A Generic, Web-based Clinical Information System Architecture Using HL7 CDA: Successful Implementation in Dermatological Routine Care

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Abstract

The requirements of highly specialized clinical domains are often underrepresented in hospital information systems (HIS). Common consequences are that documentation remains to be paper-based or external systems with insufficient HIS integration are used. This paper presents a solution to overcome this deficiency in the form of a generic framework based on the HL7 Clinical Document Architecture.

The central architectural idea is the definition of customized forms using a schema-controlled XML language. These flexible form definitions drive the user interface, the data storage, and standardized data exchange.

A successful proof-of-concept application in a dermatologic outpatient wound care department has been implemented, and is well accepted by the clinicians. Our work with HL7 CDA revealed the need for further practical research in the health information standards realm.

Keywords: medical record systems, computerized, generic architecture, systems integration, hospital information systems; CDA, openEHR, HL7, semantic interoperability

Introduction

The potential advantages of computerized patient records (CPR) versus conventional paper-based files have been known for many years \cite{1}. CPRs were envisioned to improve both routine care and research in a multiple ways. The possible benefits range from obvious ones, like readability or availability, to visionary decision support scenarios. Studies were able to support many theoretical CPR advantages, while increased experience with CPRs and clinical information systems also reveals deficiencies. Ginneken \cite{2} identifies low user-acceptance as a barrier that slows down the adoption of CPRs. This low user-acceptance results from lack of integration and missing flexibility in content and use. Other impediments mentioned are an inability to adapt to change, the lack of data exchange standards, or an insufficient financial return on investment.

The aim of this paper is to share our experiences from designing and implementing a generic clinical information system architecture. This project was initiated to implement a special-purpose application in clinical dermatology. In order to make our decisions comprehensible and to prove our concept, the context and realization of this implementation will be illustrated.

Problem

The outpatient clinic for patients with chronic wounds is a subunit of Freiburg university hospital’s dermatology department and needed an application to document their treatment. Up until this point paper files had been used to record visit findings and procedures. As the chronic wound clinic is a multi-provider facility, the main problems with the paper records were difficulties with legibility and conventions about how and what should be recorded. Further issues were the limited data reusability for research (no standardized recording practice and primarily no electronic format) and the non-existence of discharge letter writing assistance (e.g. partially pre-filled letter template).

Within the hospital an in-house developed information system is in use \cite{3}. The system provides hospital wide services such as a central document and picture archive (e.g. discharge letters, radiology images), access to lab data, and management of administrative patient data via a range of client applications. The communication between distributed components is based on HL7 v2 \cite{4}. Besides these general functions a number of custom extensions have been developed to reflect the information needs of single sub-/departments (e.g. a module to document the vein status).

An external solution had also been considered for the chronic wound clinic. After determining scope (2 forms with around 200 data items) and basic requirements (analyzing existing paper recordings, conducting a series of three observation and interview sessions, and review of the existing products in the market) it became clear that no commercial product in the small market of chronic wounds documentation systems could fulfill the special needs. Lacking customisation flexibility, unsolved integration problems, incomplete features, and unacceptable conditions of use by one vendor were the main reasons for the decision to develop an in-house solution.
Health information interoperability standards

Establishment of semantic interoperability between distributed health information systems is probably one of the most important challenges of health informatics today [5]. Most expected CPR advantages [1] are based on this premise. It is widely accepted that only well designed health information standards can solve this problem.

There are currently two major standard initiatives that aim to achieve semantic interoperability of medical information: CEN 13606 [6, 7] & openEHR (http://www.openehr.org/, accessed 29 Nov 2006) and HL7 v3 (http://www.hl7.org/, accessed 29 Nov 2006). While it is undisputed that standardized information structures have to be exchanged, the approaches to about how this can be done differ.

**HL7 Clinical Document Architecture:** HL7’s central design artefact is the Reference Information Model (RIM) from which message specifications are derived via a cascade of intermediary models. The idea is that this approach secures shared semantics. The HL7 Clinical Document Architecture release 2 (CDA r2, [8]) is an ANSI-approved exchange standard for medical documents. It has been developed according to the HL7 methodology and is fully based on the RIM. CDA r2 documents are XML instances with two main parts: a header setting the document context and the body containing the clinical report in a semantically enriched HTML-like markup. The CDA r2 specification purposely has a wide scope to be able to express any clinical document. Further constraint mechanisms are needed to enforce a particular structure. Currently, further constraints are defined by narrative ‘implementation guides’. In the future formal constraint expressions, called ‘HL7 Templates’, are envisioned for this task. In order to ease the adoption of the standard an incremental approach regarding the semantic enrichment is supported. The concept of levels reflects this design, while only a CDA r2 Level 3 document is envisioned to guarantee full semantic interoperability. CDA r2 Level 1 only expects a standard conforming document header while there are few restrictions for the body. In CDA r2 Level 2 the coarse body structure (sections) needs to be understood by the receiving system through definition of meaning in the form of terminology codes. Level 3 can be achieved by adding semantic markup (entries) for every narrative clinical statement. To adhere to the CDA’s human readability principle, level 3 markup can’t contain more information than the narrative.

**CEN 13606 and openEHR:** The openEHR Foundation is a not-for-profit company behind an open community effort to produce specifications (requirements, technical and clinical models) and reference implementations. The aim is to achieve an “open, interoperable health computing platform, of which a major component is clinically effective and interoperable electronic health care records (EHRs)” [9]. While not a standards body itself, openEHR is dedicated to work with standards organizations. The revised European standard CEN 13606 is influenced by openEHR. Like the openEHR architecture, it promotes a stable reference model, whose classes can be aggregated and further constrained by standardized, formal clinical content models called archetypes [10]. This so-called two-model approach separates medical knowledge from technical knowledge to achieve semantic interoperability and future-proof health information systems. Part two of the CEN 13606 standard has adopted the openEHR Archetype Description Language (ADL).

**Design decisions**

As a consequence of the depicted situation the following in-house solution design goals were rated with the highest priority:

- Customisation – to fit to clinical information requirements and workflow needs
- Integration – into the existing hospital IT environment
- Data sustainability and semantic interoperability – through standard conformance
- Generic methodology and components – to foster reusability in other clinical areas
- Pragmatism – to develop a solution that takes the limited resources into account and allows early utilization

**Material and methods**

The design goals mentioned above determined the choice of development technologies and the applied methodologies. To allow the possibility of reusing the system for similar documentation problems within the department of dermatology (e.g. the clinic for dermatological autoimmune diseases) it was decided to build a generic architecture that can be adapted flexibly according to new needs. XML instances of a form description language implemented in RELAX NG were pictured to drive a GUI generator. Flexibility regarding data entry items implies flexibility of the underlying database. This requirement excluded the use of the central hospital database facilities and we used a variable XML format instead. In order not to create an isolated “data island” we decided to build a XSLT transformation mechanism that could export our data to the standardized CDA r2 format. Integration with the hospital information system (HIS) was to be achieved by regular sending of CDA documents as payload in HL7 v2 messages. Administrative patient data should be similarly imported from the administrative data module of the HIS. We conceived the architecture as a web application framework whose core features (form definition language, data storage) are based on XML technologies and tools. The presented initial version also uses technologies such as PHP5 (form generator) and MySQL (4 tables: patient data, user data, XML form definition and XML form data). The necessary security is achieved as the application can currently only be accessed from within the firewalled hospital intranet. Additionally LDAP authentication and https encryption were installed.

After the development of the generic architecture, analysis and deployment of the chronic wound application were the next steps. A number of form definition iterations were planned to achieve a customized solution. This approach follows the idea of rapid prototyping [11] and allows early
user involvement to secure a high-level of user-acceptance.

Results

Overall architecture
Following the classic web paradigm the system architecture consists of a web server and database containing the application (PHP5) and a web browser on the client side to interact with the application. The application consists of: a form generator that creates HTML forms based on a formal XML form definition and modules for tasks such as user authentication, transformation to CDA r2, or integration with the HIS.

HTML form generation
The form generator component was written in PHP5 and dynamically generates HTML forms based on XML instances of a formal form definition language. These forms are used for editing and viewing. There is no restriction in the number of forms.

Form definition language: A RELAX NG schema grammar restricts the form definition elements to 6 types that can be arranged using 3 layout patterns. Additionally the form can be divided in sections and subsections. Each subsection XML tag has optional attributes to specify a terminology (e.g. LOINC or SNOMED) and the suitable code. The element types comprise the normal HTML input fields (text, checkbox, dropdown, upload) and widgets for date input (calendar) and for image display with planimetry. Each element has a mandatory label and an optional suffix.

The available layout patterns are ‘beneath’ (field elements below each other), ‘float’ (field elements next to each other), ‘table’ (configurable tabular layout).

GUI features: The Graphical User Interface (GUI) is rendered according to the form definition file. By default, every section is displayed in its own tab (see Figure 2 for a screenshot from the chronic wound application).

Data storage
The structure of the form content data depends on the form definition. To store submitted form data, a simple XML file is generated by mapping element names to their current values. This file is stored in the MySQL database together with metadata for retrieval.

Transformation to the HL7 CDA level 2
Based on former experiences with the first release of CDA [12, 13], we developed the framework according to the CDA r2 specifications. Provided correct code mappings exist in the form definition, an XSLT script that creates a CDA r2 Level 2 document can be derived automatically from the form definition. The CDA body content is created from the flexible form definition and the corresponding form data, while the metadata in the CDA header is based on information that is invariably required by the stable module.

Integration with the HIS
Integration with the existing HIS infrastructure is guaranteed by import of master data and export of CDA documents once they are approved by the supervising physician. Technically, import and export works by transferring XML documents via a HL7 v2 service interface provided by the HIS.

Implementing the chronic wounds application
Using the results from the scope and basic requirements analysis (conducted prior to the framework realization), an initial form definition was built by one author with good medical and IT knowledge. Consequently, 5 half-hour sessions with one medical user and one author were sufficient to reach the final definition.

In order to cover the use cases of the chronic wound clinic it was decided to have two types of forms: an ‘initial assessment’ form and a ‘follow-up’ form. The ‘initial assessment’ form contains the detailed patient history and information about special tests, that aren’t performed during every visit. It is primarily filled during the first visit, but it can also be updated later. A new ‘follow-up’ form is completed during each subsequent visit, documenting the current status and determining the further procedure.

Discussion

Proof of concept
The first application of the presented framework has been successful. It is used daily by 3 nursing staff and 4 physicians. During the first 2 months of use about 500 visits of 150 patients have been documented. Although the system doesn’t
provide all possible features yet (see the section ‘Future’),
early positive user reactions show that the system provides
major improvements to the former solution. A study to
analyse the system usability and the added value of the
solution is planned.

The user involvement during requirements and implemen-
tation iterations was very valuable for both parties
(medical and technical) and we can confirm similar experi-
ences mentioned in the literature [2, 14]. Having the
possibility to make quick adaptations to the form defini-
tion and displaying the result instantly helped the
clinicians immensely to assess the current form and rec-
ommend improvements. The generator driven
evolutionary approach described by Lenz and Kuhn [15] is
similar in the rapid prototyping respect but manages sys-
tem integration differently.

Integration

The presented architecture is potentially autonomous, but
an integration with the central HIS components proved to
be possible. The decentralized integration strategy is based
on the standardized messaging exchange format HL7 v2.
An direct extension of the HIS would have meant a pro-
longed development cycle and a high degree of inflexibil-
ity (limited existing data structures), which possibly could
have lead to compromises in design.

CDA standard

Standard support is crucial for inter-organizational infor-
mation exchange and must be a goal of every modern
clinical information system. We decided to use the HL7
CDA r2 standard. Its document orientation suits the form-
based framework well, and more importantly, it was a
pragmatic choice that could be implemented relatively eas-
ily on top of ubiquitous XML tools. Currently, the
generated CDA documents conform only to Level 2. The
generation doesn’t impose major difficulties provided suit-
able codes are found and set in the form definition. First
experiments with Level 3 markup showed that it will not
be easy to automatically create semantically correct CDA
entry statements. Especially the necessary combination of
several entries or the expression of post-coordinated
SNOMED terms showed much arbitrariness.

Total semantic interoperability means that a receiving sys-
tem can derive the same meaning from a standardized
information unit (e.g. a CDA document) as the sending
system. This must be true for any CDA document. In our
opinion for this long-term goal the CEN 13606/openEHR
approach using coherent, standardized content models
(archetypes) seems currently better suited. HL7 is aware of
this “gap”, which HL7 templates are supposed to fill. Fur-
ther research regarding CDA r2 Level 3 compared to CEN
13606/openEHR is needed.
Future
Besides the necessary research mentioned in the preceding discussion sections, various practical and technical improvements to the framework could be explored and implemented to further address issues like the ones mentioned in the introduction (e.g. data reuse). Routine care would benefit greatly from a letter writing assistance tool or a history feature where certain entries can be viewed over time (e.g. numerical values as a chart). An “XML2relational” data dump tool would allow analysing the collected data with conventional statistics programs. At the moment, only one version of each form is valid. A variable versioning mechanism would overcome this restriction. Technically, a re-implementation of the architecture based on pure XML technologies such as XForms, the Apache Cocoon Framework, and a XML database would be interesting.

Conclusion
This article describes a generic system architecture framework for health care applications. Through an autonomous concept special-purpose, form-based solutions that are customized to the needs of clinical users can be developed.

The HL7 CDA r2 standard was used to ensure system integration. A proof-of-concept implementation for routine care shows its applicability.

To what extend HL7 CDA or alternatives like openEHR can enable full semantic interoperability needs to be explored in further practical trials.

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References

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