SemanticHealthNet

Strategic deployment of structured clinical models for medical subdomains

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**Annex 6
to SHN Work Package 3
Deliverable D3.3**

Final version, March 31, 2015

Document description

Deliverable:	Annex 6 to SHN WP3 Deliverable D3.3
Publishable summary:	In this Annex, several initiatives for structuring clinical models are described, with their usefulness for diverging goals in health care, multi-disciplinary collaboration between medical and allied health subdomains, preservation of contextual information, and support for archiving and legacy conversion.
Status:	Final draft
Version:	1.5
Public:	x Yes
Deadline:	March 31, 2015
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Note :

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Introduction

The selection, implementation and certification of electronic health records (EHR) could benefit from the required use of one of the established clinical model approaches. This becomes even an essential asset for the lifelong record of individuals, where issues about data permanence and preservation surface. Currently EHR vendors are excused from adhering to any standard for clinical data, where it is known for some 20 plus years that standardization of medical data is a cornerstone for patient safety, interoperability, data retrieval for various purposes and the lifelong preservation of such data. This annex will briefly introduce the issues and gives a brief recommendation for future work in this area.

Clinical Modeling Initiatives: too many or too little?

We see various examples of clinical modeling initiatives in the last decades. This clinical modeling work started with the invention of the two level modeling approach for EHR by Rector et al (1992). In this approach, the basic EHR system functions and the specification of medical content are separated out in two levels, each level handling parts of the EHR functionality. Level one addresses the basic system functions, level two the required variations in content to address the diversity of patient populations. Applying clinical models allows for extreme variations, while at the same time being based on the highest level of standardization possible.

Goossen et al (2010) reviewed 6 initiatives that know each their implementations. The examples reviewed include the Intermountain Health Care Clinical Element Models (CEM), the ISO 13606 archetypes, the OpenEHR archetypes, the HL7 v3 templates for Care Record message and for CDA, the Korean Clinical Contents Models and finally the Detailed Clinical Models based on Unified Modeling Language (UML) practiced by HL7 International and in the Netherlands.

However, since then three additional initiatives evolved: the development of the Clinical Information Modeling Initiative (CIMI) approach which takes into account a basic meta model in UML (BMM) to define clinical models and to keep them consistent over time. CIMI uses the archetype definition language (ADL), but upgraded this to version 2.0 which overcomes many of the limitations of older archetypes. ADL 2.0 now includes code bindings for instance. The second new initiative is the Fast Health Interoperable Resources (FHIR) ® from HL7. Instead of the earlier v3 approach, FIHR does not require all resource content to be specified according the standard, but also allows extensions. FIHR standardizes 80% and leaves 20% open. FIHR uses modern technology as Restful interfaces and JSON. A caveat is that FIHR allows non standardized content, hence hampering interoperability in favor of speed. Finally, the Semantic Health Net approach deploys ontology based modeling, using the Web Ontology Language (OWL) representations in which the triplets are the core (Martínez-Costa et al, 2015).

How do the new kids on the block perform compared to the older six?

The review carried out by Goossen et al (2010) used a bottom up approach, identifying the single data element as the atomic level of modeling, specify this, and from there on move upward to nesting models, compose models into clinical meaningful functions, combine it all to a EHR. This approach is still very workable, and moves to become the gold standard for comparing clinical models. In particular, now the ISO Technical Specification 13972 on Detailed Clinical Models expresses the requirements for clinical models independent of the logical modeling approach or the technical implementation formalism of choice. It is beyond this contribution to discuss all of the TS 13972, but the core will be discussed here.

The core requirements for clinical models are: name for each data element in the model, definition of the date element, unique binding of the data element to a unique code from a standardized terminology, data

type, if data type is a physical quantity then the unit must be added, if data type is a coded element with a value set, then each value must have an unique code. The first impression of these three new approaches is that CIMI, FHIR ® and SHN will meet these minimum requirements, but additional review is recommended to get a precise comparison.

Clinical Models are really useful for many health care goals

The various models described above are known to be helpful for various uses of health related data. Some uses include capturing, managing and storing clinical care, facilitate clinical decision support, allowing aggregations for quality indicators, epidemiology, clinical trials and management information.
Such use and reuse of clinical data do require that the unique semantics of each data element can be determined and can be maintained over time. Hence storage of the unique code together with the data, and preferred also with a tag to the clinical model the data is based on will largely facilitate life long use of a person's data for his/her health to benefit from it. This implies the golden rule that every data element must have it unique code from a controlled and standardized terminology, such as Snomed CT, LOINC or ICNP, etc.

Transformation of clinical models and issues coming up

Various projects assume that their clinical models, when the logical model is iso-semantic (CIMI, 2010), can be transformed from one formalism to another. Smits et al (2015) argue such transforms carried out between DCM in UML and FHIR® lead to information loss. However, their paper is based on DCMs that are not completely expressed in the tools applied (The DCM UML tool requires each data element and its specification to be computable, up to the level of computable value sets. The review by %%% used DCMs that had many specifications attached in text files).
Another issue in clinical modeling is where does the clinical model stop and where does another model approach (that of compositions) start. There is some understanding that a clinical model is small, has up to tens of data elements, but must be seen either as atomic such as the Body Mass Index which is a single derived data element, or as molecular. Molecular examples include a blood pressure DCM or archetype covering data elements for systolic value, diastolic value, average value, body position etc. Molecular examples are also assessment scales, such as Apgar score (Cuggia et al, 2009), Glasgow Coma Score (Goossen & Oemig, 2014) and many of such instruments that have a sum score derived from a collection of 1-n single data elements. The moment that a full body exam is carried out, an assessment form is used, etc, we are talking about compositions. Smits et al (2015) reviewed the care plan model, but in fact a care plan model would entail six to hundreds of DCMs and is therefore hardly comparable because it requires the top down comparison (Goossen et al, 2010). Would their transform been handled using the gold standard of comparing, mapping and transforming from the single data element, their conclusion might have been different.
On the other hand we have seen in SHN that conversion from one model to another is very well doable, and SHN promotes the use in the background ontologies to analyze the source model, set the rules for proper representation and from this representation move to the target model (Martínez-Costa et al, 2015). Proper transforms between iso-semantic models is certainly an issue to address in further research and practice environments (CIMI, 2015, Martínez-Costa et al, 2015).

Nesting nesting nesting required for multidiscipline approaches and contexts

Some of the core standards used in clinical modeling have one thing in common: they create a reference (information) model which holds the small classes with baseline characteristics (the first of the two level

modeling). From these classes domain models can be developed, using overall characteristics for that clinical domain. These models are often specified into implementation artifacts as an EHR summary, a message, entry form etc. And then, the second level specifies the clinical content in the various clinical models. This way a cascade of models can be created from a domain to a section to a model to a data element. Some models are generic and can be specialized. Nesting becomes possible for even further details or variations. On the other hand, the bottom up approach from many small clinical models to numerous compositions becomes possible: standardizing to the maximum on detail and allowing maximal variations in compositions. Two well known specifications include the 13606-1, where the single entry is clustered into sections, folders and finally the full health record. The HL7 CCD standard has 15 base categories such as patient, diagnose, vital signs, medications, allergies and more. Such standards are very useful for ordering the content into clinical meaningful manners. Hence it offers context and multidisciplinary recognition. Contexts exist in many forms, such as time and location, phase in a care process, a small component in a whole (such as one data element as part of a whole clinical model, or a DCM as part of a larger composition such as the discharge summary. Also, whether something is a request, a promis, a goal, or an event (to paraphrase the HL7 v3 moodcodes that define this), forms an important context. Clinical Models must be able to define multiple contexts, either intrinsic to the model, or relevant to its use in a process or composition. The use of clinical models can to a large extend be discipline independent. For example, in principle, when the proper instructions are used, it would not matter for normal circumstances for many health care observations or actions which discipline is performing it. However, the discipline carrying it out would be part of the context. And, some health care activities are exclusive to specific disciplines. This is often regulated by legal boundaries or professional guidelines. The use of clinical models would support multidisciplinary work due to better mutual understanding on behalf of the patient.

The fools with the tools make the rules

This saying of the Results 4 Care DCM tool developer illustrates well how important tools are in the development, maintenance and deployment of clinical models. He has worked on the DCM tool, the BMM and the CIMI reference model, in particular to create the iso-semantic transformations. Part of that work is included in the review of clinical modeling tools by Moreno Conde (2015). He summarizes requirements for clinical modeling tools and reviews several examples as for archetypes, HL7 templates and Detailed Clinical Models, and specifies these for various roles in the creation, modeling and implementation of clinical models, among others. It is beyond the scope of this short contribution to go into details, but suffice with pointing to the importance of this, in particular where such tooling facilitates in the validation of the quality of content, modeling, code bindings and additional criteria.

Towards lifelong preservation of clinical data

While the papyrus roles, the 5th century codexes, the large foliants in paper manually copied by monks last for many centuries, and similarly the paper medical records stay in good shape for decades, it is well known that the 'smart' digital data storage based on magnetics we use in modern computer systems definitely do not last longer than a decade. In some instances it will be only some years. So were paper can simply get lost my misplacing, bytes can vanish too. The Committee on Data for Science addressed this issue in the 2012 CODATA conference in Tapei where the topic of lifelong preservation of health records content was addressed a first time.
Data-intensive science plays an important role in transforming raw observations into applicable, intelligible results and discoveries. In healthcare such discoveries will increasingly be based on observational patient data coming from electronic health records, apps and devices and clinical data warehouses. Of course this implies storage of Petabytes, Exabytes, Zettabytes and even more of patient related data. And these must be stored lifetime for individuals, and grouped into meaningful datamarts for populations' research. An additional issue is the need to integrate diverse health records that have been

captured in different settings and different EHR systems, and data from various source systems and in modern times apps on smart phones and other e-health applications.

Hence the question about permanence of clinical data becomes obvious. This means that not the hardware on which data are stored is key and not the software, but the informational structures and very importantly, the meta-data about clinical data. Goossen (2014) addresses these issues of data permanence and preservation, and gives some first directions how to handle this both on conceptual, logical and technical levels. Clinical data modeling, and governing these models is of the highest value for healthcare. Goossen & Goossen-Baremans (2013) specify how the clinical governance of detailed clinical models can be carried out, and that this even would require national organizations working on this. Discussions in SHN show that the scope of governance should even be the European level, in particular since we do see increased cross boarder data exchange in healthcare, such as in the epSOS project.

Conclusion and recommendation

We see several approaches in clinical modeling emerging in the past decade. Important is that despite some different approaches, commonalties get more attention. With the ISO TS 13972 criteria are expressed for the conceptual component of clinical models (the evidence base from the medical knowledge), the logical model (data elements, code bindings, data types, units, value sets, relationships), and the way various technical formats can be supported. The options provided by CIMI, DCM tooling and SHN to transform iso-semantic models is seen as an important way format, e.g. to capture on the enormous investments in time, money and energy put in the clinical model development and deployment.

This situation also implies that there is no excuse for escaping the use of clinical models in EHR systems and other health information technology. The recommendation should be to be obliged to use at least one clinical model formalism. The translation tools will facilitate to exchange between various systems based on different modeling paradigms. So, there is choice between the various clinical models and formalisms, but it is a must to choose at least one. Clinical models do serve many purposes in clinical practice, decision support and aggregation purposes. One additional use becomes increasingly important: clinical models are a cornerstone for data preservation during a person's lifetime.

All these arguments for use however, are dwarfed by the ultimate reason for required application of clinical models: that is that patients are entitled to receiving the best electronic support of their care based on the state of the art technology. Using clinical models implies that we can move from semantic interoperability – i.e. understanding what is exchanged – to focus on pragmatic interoperability: that is to do the right thing on behalf of our patients when the information is understood and put into the proper action!

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