Clinical Model and Archetype Management System in a Regional Health Project

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Abstract— **Concept Oriented Repository (ROC) is a tool developed for the management of data structures and concept definitions used in Electronic Health History (HSE) project from Valencia Health Agency (AVS). The tool uses the Detailed Clinical Models (DCM) as a way to define clinical concepts independently of the healthcare standard chosen on the organization. These definitions create a common framework where different actors from the agency can come to agreements on which elements are part of each one of the concepts included in HSE. These concepts can be used later for the definition of technical artifacts (data structures, forms, messages) on AVS information systems.**

Keywords— **Archetype, HL7, Knowledge management, Semantic interoperability.**

I. INTRODUCTION

Putting the knowledge on the center of Health Information Systems is one of the most important trends all around the world. Several organizations and committees are working in different alternatives to define reusable clinical concepts. In fact, the use of formal concept definitions is already in use in countries such as UK, Australia, Brazil, Netherlands, or Sweden. There are more than 15 clinical concepts repositories in the world that use different formats for concept definitions. The NEHTA Clinical Knowledge Manager [1] (a national version of the openEHR Clinical Knowledge Manager [2]), Clinical Element Models (CEM) by Intermountain Healthcare [3] or HL7 CDA and DICOM IHE profiles [4] are examples of the importance of this approach.

The main problem with this approach is that each repository represents the concept in a particular standard or format. R relationships between similar concepts represented in different standards are unknown, which at the end hurts interoperability. Detailed Clinical Models (DCM) where created from the need of making compatible and connect those concept definitions. DCM provide an abstraction layer independent of the chosen standard. DCM group all available concept definitions into known clinical concepts (i.e. discharge report, patient summary, etc.).

DCM can be defined in a conceptual and structural way [5]. Conceptually, DCM are information models of a discrete set of precise clinical knowledge which can be used in a variety of contexts. Structurally DCM are descriptions of items of clinical information that include the clinical knowledge on the concept, the data specification, a model and where possible, technical implementation specifications. Provide data elements and attributes, including possible values and attribute types, needed to express clinical reality in an understandable way for both clinical domain experts and modelers.

DCM are the basis of the Concept Oriented Repository (ROC) developed in the Electronic Health History (HSE) project from Valencia Health Agency (*Agencia Valenciana de Salut*, AVS). Main purpose of this project is to guarantee access to the relevant clinical information to both patients and health professionals.

There is also a need to provide methodologies and tools to manage these new artifacts and ease its use on health information systems. ROC objective is to provide a platform for the management and governance of detailed clinical models and allow its use on AVS Health Information Systems.

II. METHODOLOGY

The Concept Oriented Repository developed for AVS HSE project implements following characteristics:

A. Independency of standards, specification models and languages

The repository can manage DCM specifications in any native format, from text documents, spreadsheets, or pdf documents to computable definitions such as ADL archetypes or references to the executable programs used to give support to that concept (such as Java or XQuery programs).

B. Colaborative edition

One of the basic aspects of the tool is to ease the concurrent and collaborative edition of concepts. The tool allows the creation of specific working groups for domains or even specific concepts by defining roles and permissions both at concept and application level. The tool also provides the user with more mechanisms to ease collaborative edition of concepts, like being able to subscribe to concepts to be informed of their changes or providing a notification wall with the latest changes on the subscribed concepts. The repository also includes a comment system to let users suggest improvements during concept lifecycle.

C. Search concepts by its structure, content, metadata, or ontology

Repository includes the definitions of a set of metadata associated to each DCM. Metadata include fields such as unique name, description, DCM Type, version, original language and translations, lifecycle state, authors, managers, authoring and revision dates, etc. To obtain this minimum metadata subset we analyzed the proposed metadata in ISO 13972 draft "Quality processes regarding detailed clinical model development, governance, publishing and maintenance" [6], CEN TS 15699 [7], which is a extension of Dublin Core norm [8] for healthcare domain, and metadata set defined in CEN EN13606 part 2 [9] for archetype definition. Additionally, resources related to each DCM have also associated metadata (such as author, description, language, format, or organization) to ease resource identification and discovery. Finally, if the associated resource is defined in a computable format (such as an ADL archetype) system can search for specific information inside it.

D. Management of concept evolution

ROC implements a model to manage the lifecycle of DCM from their creation as drafts, marked as public or private, creation of new versions, marked as obsolete or revised, etc. This, in addition to the version history makes possible to retrieve a present or past DCM definition when desired. In particular, concepts can be in one of the following stages: Draft, Team review, Public, Validated, Obsolete, and Revoked. 'Draft' status is used for the first upload or creation of a concept which its validity is yet unknown. 'Team review' status is used for a concept which is being iteratively revised by a team to reach a consensus on it. 'Public' status is used to mark a concept which is mature enough to be used but has yet to be validated on a live system. The latter is marked with 'Validated' status. From there a concept could be marked as 'Obsolete', marking that concept is not valid on its current form and probably would

need a new version to be correct again or 'Revoked' that implies that the concept itself is no more valid and should not be versioned or specialized.

E. Multilingual support

Both concepts definition and the repository User Interface allow the use of multiple languages. A subset of the concept metadata has been considered to be language dependent and can be easily translated within the tool..

F. User management

Different roles with different permission set are defined depending on the role of the user in the system (concept creators, reviewers, translators, technical staff, etc.). The repository provides different functionality depending of the effective role of each user.

III. RESULTS AND DISCUSSION

Concept Oriented Repository is a web application developed in Java using Vaadin framework [10]. It is connected to the AVS authentication system in order to be easily included on the AVS workflow.

The designed system architecture (Figure 1) provides support for the normalization, discovery, and publication of concepts through a UI and web services. It also provides an audit system for administrators.
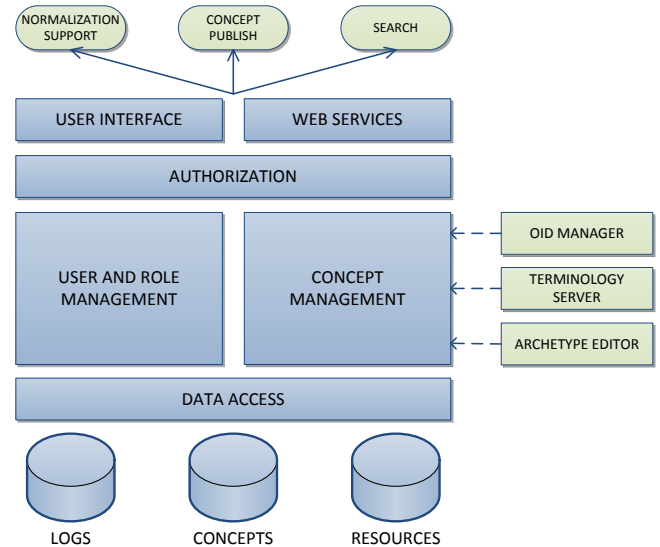

Fig. 1 ROC architecture

The repository is also related with other tools available in the AVS, such as the OID manager (GOID) to assign unique identifiers to DCM, archetypes and available implementation guides, access to the terminology service for the mapping of the concepts to available medical terminologies, and archetype editors that will be used for the definition and validation of the concepts stored in ROC.

ROC eases the coordination in the development, maintenance, and evolution of DCM avoiding the overlap of concepts over different healthcare domains. It promotes the creation of a validated reference set of DCM based on clinical evidence (when possible). Allows the persistence of DCM independently of their format and provides mechanisms for the access and localization of existing DCM.

The tool provides mechanisms to link concepts. In addition to versioning and specialization, ROC allows the definition of semantic links in the form of inclusions, exclusions, and associations. Inclusion can be seen as the containment of one concept inside of another one. On the other hand, exclusion marks the prohibition of containment (the concept is not part of the other). Association is a weaker relationship between concepts meaning that two concepts are somehow related. Figure 2 shows an example of possible DCM relationships on the repository.
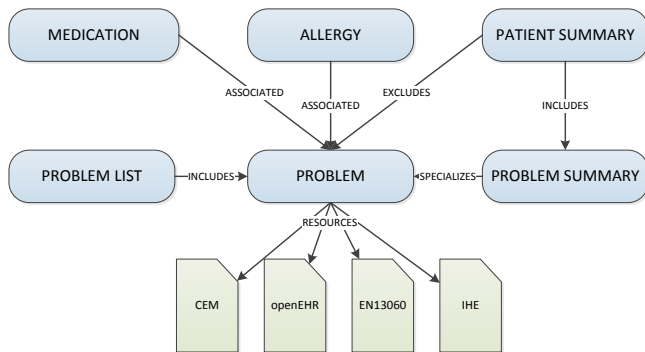

Fig. 2 ROC architecture

In this example, problem summary is a specialization of problem. Both medication and allergy are associated with problem DCM. Patient summary only contains a problem summary, but not the full problem, so problem is excluded and problem summary is included into patient summary. Problem is included into the DCM problem list (we could also have excluded problem summary from problem list). The DCM of problem has also different associated resources: three structured resources (two archetypes, openEHR-EHR-EVALUATION.problem.v1 and CEN-EN13606-ENTRY.problem.v1, and the CEM definition for

problem called HealthIssue) and the IHE profile of Concern Entry. All the metadata, relationships, and associated resources are what we call a DCM on the repository. It is worth noticing that ROC should not be considered ontology, as DCM rely on these three parts to be fully defined.

All these kinds of relationships between concepts are shown in the tool as mindmaps, which makes them easier to understand and maintain.

IV. CONCLUSSIONS

The definition of clinical concepts independently of the standard of the health information systems is currently one of the main trends around the world. The work currently being developed at Clinical Information Modeling Initiative (CIMI) working group [11] tries to create a model for the concept definition independently of chosen clinical records representation standards and propose it as a standard to the OMG. CIMI participants include IHTSDO, HL7, CDISC, EN13606 association, openEHR, Mayo Clinic, National Health Service (UK), or National Institute of Health (US). ROC is totally aligned with this philosophy and could support this future standard.

One of the proposed improvements is to integrate the repository in the concept development process. Connecting ROC with a tool like LinkEHR archetype editor [12] assures that archetypes included in ROC would be valid syntactically and semantically according to a chosen reference model.

Both concept edition process and lifecycle management require the implication and communication of all the different actors of the project. Success in this project would come from the understanding and cooperation among the members of the multidisciplinary team in charge of the creation and management of the concepts. Finally success will also come from the effective use of the concepts as reference definitions in AVS systems.

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