Design and Implementation of "Two-level" Clinical Information Systems, Based on Archetypes*

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Abstract

Normaly during a clinical information system design process, business entities are modelled directly into software and database models. Using this methodology in the healthcare domain, where the total number of concepts and their rate of change is high, clinical information systems turn out to have a short life cycle and to be expensive to maintain.

This paper describes the separation between the levels of knowledge and information, in the process of designing clinical information systems. It presents an implementation using an adopted domain reference model, which is based on relevant work of international standardization bodies, a specific implementation of clinical information systems based on the two-level modelling methodology and the concept of archetypes, and concludes by discussing advantages and limitations of such an approach.

Introduction

Designing and building a clinical information system is a difficult and time-consuming process. Developers have to meet domain specialists, write down the requirements and define models for their business entities. These models are the starting point for building the clinical information systems. This approach is repeated every time users define new requirements, or developers fail to represent a real world entity in a class or in a relational schema. This methodology does not work well in healthcare domain where the total number of concepts and the concepts themselves are rapidly changing.

Therefore an attempt was made to separate the level of knowledge from the level of information. As a result, developers become responsible only for a system's reference model (database schema) while users are now able to define the level of knowledge at runtime. Such a definition implies the creation of clinical documents, which are based on the reference model and describe a domain concept. These documents, called archetypes, are the business entities represented in the clinical information systems. Furthermore the adopted domain reference model is based upon relevant work of international standardization bodies and contains a limited and constant number of entities.

By adopting such a "two-level" methodology, clinical information systems can be built faster and last longer. Moreover, domain specialists have the ability to define new concepts, or edit/ reuse existing concepts in order to create new composite concepts.

This paper begins by presenting a number of approaches towards modelling Electronic Healthcare Record (EHR) systems and related work from European and international organizations. The following section presents the proposed system architecture, which has been developed at the Center of Medical Informatics and Health Telematics Applications (CMI-HTA) at the Institute of Computer Science (ICS) of the Foundation for Research and Technology- Hellas (FORTH) as well as design considerations[1][2]. A "two-level" clinical information system implementation is presented, based on archetypes. Finally, the paper concludes and future work is discussed.

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Related Work

A number of EHR standards and frameworks have been developed to assist with the interoperability and integration of distributed EHR information.

The European pre-standard ENV 13606:2000 [3] was first published in 1999 by the technical committee TC251 of the European Committee for Standardization (CEN). It proposes a set of interoperability measures to facilitate the communication between heterogeneous systems with respect to the requirement, that the meaning of clinical data, primarily intended by the original author, must be preserved faithfully and presented by the receiving system, even if the underlying system architectures of the sender and receiver vary. Part 1 of the pre-standard defines the architecture of an Electronic Health Care Record (EHCR). It does not define how this record is actually stored within a system but it is concerned with how such an EHCR is communicated between different systems.

Health Level Seven (HL7) is one of several American National Standards Institute (ANSI) accredited Standards Developing Organizations (SDOs) operating in the healthcare arena. HL7 is a standard in health care that does not focus on the requirements of a particular department in a health care organization but it addresses the entire health care organization. It does not assume or make any assumption of data storage within applications but it is designed to support various health care systems, both centralized and distributed systems, in heterogeneous environments to communicate with each other.

The Reference Information Model (RIM) is the cornerstone of the HL7 Version 3 development process [4]. RIM is a large pictorial representation of the clinical data (domains) and identifies the life cycle of events that a message or groups of related messages will carry. It is a shared model between all the domains and as such is the model from which all domains create their messages. In addition the standard's goals are to define the content in order to increase precision and reduce implementation costs.

Recently, an architecture based on a "two level" approach to building Electronic Healthcare Record systems has been presented[5]. Beale on [6] separates the semantics of information and knowledge into two level methodologies. The first level of reference model, the level of software objects models and database schemas which are used to build information systems. It must be small in size, in order to be comprehensible, and contain only non-volatile concepts in order to be maintainable. The second level is the knowledge level, requiring its own formalism(s) and structure, and is where the numerous, volatile concepts of most domains are expressed.

The aim of openEHR [7] is to facilitate the creation and sharing of health records by consumers and clinicians via open-source standards based implementations. It promotes and publishes the formal specification of requirements for representing and communicating electronic health record information, based on implementation experience, and evolving over time as health care and medical knowledge develop. Furthermore it promotes and publishes EHR information architectures, models and data dictionaries, tested in implementations, which meet these requirements.

Domain Architecture

Clinical information systems manage information about encounters of a patient and store summarized info of "Who/ What/ When/ Where/ Why/ Whom". In a patient centric, or encounter oriented implementation, the minimal dataset requires information for

- patient identification;
- reason of contact;
- medical history;
- medical examinations; and

- diagnosis-treatment.

Having knowledge of the above characteristics, an attempt was made to separate the level of knowledge from the level of information while using a two-level methodology. Knowledge is based on a general and constant over time model and instances of information corresponding on a specific model. As a result, developers are responsible only for a system's reference model (database schema) and users are able to define the model of information at runtime.

This definition arises during the creation of clinical documents by means of the eXtensible Markup Language (XML) at runtime, which are based on the reference model and describe a domain concept. These documents, called archetypes, are the business entities represented in the clinical information systems.

The adopted domain reference model contains a limited number of entities remaining constant over time and is based upon relevant work of international standardization organizations. The presented implementation, as far as patient identification is concerned, adopts the reference model of Person Identification Service (PIDS) [8] from Health Domain Task Force (HDTF) of Object Management Group (OMG) . Clinical information can not be stored using a reference model similar to the PIDS conceptual model. So, in order to manage different types of observations, defined at runtime from a clinical observation archetype, a reference model was designed based on the OMG's Clinical Observation Access Service (COAS) [9]. Figure 1 presents the top diagram of the COAS conceptual model.

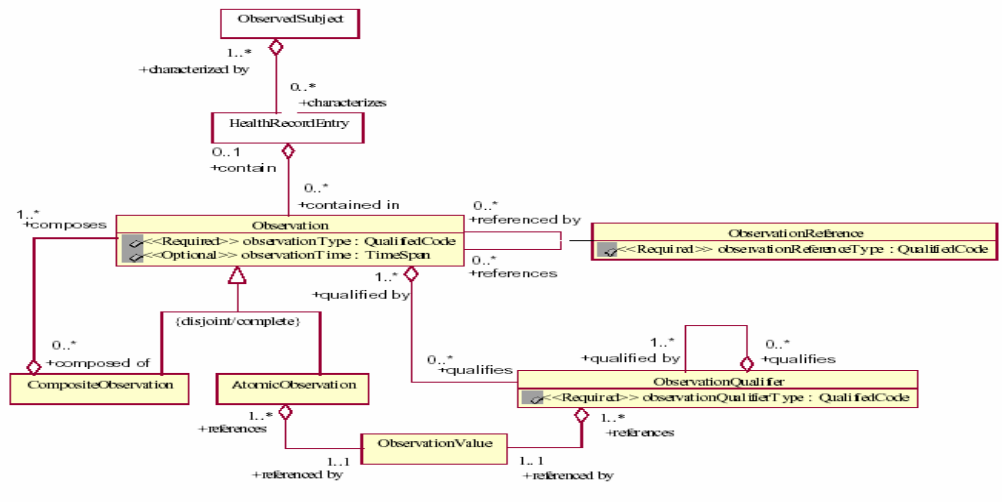

Figure 1. The Adopted OMG COAS Reference Model.

Implementation

The reference models of COAS and PIDS, that were described in the previous section form the core of the system's proposed database schema. This database schema is small in size, in order to be comprehensible, and contains only non-volatile concepts in order to be maintainable. In the implemented schema there are only two main concepts, Patient and Encounter, that exist always.

Significant clinical information to be managed is produced at the point of care (e.g. during a medical encounter) and is modelled to follow the Subjective Objective Assessment Plan (SOAP) model [10] (see Figure 2). .

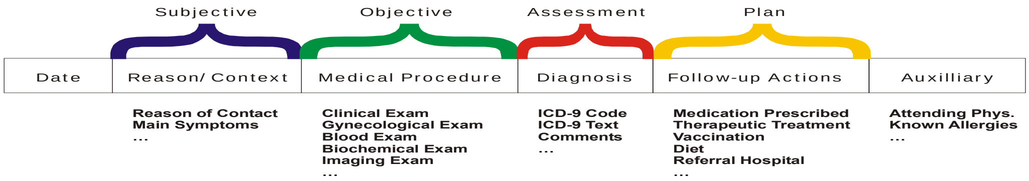

Figure 2. The COAS Reference Model is configured to Manage Medical Encounter Entries Following the SOAP Model.

These information instances (domain concept models) could be defined by authorized users at runtime, using an archetype editor. An application with a graphical user interface for creating XML documents that describe the business entities, which the clinical information system can represent, is depicted in Figure 3.

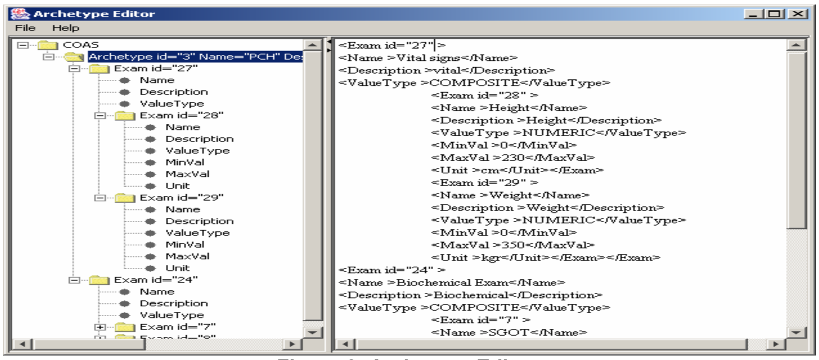

Figure 3. Archetype Editor.

Users have the ability to define two major types of archetypes; those that define a model for “patient identification” and those that define a model for “clinical observations”. Each archetype, defines a different model for patient identification, and therefore enables the management of different ID domains by the clinical information system. Elements of this XML document are traits, useful for identification purposes. Accordingly, each archetype that defines a model for clinical observations is a different clinical domain and elements of this XML document are different types of clinical observation. Figure 4 presents two instances of archetypes that describe two different ID domains. These documents identify a person using a different sequence of traits and can configure the clinical information system under consideration.

Figure 4. Alternative Examples of a PIDS Archetype.

Figure 5 presents two instances of the clinical information system. These belong to two different systems having their own patient identification model, described by the archetypes of Figure 4. Consequently, the clinical information system can be tailored to specific domain needs by the expert who creates the archetypes. For example, system A could belong to a primary healthcare information system and system B could belong to a laboratory information system(LIS).

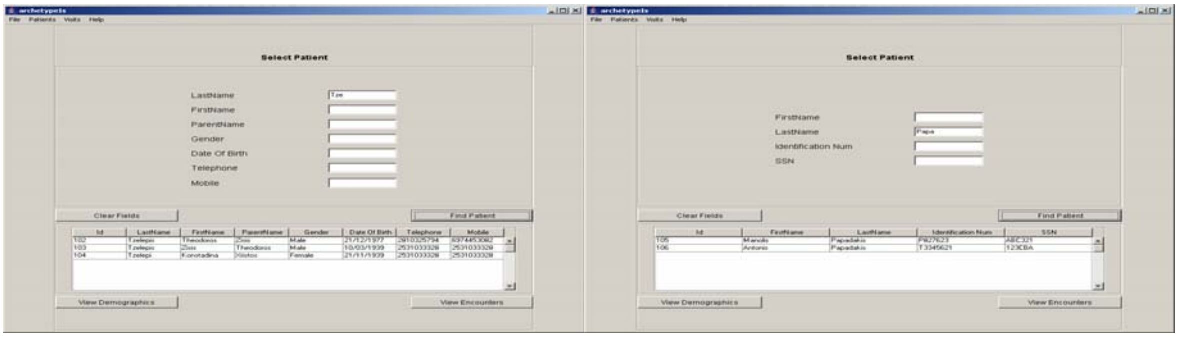

Figure 5. Patient Demographics Management.

Accordingly, archetypes describing clinical observations define the clinical context that the information system represents. Figure 6 presents the second type of archetypes containing information about clinical observation types.

Figure 6. Alternative examples of a COAS Archetype.

Each archetype defines its own clinical information system that is represented by the appropriate user interface which is dynamically created (Figure 7).

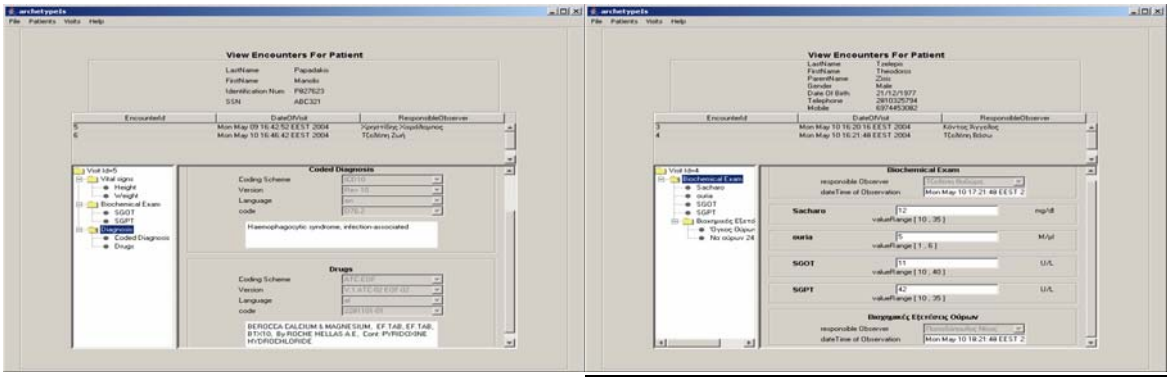

Figure 7. Management of Clinical Information

Discussion

This paper has presented a “two-level” methodology that has been used to develop clinical information systems that are highly adaptable to future requirements and satisfy user needs. When followed, this approach can deliver systems than can be designed rapidly, cost less, and can be maintained easily.

An archetype editor can be used by domain experts in order to define the model of information, creating archetypes for patient identification and types of clinical observations and new archetypes can be defined by users, by reusing elements of already existing archetypes.

The adopted reference model, based on the PIDS and the COAS reference models, proved that customizable systems can be build. Such systems can be used as building blocks of more composite information systems to support the needs of any healthcare organization.

It is a fact that database systems based on a general model are expected to have degraded performance, since the tuples required to maintain live data is much higher. Nevertheless, the expected delay at the process of storing and retrieving data can be counterbalanced by means of proper data base indexing.

Future work could be an implementation of "two-level" methodology with a reference model based on HL7's RIM or ENV13606 reference model. Also archetypes could be defined by means of the Resource Description Framework (RDF)[11]. RDF is a framework for metadata which provides interoperability between applications that exchange machine-understandable information on the Web.

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