MEDINFO 2007
HISA Ltd Australia
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Aligning HL7 CDA Templates and CDISC ODM An Experiment in Cardiovascular Radiology

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Abstract

There are few implementations of automatic extraction of clinical data from Electronic Health Record (EHR) to clinical research data management system (CDMS). At the G.Pompidou European Hospital (HEGP), cardiovascular radiology reports are captured twice, first in the EHR and then in a national CDMS dedicated to clinical research in arteriography. The objective is to develop tools for producing both an HL7 CDA report for patient care and a CDISC ODM message for clinical research from a single multipurpose form. We adopted and compared two approaches: 1) implementing a single "care-research" form within the EHR and aligning XML structures of HL7 CDA document and CDISC ODM message to export relevant data from EHR to CDMS; 2) displaying a single "care-research" XForms form within the EHR and generating both HL7 CDA document and CDISC ODM message to fill directly both EHR and CDMS. The solution based on XForms avoids overloading EHR with irrelevant information. Beyond syntactic interoperability, a perspective is to address the issue of semantic interoperability between both domains.

Keywords:

HL7, CDA, CDISC, ODM, medical records systems, computerized, biomedical research; clinical trial

Introduction

Considerable efforts were realized for standardization and communication of medical information for both patient care (driven by HL7 (HL7 RIM, Clinical Document Architecture (CDA))) and biomedical research (driven by CDISC (Clinical Data Interchange Standards Consortium).

In 2004, CDISC initiated the Biomedical Research Integrated Domain Group (BRIDG) that addresses the issue of interoperability between systems that capture patient data, as Electronic Health Records (EHR) and clinical data management systems (CDMS) for biomedical research [1]. In addition, within the IHE (Integrating the Healthcare Enterprise) initiative, an integration profile called RFD (Retrieve Form for Data-capture) provides a method for gathering data within a user's current application to meet the requirements of an external system [2]. RFD aims at supporting the retrieval of forms from a form repository, display and completion of a form, and return of instance data from the display application to the source application.

Although there is an issue to connect patient care and biomedical research, nowadays, in practice, clinical trials or epidemiological studies often require specific manual entry of data, some of which already reside in the EHR [3,4].

Material and methods

Nowadays, in the G.Pompidou Hospital (HEGP), radiologists enter clinical data of arteriographies through a form of the EHR (DxCare®, Medasys©) and then fill another form of a national CDMS for clinical research in cardiovascular radiology (AIR On Line (AOL)®, Kika Medical©).

We used a two steps methodology to implement a solution to capture data for both patient care and research in the cardiovascular radiology domain.

Designing a multi purposes "patient care-research" form

Items required for patient care and for clinical research were analysed and compared.

A single multi purposes form was designed including all the required items for cardio-vascular radiology. Since we could only make changes in the EHR forms, to evade semantic interoperability issues, the items that were required in both contexts (patient care and research) were represented according to the research context. We took into account the data types, the modalities of answer and the data type controls of the CDMS for clinical research.

The multi purposes form was implemented on one hand in DxCare® ("Care-research" CV form(a)) and on the other hand using the standard XForms ("Care-research" CV form (b)).

Exporting data from EHR to clinical data management system (CDMS)

We analyzed the differences between the HL7 CDA [5] and CDISC ODM models on both a structural and organizational point of view (with regard to the context of data capture).

We implemented two approaches to export data from EHR to clinical data management system (CDMS):

The first approach consists in 1) generating for each instance of the "Care-research" CV form (a) implemented in DxCare® the corresponding HL7 CDA document and 2) aligning XML structures of HL7 CDA document and CDISC ODM messages to export relevant data from EHR to CDMS (figure 1).

The second approach, based on the IHE integration profile RFD, consists in displaying the "Care-research" CV form (b) implemented using XForms technology [6] within the EHR and generating both HL7 CDA document and CDISC ODM message to fill directly both EHR and CDMS (figure 2).

Results and discussion

The comparative analysis of clinical data captured in patient care and clinical research showed that, in the domain of cardio-vascular radiology, 93 clinical items are relevant for patient care and 136 for clinical research. The mixed "Care-Research" CV form contains 198 items.

The comparative analysis of both standards HL7 CDA and CDISC ODM showed that some differences are due to different contexts of data capture in patient care and clinical research. These differences intervene primarily in the representation of the patient's administrative data. With regard to the structure of the models, the HL7 CDA model allows representing clinical data according to an infinite depth of sections since CDISC ODM proposes only three levels of depth to represent clinical study data. The generic solution used to generate a CDISC ODM message from an HL7 CDA document including more than three levels of depth is to concatenate labels of items from the sections above section 3 and to group them under only one item group. « Section 1 » in the CDA document is aligned with the ODM « FormData » tag. Items of the last section in the CDA document (« section n ») are copied in the ODM « ItemData » tag. Label of « ItemGroupData » results from concatenation of items of the « section 2 » to « section n-1 ».

Tools were developed to implement two approaches to export data from EHR to clinical data management system (CDMS).

The tool developed according to the first approach uses the mixed "Care-Research" CV form implemented in DxCare (198 items) and produces a CDISC ODM message including 136 items for biomedical research (figure 1).

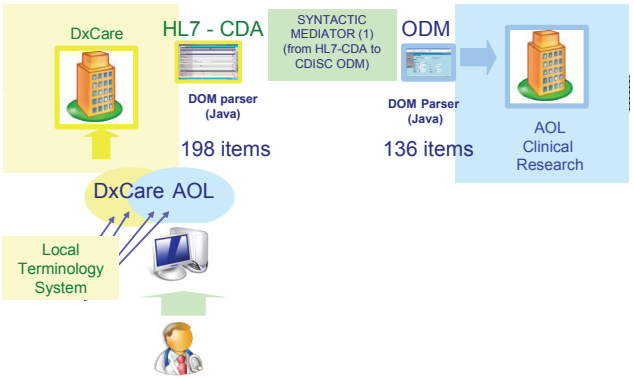

Figure 1- Production of a CDISC ODM message from a HL7 CDA document and using a mapping file

The tool developed according to the RFD profile produces an HL7 CDA document including 93 items dedicated to patient care and a CDISC ODM message including 136 items dedicated to biomedical research from the same single "Care-Research" form implemented in XForms (198 items) (figure 2).

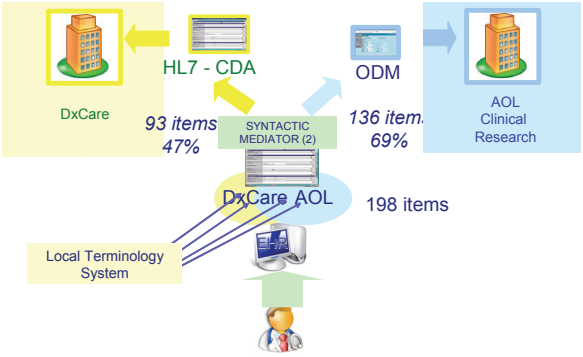

Figure 2- Production of a HL7 CDA document and a CDISC ODM message from a multi-purpose XForms form

We showed that it was possible to exploit for clinical research data captured in the EHR during patient care. The benefit for healthcare providers consists of the absence of time consuming and error prone double data entry, the automatic transfer of administrative and clinical data relevant for biomedical research towards a national CDMS and the storage of a structured data containing information necessary for patient safety in the EHR (for example adverse events).

A first limit of this work is that the tools were not tested in daily practice. We are working with Medasys© and a company developing CDMS for clinical research to implement

this workflow in HEGP. Another limit is that this experiment only addresses syntactic interoperability between standards of patient care and clinical research. There is an issue to solve semantic interoperability between applications while implementing integration profiles between patient care and research.

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