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A Prototype Model Using Clinical Document Architecture (CDA) with a Japanese Local Standard : Designing and Implementing a Referral Letter System

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Abstract

Since clinical document architecture (CDA) became an American National Standards Institute (ANSI)-approved health level seven (HL7) Standard, many countries have begun making an eff ort to make local standards conform to CDA. In order to make CDA compatible with the many diff erent local standards existing in diff erent countries, we designed a prototype model using HL7 CDA R2 with medical markup language (MML), a Japanese medical data exchange standard. Furthermore, a referral letter system based on this model was developed. Archetypes were used to express medical concepts in a formal manner and to make 2 diff erent standards work collaboratively. We share herein the experience gathered in designing and implementing a referral letter system based on HL7 CDA, Release 2 (CDA R2). We also outline the challenges encountered in our project and the opportunities to widen the scope of this approach to other clinical documents.

KEYWORDS: health level seven, clinical document architecture, medical markup language, archetype

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A Prototype Model Using Clinical Document Architecture (CDA) with a Japanese Local Standard: Designing and Implementing a Referral Letter System

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Since clinical document architecture (CDA) became an American National Standards Institute (ANSI) -approved health level seven (HL7) Standard, many countries have begun making an effort to make local standards conform to CDA. In order to make CDA compatible with the many different local standards existing in different countries, we designed a prototype model using HL7 CDA R2 with medical markup language (MML), a Japanese medical data exchange standard. Furthermore, a referral letter system based on this model was developed. Archetypes were used to express medical concepts in a formal manner and to make 2 different standards work collaboratively. We share herein the experience gathered in designing and implementing a referral letter system based on HL7 CDA, Release 2 (CDA R2). We also outline the challenges encountered in our project and the opportunities to widen the scope of this approach to other clinical documents.

Key words: health level seven, clinical document architecture, medical markup language, archetype

Transferring patient information between medical care sites is necessary to deliver better patient care and to reduce duplicate laboratory examinations and prescriptions [1, 2]. In Japan, the referral letter is the most common document used to exchange clinical information between different medical care sites. Though many patient record systems in Japanese hospitals are computer-based, referral letter systems are still primarily paper-based. A computer-based system for the referral letters has not been utilized because different patient record systems are used, and clinical information is stored with many kinds of proprietary

formats, resulting in severe interoperability problems.

The interoperability in medical information exchange can be assessed at 2 levels <http://www.w3.org/2005/04/FSWS/Submissions/46/SWS4HC.pdf>. One is the syntactic level, where reliable exchange of information without error takes place, and the other is the semantic level, where correct interpretation and use of exchanged information occur. To address the issue at the syntactic level, several approaches have been developed such as extensible markup language (XML) and web service. However, at the semantic level the problem remains very difficult since the medical information itself is rather complex.

To solve the interoperability problem, several standards are currently under development that aim to

provide specifications in exchanging clinical information. These standardization efforts include health level seven (HL7) <http://www.hl7.org/> and medical markup language (MML) <http://www.medxml.net/>.

The main objective of this project was to design a prototype model using HL7 clinical document architecture (CDA) with the local standard. Another goal was to develop a referral letter system for electronic exchange of clinical information. Finally, we considered that other developers would be able to reuse the libraries developed in this project, thus aiding in the quick development of other applications.

HL7 CDA.   HL7 CDA is an American National Standards Institute (ANSI)-approved HL7 standard that defines the structure and semantics of medical documents for the purpose of exchange. CDA documents are encoded in XML. All the elements of CDA derive their meaning from the HL7 reference information model (RIM), an object-oriented data model [3]. It provides the ability to use various codes and vocabularies in the document, which will enable the sending and receiving systems to share well-defined, unambiguous information.

A CDA document contains a header and a body. The header identifies and classifies the document and provides information on authentication, the encounter, the patient, and the involved providers. The body contains the clinical report and can either be an unstructured sentence or a structured markup. A structured body is composed of nestable document sections. Each section can contain a single 'narrative block' and any number of CDA entries and external references.

MML.   MML was developed in the mid 1990s by the Electronic Health Record Research Group in Japan. Its purpose is to provide a standardized method of exchanging medical documents and other clinical data. MML version 3.0 uses the XML-based HL7 clinical document architecture release one (CDA R1) format with a local header extension to store MML-specific header fields and local markup to store the MML-specific content. MML is actively used in Japan [4].

Comparison between CDA and MML.   CDA is used worldwide, whereas MML is actively used in only a limited area. CDA is complex and difficult to implement [5]. MML is more user-friendly and easier to understand since the number of classes is smaller

and the overall data structure is more intuitive. A matured MML implementation guide is provided for developers.

CDA is content-neutral in the sense that it only defines the structure in which that content must be formatted and coded for exchange, and it does not prescribe the clinical content of a document. For example, in the CDA body, sections are included to present the clinical content of the document. A nested *section.code* must be encoded to represent a particular section type such as the family history, medication, or observations. As CDA does not prescribe what specific clinical content should or should not be included in a clinical document, it is too general to create a referral letter document [6]. On the other hand, such constraints are clearly defined in the MML modules. MML specifies more restrictions on the structure and content of a document.

Limitations of CDA.   Although CDA successfully covers the structures of clinical documents, it intentionally leaves out security and transportation issues. The exact method used is outside the scope of standard, and some implementation technology must be utilized to complete the implementation [7].

Archetype as a formal concept model. Archetype is a reusable, structured model of a clinical information concept <http://svn.openehr.org/knowledge/archetypes/dev/index.html>. It can be formally expressed in archetype definition language, and tools are available to edit and validate archetype instances [8]. An archetype can form a clearly defined semantic unit that expresses one clinical concept. Although an archetype is terminology-neutral, external terminologies such as the systematized nomenclature of medicine-clinical terms (SNOMED CT) and the laboratory observation identifier names and codes (LOINC) can be bound to express the meanings of a specific concept. Furthermore, a reliable path can be bound to the concept.

An archetype is composed of 3 sections: a header section, definition section, and ontology section. The header section contains a unique identifier for the archetype, a code identifying the clinical concept. The definition section contains data definitions and the restrictions in a hierarchical structure. The ontology section contains constraints on text or terms and bindings to terminologies.

In this project, archetypes were used to define

medical concepts for use in both CDA and MML. An open-source archetype editor, the Liu Archetype Editor <http://www.imt.liu.se/mi/ehr/tools/>, was used to create and edit the archetypes.

Materials and Methods

HL7 CDA XML schemas. The HL7 CDA schemas are generated via an automatic process from the HL7 CDA domain refined message information model. These schemas can ensure that the document instance is a compliant CDA document conforming to the CDA constraints.

MML DTD list. MML use document type definitions (DTD) to express the model structure. There is a list of DTD libraries available from the MML website <http://www.medxml.net/mml30/mmlv3_index.htm>.

Generation of a basic HL7 CDA library. XML is not a full programming language, in the sense that it cannot be compiled or executed as an executable file. Program coding is most commonly used to create, validate, process, transform, modify, or perform operations on an XML document. In the majority of cases, building applications using HL7 CDA utilizes HL7 CDA schemas. These schemas are generally embedded in the applications in order to build a serialized CDA document in XML format for the purposes of communicating with other systems and to validate serialized CDA documents coming from other systems. A basic HL7 CDA library was generated to simplify the process of retrieving or populating data with CDA XML documents using object-oriented techniques. The structure of the CDA document was unchanged in this library.

Development of archetypes and an interface library. The major challenge in developing the application was the mapping of different data fields to the corresponding CDA concepts. Even if we only want to put a patient name into a CDA document by using the basic HL7 CDA library, 7 classes are needed and the hierarchy of these classes must be used correctly. The complexity of the CDA structure and the basic library will add much to the efforts of the developer who is not familiar with HL7 CDA and HL7 RIM. An intuitive, flexible, and easy-to-use library was therefore proposed to lower the initial hurdle of using HL7 CDA.

First, after analysis of the HL7 CDA domain refined message information model and the corresponding modules of MML, appropriate concepts presented both in CDA and MML were listed. Concepts not required by the referral letter domain were ignored. These listed concepts were modeled in archetypes, and the Liu Archetype Editor was used to build these archetypes. Some extra constraints were added to the definition depending on some additional local rules. Finally, an interface library was developed based on the definitions of these archetypes.

Implementation of the interface library. After development of the new HL7 CDA interface library, an implementation of the library was developed to connect the interface library to the Basic HL7 CDA library. The most complex job of transferring data fields in the interface library to the corresponding CDA fields in the basic HL7 CDA library was carried out in this step. This intuitive interface library and its implementation may be reused in other applications, and the developer will not be frustrated by the complexity of the basic HL7 CDA library.

Development of the custom control library. Although web solutions provide a variety of useful controls and components, existing controls leave out many common situations that the developer must deal with. For example, one common scenario is that the user can input any number into an input field while this input field is used for recording a person's age. Another reason for building custom control is to express a more specific concept in one control. Composite controls, which consist of several normal controls, were developed for this reason. The overview of libraries is shown in Fig. 1.
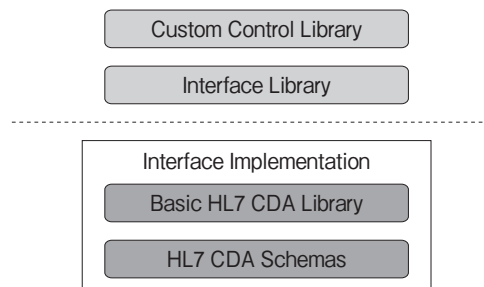
Fig. 1   Overview of the structure of the libraries.

Development of a web-based system.   The web-based system utilizes a well-known architectural technique to further simplify the process of building applications. The architecture used is the model-view-controller (MVC) pattern [9]. With this pattern, the key components of an application are separated from one another to simplify development. MVC architecture divides the application into 3 co-operative layers: a view layer, a controller layer, and a model layer. Changes in one layer have only minor effects on other layers.

Results

A promising approach to create, validate, process, transform, and modify HL7 CDA documents was provided. Improvements can be made based on this approach.

Basic HL7 CDA library.   Five core schemas of RIM and two CDA Schemas were used to develop the basic HL7 CDA library. Eighty-eight class files were generated to present the CDA elements, and 284 class files to represent the HL7 data types and vocabularies.

Developed archetypes.   Common concepts like telephone numbers, addresses, and names were mod-eled into common archetypes. These archetypes were referred by the archetypes derived from high-level concepts. Four concepts, patient, author, receiver, and related document, were modeled in the CDA header. Ten clinical concepts in the referral module of MML and the CDA body were referred and modeled into the archetypes. Codes of representing the concept meanings were stated in the archetype. Due to the lack of a global terminology solution, both SNOMED-CT and the Japanese Set of Identifiers for Medical Record Information eXchange (JMIX) were used to encode the concept. Fig. 2 shows the clinical document archetype defined in the Liu Archetype Editor.

While defining archetypes, a simple hierarchy structure was adopted in order to decrease the complexity of the model. For example, Fig. 3 shows a comparison of the patient name presented in the CDA model and the archetype model.

Interface library and its implementation. The definition of the interface library was based on the archetypes, and the corresponding implementation was developed in C sharp language. The interface of address and its implementation is shown in Fig. 4.

Custom control library.   A control library was developed based on the HL7 CDA interface library so that every control could be treated as a standard HL7 CDA concept. For example, Fig. 5 shows an address control developed for inputting addresses in Japan. This control is composed of 17 basic controls, including labels, buttons, and input fields. In the zip code input field, a rule was defined to check reasonable
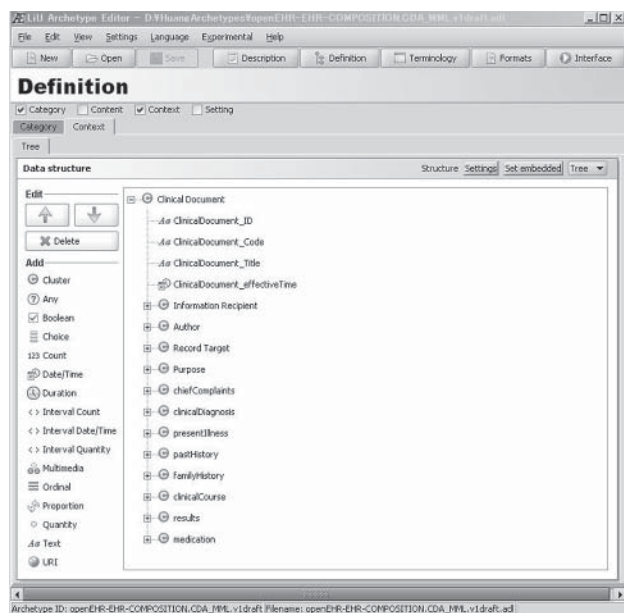

Fig. 2   A screenshot from the LiU Archetype Editor displaying the clinical document composite archetype.
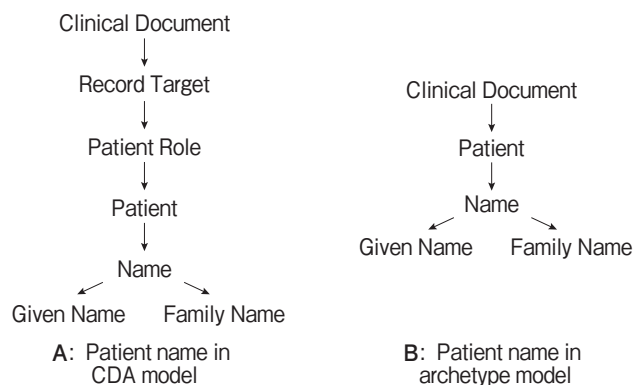

Fig. 3   The name concept in the CDA model and archetype model.

```
public interface InterfaceAuthor
{
    InterfaceAddress Address { get; set; }
    InterfaceGender Gender { get; set; }
    InterfaceIdentity MasterCardID { get; set; }
    InterfaceOrganization Organization { get; set; }
    InterfaceIdentity PersonalID { get; set; }
    InterfacePersonName PersonName { get; set; }
    InterfaceTele Telecom { get; set; }
    InterfaceBirthday BirthDay { get;set; }
}
```

```
[Serializable]
public class ImpAuthor : InterfaceAuthor
{
    private InterfaceIdentity _masterCardID;
    private InterfaceIdentity _personalID;
    private InterfaceGender _gender;
    private InterfaceBirthday _birthDay;
    private InterfaceTele _telecom;
    private InterfaceAddress _address;
    private InterfacePersonName _personName;
    private InterfaceOrganization _organization;

    public ImpAuthor()...
    public ImpAuthor(InterfaceAuthor inAuthor): this()...
    public InterfaceOrganization Organization...
    public InterfaceAddress Address ...
    public InterfaceTele Telecom ...
    public InterfaceGender Gender...
    public InterfacePersonName PersonName...
    public InterfaceIdentity PersonalID...
    public InterfaceIdentity MasterCardID...
    public InterfaceBirthday BirthDay...

    public override string ToString()...
    public void SetValue(InterfaceAuthor author)...

    private POCD_MT000040Author _HL7Author;
    public POCD_MT000040Author HL7Author...
}
```

Fig. 4   Interface class of address and its implementation.

input; the entry of more than 7 numbers is prohibited. The developer can easily reuse this control by dragging and dropping the control to the web page and treating it as a standard HL7 address class.

Web-based referral letter system.   This system was implemented on top of a composite library using XML technology for the data format and the CDA for structuring the referral letter for exchange. External objects such as external images and laboratory reports were referenced by CDA sections using an html link. These files are sent with a referral letter as a complete package. In the user interface layer, an extensible style sheet language (XSLT) is used to transform a CDA XML formatted document to HTML. In the model layer, the referral letter is stored as a CDA XML document in the database after extracting some critical information like the author and patient information. A hypertext transfer protocol security (HTTPS) is used to provide secured communication mechanisms between the client and server pair. A screenshot from the web-based referral letter system is shown in Fig. 6.

Fig. 5   The user interface of address custom control.

Fig. 6   A screenshot of the web-based referral letter system.

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Discussion

Several articles have described the HL7 CDA development process [10–13]. In the papers of the SCIPHOX project and the MML 3.0 project, they used the standard local markup mechanism of CDA; put the CDA body content to their local makeup to use part of their own model. As different standards and data architectures may bring about a new interoperability problem, we attempted to promote a better harmonization of HL7 CDA and MML. In this project we tried to express the corresponding concept as standard data items in HL7 CDA. We found that most of the content defined in the referral module in MML could be represented in the HL7 CDA model. They can work together to provide a worldwide standard to meet local clinical needs.

Reusability.   As CDA was conceived to represent any type of medical document, the basic HL7 library, the archetypes, the interface library and its implementations, and the custom control library can be distributed and re-used in different scenarios other than the referral letter. These libraries were intended to ease the implementation of HL7 CDA and thereby to shorten development cycles.

Understandability.   The interface library and the custom control library were introduced to decrease the complexity of HL7 CDA implementation.

Flexibility and extensibility.   The archetypes and interface classes can be easily expanded and modified.

Consistency.   Domain concepts were expressed in a formal way by using Archetype Definition Language.

Although the current implementation has many advantages, some limitations are inevitable. As already mentioned, the primary imperative in using HL7 CDA was to solve semantic interoperability. Unfortunately, the same XML element may mean different things to different people. Even if 2 software developers have started with the same HL7 CDA specifications, they may have incompatible implementations. Furthermore, there may be various representations of the same clinical statement. A validation mechanism to verify the consistency with clinical documents over a network is needed as well as guidance on how to transfer one representation to another.

The research on using CDA with local standards is just beginning. Much work remains to be done, including extension of the document type scope more than the referral letter, and combination with local standards other than MML.

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