

The Prototype of Standalone Diagnostic Report Editor as a Proof-of-Concept for an Interoperable Implementation of Health Level Seven Clinical Document Architecture Standard (HL7 CDA) not Integrated with Electronic Health Record (EHR) System

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Abstract

Objectives: The concept of the study was to investigate the possibility of HL7 CDA implementation in the environment with no EHR system. The potential business and operational limitations were taken into account. **Methods:** The standalone diagnostic report editor has been chosen as a proof-of-concept prototype for such implementation. The detailed functional requirements have been defined. **Results:** The prototype has been developed as a single HTML file, containing Javascript code and embedding CDA XML template, CDA XML schema definition and XSL transformation. **Conclusions:** The HL7 CDA based solution can be implemented in the environment with no EHR system. The concept of the standalone report editor has been proven as possible and reasonable.

Keywords

HL7 CDA, EHR system, Interoperability of EHR

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1 Introduction

The Health Level Seven Clinical Document Architecture (HL7 CDA) [1,2] is commonly accepted as the standard of electronic clinical document, but its use is rather limited to the well-developed countries. One of the obvious limitations to its widespread global use is relatively low number of EHR systems implemented in some countries or regions. EHR systems are often perceived as too expensive for small medical service providers, which results in paper based cooperation between health care providers possessing EHR systems and their smaller part-

ners, like subcontractors of specialized medical services. The usual process is that the health care provider issues an order, including the referral document in paper form, to be realized by the subcontractor and then the service report document is delivered, again in paper form, to the referring organization. Both documents have to be delivered by patient. Additionally, the business requires that the subcontractor reports the service performance to the ordering organization in parallel process, often not supported by any system. The common worldwide practice of HL7 CDA implementation for referral documents [3, 4] assumes that both, the health care provider and its subcontractor, use the EHR system.

2 Objectives

Our concept was to investigate the possibility of fully interoperable implementation of HL7 CDA at small medical service provider organization, which has no EHR system implemented, to allow operational exchange of electronic medical documents with bigger partner with implemented EHR system. The investigation should take into account potential business or organizational limitations, which such implementation might face.

To prove the reason and possibility of the concept, we defined the objective of our work as to design the CDA document structure and to develop the prototype of standalone CDA document editor as a proof-of-concept. The proposed solution should meet the following criteria:

- minimum cost of software purchase and external services,
 - no database system,
 - no online connection during patient visit and document issue,
 - no need of integration with any other systems,
 - full compliance with the CDA standard and best practice of CDA implementation,
 - interoperability based on CDA only, with no extensions, no templates or profiles agreed with the referring health care provider (intended recipient of the report),
 - maximum use of data from available sources to minimize the amount of data being entered by the user.
- The report document, prefilled with (some) header data, is edited by the service performer, but the amount of data required to be entered by the user, is minimal.
 - After completion of the report, the final document is visualized in read-only mode for authentication.
 - The generated report document is CDA-conformant.
 - Both documents, the referral and the report, can be validated against CDA schema definition.
 - The report document can be printed.
 - The report document is stored in the local file system.
 - The new version of the report document can be generated based on the report document opened from the local file system.

We assumed that both CDA documents, the referral and the report, will be delivered electronically by free to choose method, not supported by our prototype. The documents will be conformant to the HL7 CDA Release 2.

3 Methods

Diagnostic ultrasound has been chosen as an example of medical service, which may be ordered by health care provider using the EHR system, but performed by subcontractor possessing no EHR system of its own.

To support the electronic exchange of medical and business information between two partners, we have specified the following functional requirements for standalone editor of diagnostic ultrasound service report:

- Any CDA-conformant referral document can be opened from the local file system and visualized.
- The header data from the referral document are used to create (part of) the header data for the report document.
- The configurable template of report document determines the XML structure of CDA document and is a source of the header data related to the diagnostic service performer.

4 Results

The functional architecture of the prototype of Diagnostic Report Editor is shown as Figure 1. The diagram also documents the implemented data flow between the Referral document, the Report Text Editor and the resulting Report document. The Referral document is a source of data related to patient, to referring health care provider and to ordered medical service. The Report Template is a source of data related to service performer and represented organization.

The CDA design of the Report document has been shown in Table 1. All CDA header values originate from the Referral document or from the Report Template, except the current date and extensions for document identifiers, which are generated by the script. Some of the prefilled values can be edited in the Report Editor. The only value in whole document, which cannot be prefilled by the system, is the actual text of the report, expected to be entered by the Report document author.

The Report document will be conformant to the HL7 CDA standard on level 2, because we assume that all system interpretable data will be contained in the CDA Header of the document. The structured body section will consist of the title and text elements, both filled in with human readable content only. However, there is no concept-related limitation to the potential use of the content based on clinical statements and upgrade to the level 3 of the CDA. It would just require more complex functionality of the Report Text Editor.

Our prototype will process the Referral document on any level of the CDA. If the Referral document is on level

3, the prototype is able to interpret the ordered procedure data and to include it to the service event element of the Report document. If there is no such data, the diagnostic service performer will be expected to fill in the appropriate fields using the Report Text Editor.

The Report document content will be constrained by the Report Template, except the constraints for the PatientRole and InFulfillmentOf.Order elements which derive from the Referral document and should be defined by its originator.

All defined functional requirements for the Diagnostic Report Editor have been implemented. Its user interface consists of two screens: the Referral Viewer (see Figure 2) and the Report Text Editor (see Figure 3). Both components use the same XSL transformation, formatting the XML CDA-conformant documents for presentation [5, 6]. To avoid the need of exchange of CDA document together with XSL file, we have decided to use our own XSL formatting of the CDA document, ignoring the xml-stylesheet processing instruction, if used in the Referral document. However, the original style sheet definition appearing in the Referral document will be copied into the Report document, assuming that the system of the referring health care provider will use the same XSL transformation for both documents. The finalized Report document is visualized for authentication (see Figure 4).

The prototype has been developed using open source components only, and does not require any commercial software to run, except Microsoft Windows operating system. The solution consists of single HTML file containing Javascript code [7]. The script uses jQuery library for all operations on XML structures and HTML elements. The jQueryUI library is used to generate and manage the user interface elements, and moment.js for date format conversion. The HTML file embeds XSL transformation, CDA XML template and CDA XML schema definition, all of them in the form of base64-encoded strings. Operational parameters related to the context of document issue are registered using Internet Explorer User Data persistence mechanism. The CSS style sheets containing user interface display elements and layouts are embedded in the same single HTML file. The prototype has been tested in Microsoft Windows environment using Internet Explorer version 7, 8 and 9.

4.1 Object identifiers

The assumed lack of EHR system and lack of any other database, results in some difficulties with proper assignment of global object identifiers (OID), which is important element of best practice of HL7 CDA implementation [8]. There are three groups of the OID processed by our prototype:

First, the OIDs being assigned by the referring organization, like PatientRole identifier. It is required by the standard and should be understood as the patient identifier assigned by the health care provider organization, but not necessarily the organization providing the partic-

ular service being documented by the CDA document. In our case we used the PatientRole.id assigned by the referring health care provider organization and taken from the Referral document together with other patient data.

The second group are the OIDs related to the diagnostic service performer. To secure global uniqueness of those identifiers, we need an external service provided by the third party, for assigning the OIDs to objects contained in the Report Template. Thus, our solution requires the registration procedure for new and modified Report Templates. Every potential user of our Report Editor will be required to fill in the registration form with his or her personal data and data of the represented organization, if applicable. The third party system assigns the relevant object identifiers at its own OID node.

The third group are the identifiers of the generated Report documents. Due to assumed lack of online connection during patient encounter, the identifiers have to be generated locally, by the script embedded in the Report Editor. The global uniqueness of the Report document identifier is secured by local uniqueness of the extension attribute and the global uniqueness of the root attribute, which is assigned by the third party responsible for Report Template generation. To restrict the possibility of generation more than one document instance with the same document identifier, we register and update after each new document issue, the next available documentId, using the Internet Explorer User Data persistence mechanism. When issuing new version of already existing document, the new version is registered as the new document instance, but using the same setId as the previous version. To restrict the possibility of generation more than one document instance with the same version number and the same setId, we need to register in the Internet Explorer User Data all documents which have more than one version, using their setId and versionNumber.

5 Discussion

Our goal was not to propose the solution to be implemented operationally, but just to explore the minimum requirements for proper implementation of HL7 CDA standard. The biggest challenge was to design the proof-of-concept prototype with no integration with EHR system. Additionally, our intention was to base the interoperability of our solution on the power of the standard itself, with no need to agree on a common implementation of data exchange with partner owning an EHR system. It should not be treated as a reasonable alternative for bigger, fully functional, shared EHR system, but the substitute for paper-based document exchange.

The reason for development and implementation of simple applications similar to our prototype is limited to specialized medical providers, which do not need the EHR system, because their responsibilities regarding medical documentation is limited to its archiving. They do not need the typical EHR system functionalities, like com-

plex searching, sharing, analysis and processing of data extracted from medical documentation. According to the current Polish regulations, there are two possible cases for such implementation:

- When the potential system owner uses electronic form of documents for their exchange with its partner, but documents are printed for the purpose of archiving.
- The partner takes over the responsibility for the whole document management process.

All the assumptions made when designing the requirements for the proof-of-concept prototype have been fulfilled. A few minor drawbacks have been identified:

- It was impossible to resign completely from external services needed to run the prototype. At the initial use of the Report Editor, its user must be registered by an external third party to generate personalized Report Template, containing newly registered individual ISO OID node, being the globally unique identifier of the service provider organization, and its sub node for the document identifiers. It is not the major problem because the external service is needed just at an initial usage of the Report Editor, but not during the operational work.
- Ignoring the style sheet instruction contained in the Referral and Report documents and using the build-in standard transformation for presentation results in different appearance of the document for its authenticator and for the recipient. The Report document is rather simple and most of its content is directly copied from the Referral document, so the recipient of the Report document will see the header of the document in the same layout as seen at the Referral document authentication.
- Document validation against the standard HL7 CDA xml schema (cda.xsd) only, with no semantic validation [9]. According to the aim of this work, the functional requirements for the prototype were minimized. It seems however, that more complex validation, against other xml schema or the rules defined in the schematron notation [10], would be reasonable. It is possible to embed the schematron, implemented as an XSLT, in the main HTML file. The schematron will use the rules contained in the separate .sch file named the same as the relevant template id used in the CDA document.

6 Conclusions

The HL7 CDA based solution can be implemented in the environment with no EHR system. The requirement of no integration with other systems, except an interoperable exchange of CDA-conformant document, has been proven as possible and reasonable to implement. A standalone CDA document editor for small, specialized medical service providers might be designed and developed with minimal cost of software purchase and maintenance. All header data for the report document may be copied from the referral document and from the report template. To allow the proper use of global object identifiers, the report template has to be generated by the external party and report document identifiers has to be generated locally by the report editor.

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