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Integration of Domain-Specific User Interfaces for Structured Data Entry in a Telemedicine Platform for Multi-Centric Research Networks

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Abstract

Standardized documentation of clinical data is essential to achieve semantic interoperability in today's heterogeneous clinical IT structures. In order to enhance data quality and user acceptance it is necessary to develop suitable user interfaces for Clinical Documentation Systems (CDS). Also, choosing the optimal storage format particularly depends on the specific purposes of the desired system. A system implementation based on the HL7 Clinical Document Architecture (CDA) is presented. There are promising results and a good user acceptance. Our approach provides a generic platform to build domain-specific user interfaces for structured data entry in a flexible and easily extensible way for multi-centric research networks.

Keywords:

remote data entry, electronic data capture, clinical documentation system, XML, HL7 CDA

Introduction

Clinical Documentation Systems (CDS) and standardized documentation can reduce the costs for data entry while the user interfaces can provide a high ease of use and support high data quality through data validation [1-2]. For storing medical data, XML standards like HL7 CDA [3] or CDISC ODM [4] can be applied. Both standards are developed by two independent organizations (HL7, CDISC) with two different objectives (primary care, medical research). In the following sections an approach is presented to integrate a Remote Data Entry (RDE) module into an existing telemedicine platform [5] using HL7 CDA. The module supports a user interface for clinical documentation (structured data and genealogies) in the German multi-centric research network for Epidermolysis Bullosa (EB), a rare hereditary skin disease. The EB network consists of 7 research centers throughout Germany involved in basic research as well as patient care.

Materials and methods

In close collaboration with the multi-centric research network the requirements for the RDE module and the structured data entry (SDE) forms were gathered. Flexibility (adjustable for different medical domains), extensibility (easy addition of further forms), maintainability (easy modifications of forms) and interoperability (interface to EPRs or EHRs) were identified as relevant requirements. A pool of data items for the SDE forms was determined and the items were grouped by topic and occurrence. The SDE forms should allow single-acquisition at patient recruitment as well as multiple-acquisition during the course of the study. Extensible table lists where data entry tables can be dynamically extended at runtime should also be possible.

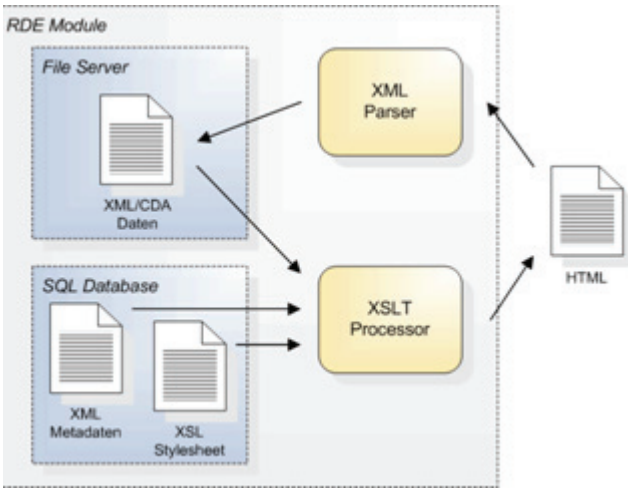

Figure 1 - Workflow for viewing and manipulating SDE forms

The RDE module was implemented on a web-based LAMPS architecture (Linux, Apache, MySQL, Perl, SSL) according to the requirements identified above. Metadata was stored in an SQL database using an entity-attribute-value (EAV) schema [6] whereas medical data items were stored in the file system. The HL7 CDA format was chosen as a suitable format for storing the medical data of SDE forms and facilitating reusability and interoperability with EPRs. During the development of the RDE module only Release 1 of HL7 CDA was available, which did not provide standard templates for structured clinical content. Local markup was devised for storing the required clinical

content in CDA R1-compliant fashion. A proprietary XML format was developed to support the different types of required SDE forms, and an XSLT stylesheet was applied to render the medical data items into HTML screen forms (Fig. 1). To guarantee consistent relationships between the XML metadata, the XSLT stylesheet and the CDA/XML document, a revision control system was integrated.

Results

The RDE module was introduced into production use in 09/2005 at the multi-centric EB research network. For entering research data six distinct SDE forms have been developed covering medical topics like patient histories, physical exams and lab findings (Fig. 2). Two clinical centers have entered more than 200 patients, and more than 150 sessions with an average of 60 minutes per sessions have been carried out. The system is currently being adapted for the additional domain of pediatric oncology.

Figure 2 – Transformation of HL7 CDA to HTML

Discussion

Storing clinical documentation content in a human-readable and machine-processable XML format allows the flexible adaptation of SDE forms for various medical domains. Creating HTML output by means of XSLT stylesheets and an XSLT processor has proved to be a robust and efficient method [7]. The architecture described here presents a setting where HL7 CDA is used primarily for data storage. However, standards like HL7 CDA or CDISC ODM can contribute to a potential semantic integration of data exchange formats. Concepts for integration of semantic interoperability into these formats already exist but are not yet fully developed (e.g. HL7 CDA Templates). In order to gain better usability the implementation of skip logic should be considered. Also, to further improve data quality, the existing simple validation checks should be extended to allow complex plausibility control mechanisms.

Conclusions and outlook

In conclusion the developed system offers great flexibility and adaptability for the definition of SDE forms for various medical domains within the same RDE platform. Using standards like XML, XSLT and HL7 CDA contributed significantly towards the flexibility of the system and could in the future pave the way for semantic interoperability with other clinical IT systems. Further development will focus on rolling out the system in additional medical domains as well as implementing complex input validation and skip logic.

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