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Peer Review of Clinical Information Models: A Web 2.0 Crowdsourced Approach

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Abstract

Over the past 8 years the openEHR Clinical Model program has been developing a Web 2.0 approach and tooling to support the development, review and governance of atomic clincial information models, known as archetypes. This paper describes the background and review process, and provides a practical example where cross standards organisation collaboration resulted in jointly agreed clinical content which was subsequently represented in different implementation formalisms that were effectively semantically aligned. The discussion and conclusions highlight some of the socio-technical benefits and challenges facing organisations who seek to govern automic clinical information models in a global and collaborative online community.

Keywords:

Informatics; Crowdsourcing; Common Data Elements

Introduction

Historically, most collaboration in the health technology domain has been through formal balloting of message or document specification standards within standards development organisations (SDOs) such as ISO TC215 or HL7 International. This approval process has had some significant success over many years in supporting interoperability of health data, however this approach is not transparent, responsive or agile enough for development, maintenance and governance of larger numbers of more atomic clinical information models.

The Clinical Models Program [1] at the openEHR Foundation [2] has developed an alternative, crowdsourced approach to the development, publication and governance of the openEHR clinical information models, known as archetypes. This methodology emphasises openness, transparency and accountability to the community.

The Clinical Knowledge Manager tool was developed directly as a result of the experience of openEHR Clinical Program leadership in working with distributed groups using technical tools such as widely used software versioning and revision control systems. It quickly became apparent that there was not only a need for versioning governance but also life cycle and naming governance plus a critical process to ensure appropriate review of the archetypes to ensure that each was fit for use in implementations.

This openEHR methodology is now in use by a number of national and jurisdictional eHealth programs around the world who are using archetypes published in this manner to underpin their local health IT infrastructure.

Background

The Clinical Model program at the openEHR Foundation is responsible for management of a set of clinical information models, known as archetypes, on behalf of the international openEHR community. The scope of responsibility includes:

- development of a set of coherent and consistent archetypes,
- commumity review and approval of the archetypes as fit for use, using a collaborative peer-review process;
- publication and life cycle management of each archetype; and
- ongoing maintenance and governance of each archetype.

Each archetype is a computable specification for a single clinical concept – intended to be a maximal data set for a universal use case. In practice, the aspirational intent of a maximal data set is usually adjusted to a practical, but inclusive, data set that can be re-used across multiple clinical scenarios.

The program utilizes an online tool to support the activites of the program – the openEHR Clinical Knowledge Manager (CKM) [3]. This tool has three main purposes – it is a public library of archetypes; an open collaboration portal; and underpins the community's requirements for complex clinical knowledge governance.

The CKM tool allows open access to all clinical information models. Registration is required to actively participate within the CKM community – membership is free and open to any interested individual or group. A broad range of professions is represented including, but not limited to:

- Clinicians;
- Informaticians;
- Software engineers;
- Terminologists;
- Academics/students;
- Administrators; and
- Consumers.

As of December 18, 2016, the openEHR CKM has:

- 500 active archetypes in varying life cycle stages, comprising an estimated 6000 data points;

- 1628 registered users from 88 countries: and
- 24 languages represented.

Communities in Norway, Australia, United Kingdom, Slovenia, Canada and Brazil are actively collaborating and sharing archetypes to minimise 'reinventing the wheel'.

openEHR peer-review process

A small number of Clinical Knowledge Administrators are appointed to collectively take responsibility for the operations of the CKM instance. They appoint editors who are charged to develop and enhance the clinical content of each archetype from its initial draft through to a published state. The CKM tool supports this iteration by enabling the editors to run a series of review rounds to gather and collate reviewer feedback and manage the associated version and audit controls.

An archetype peer-review round is manually initiated by an Editor. They invite a subset of registered CKM reviewers - selected to ensure an appropriate cross section of professions, health domains and geographical location are represented. In addition, anyone who has a special interest in participating and requests an invitation to that review will also be included. Reviewing is optional and reviewers can opt out of any review invitation.

Review rounds are typically sent out for a period of two weeks. This review period can be adjusted by editors on a per review basis.

Reviewers can comment on any or all components of the archetype, guided through the various components by a 'wizard' process. They can also respond to a some specific questions asked by the editor and targetting opinions on identified editorial issues. The only mandatory response is a final recommendation about readiness for publication:

- Accept – ready for publication;
- Minor Revision – trivial changes only (usually spelling/grammar), otherwise ready for publication without further community review;
- Major Revision – significant changes are needed, requiring further community review;
- Reject – not fit for publication or fundamentally flawed: and
- Abstain – no recommendation.

At the end of the review period the editors meet, usually via teleconference, to collectively respond to the feedback, update the archetype with agreed changes and decide on the next steps. If all recommendations are 'Accept' or 'Minor Revision' then consensus has been achieved and after the minor changes are applied, the archetype is ready to be published. If 'Major Revision' or 'Rejected' are recorded, then further review rounds are usually required until consensus is achieved.

All review comments plus the responses of the editors to each reviewer comment are captured as a record of provenance and viewable by all registered users, ensuring transparency of the desicion process and accountability of the editors to the user community.

Approach

The following narrative outlines openEHR approach using a recent example of a complex cross-SDO collaboration between the openEHR and HL7 communities for representation of Adverse Reaction Risk information models, also known as Allergy/Intolerance within the HL7 community. This narrative has been constructed retrospectively from audit trails and review round recrods captured within 3 CKM instances based the international openEHR community, Norway and Australia.

The very first iteration of the draft candidate for the Adverse Reaction archetype was authored in April 2006 by a single Australian clinical informatician, Dr Sam Heard. It was one of the first archetypes uploaded to the openEHR CKM [3] on 23 July 2008 [4]. In July 2009 this archetype commenced its' first collaborative peer-review in the openEHR CKM.

In November 2010, Australia's National eHealth Transition Authority (NEHTA, now known as the Australian Digital Health Agency [5]) forked the archetype and brought it into the Australian CKM [6,7] environment and ran a series of five archetype reviews during the period to June 2011. The resulting archetype content formed the basis for adverse reaction data points in CDA documents which are used to transmit health information from Australian primary care clinical systems into the PCEHR (now known as 'My Health Record [8]').

The Australian archetype formed the basis for a further iteration by Dr Heather Leslie which included feedback from international reviewers plus a variety of other resources including academic papers [9,10] and documents published and available at the time by NHS England [11,12], Microsoft's Clinical User Interface group [13,14], and the Royal Australian College of General Practitioners [15]. It was uploaded as a fork to the international CKM in January 2012 [16] and an international peer-review round was commenced.

In May and June 2014, further harmonisation by Dr Ian McNicoll merged feedback from the international review with content from HL7's FHIR resource and RMIM publications available at the time. In June 2014, due to the major structural changes it was uploaded as a new archetype [17] – the 'Adverse Reaction (FHIR/openEHR)' archetype with the intent of conducting a series of joint FHIR and openEHR reviews and generating both a FHIR resource AND an openEHR archetype with matching, clinically verified content at the end of the process.

In July 2014 the first joint openEHR/FHIR review was initiated. Four editors were appointed to facilitate the reviewer feedback – two from openEHR and two from HL7 and the resulting archetype was uploaded into the international CKM in October 2014 and a second review round initiated.

Concurrently, the Norwegian Nasjonal IKT team forked the archetype into the Norwegian CKM [18] in November 2014.

Resolution of the second openEHR/FHIR review round did not occur until June 2015, nearly 7 months later, due to delays caused by waiting for FHIR ballot results. This feedback was incorporated this feedback into the next archetype revision [19].

In June 2015 the third joint openEHR/FHIR review round commenced in the international CKM. Simultaneously, the archetype was updated in the Norwegian CKM, aligned the international archetype and translated to Norwegian [20]. Subsequently, in early August 2015, the first review round commenced in the Norwegian CKM. Feedback from this review was added to the international feedback so that parallel archetype development could evolve in English and Norwegian, each archetype revision now incorporating feedback from the international openEHR, Norwegian and HL7 communities.

The resulting archetype was uploaded to the international CKM in October 2015 [21] and the fourth openEHR/FHIR review round commenced. Soon after the second Norwegian review round commenced using the latest aligned and translated version of the archetype [22].

At the completion of the November 2015 review round and analysis of reviewer feedback, the editors agreed that a consensus about the archetype clinical content had been reached amongst the participating reviewers. In the openEHR archetype, all FHIR-specific components were removed and published as the 'Adverse reaction risk' archetype. The original archetype was rejected – this archetype persists in the international CKM as part of the provenance/audit trail for the published archetype but marked as not for current use.

During the review process, the FHIR team maintained an equivalent FHIR resource, adopting the changes agreed through the review process. This was the evolving artefact that was reviewed by the FHIR community. At the time of archetype publication, the content of the archetypes and the FHIR resource were aligned.

The Norwegian team updated their version of the archetype to align the content and the translation. They initiated a final review in Norwegian, commencing in late November 2015. At its conclusion the Norwegian archetype was also published within their local CKM and is now governed autonomously by the Nasjonal IKT team as per their national mandate. The agreed intent of the international and Norwegian teams is to continue to collaborate when change requests arise or new requirements are identified. These two openEHR archetypes remain semantically aligned as of December 18, 2016.

Results

It has been possible to collate review related data from each of the three CKM instances that have been used as part of the evolution of the Adverse Reaction Risk archetype through to publication.

A view of the review process is shown in Figure 1.

Discussion

This Adverse Reaction Risk archetype started its' journey as the brainchild of a single clinical informatician. After a journey of many twists and turns the final published archetype is the result of voluntary contributions from over 126 individuals, see Table 1, each contributing according to their professional background and expertise during 13 review rounds carried out in 3 CKM instances.

Table 1– Contributors statistics for each archetype

Archetype	Number of review rounds	Number of reviewers	Number of reviews
openEHR – initial	2	19	26
openEHR – openEHR/FHIR	4	38	69
NEHTA	5	37	66
Norway	2	32	42
Total	**13**	**126**	**203**

There has been no further formal joint collaboration between the openEHR and FHIR communities since the November 2015 publication. At that point in time, the great majority of clinical content in both the resulting openEHR archetype and FHIR resource were aligned as a consequence of the joint review process.

Subsequently it appears that the FHIR resource has continued to evolve in isolation, effectively splitting from the jointlyagreed artefact, apparently due to further requirements being identified in HL7 implementations [23]. This divergence is unfortunate, but unsurprising. It highlights that in order to achieve

cross-SDO standardisation of information models there will need to be a willingness to commit to an ongoing maintenance process as well.

Inclusion of the HL7 community was extremely evaluable in order to gather broader expert input and has no doubt improved the quality of the archetype. The final archetype was agreed in terms of the clinical content and then a pure openEHR archetype and a corresponding FHIR resource were developed, based on that common clinical content. This was a significant achievement, likely inevitable without a strong commitment from each party to maintain alignment.

From the openEHR point of view, the timing and frequency of the HL7/FHIR balloting process caused significant delays to the joint collaborative phase, resulting in an expected three to six months timeline for a complex information model blowing out to eighteen months. The frequent and short review cycles used by the CKM editors reflects a more agile and iterative approach targetting a single information model at a time.

The traditional SDO process is usually a closed activity in which value is placed on participation only by credentialled individuals, determined either by financial membership or nomination as an expert. By contrast, in the global Web 2.0 crowdsourced environment in which the openEHR communities of interest operate, the opposite conditions largely apply. The openEHR methodology places enormous weight on broad participation, accountability of those in roles of authority to every member of the community, and transparency at every level of governance:

1. **Participation is open and free** – participation is open to anyone who is willing to participate to the extent of their ability. It is not limited to individuals or organisations who have current paid memberships, who are nominated as 'experts', or who have been designated as 'credentialled' experts. This may be challenging to many but it supports input from the broadest professions, health domain expertise and geographical sources.
2. **Everyone can participate according to their expertise.** The user interface and review processes in the CKM tool has been developed specifically to ensure that non-technical experts, such as grassroots clinicians, can participate equally alongside the technology savvy. It removes the need for clinicians to acquire additional technical skills in order to participate. All feedback is encouraged, ranging from the smallest grammatical correction through to solutions for the most complex informatics or implementation conundrums.

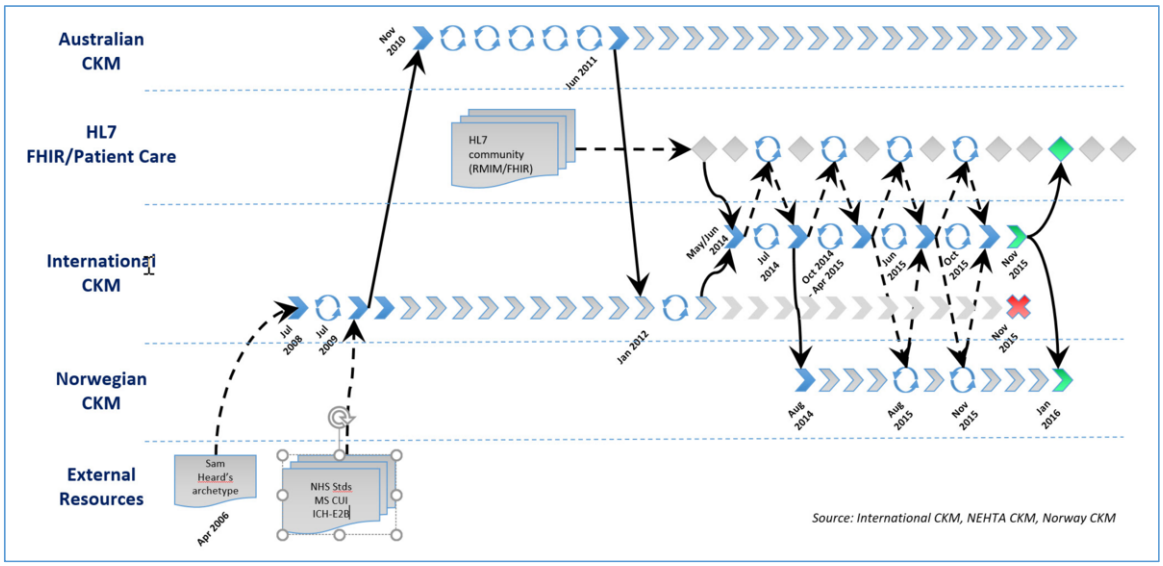

Figure 1 – Cross SDO Adverse Reaction Risk archetype collaboration process

3. **Transparency.** All of the activities and decision-making withing CKM is transparent to registered users, including but not limited to:

- Archetype reviews, especially:
    - acknowledgement of all participants and their roles;
    - clear association between reviewer comments and resulting editorial decisions;
    - number of contributions; number of review rounds; and
    - composition of the reviewer community to ensure that an appropriate expert group has been involved.
- Threaded, unmoderated discussion threads;
- Change requests by registered users and editorial responses; and
- Archetype audit trail.

If a registered user is not happy with decisions there are a number of ways of raising this with editors or via public discussion boards.

4. **Rapid and agile archetype publication.** In the work that the openEHR Clinical Modelling Program have done to date, the typical archetype review process involves 4 review rounds to achieve broad agreement on the structure and data points. Sometimes further review rounds are required, usually focussed on refinement of archetype descriptions and metadata. With an average review round duration of two weeks, this means that an archetype requiring six review rounds could potentially be published in twelve weeks. Archetypes based on established and agreed clinical content such as evidence-based cales and scores can often be published in one or two review rounds – corresponding to between two and four weeks.

Assuming modest editorial resources are available, when multiple archetypes are being reviewed simultaneously it is possible to publish archetypes in efficient and effective timeframes.

By contrast, the traditional SDO ballot process would not be sustainable in the openEHR environment where the intent is to develop, review and publish all clinical archetypes required for all clinical data recording. There is a practical need for archetype review rounds to be:

- Managed as a sequence of short, frequent review rounds that result in progressively refined iterations of the archetype;
- Initiated independently of other archetypes and for a variety of reasons, including initial publication, management of change requests and maintenance processes; and
- Run when required - sometimes in parallel with other archetype reviews and at other times on an ad hoc basis to resolve a specific issue.

5. **Shared archetypes amongst communities**. There are now a number of groups using the CKM tool as the basis of national or jurisdictional standardisation of data sets.

The traditional SDO process does not usually reveal the primary authors or contributors to their published standards, although they will possibly be known to SDO members. However the openEHR approach prioritizes transparency at every level of governance and for editors to be accountable to the CKM community:

- Free and open membership;
- Detailed audit trails to ensure accurate provenance and recording of editorial changes;
- Visibility of reviewer contributions and editorial responses
- Statistics about the review process, including:

- acknowledgement of all participants;
- number of contributions;
- number of review rounds; and
- background of all reviewers to ensure an appropriate reviewer community.

After publication of the adverse reaction archetype, collaboration between the openEHR CKM and Norwegian CKM teams has been active and ongoing. It has been successful largely because both groups are committed to working together and sharing the editorial work required to facilitate the reviewer feedback. openEHR and Norwegian editors meet regularly to collaboraton on solutions to modelling challenges, coordinate archetype reviews and update archetypes with feedback from both organisations. Reviews continue to be run in parallel in English and Norwegian on a range of archetypes - core content and specialised; simple and complex; crossing a broad range of clinical scenarios and professions. Archetype publication is based on the collective opinions of the communities that support both organisations. Both groups are willing for this to be extended to include other SDOs or national eHealth programs on request.

Conclusion

Clinical information modelling governance has been a new and largely untested challenge until recently – most of our collective experience in governance of health data standards has been at the complete message or document data set level. The Clinical Knowledge Manager tool was developed directly in response to identification of the need for efficient and responsive iterative refinement of the archetypes in response to identified requirements, especially during implementations – finding the sweet spot in the tensions between governance and evolution to ensure that the information models were safe and fit for use.

Clinical knowledge governance is a complex, evolving and poorly understood domain. The key to success of the openEHR approach, as described, is the result of humans choosing to collaborate to make a difference in the healthcare domain, using technology as the means to solve a shared problem. It is a socio-technical solution – a combination of the openEHR technical specification for an electronic health record architecture, a pioneering online knowledge governance tool, clinician engagement and a web 2.0 approach to harnessing the collective efforts of a community of volunteers.

Further analysis needs to be carried out to explore the impact of this approach as the number of published archetypes increases so that trends, patterns and conclusions can be identified.

Disclosure

The Clinical Knowledge Manager tool was developed by Dr Heather Leslie and Ocean Health Systems.

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