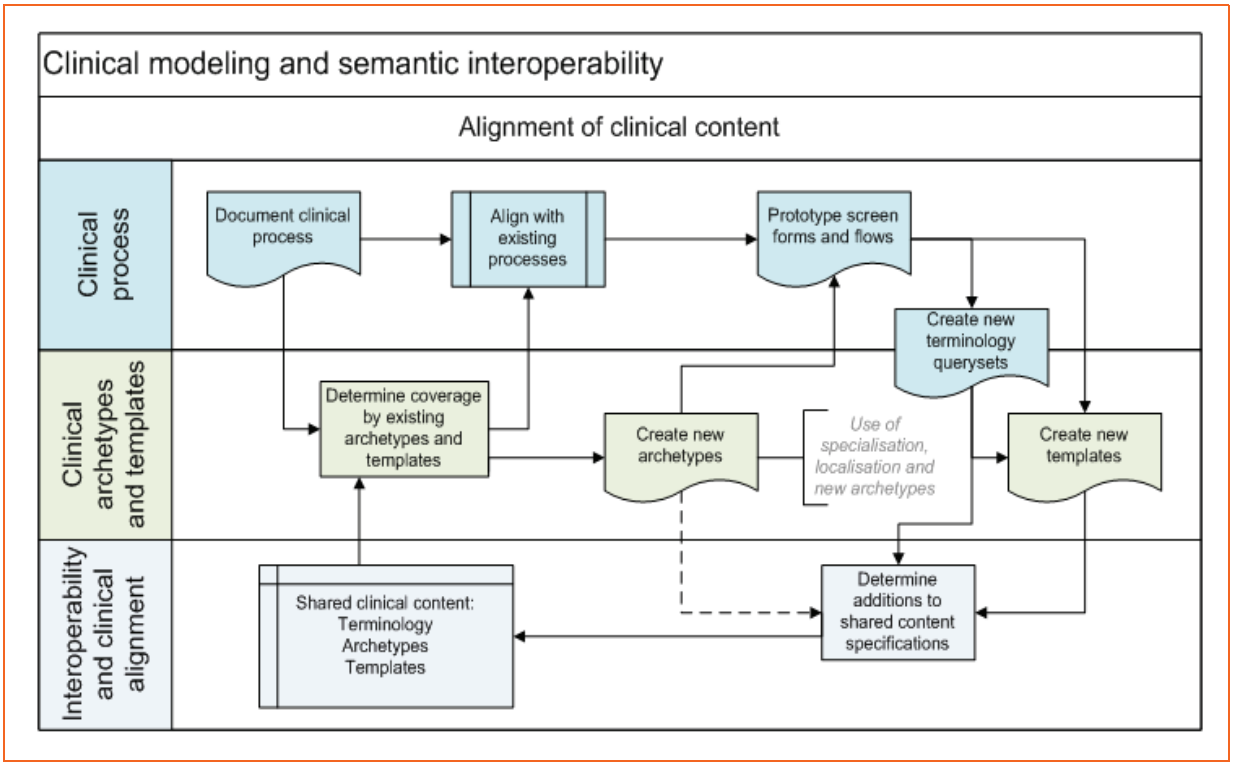

Figure 2: The specification of clinical content

For information recorded to be useful it must support the clinical process. Having documented this it is useful to align it with other similar processes if possible and at the same time determine what recorded content can utilise existing archetypes and templates (drawn from the content repository). Where there is a gap, new archetypes will need to be authored or specialisations of existing archetypes created to include all required content. Some of these will be offered to the national and international shared content libraries. The archetypes and templates chosen to support the clinical process can then be used to support prototype data entry screens. Testing will enable refinement of the terminology required and finally a suitable template that genuinely supports the clinical process will be available to vendors and the clinical community. There are a number of challenges which include:

- designing archetypes that are discreet, useful and reusable is initially very challenging but simplifies as the coverage increases;
- the decision to specialise an archetype or add (the same) constraints in a template should depend on practical value but is necessarily theoretical until there is wide usage; and
- Deciding which archetype specialisations and templates should be promoted nationally or internationally depends on very broad input to ensure that the resulting content is actually sufficient in this context.

Such a process, with attendant debate on suitable clinical archetypes, has the potential to support national healthcare transformation through ongoing process improvement. In time, this may be seen as the great strength of the approach.

4. The semantic interoperability framework

Having developed the shared archetypes and templates for specific purposes, it is now possible to generate a range of artefacts that offer a variety of ways for different stakeholders to participate. These include:

1) **Template Data Schema (XML)** which consolidates the informa-

tion model and set of archetypes into a single 'classic' XML schema which offers a simple pathway to implementation. Any data that is captured and validated against these schemas (using a range of off the shelf tools e.g. Microsoft Infopath) can be converted using a single transform script to standard openEHR (or to other known formats with a per-archetype transform). The Template Data Schema can be used for data capture and data integration in conjunction with an *open*EHR repository. The schema can contain identifying information if required, when it is known as a **Identified data schema** and used to generate messages, *open*EHR and CEN13606 extracts.

2) **Template Programming Objects** are code snippets that can be used by application developers to enable standard screen building environments to communicate directly with an *open*EHR repository via the web. This allows users to view, create and edit data in a shared repository with no special knowledge of *open*EHR or web services.

For the full power of transformation to other standards to be realised, transformation scripts are required, generally one per archetype. The framework is shown in Figure 3: Single source eHealth semantic artefacts. Thus, for a standard summary health record to be generated in CCR, HL7 CCD, CDA v1 and 2, PDF and HL7 v2, it is necessary to know how specific information such as allergies, medication, alerts, problems etc are represented in each standard. Sharing these transformation scripts and working from a high fidelity *open*EHR environment makes light work of data integration. What makes it possible is the adoption of a formal and well engineered health record architecture and tools – the *open*EHR Framework.

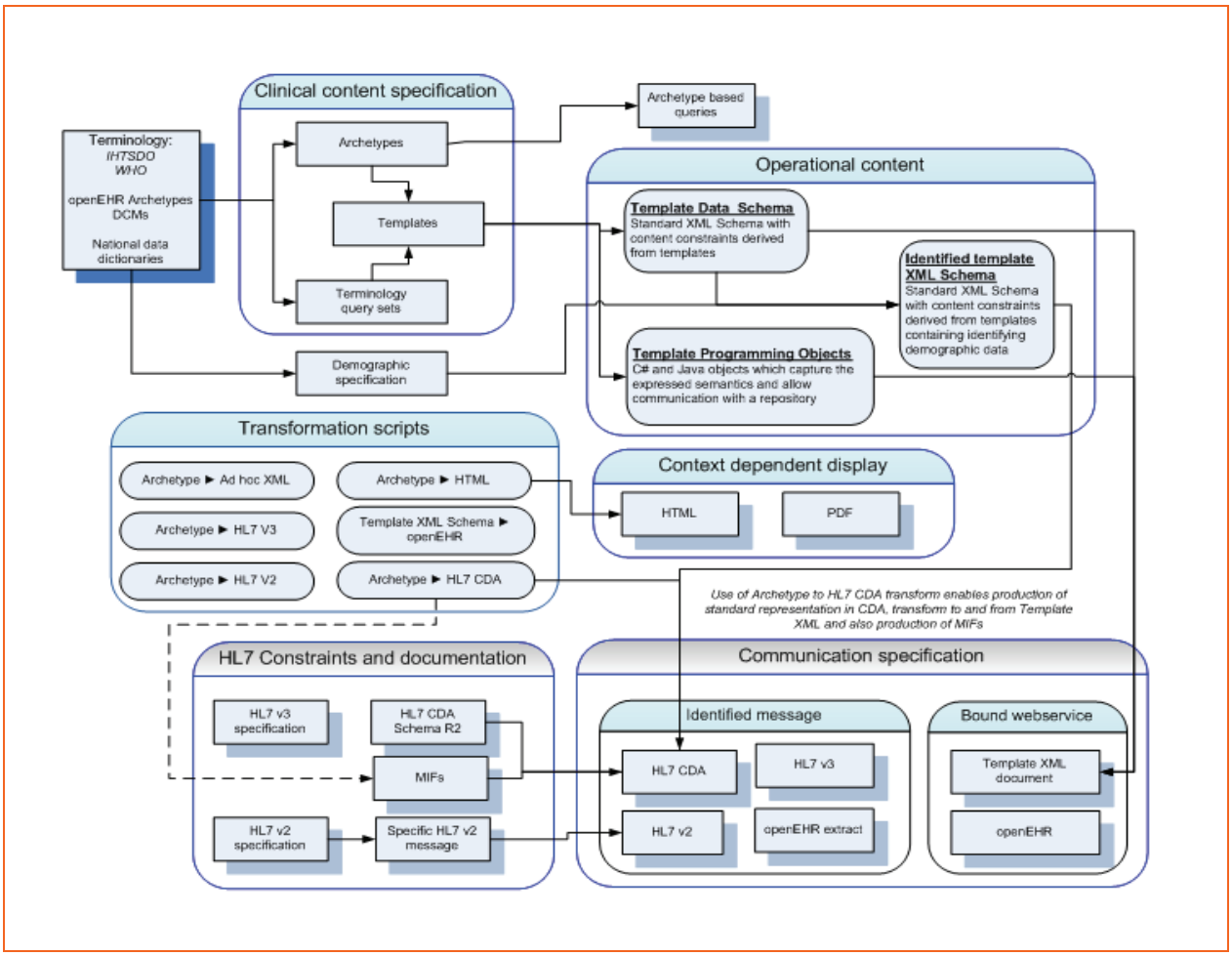

Figure 3: Single source eHealth semantic artefacts

A few scenarios are offered to illustrate how people might participate and what artefacts enable the interaction.

1) **Viewing information:** Information can be provided as **HTML**, **PDF** or other agreed formats. This can be done directly over the web or by downloading a document in a suitable format. The transforms to PDF or HTML is determined on a per-archetype basis (which can be different for different contexts). The ability to

change the view by context is very important in, for example, creating summary views, views for the patient themselves, views for different health professionals etc.

2) **Contributing to the shared EHR:** Stakeholders who are part of the health system but have limited messaging infrastructure can create **Template Data Schemas** either to populate and transform using XML tools or use within the local application that is able to incorporate XML Schemas. The validated data can be saved via a web service into an *open*EHR repository. Identification is not necessary if the stakeholder is part of the jurisdiction's authorisation framework as the *open*EHR session is aware of which EHR is currently active. **Programming objects,** based on the same template enable system developers working in C# or Java to incorporate standard data expressions into their applications and simply save this information in a shared repository.

3) **Query the shared EHR:** Archetype query language allows **authorised queries** of the shared EHR for specific content based on the archetypes. This web service allows reporting, decision support and other services to be based on the shared content specification.

4) **Create and incorporate HL7 messages and documents:** By agreeing the transform of archetypes to different formats (such as HL7 CDA, HL7 v2 and HL7 v3) it is possible to transform data conforming to the **Identified Template Data Schema**, with its standard XML validation mechanism expressing the constraints expressed in the referenced archetypes, to any message format. This does require agreed transformation scripts for each archetype. It is also possible to transform messages of that type back to XML conforming to the Template Data Schema. This provides utility in two ways: stakeholders can use simple XML schemas to validate their data; and be guaranteed to produce **standard HL7 artefacts** without detailed knowledge of *open*EHR or HL7.

5) **Create documentation or constraints in other formats:** It is theoretically possible, but has not been done due to lack of standards, to create standard specifications of HL7 CDA (**MIFs**) or HL7 v2 messages (**Documentation**) from an *open*EHR template (given the transforms are available for all the archetypes). This work is being planned at present.

The validation of the transformations, which are themselves shared assets, requires the agreement of a broad stakeholder base. The advantage of using the archetypes and transforms as the standard expression of clinical content is that it is guaranteed that each archetype will be represented identically in any message or document. Given recent concern about the variety of ways of representing the same content in different HL7 artefacts[10], this process provides a clear pathway to standardise this representation.

These participation scenarios are further illustrated in Figure 4: Maximum communication and participation pathways.

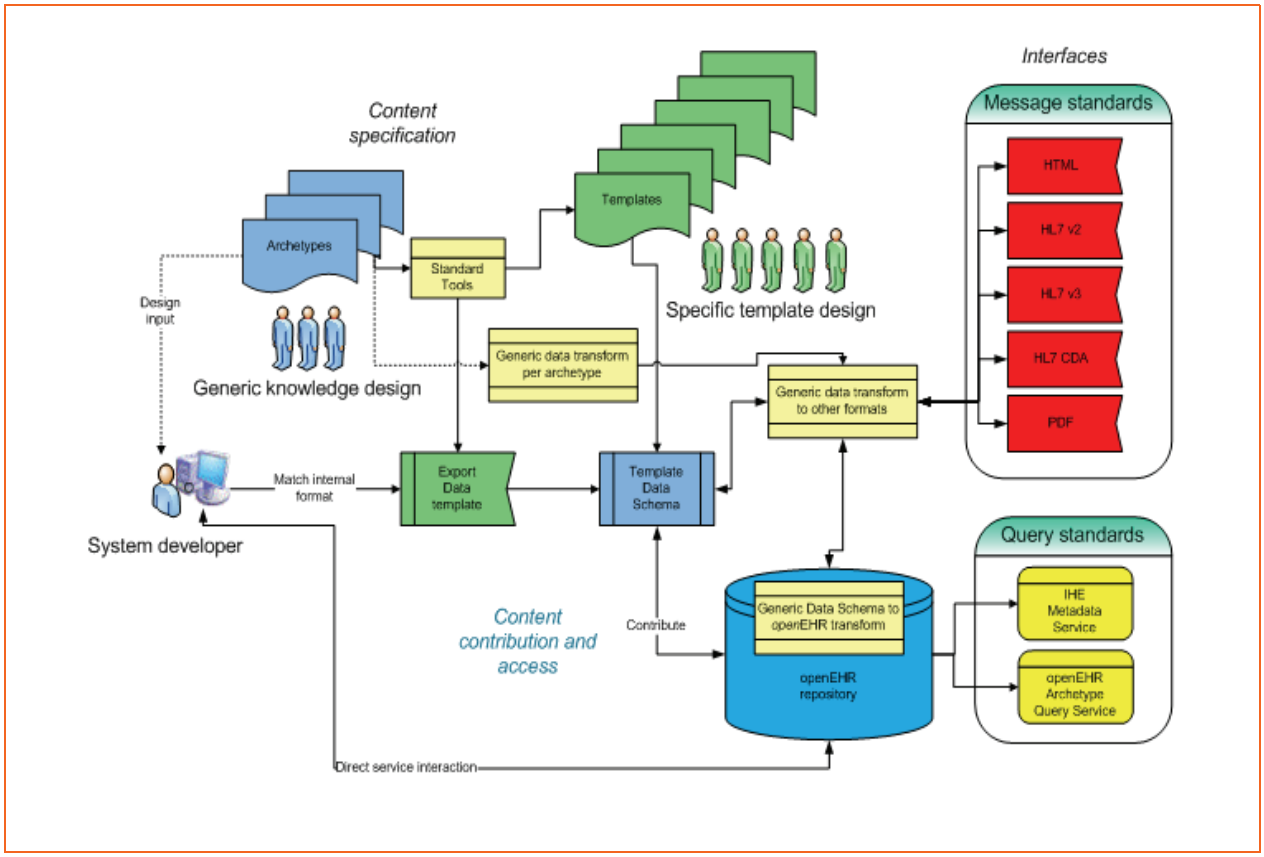

Figure 4: Maximum communication and participation pathways

5. Summary

The community-driven development of *open*EHR puts it outside the traditional standards environment and allows clinicians, patients and other stakeholders to determine the content independently of specific implementations. The *open*EHR Framework provides a unifying approach to semantic interoperability which will greatly simplify the specification of communications and clinical systems. Use of the *open*EHR Framework has the possibility to save money for national health programs as well as the resources of the international clinical community currently burdened with a myriad of charting efforts. There must be millions of hours every year spent by clinicians all over the world working on clinical documentation projects that can be greatly simplified through use of the *open*EHR framework.

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Conflicts of Interest

The author is a Director of the *open*EHR foundation and CEO of Ocean Informatics, a company involved in the definition of openEHR specifications and providing a suite of tools based on the *open*EHR architecture specification.

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