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Quality requirements for EHR Archetypes

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Abstract. The realisation of semantic interoperability, in which any EHR data may be communicated between heterogeneous systems and fully understood by computers as well as people on receipt, is a challenging goal. Despite the use of standardised generic models for the EHR and standard terminology systems, too much optionality and variability exists in how particular clinical entries may be represented. Clinical archetypes provide a means of defining how generic models should be shaped and bound to terminology for specific kinds of clinical data. However, these will only contribute to semantic interoperability if libraries of archetypes can be built up consistently. This requires the establishment of design principles, editorial and governance policies, and further research to develop ways for archetype authors to structure clinical data and to use terminology consistently. Drawing on several years of work within communities of practice developing archetypes and implementing systems from them, this paper presents quality requirements for the development of archetypes. Clinical engagement on a wide scale is also needed to help grow libraries of good quality archetypes that can be certified. Vendor and eHealth programme engagement is needed to validate such archetypes and achieve safe, meaningful exchange of EHR data between systems.

Keywords. electronic health records, semantic interoperability, archetypes, requirements

Introduction

Clinicians of all disciplines require access to detailed and complete health records in order to manage the safe and effective delivery of health care. These records need to be linked to salient knowledge and guidance, and to be shared in real time within and between care teams across geographical boundaries. The lack of informatics solutions to support these needs is widely recognised as a major obstacle to the appropriate delivery of health services [1-4]. The diversity and complexity of clinical information makes it difficult to capture this fully and faithfully on current computerised systems [5-9]. Realising the EHR is a core target of many national eHealth programmes

Considerable research has been undertaken over the past twenty years to explore the user requirements for adopting EHRs. Much of this work has now been taken forward in international standards, for EHR architecture requirements: ISO 18308 [10], and interoperability: ISO EN 13606 [11], through implementations by groups throughout the world such as the openEHR Foundation [12], and through formalisms such as the use of archetypes.

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Semantic interoperability requires standards, not just for the data to be transferred and structurally mapped into a receiving repository, but so that its clinical content can be mapped to a commonly understood meaning [13].

The need to define and share clinical data structures is not new, but such definitions have historically been represented as paper or electronic forms, templates, tables, spreadsheets, database schemata etc. These cannot easily be shared or compared, and require manual transformation by developers into EHR repository constraints. Clinical archetypes provide a systematic approach to defining clinical information structures. An archetype instance is a knowledge artefact that defines how an EHR reference model hierarchy should be organised to represent the data for an aspect of clinical recording. The kinds of meaning that are represented using archetypes are a clinical headings framework, fine grained clinical data structures, and relevant data value sets or terminology constraints, and a specification of optionality and multiplicity.

Archetypes offer a tractable way of binding generic EHR models to compositional terminology. They provide target knowledge representations for use by guideline and care pathway systems, and so support knowledge level interoperability: systems may interoperate not only at the data level, but also at the level of intended clinical meaning. EHR components identify the archetypes used when the data were created, and/or to which they map, which aids future interpretation, analysis, querying. [14]

Archetypes have been adopted as a European Standard and as an international standard (ISO EN 13606 Part 2) following over a decade of research in Europe and Australia and further development by the openEHR Foundation.

1. Methods

As clinical archetypes will direct the ways in which clinical data is captured, processed and communicated, they need to be trusted and endorsed in order to be widely adopted and used, and therefore need to be quality assured. Since the development of large libraries of archetypes by clinical communities is still relatively new, the experience and evidence base for the quality assurance and quality labelling of archetypes is not yet strong enough to support a formal certification process. However, there is a growing consensus on the kinds of quality criteria that good archetypes should meet, which were collated by the EuroRec Institute through the Q-REC project and are described below summarised from [15]. The authors have collated these requirements from a portfolio of engagement activities over the past several years, including:

- The development of an initial set of archetype representation requirements that were incorporated, refined through ballot cycles, and published within ISO EN 13606 Part 2.
- Working with consultants, GPs, pharmacists, nurses in London to design an anticoagulation shared care EHR system generated from archetypes [16], and follow on archetyped applications for heart failure, atrial fibrillation, dementia.
- Engagement with a project that has developed and deployed an epilepsy EHR in Ireland [17], and with regional EHR project in Brazil [18]
- Participation in expert workshops with the UK Royal College of Physicians, the NHS Logical Record Architecture, workshops on semantic interoperability hosted by the European Commission and the epSOS project, and workshops hosted by the EuroRec Institute.

- Conducting of three international questionnaire surveys of national standards bodies on requirements for semantic interoperability, including the usage of archetypes and equivalent clinical modelling approaches.

2. Results

The requirements below reflect the consensus findings collated from the various stakeholder interactions, surveys and empirical archetype design activities summarised above. They are expressed in narrative paragraphs for the purposes of this publication, and some have been summarised. A formal requirements specification would separate the individual statements that are independently verifiable, e.g. for conformance testing purposes, and each would be uniquely numbered and version controlled.

2.1. Business requirements

An archetype shall define a formal representation for one or more discrete kinds of clinical (health or health care) entity within an EHR, by defining the structural organisation and kinds of permitted data content for one or more clinical entities as a constraint pattern on a general electronic health record information model. It shall specify the constraint pattern in sufficient detail and with sufficient precision that different conforming clinical data instances drawn from different EHR systems can be represented consistently when using the same (specified) electronic health record information model.

2.2. Clinical requirements

An archetype shall specify the precise clinical scope of the entity (or set of entities) for which it defines a constraint pattern, shall specify any particular clinical scenarios or workflows for which it is particularly intended, shall specify any particular sub-populations of citizens for whose health or health care it particularly applies. An archetype shall specify any particular speciality, discipline or professional groups.

An archetype shall include or reference one or more terms from an internationally registered terminology system to which it corresponds most closely, in order to permit its clinical scope to be widely understood, and compared with other archetypes.

The clinical scope of an archetype shall be sufficiently precise that EHR instances conforming to the archetype may meaningfully be interpreted and analysed collectively

An archetype shall be able to include references to one or more kinds of published knowledge that have informed its overall design, and/or to which it conforms (examples of relevant knowledge include clinical guidelines, care pathways, standard data sets, professional policies, reporting templates), and references to one or more kinds of published knowledge or policy to which any individual node or nodes within it conform. An archetype shall enable any reference to published knowledge or policy to include a date when that knowledge is due to be reviewed (and therefore when the archetype itself might also need to be reviewed).

2.3. Technical requirements

The information in an archetype shall be capable of being represented using the information model specified in Section 7 of ISO EN 13606 Part 2.

An archetype shall specify the EHR information model. Every part of the archetype shall specify the class within the EHR information model that is the corresponding node for EHR instances that conform to the archetype's constraints. The identifier of an archetype, and of each of its nodes, shall be globally unique and replicated consistently whenever it is communicated.

2.4. Information governance requirements

An archetype shall always include information about the person and/or organisation that has taken primary responsibility for its creation, along with the time and location (jurisdiction) of its creation, and about the person and/or organisation that had co-ordinated the inputs into its design basis.

Any modification to an archetype shall result in a revised version that references the former version. No revision to an archetype may render non-conformant any instance of EHR data that conformed to a previous version: in such circumstances a totally new archetype shall be created and the existing archetype shall, if appropriate, be deprecated from further use.

An archetype shall reference a clear statement of any copyright or usage restrictions and licence information that apply to it.

An archetype shall list and date stamp any approvals and endorsements for its use in different jurisdictions or by different communities of practice. An archetype shall include a time-stamped indication of its intended deprecation from future use by any jurisdiction, optionally with an explanation of the reason and optionally a reference to any successor archetype(s).

3. Discussion

An important challenge in designing libraries of archetypes to meet broad areas of clinical practice is to ensure that archetypes are evidence based or meet de facto agreed clinical needs (e.g. established by consensus, or reflecting existing practice). It is also important for them to be mutually consistent and bind to terminology systems in appropriate and consistent ways. This is necessary in order to minimise the diversity of ways in which a given kind of EHR data might be represented. This consistency is needed by clinical applications, decision support and other analytic software that need to retrieve or filter EHR data, or assist users with selective navigation through a large EHR or across populations of EHRs. In order for them to be accepted and adopted widely, archetypes also have to be of demonstrable good quality. This is an area of ongoing learning through communities that have begun to build up libraries of archetypes for their clinical domains. The requirements summarized above are a starting point for defining these quality criteria.

A formal process of verification and certification is needed for archetypes that provide assurance of their suitability and safety. The EuroRec Institute is leading the development of governance practices for archetype development in collaboration with the openEHR Foundation and other organisations worldwide [19].

ISO TC/215 is developing quality requirements for Detailed Clinical Models, a generic clinical representation approach spanning archetypes, HL7 templates, and other equivalent modelling formalisms. The requirements reported here have been contributed into that work. A new European project, SemanticHealthNet, led by EuroRec, will take forward this research by bring together the Standards Development Organisations involved in developing semantic artefacts such as archetypes and terminology systems, and working with exemplar clinical domains to identify best practices in the design and quality assessment to better enable semantic interoperability.

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