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A Survey of Standard Information Models for Clinical Decision Support Systems

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Abstract. HL7 CDA, vMR, and openEHR archetypes have been utilized as standard information models for clinical decision support systems. Compared to openEHR archetypes, vMR typically requires less time to develop and extend which makes it a good fit for rapid prototyping and pilot projects, while openEHR archetypes handle the data and semantic specification better. Using CDA for clinical decision support systems is discouraged due to its complexity, steep learning curve, and potential safety issues.

Keywords. Clinical decision support systems, vMR, openEHR archetypes, CDA

1. Introduction

A fairly recent analysis of 17 high quality systematic reviews of computerized Clinical Decision Support (CDS) Systems (CDSS) showed that evidence of CDSS impact on practitioner performance and patient outcomes could be found in 57% (52/91) and only 30% (25/82) of unique studies that studied these end-points respectively [1]. Many other systematic reviews paint a similar picture on effectiveness of CDSS. New trends in CDSS research point to identification and understanding of barriers of adoption, and theoretical methods to overcome weakness of existing approaches [2], such as methods of knowledge discovery; reasoning and inference; and interfacing, sharing, and execution of CDS knowledge and interventions within Electronic Health Records (EHR) [1,2]. Service oriented architectures (SOA) accompanied by the necessary standards have been presented as possible enablers of sharing and portability of CDS capabilities across different settings [3]. Five broad categories of standards could be employed by CDSS and host systems when invoking and communicating with each other: standard terminologies, standard terminology and ontology inference, standards for representation of knowledge base and decision models of CDSS both in non-executable and executable formats, standards for defining the information model that CDSS uses for its inference, and standards for communication between the components of CDSS and host application to receive data and transmit the recommendations back [4]. Various formalisms and standards exist in each of these categories, few of which are CDSS specific. A unified information model that can be used as input and output of CDSS processes is desirable, as heterogeneity of EHRs is considered a major barrier to deployment and adoption of Clinical Practice Guidelines (CPG) and CDSS [5]. The main information model standards that have either been specifically developed or utilized for CDSS are HL7 Virtual Medical Record (vMR) [6], HL7 CDA [7], and

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openEHR archetypes [8]. This paper aims to provide an overview of these standards in terms of their adoption, evaluation, current state, and future outlook.

2. HL7 Virtual Medical Record (vMR)

HL7 vMR standard, currently at Release 2 (R2), grew out of the need to standardize the "Virtual Medical Records" concept developed earlier. vMR defines a logical information model using UML which although based on HL7 RIM, aims at hiding the complexity of full RIM and provide a simple and stable representation of clinical model for CDS knowledge engineers. The model could be further constrained using the vMR templates, and a vMR XML Specification is developed to define the physical models derived from the logical model [6]. The development of HL7 vMR was informed by a consensus based review of 20 different CDSS, both large scale home grown and a number of commercial systems from 4 countries (primarily USA) which led to inclusion of 131 data elements [9]. vMR consists of 22 classes and subclasses organized in two axes, one that presents the clinical data in 8 high level classes and the other presents clinical workflow moments. The VMR concept has been used or extended in a number of ways for CDSS before becoming a standard, most notably as a possible solution to Arden Syntax curly braces problem, by providing a standard information model [10], in the SAGE project [11], and by the Knowledge-Data Ontological Mapper (KDOM) framework to facilitate mapping and bridging the gap between abstractions utilized in the CPG definitions and EHRs [12]. vMR standard was used in a cloud based CDSS architecture as the input and output of a rule engine based on Arden Syntax, whereby EHR data received in CDA format, and social media data were converted to vMR and matched together using an ontology matching and repository service [13]. vMR is the standard of choice for a reference implementation of CDS services maintained by OpenCDS platform which has been utilized in a number of initiatives and could lead to growth of its uptake [14].

Several studies have evaluated different aspects of vMR. Ebrahimnia et al. evaluated vMR R1 against the data elements in treatment representation of a guideline based CDSS in primary care in France and found out that from the 18 elements in their model, all except one data element that could be calculated at run-time, were found in vMR. However, they also found that semantic fidelity was incompatible in 5 of the 17 mapped elements [15]. A more extensive assessment of vMR has been performed in three stages under the auspices of the EU MobiGuide project that aims to build a guideline based patient guidance system for patients with chronic illnesses through a distributed ubiquitous CDSS [16]. Initially vMR R1, CDA, and openEHR were compared based on expressiveness of the standards, user-friendliness, ability to link data with persistence models and CDSS engine, ease of representation of data and extension of the standard to represent data, provision of functionality for semantic integration (i.e., querying interfaces and support for vocabularies), security and privacy, and scalability [17]. It was concluded that the combination of vMR and openEHR archetypes based on vMR classes is the most feasible approach. This decision was based on the fact that vMR classes closely resemble the data found in EHRs, thus it would be possible to receive data from EHRs in that format. On the other hand, transforming data from vMR structure to openEHR archetypes is also possible, thus using vMR based archetypes provide additional benefits such as robust terminology binding and query and compliance with ISO/CEN 13606 norm. CDA was

not considered due to its steep learning curve and complex representation needs, and less robust terminology binding and query mechanisms compared to openEHR. The second stage was outlining potential types of vMR extensions and frequency of classes needed for representation of CPGs. Extensions included relaxation of definitions of vMR classes; using several attributes to capture the data; terminology post-coordination; and adding attributes for capturing data elements such as CPG executed step, quality of data, patient preference, and other proprietary data. Workflow related classes of vMR, such as proposal-order-result pattern, mainly used for communication of CDS recommendations, were the most frequently employed classes of vMR [18]. Finally based on experience with full modeling and implementation of the one CPG, several strengths and limitations of the vMR were identified. Expressive power, possibility of automatic mapping of EHR data to vMR, strict separation of demographics data, and ability to represent vMR in JSON and light weight XML for persistence, query, and communication between components of the system were identified as strengths, while steep learning curve for the semantics of vMR, the need to align CPG authoring tools to the standard, possible performance issues of extensions, and large effort to migrate from vMR R1 to R2 were considered as limitations [19]. Overall they reported that according to the US Health IT Standards Committee criteria [20], vMR is appropriate for large scale pilot projects like MobiGuide.

3. openEHR Archetypes

openEHR is based on a two-level modeling approach using a small stable reference model to describe generic constructs of a health record, and a detailed, domain specific and reusable definition of clinical concepts called archetypes [8]. This presents three types of entities that are required to capture health information meaning, i.e. the reference model, archetypes, and terminologies unlike vMR which only requires two levels of reference model and terminologies.

openEHR archetypes have been evaluated for CDSS in few projects. Marcos et al. in a series of articles presented a development methodology and a case study of utilizing archetypes and CPGs for delivering CDSS [21–23]. The development methodology included identification, specialization and creation of new archetypes, and had to fulfil 4 requirements: designing a collection of archetypes that present clinical decision tasks found in CPGs but not typically modeled as archetypes, explicit modeling of CPG concepts that implicitly or explicitly represent more than one archetype category, aligning granularity of CPG and clinical concepts (some CPG concepts are at higher abstraction level and need to be broken down), and extending the CPG model to include results of CPG execution that need to be stored in the EHRs for further use. In their case, 15 archetypes were required for presentation of CHF guideline, the most frequent were diagnosis and medication, of which only five needed specialization [21]. Design and prototype implementation of CPG linkage to EHR and execution showed that the mapping process could be cumbersome, but possibly highly reusable, with the additional benefits of ability for mapping at concept rather than data element level, and write back to EHRs. Furthermore, clinical and technical validity of archetypes would be assured, as in theory they are developed mainly by clinicians [22,23]. However the scalability of their approach and easy reusability of specialized archetypes have not been tested. Besides, Kashfi and Robledo found out that

development of CDSS specific archetypes by clinicians may not actually be practical, possibly due to the fact that besides the information model, the knowledge and inference model needed to be taken into consideration [24].

4. HL7 Clinical Document Architecture (CDA)

HL7 CDA is an HL7 RIM based standard that specifies the semantics and structure of clinical documents for the purpose of exchange [7]. EGADSS is the first example of a SOA design that utilizes Patient Summary CDA mapped one-to-one to CDS engine, and Arden Syntax as the rule execution engine [25]. Kazemzadeh et al. proposed a framework and architecture that supports offline mined clinical data stored in predictive modeling markup language (PMML), patient data and decision output in CDA document format, and extensions to GLIF3 to interact with the knowledge in PMML and input CDA [26]. While use of CDA allows for standard input and output of the CDS results, their method relies on generic parsers of CDA that need to be developed for each PMML. The SAPHIRE project architecture is another example where level three CDA document, an ontologically extended GLIF3 (both from workflow perspective and interactions with sections and contents of CDA), IHE XDS integration profile, and Web services technology for interacting with workflow were used to deliver a CDSS enabled monitoring platform that combines data stored in the clinical information systems with data acquired through wireless from medical sensors [27]. The difference of this approach with the earlier VMR approaches such as KDOM [12] is that it only relies on existing standards i.e. the CDA, and IHE XDS, to locate and source information from EHR and does not require development on the part of EHR to expose their data as canonical views in the respective systems database. Finally, Sáez et al. implemented an architecture for a rule based CDSS that uses CDA for both data input and result output and a binding file to map between the CDA and the inference engine [28]. Given inability of CDA to relate a set of entities, such as a set of input facts to output facts together in a relationship, they utilized a generic structure to display the rule input and results both in human and machine readable formats in the output CDA. This allowed for chaining and firing rules that provided recommendation based on the result of an earlier rule.

CDA has several limitation for CDSS use case such as structural complexity, and steep learning curve. The complexity of CDA data structure, even to the point of potentially creating patient safety issues, has also been noted by developers of the vMR standard [6]. Given most of the above mentioned efforts are from the time when vMR was not yet a standard, it may not be surprising that they have not considered or compared the two. However Sáez et al. do mention the possibility of adapting their solution to vMR as a future direction of their work.

5. Discussion

A standard information model with ability to bind to terminologies could play an important role in wider adoption of CDSS by facilitating integration of CDSS with various EHRs. HL7 CDA, openEHR archetypes, and HL7 vMR are the main standards in this area that have been used in different pilot projects or implementations of CDSS. Due to its overly complex structure and steep learning curve, CDA may not be suitable

or even safe to be used for CDSS. HL7 FHIR, an alternative for CDA, has recently been suggested as means of interoperability of CDSS with EHR data [29].

Assessment and comparison of vMR and openEHR as performed by González-Ferrer et al. [18] appears to be somewhat in contrast with findings of Marcos et al. [21–23], possibly because the vMR assessment did not involve openEHR experts. A qualitative assessment of vMR R1 and openEHR as a logical schema for capturing CPG clinical statements that can be mapped to both patient data in EHRs (input) and patient specific recommendation (output) was carried by 4 experienced informaticians (2 experts for each standard) using 10 representative clinical statements from the two CPGs used in the MobiGuide project [30]. Overall it was concluded that while openEHR serves the purpose of data and semantic specification very well, and can be used for other purposes such as secondary use of EHR data, it requires more effort and specialized tools to develop. On the other hand, creating instances of vMR takes less time as it is specifically designed for CDSS and fit for rapid prototyping in pilot projects, and variability of vMR extensions could be reduced by introduction of vMR templates. An additional benefit of vMR is its better position for harmonization with CDSS specific or other standards developed by HL7 organization, such as harmonization with HL7 Health Quality Measures Format draft standard [31]. However vMR's heavy reliance on terminology rather than more extensive information model could lead to higher variability and less reuse, opposite of what is typically expected from standards. Using terminologies versus information models to capture meaning unambiguously in clinical systems is a known problem due to overlap between them and their relative independent development over time, without enough consideration and agreement on a set of criteria that defines allocation of information items among them [32]. Some recommendations on how to deal with this issue has been provided in the past [33]. Several efforts of converging various information model and terminology standards communities have happened, such as Clinical Information Modeling Initiative (CIMI), an ongoing multi-national collaborative that aims to provide a single (later changed to two) formalism for detailed clinical models [34]. Success of such initiatives remains to be evaluated.

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