Quality of Life through Quality of Information
J. Mantas et al. (Eds.)
IOS Press, 2012

doi:10.3233/978-1-61499-101-4-43

Migration Path for Structured Documentation Systems including Standardized Medical Device Data

Ann-Kristin KOCK[a,1], Josef INGENERF[a], Stoyan HALKALIEV[b] and Heinz HANDELS[a]
[a] *Institute of Medical Informatics, University of Luebeck*
[b] *MEDNOVO Medical Software Solutions GmbH, Berlin, Germany*

Abstract. A standardized end-to-end solution has been implemented with the aim of supporting the semantic integration of clinical content in institution spanning applications. The approach outlined is a proof-of-concept design. It has shown that the standards chosen are suitable to integrate device data into forms, to document the results consistently and finally enable semantic interoperability. In detail the implementation includes a standardized device interface, a standardized representation of data entry forms and enables the communication of structured data via HL7 CDA. Because the proposed method applies a combination of standards semantic interoperability and the possibility of a contextual interpretation at each stage can be ensured.

Keywords. archetype, structured documentation, HL7 CDA, semantic interoperability, templates

Introduction

As modern healthcare becomes more dependent on medical devices accuracy and consistency of device data transmitted in clinical application systems can be crucial to patient well-being and their treatment outcome. Unfortunately, the effective transfer of medical device data (e.g. in a patient management system) is still insufficiently implemented. Manual data transfer between devices and clinical software is often fraught with errors risking accuracy of the data available to medical personal. A system utilizing automatic data entry can help to reduce these errors and with the use of approved standards, any risk to patient health can be minimized.

The company MEDNOVO Medical Software Solutions GmbH provide automatic data entry with their software product MediColor, a program designed for structured documentation in functional diagnostics. The company's products serve over 100 individual interfaces for medical devices. Furthermore a high number of data entry forms are provided to clinicians for different purposes with the need for frequent changes and updates. The forms at the schema level as well as the instantiated forms (with patient and device data) are processed rather proprietarily which complicates sharing and reuse. Many other projects have already developed approved standard-based approaches for dealing with similar challenges. Martínez *et al.* [1] implemented a combined approach of x73 and EN13606 electronic health record (EHR) systems and

[1] Corresponding Author: Ann-Kristin Kock, Institute of Medical Informatics, University of Luebeck, Ratzeburger Allee 160, 23538 Luebeck, Germany; E-mail: kock@imi.uni-luebeck.de.

Eric Brown [2] showed the advantages of the integrated use of EN13606 archetypes in HL7 CDA documents.

This paper describes an approach, that is based on a cascade of three different standards: the ISO/IEEE 11073 medical device communication standard (x73) [5], the EN13606-2 EHR communication standard (EN13606) [6] and the HL7 Version 3 CDA standard. These standards are applied to fill a variety of purposes from the device data communication via their use for documentation through to the communication of data. In this approach the standards are combined to form an end-to-end solution to the problem of data transfer and reuse.

1. Methods

As most devices are non-compliant with x73, the proprietary device data must be wrapped to simulate the functionality of the x73 standard. A typical workflow (Figure 1) starts with an HL7 V2 based order entry message from the hospital information system (HIS) to the exemplary documentation system MediColor. The system sends a message enriched with patient data to the x73 wrapper, which transforms the message into the device specific format and forward it to the device. After the acquisition of data by the device, the proprietary device data are transformed back into x73 by the wrapper and imported to MediColor.

To achieve more flexibility in design and representation of the data entry forms in the documentation system, they are redesigned into archetypes and templates according to EN13606. These representations of forms (templates) are instantly filled with data via a connection to the MediColor database. To provide interpretable data within and between healthcare facilities, the resulting EHR extract is converted via XSL transformation to the HL7 CDA standard.

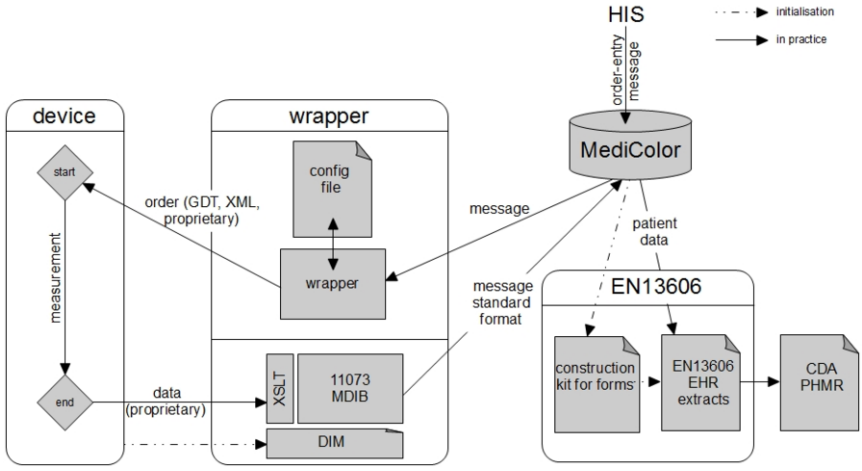

Figure 1. Overview of the systems involved in this study and the tasks implemented.

Device Interface: For accurate modeling the device internal structure, function and measured values must be known. For each device an individual model (DIM) needs to be created. In this work we concentrated on a selected ECG device, which was modeled in x73 taking into consideration all relevant patient and device information.

Data Entry Forms: The implementation of a construction kit for forms is based on EN13606, with archetypes as the representation of medical concepts and templates as the representation of data entry forms. To complement the archetypes a terminology binding is necessary, especially for the x73 nomenclature. The EN13606 approach is based on the concept of reutilization. In this particular system, all archetypes were self designed as they are determined by MEDNOVO as an internal repository. Simple archetypes were created, to obtain the greatest possible flexibility and adaptability. This repository of archetypes then serves as the basis for the design of individual forms for physicians and healthcare facilities.

Migration Path: It is not realistic that existing systems will replace their individual data entry forms immediately with archetype-based templates. In this approach previously entered patient data is exported from the database and mapped to a suitable EHR extract (Figure 2). The archetypes are defined in advance and applied to the EHR extract to generate a validated extract. The MediColor database serves as a basis for the instantiation of EHR extract as all necessary data can be exported from the database. Then, the extract is converted to be compliant with the archetypes. To generate a valid EHR extract, all mandatory values in the database must be available for export.

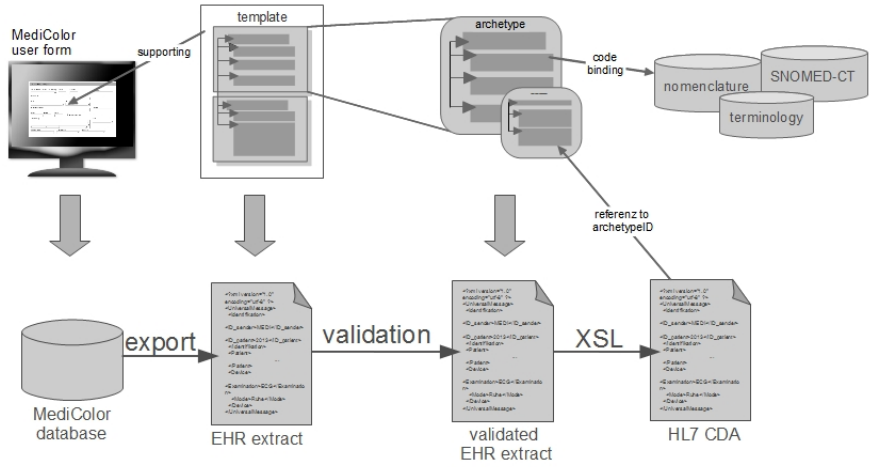

Figure 2. Based on the created forms the required data are exported and imported into the EHR extract. Afterwards the EHR extract needs to be validated against the archetypes, to check if all constraints were met. An additional transforming into the CDA is following.

Next, the instantiated EHR extract is compared to the reference model and validated against the underlying archetypes. This is the step used to guarantee the semantic interoperability and the correct representation of the content. The validation in this work is similar to the methodology of Rinner *et al.* [3] and based on the W3C XML Schema Definition 1.0 (XSD). As the exchange of EHR extracts is not yet established, the EHR extracts were converted to another standard. The HL7 CDA standard was used for this conversion due to its widespread use and the close relationship between the reference models.

HL7 CDA: In this study, the validated EHR extracts are transformed into the CDA standard. The validation ensures that all constraints and limitations are observed. A direct mapping between EHR extracts and the CDA documents is possible, as both standards are based on a reference model. Therefore, the classes in the EN13606

reference model correspond to assigned classes in the HL7 model. An example of such an assignment is the composition-class. Within the EHR extract it is comparable with a medical document, which again is comparable to the HL7 Clinical Document class. The mapping results in an HL7 CDA Release 2 compliant Personal Healthcare Monitoring Report (PHMR) document, which refers to EN13606 archetypes. This can be directly generated via an XSL transformation, since the source document (the EHR extract) is available in XML structure. Thereby, the EHR extract can be transformed into a PHMR according to the "PHMR implementation guide" [4] via an XSL processor using an XSLT style sheet. The resulting PHMR can be validated with an online CDA validator.

On closer inspection, the HL7 RIM *Observation* class, serving for the description of clinical observations, outlines two main attributes *Observation.code* and *Observation.value*. These have a descriptive purpose and record the measured values. The *Observation.code* is usually specified with external coding systems. This specification can be defined much more precisely, taking into account the developed archetypes [2]. Using an archetype as a reference, it refers not only to a code, but to a context description. By means of the archetype ID, the recipient obtains a clear understanding of the semantic interpretation.

2. Results

Not the isolated but the combinatorial use of all the named standards, with their respective strengths for supporting specific tasks, were implemented in this work. Within the scope of this project it was shown that mapping of medical device data onto the x73 standard is feasible and that this data can be presented in standard compliant exchange format. The challenge was to combine and implement these standards in theory and practice. The principal process of medical diagnostics can be related to the cascade of standards as they are used in this paper (Figure 3). The proposed method provides semantic interoperability and thus the possibility of a contextual interpretation at every stage of the cascade. This approach has worked well for your test case but more applications need to be considered to evaluate the cost-to-benefit-ratio.

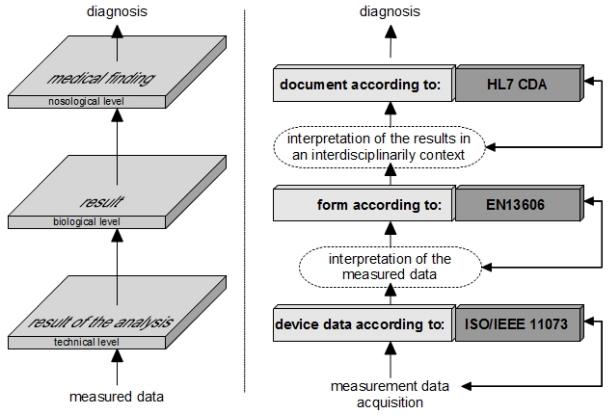

Figure 3. The left column outlines the diagnostic process and the right shows the according standard-compliant modeling at all levels of clinical diagnostics.

3. Discussion

The x73 standard has proven to be useful to enable device communication. Either x73 compliant plug-and-play devices are available or proprietary devices have to be wrapped accordingly. Ideally when ordering medical devices the user should insist on x73 compliant interfaces.

The EN13606 is used for designing archetypes, because opposed to the *open*EHR project it is approved as an official standard and used in European projects like the "Smart Open Services for European Patients" (epSOS). The necessary 46 archetypes for this project were not reused from existing repositories but redesigned. They needed to be elemental and simple to achieve greatest flexibility. The Existing forms need to be reconstructed in accordance with the agreed requirements of MEDNOVO. It was possible to export the defined archetypes and templates as an XML file, and therefore standard tools for XML processing could be used, which is beneficial for routine usage. The creation of EHR extracts after the requirements of the respective templates had to be done via an XSL transformation. For an automatic data export mapping between the database fields and the archetypes, then between the forms and the templates is necessary. It would be possible to generate the EHR extracts with no direct access to the database, as MediColor offers an XML export of values from the forms. The verification of structure and content by transformation the EHR extract to a valid EHR extract is possible. The validation against schema is well supported by standard tools.

The additional transformation into an HL7 CDA is done by comparing the occurrence of both document types. Once a document satisfies a standard, it can be easily converted to another standard. HL7 use is widespread and has a significant influence in the health sector. The transformation of the EHR extract to a CDA PHMR document was done by mapping the two reference models. In addition, to check the codes the receiving system needs access to an external terminology server. The use of archetypes in the CDA document increases the semantic interoperability and also extends the adaptability of the data for the user. Although a direct mapping between x73 device data and the HL7 CDA PHMR might be easier, the chosen approach via EN13606 archetypes increases the functionality and interoperability due to the contextual information.

If this approach is extended to further relevant devices and data entry forms the step of gradual replacement of proprietary data entry forms by archetype-based templates can be performed in order to take advantage of the automated generation of template-based user forms.

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