Health Level-7 Compliant Clinical Patient Records System

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ABSTRACT

We present the design and implementation of a Health Level-7 (HL7)-compliant web-based clinical patient records system (CPRS). HL7 is one of the leading standards for exchange of clinical and administrative data among healthcare information systems. Since the passage of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) by US government, the security of electronic medical clinical records systems is of paramount importance. HIPAA requires that various technical, physical and administrative security measures be combined to protect the privacy, integrity, and availability of patients' clinical records. The HL7 standard for clinical documents, Clinical Document Architecture (CDA), incorporates the HIPAA guidelines. Our CPRS data schema is derived from CDA that makes it naturally in compliance with the HIPAA guidelines.

CPRS provides a unique web based interface for the caregivers to browse and edit universal patient records (UPR) of their patients. To our knowledge, CPRS is one of the first applications that have implemented an HL7-compliant UPR. Using CPRS caregivers can access and edit the clinical documents of their patients from anywhere in the world.

Categories and Subject Descriptors

J.3.3 [**Life and Medical Sciences**]: Medical Information System - *World Wide Web, Microsoft.NET, XML*

General Terms

Design, Standardization, Management, Security, Reliability, Documentation

Keywords

HL7, XML, schema, universal patient records, clinical document architecture, web-based application, medical informatics.

1. INTRODUCTION

Health Level-7 (HL7) is a standards developing organization operating in healthcare arena. Its mission is to provide standards for the exchange, management and integration of data that support clinical patient care and the management, delivery and evaluation of healthcare services, and specifically, to create flexible, cost effective approaches, standards, guidelines, methodologies, and related services for interoperability between healthcare information systems [1].

In this paper we present a web-based application we developed based on HL7's Clinical Document Architecture for managing universal patient records. It is called Clinical Patient Records System (CPRS). To our knowledge, CPRS is one of the first applications based on HL7 standards [19].

The primary objective of HL7 is to draft HL7 specifications that can form the basis for the exchange, management, and integration of clinical patient care and healthcare services related data. In short, the HL7 specifications are geared towards providing a flexible cost effective approach and methodology for a robust interoperability between healthcare information systems.

HL7 is one of several ANSI-accredited Standards Developing Organizations (SDO) operating in the healthcare arena. Most SDO produce standards (sometimes called specifications or protocols) for a particular healthcare domain such as pharmacy, medical devices, imaging, or insurance (claims processing) transactions. HL7 domain is for clinical and administrative data.

HL7 is a non-profit volunteer organization [1]. Its members are the providers, vendors, payers, consultants, and government groups who have an interest in the development and advancement of clinical and administrative standards for healthcare services. In its achievements so far, HL7 has already produced, HL7 Version 2 (HL7 V2) specifications [2], which are in wide use as a messaging standard that enables disparate healthcare applications to exchange key sets of clinical and administrative data. However, the newer specification HL7 Version 3 (HL7 V3, [2]), still under development, pertains to all aspects of clinical and administrative data in health services. Unlike its older version, HL7 V3 specifications are completely based upon the Extensible Markup Language (XML) standards and so have potential to win an instant acceptance by developers and vendors alike. Further, these specifications are developed

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using the modern tools of software engineering (e.g., Microsoft Visio and Rational Rose) and, therefore, have a robust foundation.

In section 2 we present the motivation for this work. Section 3 describes HL-7 standard. We present the design of CPRS in section 4 and conclude in section 5.

2. MOTIVATION

The organization and delivery of healthcare services is synonymous with accessing and organizing a complex clinical database. Therefore, the efficiency of healthcare operations is directly linked with the amount of automation of the healthcare information system. To compete effectively in the healthcare market, the healthcare delivery agencies have a limited choice, but to go with the rapidly growing information automation flow in healthcare services.

In the past two decades, major healthcare institutions, hospitals and health insurance companies, have begun to automate aspects of their information management. Initially, such efforts were directed towards reducing paper processing, improving cash flow, and improving management decision-making. However, in later years a distinct focus on streamlining and improving clinical and ancillary services has evolved. This focus included bedside (e.g., in hospitals and other inpatient environments) and patient-side systems (e.g., in ambulatory settings) that directly affect the quality and response of healthcare services. Within the last few years, interest has also developed to integrate all the information related to the delivery of healthcare to a patient over his or her lifetime (i.e., electronic medical records). It has also been envisioned that all or part of electronic medical records should be communicable -- electronically-- anywhere in the world.

Today even average hospitals are equipped with computer systems for admission, discharge, and transfer (ADT); clinical laboratories; radiology; billing, and accounts receivable. Often different vendors develop these applications with each product derived from expensive and confidential proprietary formats. As hospitals gradually expanded their information management operations, an accompanying need to share critical data among the systems has emerged. To meet the demand, comprehensive systems that aim at tackling most of the healthcare management needs became available by selected vendors [3]. These systems come in both flavors: a centralized architecture and a distributed architecture. However, being proprietary in nature, these systems do not conform to any external standards such as HL7 and have major cost associated with them --specifically, when it comes to share information with systems produced by different vendors.

Evidently, the institutions using these comprehensive systems do not have freedom to develop or acquire individual departmental applications that may not fit within the comprehensive systems. Within any complex organization, such as hospitals, a series of incremental, departmental decisions work better than a decision from the top managerial level. So, an information exchange environment, containing fewer comprehensive systems supplemented by departmental systems or one consisting entirely of separate and discrete departmental level systems, networked together with a common message exchange language is obviously a cost effective and rational choice.

Advancement in network technologies has made it possible to integrate a set of technically and functionally diverse healthcare computer applications in a viable and cost effective manner. Generally, the healthcare applications follow a market-driven trend rather than a well-planned logical trend. Therefore, when one tries to link them together, their underlying data structure becomes fragmented. To link them, often requires ad hoc and expensive site-specific programming. This need for site-specific programming could be greatly reduced if a standard to network various healthcare applications is available and is acceptable to vendors and users alike.

Finally, the lack of data and process standards between both vendor systems and the many healthcare provider organizations present a significant barrier to design application interfaces. With HL7 V3, vendors and providers will finally have a messaging standard that can provide solution to all of their existing problems.

3. HL-7

HL7 V3 is based on a reference information model (RIM, [4]). Although RIM is not stabilized yet, once it stabilizes, it will be the most definitive standard to date for the healthcare services. Using the modern software engineering methodologies and rigorous analytic and message building techniques HL7 V3's primary objective is to offer a standard that is definite and testable, and to provide vendors ability to certify conformance of their products. HL7 V3 uses an object-oriented development methodology to derive messages from RIM. RIM is an essential part of the HL7 V3 development methodology, as it provides an explicit representation of the semantic and lexical connections that exist between the information carried in the fields of HL7 messages. The current release of HL7 V3 comprises of specifications of abstract data types, RIM (V1.23), vocabulary domain, and the accompanying XML Implementation Technology Specification (XMLITS, [5]). There are two main subject areas in RIM: the normative infrastructure and the communication infrastructure. The normative infrastructure describes the grammar of HL7 V3; whereas, the communication infrastructure defines the messaging and structured documents format to enable healthcare applications to communicate with each other.

Inside the communication infrastructure, two major subjects are identified and constructed using RIM classes: clinical document architecture (CDA) and message development framework (MDF). CDA defines a format for either storing or conveying any clinically relevant information; whereas, MDF is a format to effectively communicate any CDA based document or generic messages between the participating healthcare applications.

MDF specifies the message structure for various systems that exchange data with each other. Generally, these messages may include queries, orders, results, billing, medical records, clinical observations; resource scheduling (e.g., scheduling a x-ray machine), master file update information, ADT information, patient referral, patient care, patient scheduling. HL7 does not specify underlying architecture of the data storage and management within the applications, but is designed to support either a centralized or a distributed patient care system where data can reside within a central database or local databases. HL7 serves as a backbone for inherently disparate applications and data architectures, operating in a heterogeneous system environment, to communicate with each other.

Using XMLITS, a special interest group of HL7 V3 has recently released the XML Schemas for abstract data types, RIM, vocabulary domain, and CDA [6]. However, the schemas suffer from many inconsistencies, we took great pain in fixing numerous inconsistencies of the current release [7], and did not have access to any instance of the schema for verifying the schema. In the end, we had to significantly modify a sample CDA document [8], which fortunately was available, to fix and verify schema. The sample CDA document [8] and the set of HL7 schemas [9-12] are the starting point for this work in developing a HL7 V3 compliant CPRS.

3.1 Universal Patient Record

The vision of a Universal Patient Record (UPR) has been there for a while [13]. In general, a patient is seen by many different physicians, nurse practitioners, and other caregivers in many different healthcare organizations. The patient is therefore likely to have a corresponding set of numerous paper documents at many different geographic locations. Even when the patient has health coverage and benefit provided by only one particular provider in his/her lifetime, it is quite likely that the patient may visit many different physicians as the need arise. Over the time, this results into fragmented and inconsistent records of his/her medical history at many different locations. However, if it is possible to have just one UPR, then most of these problems with the current method of storing and accessing patient records can be addressed.

To bring the above vision to reality, we developed a web application that provides an interface to patient's UPR. The interface is called CPRS. The schema of UPR is based upon the HL7 V3 CDA schema [6]. UPR can be stored and accessed from either one dedicated server or from a group of synchronized servers. One other possibility is to use smart cards to carry personalized copies of UPR that patients can carry similar to carrying their driving licenses or credit cards [18].

3.2 Clinical Document Architecture

CDA is an extension of the structured document framework to store the PATIENT information. In particular it can hold: outpatient clinical information, inpatient clinical information, or emergency department clinical information.

HL7 CDA is a specialization of the structured document infrastructure of HL7. An instance of CDA can hold the clinical history of a patient. In fact, as we propose in this paper, it can hold the UPR of a patient. CDA can be used to combine past medical records of a patient and to automate the process of storing relevant clinical information, fully secure from unintentional human errors. UPR typically consists of clinical information of a patient generated from medical encounters over the lifetime of the patient. UPR comprises of the following parts: patient identifier, patient demographics information, and patient clinical data [13].

The Framework for CDA is still in a transition period. A draft of CDA Release-Two was published in early January 2003 [6]. However, it is not yet known when CDA Release-Two will be ready for ANSI approval. CDA Release-Two takes advantage of HL7's growing expertise in creating model-based XML standards.

A special interest group [14] is building HL7 Templates derived from CDA Release-Two to provide a formal mechanism to say that a particular instance must be a "Consultation Note" or must be a "Discharge Summary". It is also possible to specify additional constraints on a document based on whether it is a "Consultation Note" or a "Discharge Summary" by creating additional HL7 Templates at entry level. Eventually, the HL7 templates will subsume all the elements of UPR.

4. CLINICAL PATIENT RECORDS SYSTEM

The main design principles of HL7 V3 specifications require them to be able to support healthcare applications in a distributive environment. It should not be of surprise to us that this design principle formed when many web-based applications were taking leads in handling interfaces as complex as those seen only in desktop applications. To site a few, one need not look further than the role the web applications are playing in the banking and financing sector. Some of these applications have already grown to handle as complex tasks as buying or selling stocks in real-time from the comfort of a web browser [15]. From our personal experience, we know that a clinical document that can be

modified and accessible over the web will reduce much of the paperwork existing in a typical clinic.

The web-based CPRS is designed to provide caregivers a secure web-based interface to browse, search, edit, and maintain UPR of their patients. The UPR schema is based upon the CDA Release-Two schema discussed above. Being accessible over the Internet, CPRS can reduce most of the shortcomings of the current methods of storing and accessing patient records. CPRS is designed to support the full functionality of the vocabulary domain as discussed in HL7. Specifically, it has provisions to use web-services (or SQLXML, [16]) to read clinical codes from external clinical references.

For demonstration purposes, CPRS external clinical code references include: the current release of Systematized Nomenclature of Human and Veterinary Medicine (SNOMED) maintained by the College of American Pathologists and International Classification of Diseases codes (ICD-9-CM) maintained by the World Health Organization and Diagnostic. These references are stored on a SQL server database and CPRS has provisions to access them using SQLXML interface.

CPRS provides a web centric interface to UPR from anywhere in the world. Users of CPRS will have option of modifying or editing the entries of existing UPR using an auto code search functionality that uses clinical vocabulary references (including internal and external) to find the correct codes.

CPRS reads an XML-based UPR into an internal XML document and provides user-friendly web based controls and to interact with UPR. Specifically, CPRS presents the user with an interactive web-based graphical user interface to edit UPR whenever the user logs into the CPRS web site. It shall provide interfaces for term based or numerical code based search mechanism. CPRS scope presently is limited to editing existing UPR, in future one will be able to add new information to UPR.

CPRS is developed using Microsoft technologies and in particular has used C#.NET and ASP.NET to develop its interface. CPRS can be deployed on any version of Windows 2003 Server running IIS 6.0 or higher. CPRS requires SQLXML Version 3.0 and Microsoft Internet Explorer Web Control (MIEWC, [17]) to be installed on the application server to work correctly. CPRS has been tested on Internet Explorer 6.0 successfully and in future other browsers will be tested as well.

CPRS is developed using object-oriented software engineering methodology. It consists of 4 main subsystems: CDATree, CDAProperries, CDADocument, and DataConnect. CDATree is responsible for maintaining a click-able tree like view of UPR (see figure 1). CPAProperties controls the rendering and editing of attributes of any UPR node. CDADocument is responsible for converting XML view of UPR into a paper based clinical document view. DataConnect is the core of the CPRS and is responsible for handling data.

Figure 1 shows the main screen view of CPRS after a user logs on in the system. For demonstration purpose UPR consists of only one encounter of a patient. The encounter produces a “consultation report”, which is stored in UPR. As CPRS becomes more sophisticated in future, it will incorporate functionality to add any medical report to UPR over the lifetime of a patient. The browser window has two main panels: left panel and right panel. The left panel shows the TreeView interface to UPR and the right panel is further divided into two more panels: top and bottom. The top panel shows a TabView interface for the attributes of the selected node (the root node, “sample clinical document”, in figure 1). (The selected node and attribute are always highlighted in easy to identify red color font with white background.) The bottom panel shows a paper based clinical document type view (PBV) of the “Consultation Note”. All the items of PBV correspond to some node of UPR. To edit a particular item, user may click on that item. CPRS responds by auto selecting the corresponding node in right panel and displaying its attribute in the top panel. Using the “Edit” button, one can edit the value of item and change it to something else.

5. CONCLUSIONS

CPRS is a unique HL7 compliant healthcare application. In our knowledge CPRS is one of the first applications that has taken steps to bring UPR closer to reality. However, in future we expect to add the following features to UPR.

The current version of CPRS provides only a prototype of the main functionality of UPR and does not have its own security model. At present, CPRS security model is strictly based on the Microsoft provided Windows 2003 Server security model for web applications.

Sometime in future, CPRS will use a role based security model rested on HL7 security infrastructure. CDA Release-Two has provision to control the security of clinical documents at the node level, where if not declared, the security is inherited from the parent node of children. A simple attachment to CPRS can exploit this feature of CDA and render only those nodes of UPR that the user has privilege to see and/or modify. In this upgrade, one can provide a logon screen for caregivers or patients and keep track of the users access list when processing UPR for rendering purposes.

Currently CPRS only implemented “consultation notes” template out of 34 such templates that may be stored in UPR. Future versions of CPRS will implement other templates and allow user to pick any one of the templates.

The current document editing in CPRS is limited to editing via the attribute panel displayed above the clinical document panel. Users also cannot add any new section to the clinical document. In future versions of CPRS, a direct editing of clinical document will be added, alongside provision for deleting or adding new sections or section items.

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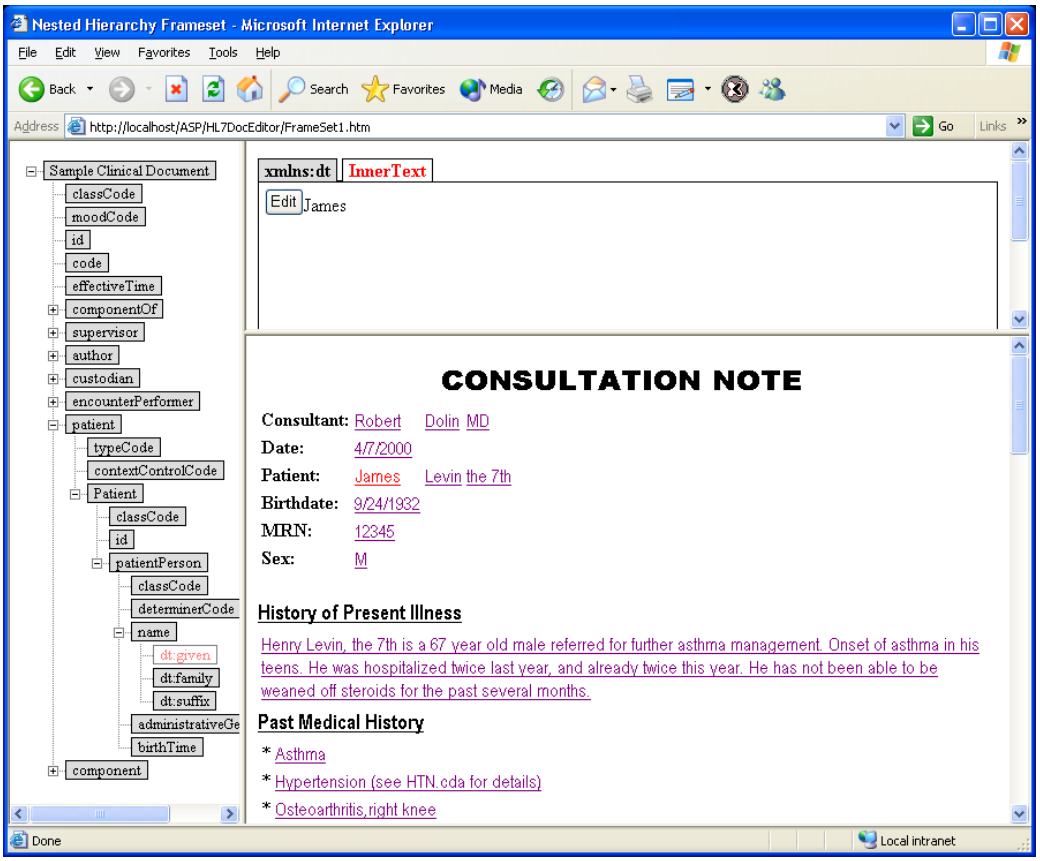

Figure 1. Clinical Patient Records System (CPRS) screen shot