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Concept, Models and Implementations for Innovative Interoperable eHealth Solutions

Editors

Bernd Blobel, Libor Seidl

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[1] Schwartze J, HaarbrandtB, Fortmeier D, Haux R, Seidel C. Authentification systems for securing clinical documentation workflows. Methods Inf Med 2014; 53 (1):3-13.

[2] Kalina J, Seidl L, Zvára K, Grünfeldová H, Slovák D, Zvárová J. Selecting relevant information for medical decision support with application in cardiology. European Journal for Biomedical Informatics 2013; 9 (1): 2-6. Available from: http://www.ejbi.org/img/ejbi/2013/1/Kalina_en.pdf

[3] Hasman A, Blobel B, Zvárová J, editors. Data and Knowledge for Medical Decision Support. Amsterdam: IOS Press; 2013.

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Contents

Concept, Models and Implementations for Innovative Interoperable eHealth Solutions

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This Special Issue of the European Journal for Biomedical Informatics contains selected papers presented at the 15th International HL7 Interoperability Conference (IHIC 2015), 9-11 February 2015 in Prague, Czech Republic.

The International HL7 Interoperability Conference series has been inaugurated in 2000 by the Board of HL7 Germany and its unforgettable Chair and interoperability pioneer Joachim Dudeck. The first event in Dresden, Germany, was entitled "Advanced Healthcare Information Standards". Over the time, the scope of those conferences has been extended, meanwhile covering – as expressed in the motto of the this year's conference – concepts, models and practical implementations, but also testing and certification processes for innovative, interoperable eHealth solutions.

The concept of interoperability has dramatically changed since the establishment of the Health Level 7 standard for of open communication between hospital organizational units in 1987 in the United States of America. For standardized electronic data interchange (EDI), the data representation at the application level, the 7th level of the ISO Open Systems Interconnection stack, has been specified for information related to common events happening in hospital care and management processes [1]. The development was guided by the Marriam-Webster interoperability definition as the "ability of a system (as a weapons system) to use the parts or equipment of another system" [2], and thereafter enhanced towards the IEEE definition as the "ability of two or more systems or components to exchange information and to use the information that has been exchanged" [3]. Both definitions focus on communications between information and communication technology (ICT) systems. Impacted by the paradigm changes towards pervasive and ubiquitous health services based on personalized, preventive, predictive and participative medicine as well as technological innovations such a mobile technologies, micro- and nanotechnologies, cloud computing, big data and analytics, etc., we meanwhile define interoperability as motivation, willingness, interest, knowledge, ability and skills to cooperate for meeting common business objectives. Simple EDI has been replaced by information exchange, nowadays followed by knowledge sharing. Such move requires that the consideration goes beyond ICT, including the real world business domains of manifold organizations and multiple disciplines as well as all possible actors such as persons, organizations, devices, applications, and components. Here, domain-specific terminologies/ontologies and their harmonization, but also business process modeling, management and optimization come into play [4, 5]. It is a challenge in open environments to guarantee the persistence of meaning throughout the entire development process from clinical models through their platform-independent informational representation, the computational aggregation and platform-specific implementation, thereby involving domain experts such as medical professionals, business people, informaticians and engineers.

This Special Issue tackles the entire spectrum including EHR systems as the core application in eHealth environments, interrelations between EHR systems and CDA repositories, CDA-based communication between services providers, the challenge of semantics keeping, implementation guidelines, conformance testing, certification for guaranteeing practical interoperability.

Conformance Section

In a proof-of-concept study, Philip Scott et al., members of The English Professional Records Standards Body (PRSB) for health and social care, reported about the development of a conformance methodology for clinically-defined medical record headings. The project aims at providing user-friendly semantic interoperability by enabling the mapping of outpatient letters to epSOS patient summaries. The conformance criteria have to be implementation-agnostic to allow the deployment of HL7 CDA documents, HL7 Fast Health Interoperability Resources (FHIR), IHE profiles or openEHR archetypes, using implementation technology specific artifacts and tests. A generic logical information model for out-

patient letters has been created, and a process for developing implementation-specific technical conformance criteria has been defined.

Boufahja et al. from the IHE Europe French Chapter analyzed the coverage of conformance of products and tools such as Trifolia Workbench, Model Driven Health Tools (MDHT), Eclipse Instance Editor (EIE), Art-Décor, the NIST Validation Tool, or the Gazelle ObjectsChecker Tool with requirements and specifications provided by the HL7 CDA R2 standard. The outcome of the different tools was quite different, and no tool met all requirements.

Integration of Different Domains

Barbara Franz and co-authors developed a practical solution for integrating different vital sign measurement devices into a patient monitoring system based on the HL7 FHIR approach. An Italian/Swiss group under the lead of Vittorio Meloni has provided an open-source library to create, parse, navigate and validate HL7 v2 compliant messages. Instead of Java or .NET, the Python programming language has been used to develop the HL7apy called library, which has been practically demonstrated and deployed in an open-source HIS. An important approach for realizing semantic interoperability is the separation of health data models defined by domain experts from technical implementations realized by IT specialists. Marten Smits et al. from the Netherland have implemented technology independent models (Detailed Clinical Models – DCMs) using CDA and FHIR. The equivalence of the outcome has been tested by transforming one technical implementation of a specific DCM into the other one, using XSLT. The authors could exemplify problems, so demonstrating that the existing DCMs are not fully technology-independent, so the resulting implementations are not necessarily fully compatible.

Business Process and System Continuance

A German group with Georg Heidenreich in the lead developed an implementation guide, combining specifications from different SDOs such as HL7, IHE and GS1 for an eSupply solution. Fernando Campos et al. from Argentina presented an approach to guarantee contingency support by realizing an HL7 CDA R2 document repository fed by EHR systems, but also by ancillary information systems such as Laboratory IS, Radiology IS, Imaging, etc., in the case of an EHR system failure. In case of a total impact, a paper repository by printing the HL7 CDA R2 documents is automatically maintained.

One paper, under the lead of Ana Estelrich jointly prepared by the French Health Information Technology Standards developing organization Phast, the HL7 Foundation Europe and liSPA Milano, addresses intercontinental interoperability of patient summaries between the European Union and the USA by mapping semantic content and value sets of the epSOS Patient Summary with those of the US Continuity of Care Document. The contribution highlights a bunch of open problems to be solved especially within the Trillium Bridge project.

All the papers have been reviewed by two independent reviewers.

The Guest-Editors are indebted to thank all authors and reviewers for their excellent work. Unfortunately, not all authors took the opportunity for revising their work based in the valuable recommendation provided by the reviewers. Finally, the Guest-Editors thank HL7 International, HL7 Austria, HL7 Czech Republic, HL7 Germany, and HL7 Switzerland for the given logistical and financial support.

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CDA R2 based document repository: a true Swiss Army Knife. Functionality: contingency support

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Abstract

The pervasive use of electronic records in healthcare increases the dependency on technology due to the lack of a physical support for the records. Downtime in the EHR system is unavoidable, due to software, infrastructure, energy failures or even natural disasters, so there is a need to develop a contingency plan ensuring patient care continuity and minimizing risks on health care delivery. To mitigate these risks, an application was developed allowing healthcare delivery providers to retrieve medication prescriptions for inpatient or emergency care patients using the CDA R2 document repository as information source. In this paper we describe the strategy and the implementation results.

Keywords

Electronic Health Record, CDA repository, contingency plan.

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1 Introduction

There is an increasing use of the HL7 CDA R2 (Clinical Document Architecture Release 2) in implementations requiring document level exchange, being interoperability the main goal [1, 2, 3]. There is also an increasing use of the electronic health record, specifically the replacement of the paper based health record to the use of Electronic Health Records (EHR) [4]. Therefore, every healthcare delivery process relies on information systems to ensure patient care. One of the biggest documented risks for continuity of patient care are mistakes in medication administration [5].

Revising all the Hospital Italiano own experiences and pertinent literature, it has been observed that when all 'redundancy' and 'control' instances designed as support to business continuity are exhausted, alternate ad-hoc methods are triggered for the protection of information which is considered crucial [6, 7].

The goal of this paper is describe the implementation of an architecture based on the CDA R2 document repository which allows physicians and nurses retrieval of the patient EHR in the case of partial system downtime, and medication prescriptions for inpatients in case of total system downtime.

2 Materials and Methods

The Hospital Italiano of Buenos Aires (HIBA) is a non-profit health care academic center founded in 1853. HIBA has a network of two hospitals with 750 beds (250 for intensive care), 800 home care patients under care, 25 outpatients care centers, and 41 surgery rooms. There are more than 2800 healthcare agents, and 1900 administrative and support staff. During 2013-2014 there were 45,000 inpatient episodes, 3,000,000 outpatient visits annually, and 45,000 surgeries (half of them for outpatients).

Since 1998 HIBA began the gradual implementation of a Healthcare Information System (HIS) based on an 'in-house' development, from capture to analysis. It includes a web based, modular, problem oriented and patient centered EHR. This EHR is known as ITALICA and allows inpatient, outpatient, domiciliary and emergency care records. ITALICA also allows ancillary services order, medication prescription, and results visualization including Imaging through a PACS (picture archiving and Communications system)

The EHR has a relational database record and also a CDA R2 document based repository, which is digitally signed by professionals participating in healthcare delivery. This repository is used to interoperate with payers, other EHRs and to make information portable for patients or other external healthcare providers. Currently there are 36.400.000 CDAs. In the document repository [8].

This kind of repository allows the organization to operate without the need for a paper record, because information exchange between actors or systems is facilitated by these documents.

For instance, for ancillary systems like Imaging or Laboratory, the order is no longer paper based but a digitally signed CDA R2. Likewise, result reports are not printed, but reviewed directly in the EHR through a CDA R2 sent by the ancillary service.

Since 2012, and based on this implementation, all the procedures and communications for business continuity while systems recover from a meaningful interruption where redesigned, mainly for the inpatient setting.

```
Document Date:
/ClinicalDocument/effectiveTime/@low
Document Type:
/ClinicalDocument/code/@code
Service:
/ClinicalDocument/legalAuthenticator/assignedEntity/representedOrganization/id/@extension
/ClinicalDocument/legalAuthenticator/assignedEntity/representedOrganization/id/@assigningAuthorityName
Patient
id:  /ClinicalDocument/recordTarget/patientRole/id/@root
root:  /ClinicalDocument/recordTarget/patientRole/id/@extension
First Name:  /ClinicalDocument /recordTarget/patientRole /patient /name/@given [1]
```

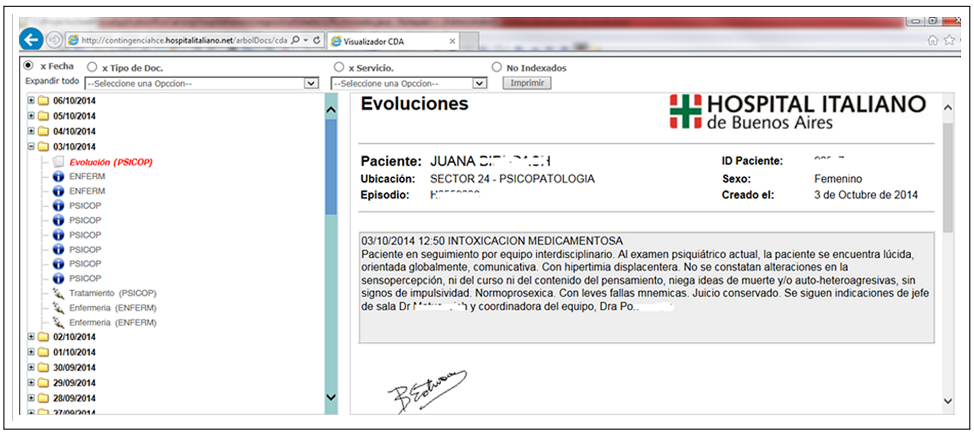

Figure 1: CDA Navigator.

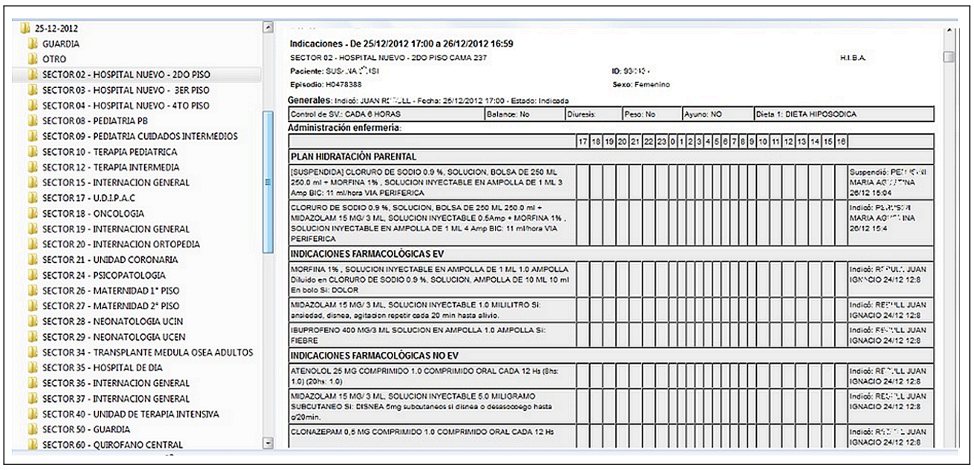

Figure 2: File Explorer for Level 2 Contingency.

Table 1: Downtime record and contingency use.

Date	Month	Year	Class	Motive	Begin Time	End Time	Total Time	Contingency level
08	March	2012	unplanned downtime	EHR Bug	9:15 AM	3:10 PM	5:55	Level 1
05	April	2012	unplanned downtime	database issues	11:10 PM	1:10 AM	2:00	Level 2
07	April	2012	planned downtime	Database maintenance	8:00 PM	10:00 PM	2:00	Level 2
27	April	2012	unplanned downtime	EHR Bug	9:50 AM	4:05 PM	6:15	Level 1
12	May	2012	planned downtime	Upgrade Database version	10:40 PM	6:30 AM	7:50	Level 2
09	June	2012	planned downtime	Increase Server memory	10:00 PM	5:00 AM	7:00	Level 2
29	December	2012	unplanned downtime	EHR Bug	5:30 AM	10:00 AM	4:30	Level 1
23	April	2013	unplanned downtime	Shutdown power server energy	5:30 AM	6:31 AM	25:01	Level 2
26	April	2013	unplanned downtime	Router down. Areas without networking	12:30 PM	1:30 PM	1:00	Level 2[1]
27	April	2013	planned downtime	Server Maintenance	6:00 PM	9:00 PM	3:00	Level 2
25	May	2013	planned downtime	Server Maintenance	4:00 PM	9:05 PM	5:05	Level 2
15	June	2013	planned downtime	Server maintenance	5:00 PM	12:38 AM	7:38	Level 2
26	July	2013	planned downtime	Install new database cluster	8:00 PM	9:30 AM	13:30	Level 2
14	September	2013	planned downtime	Upgrade switches firmware	6:00 PM	8:00 PM	2:00	Level 2
11	January	2014	planned downtime	Upgrade switches firmware	2:00 AM	6:30 AM	4:30	Level 2
24	June	2014	unplanned downtime	Database issue	12:10 PM	1:20 PM	1:10	Level 2

`Last name: /ClinicalDocument /recordTarget/patientRole /patient/name/@family`

Two levels of contingency were identified.

First, at an application level. In this level, only the EHR is not available. Causes may be a problem in a new version deployment or server issues. The entire infrastructure is available: database, networking, electric energy etc.

The second level is total impact. Usually this level of contingency occurs when the database server is down or halted during upgrades or maintenance work, data center problems affecting the server farm or storage, network outages or natural disasters.

The decision was to leverage the redundancy generated by the documentary repository to support contingency processes.

In order to mitigate the first level of contingency, a CDA navigator was developed, having as indexes some of the elements in the CDA header (metadata)

Using this index, a tree is generated, and this tree is accessed based on the patient information. From the tree root (target patient) the timeline for the inpatient (day by day) can be navigated. After selecting a specific date, the caregiver can access all the documents for the visit grouped by document type and service.

This application is deployed in a distinct server from the EHR, and with a different and redundant database. If by any-chance the EHR is not available, the document based EHR at least can be retrieved.

The second level of contingency assumes total lack of database support, application server support, energy or network connections.

In this extreme case, and only for inpatient and emergency care (average 720 beds) it was evaluated which information is essential for healthcare delivery without risks for the patient.

In this regards, two elements were key: access to the patient's prescriptions: medications, doses, indications, and diets, and proper labeling for samples or patient elements.

Based on this requirement, an application was designed. The application access every 30 minutes to the last indications for each inpatient.

Based on the documents, each computer running the application stores in a local disk a folder tree organized by service and inpatient location, where there is every indication CDA for each location.

Two folders are alternatively used for this repository. This application runs redundantly in several computers in locations strategically selected, and can only be used in contingency. These computers have a local printer and connection to the backup energy line, with UPS and printer paper stock.

In the case of natural disasters, application server downtime, database downtime, or any other contingency, these computers can be used to print the indications, and deliver health care continuity for all the inpatients in the hospital

[1] affected areas only

3 Results

Creating this backup querying the relational system generates an average of 18 queries involving 44 tables for patient. Since there are an average of 720 beds, 12960 queries would be needed every 30 minutes, and then the composition of the HTML to render for the user in screen.

Using the CDA repository, only 1 query is needed, involving a snapshot of the current active inpatients or emergency care episodes, and the query to the document repository for the URL for the last indications CDA for the patient. Rendering the information only requires transformation of the XML using an XSLT stylesheet.

Since implemented, usage record is presented in Table 1.

As an example, when there was a change of servers and database servers' operating system migration, there was a downtime for 13.30 hours. In this episode, all indications were printed. 1250 paper sheet were used, printing 759 indications in 1 hour 15 minutes.

The printing process has a predefined sequence, prioritizing critical care units, emergency care, pediatric care, and then other services and locations.

4 Discussion

This architecture allowed information to be available from all delivery care locations, and allows every actor requiring the information to access it. Portability was achieved because every record in the EHR can be shared with any individual or organization requiring access to the information.

The alternate folder strategy was required because in one of the tests if networking or energy were interrupted when the folder was being generated, its structured could be corrupted. If this happens, the other folder can be accessed.

No other experience in creating this kind of repository was found in the literature, used as redundant repository or contingency.

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A comparison of two Detailed Clinical Model representations: FHIR and CDA

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Abstract

Introduction: In recent years several standardized modeling methods have been proposed that separate health related data models from their underlying technical data model. These methods presuppose representation of information independently of (or uninfluenced by) technical considerations. Among these methods is the Detailed Clinical Model (DCM) paradigm. One of the pillars of this paradigm is that all representations convey the same meaning and are independent of the technical standard that is used and the DCM standard claims to achieve that. In this paper we will challenge that claim by modeling the specific DCMs in two different technical standards (CDA and FHIR) and testing if messages based on these models are interconvertible.

Methods: We identified and categorized the problems that may arise when mapping or combining multiple standards creating representations of selected DCMs in both FHIR and CDA to determine possible fundamental problems using a technology independent model (DCM) to represent technical models (FHIR and CDA). To test if the theoretical problems we encountered while creating our example messages also occur during the actual transformation, and to determine any additional problems, we attempted to transform the Clinical Document Architecture (CDA) representations of the DCMs to the FHIR representations using Extensible Style sheet Language Transformations (XSLT).

Results: Most aspects of the DCMs could be properly represented in both FHIR and CDA, and can be transformed from CDA to FHIR. However, we identified fundamental issues where information was lost or its meaning was changed. This results in fundamental difficulties during the implementation of the standards and when transforming one standard to another.

Conclusion: Our research shows that possible loss and change of meaning and lack of interconvertibility occurs when implementing two separate technical standards based on the same DCMs. This indicates that it does matter which technical standard is used to implement a DCM.

Keywords

Knowledge Representation; Electronic Health Records; Detailed Clinical Models

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1 Introduction

1.1 Context

Hospitals and other healthcare providing organizations typically have many different computer systems for everything from billing records to patient tracking. This software must be able to communicate with other software inside and outside the facility to share clinical information. It is important for hospitals and patient safety in general that exchanged information is not lost or altered.

There is general agreement that making clinical documentation uniform saves time and resources and the exchange of data between healthcare institutions is much simpler when there are less different data definition standards. For research and healthcare quality indicators it is also desirable that healthcare data is saved in a uniform way and close to the health processes. [1]

The eight academic hospitals in the Netherlands and the National IT Institute for Healthcare in the Nether-

lands (Nictiz), a knowledge center for IT and innovation in the healthcare sector, took the initiative to work together on standardization of health data. The project Generic Data for Patient Transfers (GenOGeg – "Generieke OverdrachtsGegevens" in Dutch), was started in January 2012 as the first project of the collaboration. The scope of the project is to create a national cross-specialty exchange dataset for when a patient gets transferred between healthcare facilities. [1]

In order to secure corresponding data, the Detailed Clinical Model (DCM) paradigm is chosen, and a sizable set of DCMs have been published as a result of this project. DCMs provide a method to specify what information is potentially relevant. DCMs combine terminology, professional knowledge, and data specification into information models, from which various technical solutions can be developed. [2] Nictiz is planning to use a Health Level Seven (HL7) version 3 Clinical Document Architecture (CDA) Release 2 standard based on the DCMs as a solution for this exchange.

Meanwhile, developments of a next version of HL7 are ongoing, coined Fast Health Interoperable Resources (FHIR), which can also be used to represent DCMs. Over the years, a lot of effort has been put in the specification of clinical data elements. Clinicians, regulatory agencies, health statisticians, institutions for quality control and others invest in clinical data standards. [3] With this growth of standards, the demand of standards that can exchange information with other standards also grows.

As the GenOGeg project constitutes a large effort from many people and different organizations, it is relevant to consider how this work will be able to cope with the inevitable change in landscape of data standards in health. For this it is vital to establish whether the current chosen implementation of DCM can be transformed into the next generation of standards.

1.2 Research

As FHIR is based on other models than HL7v3 [4], we aim to investigate to what extent CDA representations of the GenOGeg DCMs are different from the FHIR representations and which problems occur when transforming one into the other. A review about detailed clinical models states:
"DCMs organize health information via combining knowledge, data element specification, relationships between data elements, and terminology into information models that allow deployment in different technical formats." [5]

The research question of this article is: Do different representations of DCMs convey the same meaning and are DCMs independent of the technical standard that is used?

Sub questions are:

- What problems arise through conceptual analysis (creating and comparing example messages)?
- What problems does practical XSLT transformation add?

2 Background

2.1 Detailed Clinical Models

The Detailed Clinical Model methodology is a draft ISO standard (ISO/PRF TS 13972). It is used to describe a technology-agnostic data model and narrative around interpretation of the model and the data. The methodology was created to standardize the way data is modeled.

DCMs describe the structure of the clinical data that is stored in electronic patient records, sent between clinical systems, and referenced in decision support rules. DCMs also describe the line between the terminology model and the information model, which is, just like defining value sets, helpful for a compatible exchange of data. A DCM is a relatively small model, designed to express a clinical concept in a standardized and reusable way. Data elements and attributes of a clinical concept, the possible values and types, and relationships needed to convey the clinical reality are described by a DCM in a way that is readable to both modelers and clinicians. [5]

2.2 HL7 v3 CDA release 2

The HL7v3 Clinical Document Architecture (CDA) is a standard for exchanging and saving medical documents. A typical CDA document would be an admission report, discharge summary, imaging report etc. CDA uses XML, although it allows for a non-XML body (pdf, Word, jpg etc.) for simple implementations.

CDA Release 2, based on the HL7v3 Reference Information Model (RIM), basically consists of tags, which harbor the semantics for persons and document properties that can be used to describe the structure and the hierarchy of the document.

CDA release 2 was launched in 2005 and has gained much popularity internationally. The popularity comes from the simplicity of the model. The fact that the model is generic and is not bound to any domain means there is a lot of freedom during implementation. Persistence, the ability to sign documents, context, and human readability are all characteristics of the model that is defined in CDA.

2.3 FHIR

FHIR is a new draft standard based on emergent industry approaches. FHIR claims to combine the best features of the previous HL7 standards while being fast and easy to implement. [6] The FHIR standard can be used as a stand-alone data exchange standard, but can also be used in partnership with existing widely used standards. [7] The basic building block of a FHIR document is a resource. An example of a patient resource can be found in Figure 1.

Resources have a wide range of uses, from clinical content such as care plans and diagnostic reports through infrastructure such as Message Header and conformance statements. [7] Resources define all exchangeable content, despite the fact they are used in totally different fashions, they all share the following set of characteristics:

- A common way to define and represent them, building them from data types. that define common reusable patterns of elements.
- A common set of metadata.
- A human-readable part.

FHIR's philosophy is to build documents from a set of resources that, either by themselves or when combined, satisfy the majority of common use cases. Extensions can be used to cover the remaining content as needed. Usually, specific use cases are implemented by combining resources through the use of resource references. [7]

3 Methods

To challenge the claim of compatibility of two representations of the Detailed Clinical Models, we chose CDA for being the most frequent implementation and FHIR for being its most likely successor. To determine the presence of fundamental and less severe problems which could occur when representing a technology-independent model (DCM) in a technical model (FHIR and CDA), we created example messages based on the GenOGeg's DCMs in both representations (FHIR and CDA).

To test if the theoretical problems we determined while creating our example messages also occur during the actual transformation, we attempted to transform the CDA representations to the FHIR representations of the DCMs using Extensible Stylesheet Language Transformations (XSLT).

A visual representation of the methods is depicted in Figure 2.

3.1 Creating example messages

To establish the presence of problems which could occur when trying to fit a technical model (FHIR and CDA) onto a technology independent model (DCM), we created example messages based on the GenOGeg's DCMs.

These DCMs are particularly suitable for this research because they are widely accepted, describe a representative set of data, and are the first DCMs on a national cross-specialty level.

We made a selection of the DCMs, where we expected most problems would arise. We selected the DCMs due to their amount of complexity as opposed to the ones we did not select. The DCMs and the reason for their selection can be found in Table 1.

DCMs are technology-independent models that are not bound to any technical standard and have already defined the clinical concepts in a standardized and reusable way. Therefore we used DCMs as a starting point and attempted to fit them into two technical models (FHIR and CDA). To overcome the fact that FHIR is still in Draft Standard for Trial Use (DSTU), we adjusted our representations to the latest version of FHIR when revisions were made to the FHIR standard during our study.

We will describe here how we used the implementation guide of GenOGeg's American equivalent, the Consolidated Clinical Document Architecture (C-CDA), as the implementation guide of the GenOGeg project was not yet finished.

The implementation guide describes how to model document body entries and provides example messages, which we remodeled to represent a DCM. Each part of each DCM was mapped to corresponding document body entries described in the C-CDA implementation guide. We used XML schema validation to check the validity of our messages. The purpose of an XML Schema is to define the legal building blocks of a specific XML document (for example FHIR) and validate if an XML message is in accordance with these building blocks.

As CDA is a rather flexible standard, it is more than likely that different modelers create different CDA representations based on the same DCMs. To prevent outcome bias due to keeping FHIR in mind when creating our CDA representations, we used the rules and CDA subset of the C-CDA.

To create the FHIR example messages for the DCMs, we started by studying the FHIR specification [8]. In the specification, examples were provided, which we used as a template to create our messages. From the list of resources we selected the resource that corresponded with the DCM model, which could be retrieved from the FHIR specification.

We remodeled the examples so they conformed to the rules of a DCM representation. To check the validity of the XML document of our newly created example messages we used the FHIR-atom XML schema validation.

3.2 Comparing example messages to identify discrepancies

From the start of example message creation, we kept an inventory of problems. We documented the problems we had when representing a DCM using FHIR and CDA. With each step we took in the process we assessed whether the example message was still in accordance with the DCM or that change or loss of meaning occurred with the last adjustment.

We compared the semantics of the FHIR and CDA example messages on each element and identified and categorized the differences between both representations. The initial categorization was based on problems described in literature [3, 9, 10, 11], and consisted of: Problems with coded values; Difference in Relational Structures / Hierarchies; Difference in requirements and restrictions; Use

of narratives. For problems that could not be categorized additional categories were introduced.

3.3 Transforming the CDA example messages to FHIR

To test if the theoretical problems while creating our example messages also occur during actual implementation, and to identify if any additional problems arise, we attempted to transform the CDA representations to the FHIR representations of the DCMs using XSLT. XSLT is a language for transforming XML documents into other XML documents. [12] The input and the output for XSLT are the same type of objects (both XML). This has immediate benefits: for example it is possible to do a complex transformation as a series of simple transformations, and it is possible to do transformations in either direction using the same technology. [13]

During the transformation of each CDA example message we assessed whether we had to remove, add or change information to come to a valid FHIR message, which we validated using the FHIR-atom XML schema.

Figure 1: Example of a patient resource [6].

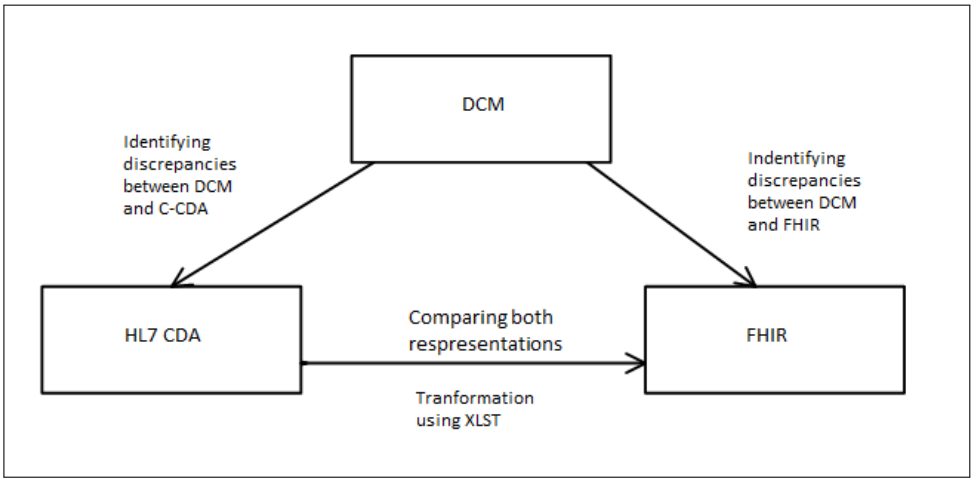

Figure 2: Visual representation of the methods.

Table 1: Selected DCMs, with rationale for their use.

DCM	Reason for selection
Alert	Ambiguous definitions, expected mismatch between technical models
Barthel Index	To compare support for scores and composite observations
Family History	Possible relationship problems
Lab Report	Hierarchy of report/section/observation, coding systems, work-ow data elements
Medication	Definition and scope of major components of the medication workflow
Patient	Because it's needed for the CDA header
Plan of Care	Complex, scope, tension between free text/structured representations

All problems and proposed solutions we encountered along the way were documented.

4 Results

The problems we encountered are each described in a separate section. In these sections we describe whether we encountered the problems during the creation of our representations of the DCM, the transformation of the CDA representation to FHIR, or both. All FHIR and CDA representations and XSLT files used for the transformation from CDA to FHIR can be found on Github (`https://gist.github.com/mmsmits/57e027d5435d678b95ad`).

Table 2 shows the category of the problems we encountered, where we encountered them, whether they are described in the literature, and in which section they are described.

4.1 Coded values

We encountered differences in the use of coded values in DCMs, FHIR, and CDA. Coded values can be used to define observations (e.g. SNOMED CT codes), but also for other purposes, e.g. to give a care plan a status.

As shown in Table 3, the status codes in DCMs and in FHIR differ significantly.

- Planned: The plan is in development or awaiting use but is not yet intended to be acted upon.
- Active: The plan is intended to be followed and used as part of patient care.
- Completed: The plan is no longer in use and is not expected to be followed or used in patient care.

These codes are not fully translatable to each other; "new" can be mapped onto to "planned", but one cannot map "cancelled" and "aborted" to "completed".

To represent that a care plan is "ordered", the DCM and CDA both use a CCD code, whereas FHIR uses a different resource with a subject that refers to the actual care plan. This order resource requires information that CDA cannot provide.

Another problem occurred when we modeled the normal ranges of the different lab results. In C-CDA the normal range of Hemoglobin is modeled as shown in Figure 3

It specifies the normal ranges for males and females in semi-structured text. In FHIR the same is modeled fully structured, as shown in Figure 4.

```
<referenceRange>
    <low>
        <value value="13.8"/>
        <units value="g/dl"/>
        <system value="http://unitsofmeasure.org"/>
        <code value="g/dl"/>
    </low>
    <high>
        <value value="18.0"/>
        <units value="g/dl"/>
        <system value="http://unitsofmeasure.org"/>
        <code value="g/dl"/>
    </high>
    <meaning>
        <coding>
            <system value="http://snomed.info/sct"/>
            <code value="248153007"/>
            <display value="Male"/>
        </coding>
    </meaning>
</referenceRange>
<referenceRange>
    <low>
        <value value="12.1"/>
        <units value="g/dl"/>
        <system value="http://unitsofmeasure.org"/>
        <code value="g/dl"/>
    </low>
    <high>
        <value value="15.1"/>
        <units value="g/dl"/>
        <system value="http://unitsofmeasure.org"/>
        <code value="g/dl"/>
    </high>
    <meaning>
        <coding>
            <system value="http://snomed.info/sct"/>
            <code value="248152002"/>
            <display value="Female"/>
        </coding>
    </meaning>
</referenceRange>
```

Figure 4: A normal range of hemoglobin represented according to the FHIR specification.

Table 2: List of encountered problems.

Problem	Representations	Transformation	Literature
Coded values	X	X	X
Difference in Relational Structures / Hierarchies	X	X	X
Requirements and restrictions	X	X	X
Narrative		X	X
Null avors and negation indicators		X	
Meaning of attributes		X	

Table 3: Care plan status codes in DCM and FHIR.

DCM Concept Name	DCM Concept Code	FHIR Code
Ordered	New	Planned
Requested	New	Planned
Pending	Active	Active
In Process	Active	Active
On hold	Held	??
Cancelled	Cancelled	Completed
No show	Aborted	Completed

Transforming plain text (C-CDA) to coded values (FHIR) is hard, because first the meaning of a character or combination of characters has to be defined, after which the combination of codes to be used has to be established. This particular example with transforming reference ranges only occurs due to the restrictions of C-CDA, but it serves well as an example to show the difficulties that might occur when one standard represents information in plain text, while another uses coded values.

4.2 Different Relational Structures/Hierarchies

Some DCMs have a different structure and hierarchy than their representation. One of the best examples for this is Alert. The DCM of alert is shown in Figure 5, the structure of the representation of the Alert DCM when modeled in FHIR can be viewed in Figure 6.

The DCM complies with the model used in C-CDA as they are both based on the same RIM, because the alert DCM has been inspired by the Continuity of Care Record (CCR) and Continuity of Care Document (CCD), which are both constraints of CDA. So clearly, the model the DCM author had in mind has influenced the design of the DCM, failing the basic premise that a DCM is technology-agnostic.

In FHIR, alert is modeled slightly differently, as a stand-alone resource.

It contains a category and a note. It can however also have one or multiple extensions (like all FHIR resources). So, if an alert refers to a condition (MRSA) or an allergy/intolerance, one can extend the resource with a resource reference to a condition, allergy, contraindication or any other resource.

So there are clearly some differences between the two structures:
In the DCM, the alert concept directly refers to the reaction and its criticality. This criticality can be mapped to FHIR on the severity of the Allergy or on the severity of the symptom of the adverse reaction. The latter is the one to choose, however, some confusion may easily arise here.

The same goes for the BeginDateTime attribute of an alert in the DCM, which is defined as:
"The date and time the allergy, the adverse reaction or the warning has been set as an Alert" [14]

The problem is where to specify this date in the FHIR representation. The alert does not have a date attribute, the allergy has an attribute for the date the allergy is recorded, and the adverse reaction has an attribute which defines the date the reaction began and exposure has an attribute for the initial date of the exposure that is sus-

```
<referenceRange>
  <observationRange>
    <text>M 13.8-18.0 g/dL ; F 12.1-15.1 g/dL</text>
  </observationRange>
</referenceRange>
```

Figure 3: A normal range of hemoglobin represented according to C-CDA.

pected to be related to the reaction. None of those will actually do. You could however make another extension to alert which specifies the date the alert has been recorded.

These problems are a result of the fact that the technology-independent model and the technical model both have different structures and hierarchies, and therefore some attributes might have a slightly different meaning in both models.

4.3 Requirements and restrictions

Different standards have different restrictions and different requirements. For example: A FHIR resource could define an attribute as mandatory, while the DCM or CDA does not. This could form a problem with the transformation: When one transforms a message which lacks an attribute that is mandatory in the target representation, the resulting message will be invalid. The same goes when transforming a message to a representation in which the cardinality of an attribute is lower.

It can even be argued whether the representation of the DCM is still valid if the DCM does not define an attribute as mandatory, while FHIR or CDA does.

For example, we encountered a problem with the total score of the Barthel Index. In FHIR, we used another question in the questionnaire to define this, the questionnaire defines the total score as an answer and the interpretation of the total score in a text attribute. In CDA the total score can be defined in the top of the Assessment Scale Observation, however, there is no attribute to define the interpretation of the score. The best solution, however not ideal, is to add a reference range to define the interpretation.

The difference in requirements and restrictions between CDA, the DCMs, and FHIR also posed a problem when transforming the CDA representation of the DCMs to FHIR. More restrictions in FHIR can result in loss of meaning, while more requirements enforce manual addition of information to the FHIR representation. We encountered such a problem during the transformation of a care plan. A care plan consists of one or multiple components. According to the DCM, these four components are allowed: Encounter, Medical devices Medicine, Vaccination Activity, Other.

Whereas the DCM only requires a reference to the encounter [14] (as does the C-CDA implementation guide [15]), FHIR in addition requires an encounter state and an encounter class, which cannot always be extracted from the CDA representation, because it is not mandatory. Consequently, these attributes must be added manually to the FHIR representation.

4.4 Narratives

Both CDA and FHIR enable addition of narratives to messages. In both standards reference is possible to coded entries in a document. This is a similarity that immediately forms a problem when transforming one representation into the other. The problem arises when one entry in CDA becomes two entries in FHIR. This would require a

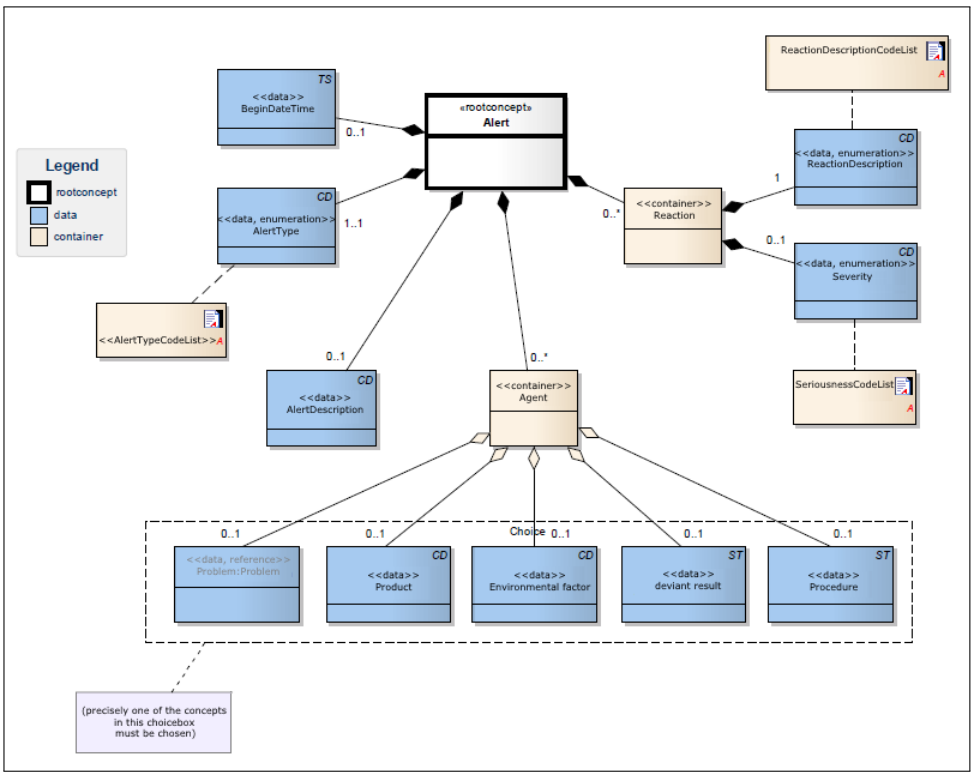

Figure 5: The Detailed Clinical Model of an Alert (remodeled in English for readability) [14].

choice to which entry the narrative refers. When choosing to refer to both, it is hard to define what the reference means. It could mean that the narrative describes a combination of both entries or that it describes two totally separate entries.

Furthermore, the syntax in which the narrative is defined differs: CDA defines its own XML syntax for narrative content, loosely based on HyperText Markup Language (HTML). FHIR makes use of a constrained set of Extensible HyperText Markup Language (XHTML) which is somewhat more expressive than the CDA markup. [16] This means we would have to transform not only the content and references to the entries, but also the syntax.

4.5 Null flavors and negation indicators

In healthcare, it's quite common for data to be unknown, unavailable, have an exceptional value or otherwise fall outside the bounds of a "normal" value. To deal with this, CDA uses the concept of "null flavors", i.e., the different meanings of null values. Examples are: "Unknown", "Not asked", "Positive infinity", "Trace amount", "Masked", and "Other". Null flavors are used on almost every attribute and data type property in its models. Unless an element is explicitly marked as "mandatory", which means no null flavors are permitted, these null flavors can appear anywhere. [4] One example is shown in Figure 7, which represents that the quantity of a maximum dosage of a certain medication is unknown.

```
<maxDoseQuantity nullFlavor="UNK">
        <numerator nullFlavor="UNK"/>
        <denominator nullFlavor="UNK"/>
</maxDoseQuantity>
```

Figure 7: Example of null flavors in CDA.

FHIR handles null flavors exactly opposite to CDA. In FHIR use of a null flavor must be explicitly allowed, whereas in CDA it is allowed by default, by defining null flavors in the core specification and constraining them (using a specific value set) to those relevant to a specific element.

The same goes for negation indicators. In CDA one can add a negation indicator on almost any act. For example: a negation indicator could specify that a patient was not given a certain medication. In FHIR negation indicators can be added only on places where they are explicitly allowed. In the FHIR specification of the medication administration for example, specific attributes are added to indicate if and why a medication was not given. An example can be found in Figure 8.

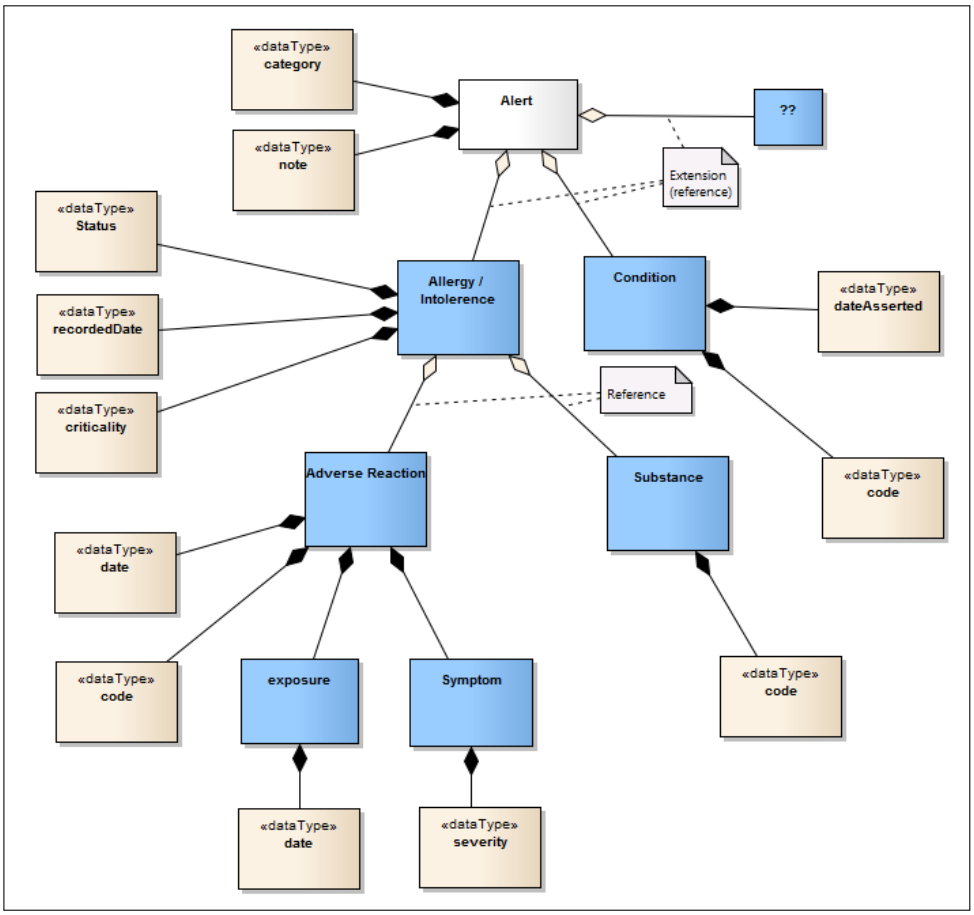

Figure 6: Representation of the alert DCM when modeled in FHIR.

Because CDA allows null flavors and negation indicators almost everywhere and FHIR allows them only on specific elements, it is difficult to transform a CDA document into a FHIR document without loss of meaning. A solution might be to use extensions for this, however most FHIR developers would not expect these extensions.

4.6 Meaning of attributes

Some attributes in FHIR and CDA look similar, but can have a slightly different meaning or a meaning which can be discussed. Because of this difference or vagueness, these attributes are difficult to transform from one representation to another.

For example, CDA uses one general EffectiveTime attribute to specify dates and times in AllergyIntolerance. To create an AllergyIntolerance section in a CDA document a couple of these date attributes are mandatory:

- The effective time in the section which contains all of the patient's allergies and intolerances.
- The effective time of each separate allergy or intolerance.

However, the C-CDA implementation guide [15] does not specify the exact meaning of these effective time attributes, e.g., whether the first descriptions means the time that the first allergy or intolerance was identified. Although probable, this is not explicitly stated. Because of this vagueness, we cannot be sure how to represent this date in a FHIR message. The effective time of each separate allergy and intolerance is probably the time the allergy has been recorded, and therefore can be transformed to the recordedDate attribute in a FHIR message.

5 Discussion

Most aspects of GenOGeg's DCMs can be properly represented in both FHIR and CDA, and can be transformed from CDA to FHIR. However, in our study some fundamental problems arose, which could trouble a proper implementation of two standards based on the same DCM. Creating the CDA and FHIR representations of the DCMs shows that combining or mapping different standards could result in several conflicts. The transformation of the CDA representation to FHIR confirms these conflicts and adds several others to the list. Problems we encountered refer to the following aspects:

- Coded values
- Relational structures / Hierarchies
- Requirements and restrictions
- Narrative
- Null flavors and negation indicators
- Meaning of attributes

All problems in these aspects result in either loss or slight change of meaning, and fundamental difficulties during the implementation of the standards and when transforming one standard to the other.

This study shows that DCMs are not technology-independent, i.e., not every representation of a DCM is necessarily interconvertible with others. Therefore, to allow the implementation of multiple technical models in a DCM, modelers should anticipate on the technological models to be used when defining the DCMs.

As we had to create the CDA example messages ourselves, the definitive GenOGeg CDA messages may slightly differ from the messages that were developed for this study.

We only transformed our messages from CDA to FHIR, not in reverse direction. However, we are quite certain this would not have resulted in fundamentally more problems, as mapping of the representations involves bi-directional analysis and comparison.

The selection of the DCMs was done by one individual, which may have caused selection bias. However, because of the amount of complexity of the selected DCMs we are fairly certain that the majority of the possible problems have arisen from the selected DCMs.

A strength of this study is that we used an XSLT transformation to back up our conceptual analyses through representing the DCMs in both standards. The transformation also identified problems that would not have

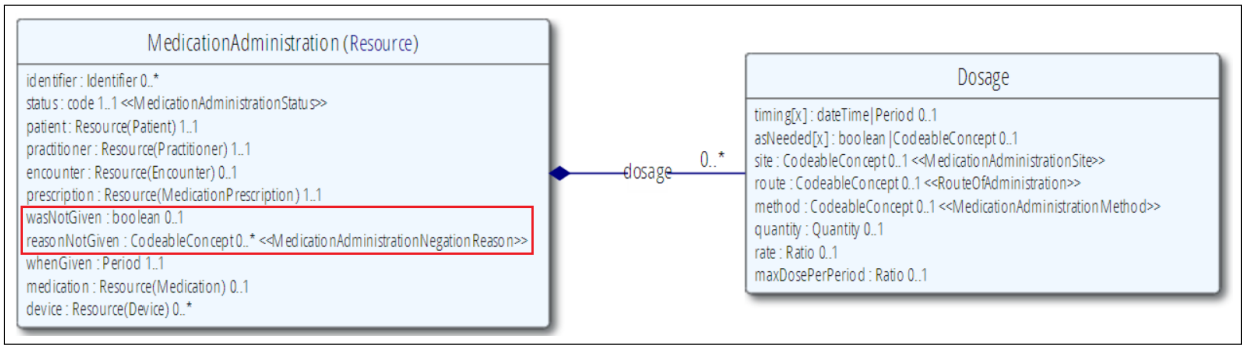

Figure 8: FHIR specification of the medication administration resource [8].

arisen otherwise. Even more, all problems identified by the creation of example messages were also identified by the transformation. As both the CDA and FHIR representations are defined in XML, and XSLT is designed to transform XML documents into other XML documents, the choice to use XSLT instead of other methods was a natural one.

Although there is research on mapping or combining two standards, this study is to our knowledge the first to determine if two standards based on the same DCM are interconvertible and retain meaning. Other studies [3, 9, 10, 11] concluded that only small problems arise when mapping or combining two standards, and leave the bigger problems untouched. Goossen et al. identified that HL7 templates and 13606 archetypes object models can be compared on nine different levels [3], but only describe problems in the first 4. Our study shows that fundamental problems occur on the levels that Goossen et al. do not describe.

The conclusions of our study disagree with the findings of earlier studies as we conclude that with the different procedures and techniques and a broader scope we find several fundamental and unresolvable problems. Actually implementing conversions forced us to face problems that will arise. A paper by Blobel et al. [17] agrees that existing modeling approaches show fundamental weaknesses and differences in maturity and are not all capable to represent the same information.

Because the study is based on a real-life use case (GenOGeg) it can be very useful for its decision makers. The problems we identified are generic and therefore could also be useful for similar projects. The study shows that the GenOGeg's current DCMs are not fully compliant with multiple standards, which is relevant information for both the decision makers working with Nictiz and the academic hospitals, and the active community using detailed clinical models. We hope this study will encourage modelers to take the possibility of the implementation of multiple standards into account when defining future detailed clinical models.

Because FHIR is still in DSTU major revisions in the FHIR standards can still be made. This study could be input into the standard formation process of FHIR, especially in the area where interoperability with other standards is involved.

Using other standards (OpenEHR, ISO-13606, RDF etc.) in addition to FHIR and CDA could give new insights in which problems arise when combining multiple standards based on the same DCMs.

Because the demand of standards that can exchange information with other standards grows, research needs to be done to determine if the current DCM approach needs to be revised to allow for implementation of multiple standards.

6 Conclusions

Different representations of a DCM do not necessarily convey the same meaning. In our study we showed that both CDA and FHIR are not fully compliant with each other and with GenOGeg's detailed clinical models when it comes to restrictions and requirements, coded values, relational structures, narrative, null flavors and negation indicators and meaning of attributes. This results in possible loss of meaning and lack of interconvertibility when implementing two separate standards based on the same DCMs. This indicates that it does matter which technical standard is used to implement a DCM.

List of Abbreviations

C-CDA	Consolidated Clinical Document Architecture.
CCD	Continuity of Care Document.
CCR	Continuity of Care Record.
CDA	Clinical Document Architecture.
DCM	Detailed Clinical Model.
DSTU	Draft Standard for Trial Use.
EHR	Electronic Health Record.
FHIR	Fast Health Interoperable Resources.
GenOGeg	Generic Data for Patient Transfers.
HL7	Health Level Seven.
HTML	HyperText Markup Language.
MRSA	Methicillin-resistant Staphylococcus aureus.
Nictiz	National IT Institute for Healthcare in the Netherlands.
RIM	Reference Information Model.
XHTML	Extensible HyperText Markup Language.
XML	Extensible Markup Language.
XSLT	Extensible Stylesheet Language Transformations.

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IHE/HL7 Implementation Guide for eSupply

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Abstract

The use of eCommerce solutions in the German health care market is hindered by fragmented solutions and lack of guidance to the use of standards. Especially the area of procurement is mainly dominated by proprietary solutions. Also, the splits in the area of information transfer - which are attributable to the non-coverage usage of standards – result in delays, transcription errors, wrong orders and patient confusion. The project "Standards zur Unterstützung von eCommerce im Gesundheitswesen" (eCG) w a s launched in August 2012 and i s funded by the German Federal Ministry for Economic Affairs and Energy – "Bundesministerium für Wirtschaft und Energie" (BMWi) – within the programme "Mittelstand Digital". The eCG project consortium consists of "Hochschule Niederrhein" (HSNR), "Zentrum für Informations- und Medizintechnik der Universitätsklinik Heidelberg" (ZIM), The German Medical Technology Association "Bundesverband der Medizintechnologie" (BVMed e.V.) and "Integrating the Healthcare Enterprise" in Germany (IHE Deutschland e.V.).

One of the main goals of this project is to design a sustainable supply system for healthcare and subsequently produce a significant increase of potentials for efficiency within the health sector by developing interoperability between different, already used standards in the healthcare and the logistics domain. After a literature research and analyses of business processes in hospital new IHE Integration Profiles were modeled in order to describe the interaction between different (software) actors in a hospital starting with ordering products in a point of care until buying it by an external vendor. These profiles are described in an implementation guide "eSupply in Healthcare". For transactions between the actors HL7 v2 messages and GS1 standard were used.

Keywords

Health Information Systems, eSupply, Interoperability, eCommerce, eStandards, eProcurement, Health Level Seven

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1 Introduction

The use of eCommerce solutions in the German health care market is hindered by fragmented solutions and lack of guidance to the use of standards. Especially the area of procurement is mainly dominated by proprietary solutions. Also, the splits in the area of information transfer - which are attributable to the non-coverage usage of standards – result in delays, transcription errors, wrong orders and patient confusion. The project "Standards zur Unterstützung von eCommerce im Gesundheitswesen" (eCG) was launched in August 2012 and is funded by the German Federal Ministry for Economic Affairs and Energy – "Bundesministerium für Wirtschaft und Energie" (BMWi) – within the programme "Mittelstand Digital". The eCG project consortium consists of "Hochschule Niederrhein" (HSNR), "Zentrum für Informations- und Medizintechnik der Universitätsklinik Heidelberg" (ZIM), The German Medical Technology Association "Bundesverband der Medizintechnologie" (BVMed e.V.) and "Integrating the Healthcare Enterprise" in Germany (IHE Deutschland e.V.). One of the main goals of this project is to design a sustainable supply system for healthcare and subsequently produce a significant increase of potentials for efficiency within the health sector by developing interoperability between different, already used standards in the

healthcare and the logistics domain. This article's main focus is on the role of IHE Germany e.V. in terms of the desired interoperability between GS1 and HL7 standards and messages and associated terminologies.

2 Objectives

2.1 Integrating the Healthcare Enterprise (IHE)

"Integrating the Healthcare Enterprise is an initiative by healthcare professionals and [IT system] industry to improve the way computer systems in healthcare share information" [1]. In 1998 the initiative was founded by the Healthcare Information and Management Systems Society (HIMSS) and the Radiological Society of North America (RSNA). [2] IHE is an international organization with established national deployment committees in 17 countries across the world [3]. IHE does not provide additional standards but specifies the harmonized use of already established standards. The initiative develops and publishes comprehensive, generic technical profiles which can be used for implementation of IHE compatible systems within the healthcare sector. Proven IHE profiles already exist for instance in the domains of radiology, cardiology and pharmacy. It is planned to develop and harmonize a profile specific for some new domain for "eSupply in Healthcare" within the project eCG [4].

2.2 GS1

With large corporate members in over 100 countries around the world, the, non-profit organization GS1 is one of the key providers of supply chain related standards. In general logistics ("MaWi") especially the GS1 identification standards e.g. GTIN (for orderable items), GLN (for addresses and contacts) and transaction standards like GS1 XML "catalogue item notification" (for item master data) are widespread and widely-used. Since GS1 standards are predominantly used to enable an efficient electronic communication between commercial partners they are mostly used in the supply departments of clinical institutions – but not on the rather care-oriented IT systems. One of the main preconditions to avoid media discontinuity and interface problems is to integrate product infor-

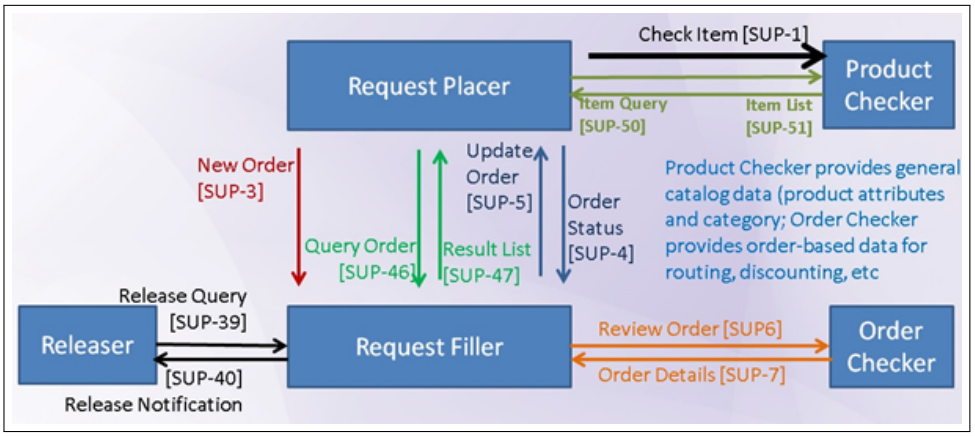

Figure 1: Possible IHE integration profile for Clinical Order.

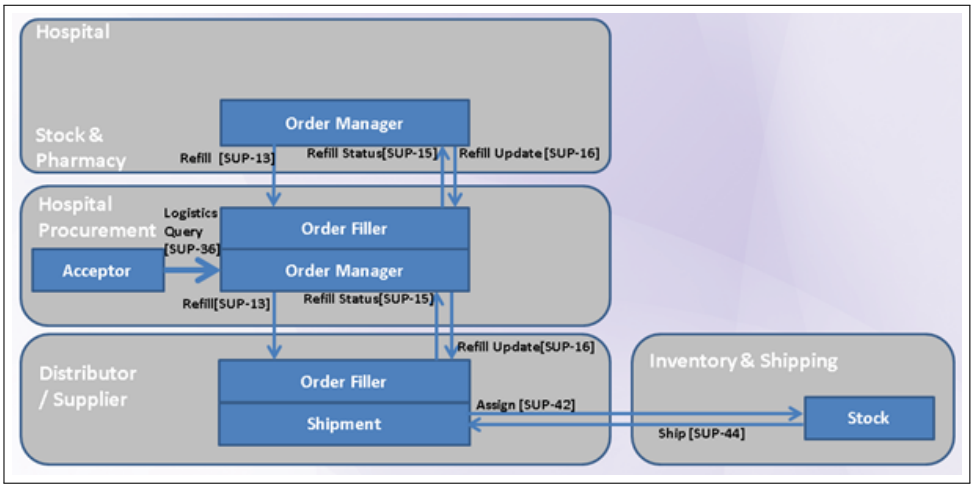

Figure 2: Possible IHE integration profiles for Supply and Stock management.

mation from the GS1 standard system into departmental IT and point-of-care IT systems [4].

2.3 GS1 & HL7 & IHE

Within a "Memorandum of Understanding" in the year 2007 HL7 and GS1 declared their purpose of cooperation with the aim of developing global standards to improve patient care. In October 2013 at GS1's semi-annual Healthcare Conference they renewed their Memorandum of Understanding to work together to reduce medical errors and improve the efficiency of the supply chain within the healthcare market [5]. "For example, it is requested to integrate GS1 identification standards and attributes into HL7 messages to make them available within the clinical information systems" [4]. Within the project eCG a specific guideline for "eSupply in Healthcare" is going to be developed which defines the interaction between HL7 and GS1 standards with terminologies such as eCl@ss, Pharmacy Product Number (PPN / PZN) and SNoMed CT in special integration profiles [4].

3 Methods

As a foundation for practical generic profiles IHE analyzes typical clinical use cases and – driven by the architectural principles of decoupling and information cohesion – defines IHE integration profiles with independent, stateful "actors". Each integration profile specifies actors by their information as well as their communication interface – the so-called IHE transactions. The content of these transactions is based on existing international standards like DICOM and HL7 and is defined in the transaction specification. The IHE integration profiles together with the related transaction specification make up a Technical Framework – each grouped for a medical domain.

IHE profiles offer a common language for both healthcare professionals and vendors to discuss their special needs. The development cycle for IHE integration profiles describes how these profiles have to be discussed, documented, reviewed and tested [6]. Both parties can refer to integration profiles when they identify required actors and transactions to describe a specific clinical IT solution. On the other hand the profiles are generic enough to allow adaption to a given IT environment.

The use-cases of project eCG describe mostly a "supply" scenario where an order is dedicated to fill the costumer's local stock or notify consumption from the stock. That means that in the normal use-cases of the project eCG, there is no need to transmit patient data nor dispense or prescription data to logistics IT- systems.

The proposed Integration Profiles for eSupply shall integrate clinical IT systems with logistic IT systems and material management IT systems. Within the eCG – project IHE performed an initial analysis of the results provided by literature research, questionnaire survey and process and system analysis. Afterwards the Integration Profiles were modelled and the transactions were specified as HL7 v2 messages or GS1 messages.

4 Results

Nine distinct areas where the IHE approach may improve the procurement and supply in hospitals have been identified. Those nine areas are potential candidates for IHE integration profiles for eSupply:

- "Point-of-care order: Order of stock-keeping or non-stock-keeping products performed by an end user like a physician or nurse
- Catalog management: Maintenance and distribution of product master data and supplier information
- Stock management: Reorder of stock-keeping products and stock-control
- Claims and payments: Management and handling of invoices, creditors, liabilities, demand notes and credit items (in case of product returns)
- Assets invested: Identification and tagging of assets for inventory and further tracing
- Supply chain intelligence: Methods regarding commercial and technical analyses of the supply chain and the procurement process
- Logistics and distribution: Management and optimization of the physical distribution regarding the ordered products
- Quality and validation: Total data quality management with regard to the entire procurement and supply process
- Medical reasoning and lookup: Clinical/pharmacological knowledge base for inference, e.g. as a support for searching a specific product" [7]

The eSupply scenario relies on a clinical IT-system which accesses a product catalog and compiles a clinical order that is being forwarded for further processing.

The eCG solution is to describe a generic sequence covering most of the practical clinical order use-cases, which suggests to identify the following attributes [8]

- Customer (order placer)
- Product
- Quantity and Packaging
- Global Trade Item Number (GTIN)
- Price
- Seller / Supplier

- Supply Contract

Two IHE integration profiles for eSupply are described exemplarily.

4.1 Point-of-care Order

The IHE candidate integration profile Point-of-care order describes the creation and internal forwarding of an electronic procurement order starting from a REQUEST PLACER (former Order Placer) – at this point of the workflow the clinical order is not a legal order, but an internal request – at the point-of-care towards an internal REQUEST FILLER (former Order Responder) like e.g. an internal procurement office. Before the request is sent to the request filler the PRODUCT CHECKER verifies the clinical order which may contain one or multiple different items, each describing a product that is specified in a hospital's product catalogue. The REQUEST FILLER receives the checked items as a clinical order, subsequently the ORDER Checker (former Order Reviewer) examines the order as a whole and may respond with a modified order which may substitute the ordered items, change the units of measure or just adjust the quantities of the order [7]. The REQUEST FILLER is also responsible for the delivery, manufacture or purchasing of the items. REQUEST PLACER implementations do not manage state – neither product catalogue nor list of pending orders – and therefore can easily be implemented by lightweight clients at the point-of-care, as thin "apps" in the Hospital Information system (HIS).

4.2 Stock Management

Another important IHE integration profile is Stock Management which describes the physical resupply of the department / hospital stock by the actor ORDER MANAGER. According to appointed refill strategies, the ORDER MANAGER actor sends a refill request to the ORDER FILLER. It is responsible for providing the required items.

In a complex supply chain these actors can be cascaded. The "ORDER FILLER" itself can play the role of an "ORDER MANAGER" and send a refill order to another "ORDER FILLER". The Stock Management profile can therefore be used to implement several organizational levels of stock-keeping within a hospital and its suppliers. [8]

4.3 Combination of different IHE integration profiles

It is also possible to combine various IHE integration profiles and its associated actors. Figure 3 shows the combination of the cascaded profile Supply and the profile Shipment.

It must be noted, that eSupply can also be combined with actors of the IHE profiles from Pharmacy, IHE Information Infrastructure or, Radiology.

4.4 Transactions

The above mentioned transactions were described by HL7 v2 and GS1 transactions. HL7 messages were used for internal clinical messages and GS1 transactions to order products from an external vendor. Global Trade Identification Numbers (GTINs) can be used to identify products within RQD segments of OMS stock order messages in Hl7 v2.

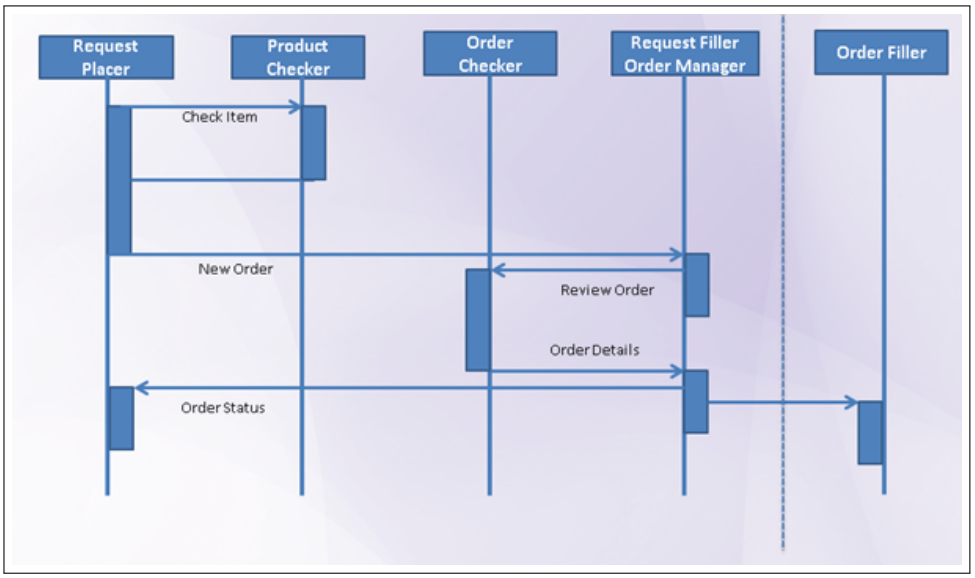

Figure 3: Example sequence for order process based upon potential IHE integration profiles.

5 Discussion

Almost every stakeholder within the healthcare industry expects a guidance regarding the realization and planning of electronically supported procurement and supply processes [7]. The proposed IHE integration profiles for Clinical Order and Supply specify a flexible, scalable architecture for electronic procurement in the hospital. Due to the use of GS1 identifiers in HL7 and GS1 based messages it is possible to bridge the gap between the clinical applications and external vendors.

These actors shall now be tested by implementation and integration into a Hospital Information System.

Acknowledgement

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Developing a conformance methodology for clinically-defined medical record headings: A preliminary report

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Abstract

Background: The Professional Records Standards Body for health and social care (PRSB) was formed in 2013 to develop and assure professional standards for the content and structure of patient records across all care disciplines in the UK. Although the PRSB work is aimed at Electronic Health Record (EHR) adoption and interoperability to support continuity of care, the current technical guidance is limited and ambiguous.

Objectives: This project was initiated as a proof-of-concept to demonstrate whether, and if so, how, conformance methods can be developed based on the professional standards. Methods: An expert group was convened, comprising clinical and technical representatives. A constrained data set was defined for an outpatient letter, using the subset of outpatient headings that are also present in the epSOS patient summary. A mind map was produced for the main sections and sub-sections. An openEHR archetype model was produced as the basis for creating HL7 and IHE implementation artefacts.

Results: Several issues about data definition and representation were identified when attempting to map the outpatient headings to the epSOS patient summary, partly due to the difference between process and static viewpoints. Mind maps have been a simple and helpful way to visualize the logical information model and expose and resolve disagreements about which headings are purely for human navigation and which, if any, have intrinsic meaning.

Conclusions: Conformance testing is feasible but non-trivial. In contrast to traditional standards-development timescales, PRSB needs an agile standards development process with EHR vendor and integrator collaboration to ensure implementability and widespread adoption. This will require significant clinical and technical resources.

Keywords

Medical records; Electronic health records; HL7; IHE; OpenEHR; Archetype; CDA; FHIR Conformance; Testing

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1 Introduction

1.1 Clinical Leadership

Health and social care information technology projects have typically been technically-led not clinically-led and this has frequently been identified as a significant risk factor [1, 2]. By analogy, the development of information standards is as much at risk from lack of clinical leadership as the design and deployment of software.

In an attempt to bring clinical leadership to the production of standards for patient records, in 2002 the Health Informatics Unit of the Royal College of Physicians

(RCP) began investigating variations in current record-keeping practice [3, 4]. This work led to a joint project on generic medical record keeping standards commissioned by NHS Connecting for Health and led by the RCP, with involvement throughout from other professional bodies and patients, resulting in the first version of standards for the content and structure of patient records, published in 2008. That project was followed in 2010-12 by a Joint Working Group set up by the Department of Health Informatics Directorate (the first successor body to NHS Connecting for Health), to resolve the governance of multi-professional standards. The Joint Working Group made a series of recommendations, including the observation that "Technical standards alone do not ensure the ability for information systems to transfer interpretable health data around the NHS" [5]. It was also recommended that a new group should be formed, provisionally called the "Professional Records Standards Development Body" (PRSDB), to continue and extend the work of developing and assuring professional guidance for patient record content and structure across all care disciplines in the UK.

The Professional Records Standards Body for health and social care (PRSB) was formed in 2013 as a Community Interest Company. Its stated objects in its Articles of Association were: "to ensure that the requirements of those who provide and receive care can be fully expressed in the structure and content of health and social care records." The founder members were: National Voices (an umbrella patient group organisation), the Royal College of Physicians, the Allied Health Professions Federation, the Royal College of Nursing, the Royal College of General Practitioners, the Royal College of Pathologists, the Royal College of Surgeons of England, the Royal College of Psychiatrists, the Royal College of Paediatrics and Child Health, the Academy of Medical Royal Colleges, the Association of Directors of Adult Social Services and the British Computer Society (BCS). PRSB also has representation from the Health and Social Care Information Centre (HSCIC), the Scottish Government, NHS Wales and the Northern Ireland Department of Health, Social Services and Public Safety.

One of the early standards endorsed by the PRSB was the 2013 version of the standards for the content and structure of patient records [6].

1.2 Technical Conformance

The end goal of PRSB is computable but user-friendly semantic interoperability. The PRSB business plan for 2014-15 contained a work programme which included an intention to: "Develop [an] internal proposal on whether and how PRSB should offer an IT application certification service". The feasibility of a certification scheme is based on the fundamental assumption that PRSB standards are sufficiently well-defined to form the basis of a testing mechanism of some kind. However, the existing guidance on the structure and content of patient records [6] is deliberately written from the perspective of a clinical user not a technical implementer. The way that headings and sub-headings are described is typically fairly loose, mostly based on examples rather than precise definitions (Figure 1). Even the amplified text in the technical annexes tends to be illustrative rather than normative (Figure 2). In fact, the RCP web page for the technical annexes specifically states that they are not intended to pro-

Medications and medical devices

Subheading	Clinical description
Medication name	May be generic name or brand name (as appropriate).
Medication form	Eg capsule, drops, tablet, lotion etc.
Route	Medication administration description (oral, IM, IV, etc): may include method of administration (eg, by infusion, via nebuliser, via NG tube) and/or site of use (eg, 'to wound', 'to left eye', etc).
Dose	This is a record of the total amount of the active ingredient(s) to be given at each administration. It should include, eg, units of measurement, number of tablets, volume/concentration of liquid, number of drops, etc.
Medication frequency	Frequency of taking or administration of the therapeutic agent or medication.
Additional instructions	Allows for: • requirements for adherence support, eg, compliance aids, prompts and packaging requirements • additional information about specific medicines, eg, where specific brand required • patient requirements, eg, unable to swallow tablets.
Do not discontinue warning	To be used on a case-by-case basis if it is vital not to discontinue a medicine in a specific patient scenario.
Reason for medication	Reason for medication being prescribed, where known.

Figure 1: Example of record heading definitions.

vide a technical specification for implementing the headings in EHRs [7].

In January 2014, PRSB asked the BCS to initiate a project to address the viability of a conformance scheme. The aims of this project were found to coincide with the interests and objectives of the EU-funded Semantic HealthNet thematic network [8], which offered to partly fund the work.

2 Methods

2.1 Scope

The purpose of this project was to determine whether, and if so how, selected PRSB standards could be verifiably implemented as conformant technical artefacts. This was explicitly limited to a proof-of-concept and excluded any operational deployment. The example instance selected was the outpatient clinic letter, from hospital consultant to general practitioner (GP), based on outpatient record headings in [6] and the example template [9]. The scope was restricted to data items contained within the definition of the extended data set for the epSOS patient summary ([10], section 6.2, pp 43–50), with the addition of information structurally required for a minimally functional letter (for example, outpatient clinic details). The epSOS constraint was applied for two reasons: firstly, to compare the definition and interpretation of the epSOS patient summary content (a specific use case) with the generic record headings; and secondly to limit the number of data items to a tractable size.

The project set out to consider implementation using a plurality of technical standards and methodologies: HL7 CDA and/or FHIR, IHE profiles and/or XDS metadata and openEHR archetypes. We aimed to utilize the SNOMED CT concepts developed for high-level record headings [11] and sought to coordinate with other HSCIC work on the Clinical Documentation and Generic Record Standard (CDGRS) [12].

The project objectives were to determine: (1) what methodology to adopt to produce implementation-agnostic conformance criteria from the PRSB documentation; (2) which artefacts to produce for each technical standard; (3) what specific conformance tests to use for each technical artefact; and (4) what conformance claims could be reliably asserted. It is intended that the eventual conformance specification be adopted by EuroRec for promotion within EHR quality labelling schemes across Europe.

2.2 Approach

An expert group was convened, comprising clinical and technical representatives. The technical members of the project team included leaders from openEHR, HL7 UK, IHE-UK, EuroRec and the HSCIC. We adopted an iterative approach to seek consensus on how to model the PRSB standards, anticipating that each stage of refinement would produce a set of assumptions and clarifications for resolution by discussion between the domain experts and with the clinical advisors. For two reasons, we decided that the most flexible approach was to start by producing an implementation-agnostic representation (sometimes called an abstract information model). Firstly, this would enable the structure and content requirements to be presented and debated with clinical advisors more simply and accessibly than could be achieved using any kind of technical diagram (even simple UML). Secondly, it de-coupled the information structure from any particular implementation formalism and could therefore enable traceability from a single authoritative definition of structure and content through to multiple realisations in disparate technical representations. (At this stage, the traceability would be by human inspection. This could

Dose	This is a record of the total amount of the active ingredient(s) to be given at each administration. It should include, eg, units of measurement, number of tablets, volume/concentration of liquid, number of drops, etc.	Medication dose is an attribute of medication record. This is a record of the total amount of the active ingredient(s) to be given at each administration. In 'dose based prescribing', where a VTM is used, strength is expressed as a separate attribute, whereas in 'product based prescribing', it is usually included as part of a VMP or AMP. dm+d: where strength is expressed as part of a VMP or AMP. SNOMED CT: used where a VTM is used and strength is expressed separately. Allow for mass per unit volume format, to allow for liquid preparations. Where prescribing co-name drugs (eg co-trimoxazole), a strength must be specified for each active ingredient. Also see NHS dose syntax. NHS dose syntax could be used, but has not yet been through clinical assurance, and would need to be, for it to be recommended for use.

Figure 2: Example of technical annex explanations.

become a computational validation, subject to the availability of suitable tooling.) Being generic across the selected technical standards, this agnostic form would also underpin interoperability testing for transformations between the standards.

3 Results

3.1 Data Set Constraints

The first step was to constrain the outpatient headings to the data elements in the epSOS patient summary. Many of the elements from the two sources were transparently equivalent, but there were several significant differences of viewpoint or meaning. For the purposes of our proof-of-concept, we noted the issues and made pragmatic consensus decisions that would enable us to progress with our generic model. The notable issues are addressed in section 4.1.

3.2 Implementation-Agnostic Model

The abstract model was produced as a mind map, showing headings as sections and sub-headings as subsections (Figure 3). After several iterations to clarify questions of interpretation and process, we settled on a high-level structure that was sufficient for our purpose. Pragmatic decisions were made about whether sections were mandatory, required or optional and when there was ambiguity about whether a sub-heading was a section (simply a record organizer for human purposes) or a semantic unit. The abstract model only showed sections, not semantic content. The principal output was not the model itself but the process needed to derive it.

3.3 openEHR Archetype Model

Our openEHR designer produced a set of openEHR archetypes and templates, re-using components including detailed medication models based on UK GP2GP, NHS Scotland messaging models [13] and the detailed RCP medication technical annex [14]. These were combined with other archetypes drawn from the international openEHR repository [15] and a set of new higher-level archetypes aligned with the PRSB headings.

The key issue here was that detailed sub-headings were often insufficiently defined to support interoperability and the elements within artefacts may not match headings precisely.

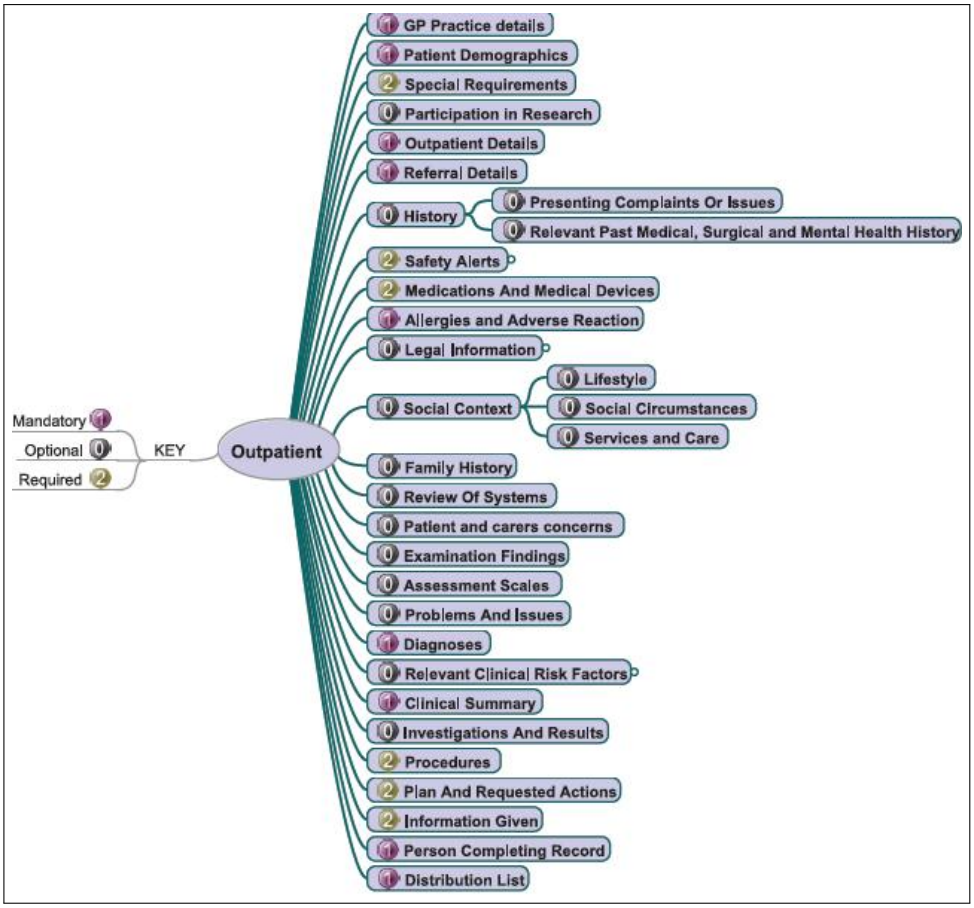

Figure 3: Top-level view of abstract model with selected sections expanded.

3.4 HL7 Artefacts

We investigated the feasibility of representing the outpatient letter with PRSB headings in FHIR resources, using the current FHIR Draft Standard for Trial Use (DSTU) as baseline. This was done through element-by-element analysis of the archetype model, to see whether each of the approximately 500 data elements could be represented in terms of the core resources of the current FHIR DSTU; if it could be so represented, the path in the relevant FHIR resource was recorded in a spreadsheet, against the archetype element.

Complex exchanges are represented in FHIR as Atom-Feed Bundles, which are flat structures of resources represented in XML or JSON, with references between the resources. There are various ways in FHIR to convey clinical documents; the main native FHIR representation is as a Composition resource which holds a hierarchy of sections and sub-sections, which in turn refer to other resources. The referenced resources may be in the same bundle or separate.

Therefore in representing a document which conforms to the PRSB clinical headings in FHIR, the entire structure of PRSB headings and sub-headings is represented in sections and sub-sections of one Composition resource, with references out to other resources to hold the detailed clinical information. This makes the FHIR bundle easier to understand and analyse than the comparable deep nested structures in HL7 Version 3 or CDA. None of the paths in the FHIR representation of the archetype model are very long.

For a purely human-readable document (analogous to a CDA level 0 or 1) the FHIR resources representing detailed clinical information could be resources with only Narrative content, bound together by the sections and sub-sections (headings) in the Composition resource; this would constitute the 'low road' to a PRSB-conformant FHIR bundle. However, we have mainly investigated the 'high road' where the resources also represent the clinical information in coded form. In this case, the resources should still contain human-readable narrative; a sender may choose to generate some of this narrative automatically from the coded data. The FHIR technical analysis is ongoing. The main results so far are as follows:

- There is no difficulty in defining a Composition Resource whose sections and sub-sections reflect the PRSB headings, because the section and sub-section structure of a FHIR Composition resource is entirely flexible. But this has not yet been done in detail; nor has a specifically profiled Composition resource been developed.

- For certain kinds of information in the outpatient letter (such as referrals), the appropriate FHIR resource does not yet exist in the current DSTU. The recommended FHIR approach to this issue (which is to define what you need as an extension of the 'Other' resource) seems very inelegant and unsustainable, and was not investigated. Some of the required resources are being addressed in the current new DSTU under development.

- In cases where the required information does fit in an existing core FHIR resource, generally the level of fit with the Archetype model at the element level was fairly good.

- Nevertheless, at a detailed level we have found many instances of either awkward partial fits (where the FHIR and Archetype definitions are similar but not identical), or of data elements in the archetype model but not represented in the core FHIR resources.

- These instances point to a need to profile and extend the FHIR resources in order to get a good fit with UK and PRSB requirements, however this is an expected stage in national FHIR adoption.

The analysis of the archetype model in terms of CDA (using the UK NPfIT defined profiles and templates) has just been started but no results are ready to report at the time of writing.

3.5 IHE Metadata Definitions

In parallel to this project, IHE-UK had decided to produce generic metadata definitions for a broad range of clinical documentation. This was initially targeted at XDS implementations, but over time it has taken a broader perspective to consider metadata requirements for other platforms. The primary objective of this work is to identify the elements of metadata required to satisfy searches of an electronic patient record for clinical documents relevant to a patient's care, such as specialty, document type, author, following normal patterns of usage in the UK. The possibility of including details of PRSB sub-headings within the metadata is being considered, which might allow simple and efficient location of documents which contain particular information, such as a patient's current medication or problem lists.

3.6 EuroRec Proposals

The EUROREC Institute (EuroRec) is an independent not-for-profit organisation, promoting in Europe the use of high quality Electronic Health Record systems (EHRs). One of its main missions is to support, as a European certification body, EHR quality labelling and defining functional and other criteria.

Inherent within this mission is the promotion of the adoption of relevant standards to achieve greater interoperability across all health systems. Semantic interoperability is recognized to be especially challenging. Its

success lies in the co-creation of standards between professional bodies and health informatics SDOs that provide a useful and usable level of clinical domain coverage and granularity. It is also important to achieve a balance between a tight enough specification for robust computability and a flexible enough approach that recognises the individuality of patients and the inherent and appropriate variability in clinical practice between settings and countries. Through projects like SemanticHealthNet, EuroRec is highlighting the importance of this multistakeholder engagement and helping to understand how this co-creation can best be supported. The work reported in this paper is indeed an example of this, in which clinical professionals from the PRSB are working with the informatics experts to co-create a specification that can be used for conformance testing.

EuroRec will subsequently include these criteria within its portfolio of EHR quality labeling statements, and use them in its future certification programmes across Europe. EuroRec will work with the BCS and other bodies involved in this work to promote and deliver such certification in the UK.

3.7 Conformance Methodology

Based on iterative discussions, we determined that the following steps were needed to derive an abstract information model from the clinical record headings. These steps probably seem like stating the obvious to experienced information modellers, but we found the need to make the process explicit to help clinicians understand why the extant professional guidance was not in itself sufficient to develop technical conformance criteria.

- Decide whether headings and sub-headings are "sections" or "entries" (using EN ISO 13606 terminology).
- Assert the optionality (mandatory, optional, required) and cardinality (for example, one-to-many, one-to-one) of each element, and hence minimal conformance to the model.
- Infer the formal definition of the headings and subheadings; in some cases this required re-labelling (e.g. "GP details") or re-grouping (e.g. "Social context").
- Identify patterns of data that can be handled similarly (e.g. "Referral details" and "Outpatient details").
- Specify single precise data definitions and particular forms of data representation (e.g. what can be free text and what must follow a defined structure or use a particular terminology or value set).
- Disentangle the various perspectives in the professional guidance, for example whether the description is static (e.g. "GP details") or process-based (e.g. "History"). The variance in perspectives sometimes embeds use case constraints into a supposedly generic standard and complicates its interpretation.
- Clarify inconsistencies between structural hierarchies, such as the typical message structure convention of separating administrative ('header') from clinical ('payload') content.

We have also drafted conformance level definitions, but these are under review at the time of writing so are excluded from this report. The general principles are comparable to the CDA R2 constraint levels [16].

4 Discussion

4.1 Comparison of epSOS Patient Summary with Generic Patient Record Headings

The use cases of these two documents are different, so it is not surprising that there are variances in data element content and interpretation. However, some of the differences are notable and suggest that modification or clarification is needed in one or other data set. All the data items in the epSOS "Patient Data" section were readily mapped, apart from "Insurance number" which is not currently applicable in the UK health system. In total, 33/42 data items in the Patient Summary were mapped to the RCP headings and nine items were judged out of scope. Apart from document author, none of the items in the Summary Data (actually metadata) part of the epSOS data set were mapped as the RCP scope excludes metadata.

We found one example of data present in the epSOS Patient Summary not found in the RCP headings:"Vaccinations" – this is a recognized gap in the existing headings guidance.

For some other items it is unclear whether they are the same in the two data sets:

- "Autonomy/Invalidity" in epSOS might be part of "Special Requirements" or "Social Context" in the RCP headings.
- "Expected date of delivery" in epSOS might be part of "Relevant past medical, surgical and mental health history" in the RCP headings.

The structure of data in the Medication Summary part of the epSOS "Patient Clinical Data" section is very different to "Medications and medical devices" in the RCP headings, but we decided that as sections they could be treated as synonymous for the purposes of this project.

4.2 Mind-Mapping as a Design Tool

Mind maps have been a simple and helpful way to visualize the abstract information model and expose disagreements about which headings are purely for human

navigation and which, if any, have intrinsic meaning. This is valuable both for non-technical designers to grasp definitions and conceptual relationships between elements of the model, and for designers from diverse standards backgrounds to agree a common understanding.

5 Conformance Testing

The timescale of the project has not permitted actual conformance testing. We have determined the process that would be necessary to produce testable specifications for certain implementation artefacts (CDA templates and FHIR profiles) that can be traceably derived from an abstract information model. Standard CDA conformance testing methods such as Schematron [17] could be applied to the derived artefacts.

The project has made the working assumption that clinical headings and subheadings are fixed at a point in time (though subject to an agile maintenance cycle) and expressed in abstract information models and specific use case profiles (e.g. "Outpatient letter" is a particular use of the generic headings in the "Outpatient record") comprising a set of constrained information components. We propose that conformance assessment should not be rigid and solely mechanistic, but reviewed on a "comply or explain" basis [18] that allows for constrained adaptation by region or discipline (that still requires "core" content, however defined) and varying levels of adherence.

5.1 Implications for PRSB Processes and Resources

One of the major benefits of this project has been the increased understanding of the importance of clinical and technical partnership. Clinical meaning can be difficult to define with sufficient precision to create unambiguous computable artefacts. An example can be afforded by the long history of debates on the definition of "diagnosis" as differentiated from "symptom" or "problem". The dialogue can be not dissimilar to that had by a group of US and UK citizens when the two natural English-speaking populations have a subtly different understanding of a word that is common to both dialects. Without the dialogue, misinterpretation by one of the other is very real risk. This clinical/technical discussion is critical to ensure the realisation of the shared objective of creating an electronic record that meets the requirements of patients and clinicians.

The first generation of implementations in EHRs and integration services will face numerous questions and issues to resolve. We believe that implementers will not be satisfied, and may lose interest, if resolution only progresses in the glacial timescales of traditional standards-development organizations. We argue that PRSB needs an agile standards development process with EHR vendor and integrator collaboration, and a technical/clinical partnership that maintains a continuing dialogue with the professions and patients, to ensure implementability and widespread adoption. This will require significant clinical and technical resources.

5.2 Adoption and Wider Applicability

The focus of this project has been implementation of the professional guidance in EHRs and communications. This begs the question of human adoption of the guidance and its fundamental usability regardless of how it is technically represented or transmitted. Work to date has attempted to address this by distinguishing "core" headings from the larger superset, however the practicality of this has yet to be demonstrated in real world implementation.

If a conformance scheme seems viable following industry consultation, our aim is to help to lay the groundwork for a collaborative European partnership (that takes a global perspective) between EuroRec (dealing with functional and non-functional requirements), HL7 Europe (dealing with CDA templates, FHIR profiles and other artefacts), IHE Europe (dealing with profiles and metadata definitions), the openEHR Foundation (dealing with archetypes)), the PRSB (providing patient and care professional perspective), and other relevant participants.

Our aspiration is to converge with the EU eHealth Network strategy and the Semantic HealthNet recommendations. Through other modelling activities, in the domain of heart failure, that project has already begun to highlight the challenges of developing a mutual understanding between clinicians and health informatics standards developers, for representing clinical information to a suitable granularity and precision that meets both sets of needs. The work reported here will be adding further evidence of these challenges and of ways in which they may be tackled.

We recommend that as this work progresses it should consider whether a broader contextual model of care concepts such as ISO 13940 (ContSys) could help to unify definitions and clarify viewpoint discrepancies.

5.3 Evaluation and Further Work

We have achieved our first objective, to determine a methodology to produce implementation-agnostic conformance criteria from the PRSB documentation (see 3.7 above). The second objective, to select artefacts to produce for each technical standard, is also complete (see 3.3 and 3.4). We have not yet fully addressed the question of specific conformance tests to use for each technical artefact and therefore what conformance claims could be reliably asserted. We also need to finalize our analysis of FHIR and CDA artefact creation and the definition of conformance levels.

6 Conclusions

Clinical leadership in the design of professional information standards is highly desirable to ensure that EHRs and communications are safe, effective and efficient. The partnership between clinicians and implementers from varying standards backgrounds in this project has demonstrated that the goal of traceably conformant systems and communications is in principle achievable, but non-trivial. Realization of this vision will require substantial investment, a pragmatic culture and a sufficient resource base of skilled clinicians and informatics specialists that can translate between disparate worldviews.

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HL7apy: a Python library to parse, create and handle HL7 v2.x messages

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Abstract

HL7 version 2 is the most popular messaging standard for clinical systems interoperability. Most of the tools for messaging management are Java or .NET based, while Python programming language lacks of comparable solutions. This paper describes HL7apy, an open-source HL7 v2 compliant messaging library, written in Python. The library offers means to create, parse, navigate and validate messages. As an example application, we present a full implementation of the IHE Patient Demographics Query ITI-21 transaction. The resulting module has been integrated in GNU Health, a popular open-source Hospital Information System.

Keywords

HL7, Python, API, Interoperability

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1 Introduction

HL7 (Health Level 7) is a well-known and widely used standard for the exchange, integration, sharing and retrieval of electronic health information. It supports clinical practice and the management, delivery and evaluation of health services. "Health Level Seven International" [1], founded in 1987, is the main organization responsible for HL7 development and maintenance. It defines several standards, grouped into reference categories.

In this paper we describe HL7apy, a new Python package to manage HL7 v2.x messages. It uses Python natural terseness to express and operate HL7 messages in a concise manner. We expect it to be useful for fast protyping of HL7-compliant software and potentially for the development of full applications. As an example, Listing 1 contrasts the code required to create the part of a message using HL7apy to the code required to perform the same task with Java HAPI [2], currently the most popular library for HL7 messaging.

```
# Python version

adt_a01 = Message("ADT_A01")
adt_a01.msh.sending_application.hd_1 = \
  "Sending App"
adt_a01.msh.sequence_number = "123"

adt_a01.pid.patient_name = "Doe^John"
adt_a01.pid.patient_identifier_list = "123456"

// Java version

ADT_A01 adt = new ADT_A01();
adt.initQuickstart("ADT", "A01", "P");

MSH mshSegment = adt.getMSH();
mshSegment.getSendingApplication().
 getNamespaceID().setValue("Sending App");
mshSegment.getSequenceNumber().setValue("123");

PID pid = adt.getPID();
pid.getPatientName(0).getFamilyName().
  getSurname().setValue("Doe");
pid.getPatientName(0).getGivenName().
  setValue("John");
pid.getPatientIdentifierList(0).getID().
  setValue("123456");
```

Listing 1: A comparison of the code needed to create the same message from scratch using HAPI and HL7apy. The message example and the Java code are taken from HAPI official examples.

1.1 HL7 Standards

The HL7 standard includes different versions that were developed in different periods of time and with different purposes:

- **HL7 version 2 (HL7 v2)** [3]: it is the older messaging standard; it allows the exchange of clinical data between systems and it is designed to support both central and distributed patient care systems;
- **HL7 version 3 (HL7 v3)** [4]: created with a completely different philosophy from v2; it proposes a new approach for data exchange, based on a Reference Information Model (RIM) and XML.
- **HL7 FHIR (Fast Healthcare Interoperability Resources)** [5]: it has been developed with the aim to simplify and accelerate HL7 adoption by being easily consumable but robust, and by using open Internet standards where possible [6].

HL7 v2 is used worldwide to solve interoperability problems, although the "raw structure" of its messages is less human readable and machine computable than v3, which is XML-based; furthermore, v2 is still the reference version of the IHE (Integrating Healthcare Enterprise) consortium [7]. In part this is due to the fact that HL7 v3 (and the RIM in particular), in spite of ten years of development, is still a work-in-progress undergoing intense discussions on its design [8]. FHIR has been developed to overcome these issues but it is a young standard and it will need more years of development to be an effective tool.

HL7apy focuses on HL7 v2 messaging standard.

1.2 HL7 Messaging Tools

The increasing diffusion of the HL7 v2 standard has spurred the development of several software libraries aimed at simplifying raw messages management. The most popular open-source libraries available are the following.

- **HAPI**: a Java-based HL7 v2 library providing classes for messages parsing, creation and validation. Both parser and validator strictly follow the XML message structure provided by the standard;
- **NHapi** [9]: a porting of HAPI for the Microsoft .NET framework;
- **python-hl7** [10]: a minimalistic Python HL7 v2 messages parsing library that implements basic functionality without validation. It includes the implementation of a simple MLLP[1] (Minimal Lower Layer Protocol) client for sending messages.

[1]MLLP protocol is the minimalistic OSI-session layer framing protocol used to send HL7 messages

In addition to software libraries, HL7 messaging functionality is also provided by data integration software, which are integration gateways that support multiple data formats and connectors. Two of the main tools are the following.

- **Mirth Connect** [11]: an open-source healthcare integration engine specifically designed for HL7 message integration, written in Java. It provides all tools to build integration channels able to connect a wide range of data sources. It also provides tools for HL7 message parsing and validation;
- **Interfaceware/Iguana** [12]: a commercial software for the exchange, transformation and parsing of HL7 messages, providing a mean to map message fields, transform them and validate messages.

1.3 HL7apy

The diffusion of the Python programming language has been increasing over the years [13], particularly in the scientific domain [14]. The reasons for this popularity may be attributable to the language being relatively easy to learn and offering high programmer productivity. A recent study [15] indicates that with scripting language, designing and writing the program takes no more than half as much time as writing it in C, C++ or Java and the resulting program is only half as long, making it a good choice for fast prototyping. Despite Python's popularity, it is missing a feature-complete library for HL7 messaging. The aforementioned python-hl7 only implements basic features such as message parsing and ER7-encoding, while lacking important functionality such as message validation, custom separators support and structured parsing according to HL7 messaging schemas or custom message profiles.

Our motivation for the development of HL7apy comes from all these factors. The library main functions are messages creation, parsing and validation; it supports HL7 key features like custom encoding characters, message profiles and Z-elements.

The rest of the paper is structured as follows. Section 2 describes the library architecture and its main functionality; Section 3 summarizes the current features and briefly describes a real use case HL7 module implemented with HL7apy; Section 4 presents conclusions and planned future developments.

2 Methods

This section introduces all the major components of HL7apy.

Figure 1 shows the overall architecture of the library: it is composed by two utilities scripts, that generate python modules for every HL7 v2 minor version (XSD Parser) and serialized files for message profiles usage (Message Profiles Parser), and by the inner components that create

and manage messages (Core classes), parse ER7-encoded messages (Message Parser) and validate messages (Validator).

First we will introduce the utilities that are provided with the library then, we will explain its inner components.

2.1 Utilities

HL7apy includes utility scripts that are used to create concise descriptions of HL7 messages structures, needed by the rest of the library. These utilities are:

- XSD Parser
- Message Profiles Parser.

2.1.1 XSD Parser

The XSD Parser processes all the HL7 XML schema files and generates a set of Python modules, one for each HL7 v2 minor version.

The schemas are XML documents provided by HL7 International organization itself. They contain the lists of all elements (messages, segments, fields and datatypes) and, for each one of those, they describe their children with cardinality and datatype (the latter only in case of fields and complex datatypes). These files can be used for HL7 validation by third-party libraries and applications. As an example, Listing 2 shows a snippet of the XML structure of the ADT_A01 message defined in the ADT_A01.xsd file and its representation in HL7apy.

```
<!-- XSD Schema definitions -->

...
<xsd:complexType name="ADT_A01.CONTENT">
  <xsd:sequence>
    <xsd:element ref="MSH" minOccurs="1"
      maxOccurs="1"/>
    <xsd:element ref="SFT" minOccurs="0"
      maxOccurs="unbounded"/>
    <xsd:element ref="EVN" minOccurs="1"
      maxOccurs="1"/>
    <xsd:element ref="PID" minOccurs="1"
      maxOccurs="1"/>
    ...
    <xsd:element ref="ADT_A01.PROCEDURE"
      minOccurs="0" maxOccurs="unbounded"/>
    <xsd:element ref="ADT_A01.INSURANCE"
      minOccurs="0" maxOccurs="unbounded"/>
    ...
  </xsd:sequence>
</xsd:complexType>
...
<xsd:complexType name="ADT_A01.PROCEDURE.CONTENT
    ">
  <xsd:sequence>
    <xsd:element ref="PR1" minOccurs="1"
      maxOccurs="1"/>
    <xsd:element ref="ROL" minOccurs="0"
      maxOccurs="unbounded"/>
  </xsd:sequence>
</xsd:complexType>
<xsd:complexType name="ADT_A01.INSURANCE.CONTENT
    ">
  <xsd:sequence>
    <xsd:element ref="IN1" minOccurs="1"
      maxOccurs="1"/>
    <xsd:element ref="IN2" minOccurs="0"
      maxOccurs="1"/>
    <xsd:element ref="IN3" minOccurs="0"
      maxOccurs="unbounded"/>
    <xsd:element ref="ROL" minOccurs="0"
      maxOccurs="unbounded"/>
  </xsd:sequence>
</xsd:complexType>

# HL7apy representation

{"ADT_A01": ("sequence",
  (("MSH", (1, 1)),
   ("SFT", (0, -1)),
   ("EVN", (1, 1)),
   ("PID", (1, 1)),
   ("ADT_A01_PROCEDURE", (0, -1)),
   ("ADT_A01_INSURANCE", (0, -1)))),
 "ADT_A01_INSURANCE": ("sequence",
  (("IN1", (1, 1)),
   ("IN2", (0, 1)),
   ("IN3", (0, -1)),
   ("ROL", (0, -1)))),
 "ADT_A01_PROCEDURE": ("sequence",
  (("PR1", (1, 1)),
   ("ROL", (0, -1)))),
}
```

Listing 2: A snippet of XSD schema for ADT_A01 message and its HL7apy representation.

The code generated by the XSD parser is used by the core classes and is the foundation of the entire library.

2.1.2 Message Profiles Parser

This utility compiles an XML message profile in a more *pythonic* format. This strategy is similar to what is done with the XSD Parser, though in this case the output are not Python modules but *cPickled*[2] serialized files that can be dynamically loaded at runtime. The Message Profiles Parser should be run every time an interoperability scenario requires a particular profile.

The concept of Message Profile was introduced for the first time in HL7 v2.5, which stated that it is "an unambiguous specification of one or more standard HL7 messages that have been analyzed for a particular use case" [16].

HL7apy can create message profiles by using the static definition [16] of the message profile in XML format. The parser takes as input a static definition in XML and produces a file containing the structure for every message it defines. The outcomes are similar to the ones produced by the XSD Parser with one main difference: the structures of the children are all included within the parent's and they are not expressed using a reference. The reason for this is that every single element in the static definition can potentially specify a different cardinality, length

[2] cPickle is a Python module that supports serialization and deserialization of Python objects

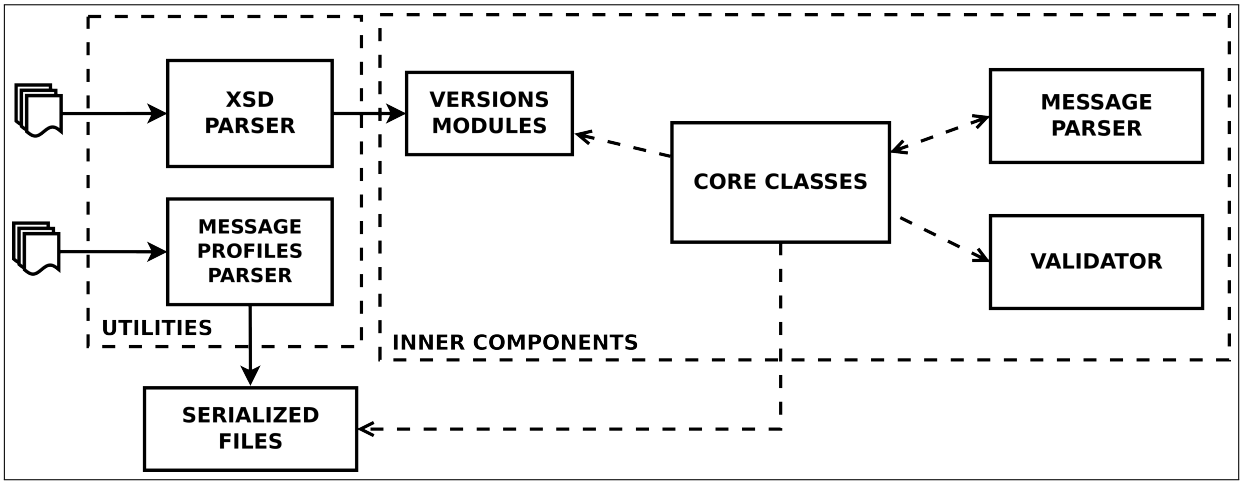

Figure 1: HL7apy overall architecture

or datatype than the same element of another message in the profile. For instance, consider the two snippets in Listing 3.

```
...
<Segment Name="PID" Usage="R" Min="1" Max="1">
  <Field Name="Patient ID" Usage="X" Min="0"
    Max="*" Datatype="CX" Length="1904">
  ...

...
<Segment Name="PID" Usage="R" Min="1" Max="1">
  <Field Name="Patient ID" Usage="X" Min="0"
    Max="*" Datatype="CX" Length="20">
  ...
```

Listing 3: A snippet of a message profile with two definitions of the Patiend ID field. The definitions specify different length for the same field.

The two *Patient ID* field versions have different lengths, so it is impossible to use one PID definition for all the messages of the profile.

Listing 4 shows an example of the IHE PDQ message profile and its HL7apy representation.

```
<!-- Message Profiles XML definition -->

...
<HL7v2xStaticDef MsgType="RSP" EventType="K22"
    MsgStructID="RSP_K21" EventDesc="RSP - Get
    person demographics response" Role="Sender">
  <MetaData Name="" OrgName="IHE" Version="2.4"
      Status="DRAFT" Topics="confsig-IHE-2.5-
      static-RSP-K22-null-RSP_K22-2.3-DRAFT-
      Sender"/>
  <Segment Name="MSH" LongName="Message Header"
      Usage="R" Min="1" Max="1">
    <Field Name="Field Separator" Usage="R" Min
        ="1" Max="1" Datatype="ST" Length="1"
        ItemNo="00001">
      <Reference>2.15.9.1</Reference>
    </Field>
    <Field Name="Encoding Characters" Usage="R"
        Min="1" Max="1" Datatype="ST" Length="4"
        ItemNo="00002">
      <Reference>2.15.9.2</Reference>
    </Field>
    <Field Name="Sending Application" Usage="R"
        Min="1" Max="1" Datatype="HD" Length
        ="180" Table="0361" ItemNo="00003">
      <Reference>2.15.9.3</Reference>
      <Component Table="0300" Name="namespace ID
          " Usage="R" Datatype="IS" Length="20"/>
      <Component Name="universal ID" Usage="C"
          Datatype="ST" Length="199"/>
      <Component Name="universal ID type" Usage
          ="C" Datatype="ID" Length="6" Table
          ="0301" />
    </Field>
...

# HL7apy representation

{"RSP_K21": ("mp",
  "sequence",
  "RSP_K21",
  (("mp",
    "sequence",
    "MSH",
    (("mp", "leaf", "MSH_1", (), (1, 1),
       "Field", "ST", 1, None),
     ("mp", "leaf", "MSH_2", (), (1, 1),
       "Field", "ST", 4, None),
     ("mp",
      "sequence",
      "MSH_3",
      (("mp", "leaf", "HD_1", (), (1, 1),
        "Component", "IS", 20, "HL70300"),
       ("mp", "leaf", "HD_2", (), (0, 1),
        "Component", "ST", 199, None),
       ("mp", "leaf", "HD_3", (), (0, 1),
        "Component", "ID", 6, "HL70301")),
      (1, 1),
      "Field",
      "HD",
      180,
      "HL70361"),

   ...
```

Listing 4: A snippet of the IHE PDQ message profile and its representation in HL7apy.

2.2 Inner Components

In this section we detail the inner components of the library, which are:

- Core Classes
- Validator
- Message Parser

2.2.1 Core Classes

The core classes offer an API to create HL7-compliant messages, navigate their structure and manipulate HL7 elements, thanks to a tree-like representation of the element relations (e.g., a Message can contain only instances of Segments or Groups, a Group can contain Segment instances only, etc.). These classes allow the developers to express operations in a very compact form, as already shown in Listing 1.

The library defines the following classes to represent all the HL7 elements.

- Message
- Group
- Segment
- Field
- Component
- SubComponent
- Base datatype classes (e.g., ST, DT, FT, etc.)

Figure 2 illustrates the main classes and their relationships. We can notice two other classes, apart from ones listed above: the `ElementFinder`, used to search element's structure in the minor version's modules, and the `ElementProxy`, used during the elements' navigation.

The next sections illustrate the main operations that can be performed using the core classes.

Elements Instantiation. The developer can instantiate HL7 elements simply by specifying their structure and/or version (Listing 5).

```
from hl7apy.core import Message, Segment,
    SubComponent

adt_a01 = Message("ADT_A01", version="2.5")
ins = adt_a01.add_group("ADT_A01_INSURANCE")

pid = Segment("PID")

s = SubComponent(datatype="FT")
s.value = FT("some information")
```

Listing 5: Examples of element instantiation.

Under the hood, the helper class `ElementFinder` is used by the core classes to retrieve the element definitions described in 2.1.1, thus enabling validation and traversal of children.

As soon as the Message is instantiated, the MSH segment is automatically created and some of its required fields are populated with default values (e.g., default separators for MSH-1 and MSH-2 fields).

Alternatively, one can specify a message profile as the reference of the `Message` at instantiation (Listing 6).

```
mp = hl7apy.load_message_profile("./pdq")
m = Message("RSP_K21", reference=mp["RSP_K21"])
```

Listing 6: Instantiation specifying a message profile.

It is also possible to create custom elements (Z-elements), as long as they follow the correct naming convention.

```
segment = Segment("ZIN")
field = Field("ZIN_1")
```

Listing 7: Instantiation of Z-elements.

To be more flexible, the library allows the creation of HL7 elements without specifying their structure. In this case, the message cannot be considered validated according to the HL7 schemas. The validation process is described in detail in Section 2.2.2. The Listing 8 shows the instantiation of a custom field that is added to a PID segment.

```
from hl7apy.core import Segment, Field

segment = Segment("PID")
unkn_field = Field()
segment.add(unkn_field)
```

Listing 8: Instantiation of custom elements.

Element Navigation. Since the library exposes a DOM-like API, the developer can easily access the children of a given element by simply using their name, description or position.

```
from hl7apy.core import Message, Segment, Field

s = Segment("PID")
s.value = "PID|||654321^^^123456||" \
  "Family^Name^^^^^"

# by name, it refers to a Field instance
print s.pid_5

# by description, it refers to a Field instance
print s.patient_name

# by position, it refers to a Component instance
print s.pid_5.pid_5_1
```

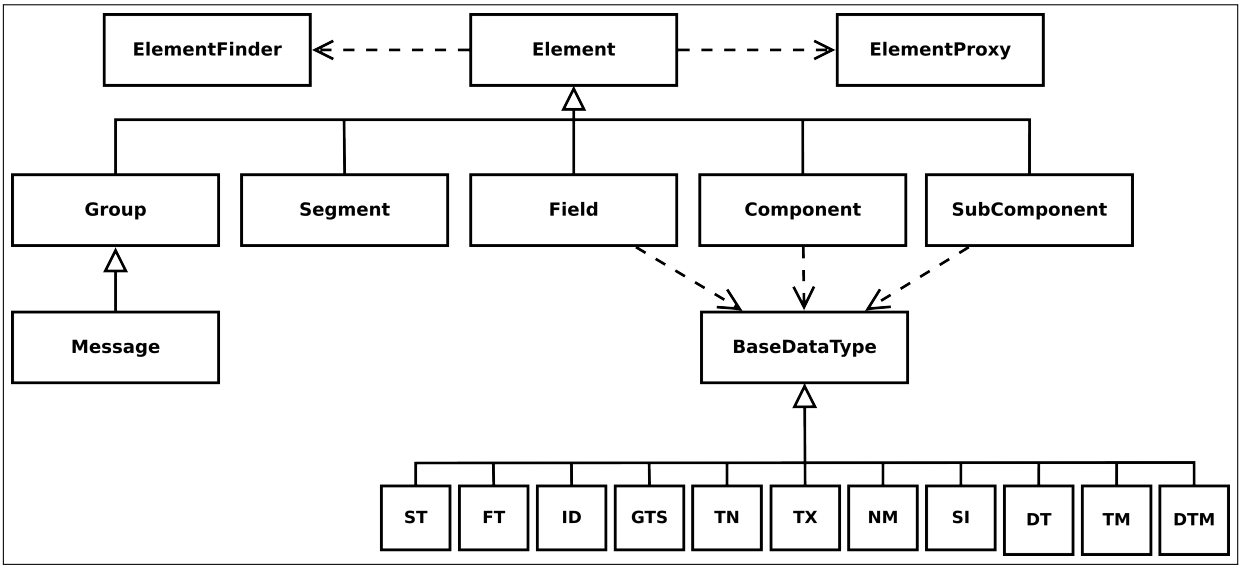

Figure 2: The architecture of HL7apy core. The main classes are shown

```
message = Message("RSP_K21")

# by description, recursively on the message
# children
print message.msh.date_time_of_message.time

# iterates over PID-5 children of the PID
# segment
for name in s.pid_5:
  print name

# iterates over all the fields of the PID
# segment
for child in s.children:
  print child

# its datatype is CX
org_5 = Field("org_5")
org_5.value = "^^^^^^^^^AG&&DEP"

# it returns the tenth component of the field,
# it is the same as org_5.cx_10
print org_5.org_5_10

# it returns the third subcomponent of the tenth
# component of the field, it is the same as
# org_5.cx_10.cwe_3
print org_5.org_5_10_3
```

Listing 9: Elements navigation. An element can be accessed by name, description or position.

When accessing a child element list without specifying an index, the library, by means of the `ElementProxy` class, automatically returns the first child. Other child elements can be accessed by specifying the appropriate index.

```
# it is the same as s.pid_13[0]
print s.pid_3.to_er7()

# if it exists, it returns the second
# instance of pid_13
print s.pid_3[1].to_er7()
```

Listing 10: Access to elements by index. If an index is not specified the library returns the first child. Other child elements can be retrieved by using the appropriate index.

Elements Population. For convenience, it is possible to populate an element or its children by:

- assigning the ER7 representation,
- calling the dedicated parsing functions,
- copying another element instance,
- assigning the base datatype value (e.g., a string, a number, etc.),
- assigning a base datatype instance.

```
m = Message("ADT_A01", version="2.5")

# base datatype value (string)
m.msh.msh_3 = "GHH_ADT"

# it will create to an instance of
# DTM base datatype
m.msh.msh_7 = "20080115153000"

# ER7 representation, MSH_9 is a complex
# datatype of 3 components
m.msh.msh_9 = "ADT^A01^ADT_A01"

# copy from another element
m.evn.evn_2 = m.msh.msh_7

# parser function
m.msh.msh_9 = hl7apy.parser.\
  parse_field("ADT^A01^ADT_A01", name="MSH_9")

s = SubComponent(datatype="IS")
```



```
# base datatype instance (IS)
s.value = IS("AAA")
```

Listing 11: Examples of elements population.

Element Encoding. The developer can generate the ER7-encoded string of a core class instance using both default or custom encoding characters (Listing 12). In the case of Message class it is also possible to generate the MLLP-encoded string.

```
from hl7apy.core import Message
from hl7apy.parser import parse_field

custom_chars = {
  "FIELD": "!",
  "COMPONENT": "@",
  "SUBCOMPONENT": "%",
  "REPETITION": "~",
  "ESCAPE": "\$"
}

msh_9 = "ADT^A01^ADT_A01"
field = parse_field(msh_9)

# it will use default encoding chars
print field.to_er7()

# it will use custom encoding chars
# defined above
print field.to_er7(encoding_chars=custom_chars)

m = Message('RSP_K21')
print repr(m.to_mllp())
```

Listing 12: Elements encoding in ER7/MLLP form. The developer can also specify custom encoding characters.

2.2.2 Validator

One of the most important features implemented in HL7apy is the validation of messages, since it ensures their compliance with the standard for the specific message type and HL7 minor version.

In an ideal world every message would adhere to the HL7 specification; however, real-life applications encounter messages that do not conform. Common issues are for example fields with more components than expected or messages with prohibited segments. For this reason HL7apy implements two levels of validation: `STRICT` and `TOLERANT`.

When a message is created using `STRICT` validation, the library verifies the exact adherence of the message to its message type. In particular, it checks that:

- all the expected elements are present;
- there are no unexpected or unknown elements;
- the cardinality of all elements is correct;
- the datatypes of the fields, components and subcomponents are correct.

On the other hand, the `TOLERANT` validation level is more permissive and allows some operations like:

- instantiating unknown elements;
- changing the default datatype of a field, component or subcomponent;
- ignoring the cardinality of the elements (e.g., inserting more identical elements than allowed or missing a required element).

Naturally, some operations are not allowed in `TOLERANT` mode either. For instance, it is not possible to insert a PID-1 field into an SPM segment.

Validation is performed in two phases. The first one checks that message creation and population do not violate the rules of the chosen mode. As soon as an error occurs, an exception is raised (e.g., when in `STRICT` mode it is inserted an unexpected segment to a message or when it is created an unknown element). The second phase must be forced by the developer using the `Validator` class.

The `Validator` class performs a `STRICT` validation of an `Element`. Its `validate()` method accepts an `Element` object and validates it against its HL7 structure or against a message profile, if specified in input. In particular it verifies element's cardinality, datatypes correctness and emits warnings, which are minor errors that don't invalidate the message (i.e., HL7apy doesn't raise an exception) but should be fixed to guarantee its complete compliance. Examples of errors in this category are:

- fields that exceed their maximum value;
- fields with a value not in their HL7 table.

Warnings and errors can be gathered together in a report file by explicitly requesting it at validation time. This feature can be especially useful to diagnose and resolve errors in the interoperability testing phase. For instance, the functionality can be used to verify the conformance of the system to an IHE profile.

It is worth noting that the `Validator` checks for the presence of issues that cannot be detected during the first phase, in particular, the absence of required elements. Thus it is wrong to consider a message completely valid without using the `Validator`.

2.2.3 Message Parser

The Message Parser is the module that provides all the functionality needed to parse an HL7 message encoded in the ER7 format. The parsing is started by the `parse_message` function which takes an ER7 string as input. The string is interpreted according to the encoding characters specified in the MSH-1 and MSH-2 fields. The parsing of sub-elements is delegated to purpose-specific functions (e.g., `parse_segment`, `parse_field` and so on). Every function generates an instance of the core classes and attaches it to the correct parent object, resulting in

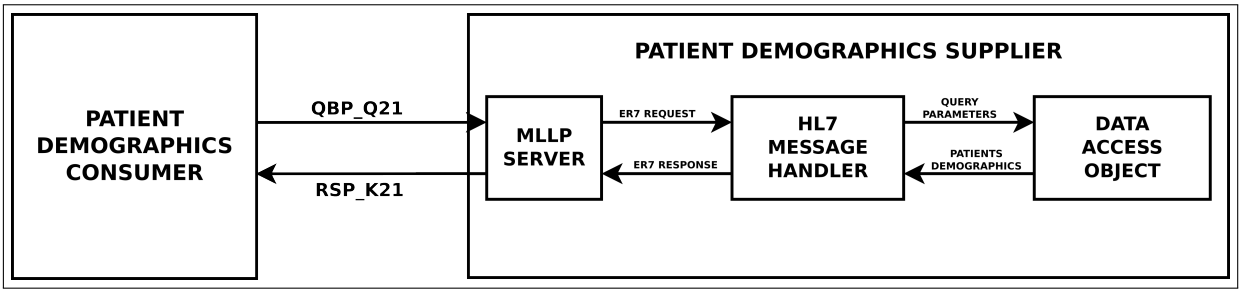

Figure 3: PDQ transaction diagram. The PDQ Supplier shows the components included in the PDQ module

.

the tree structure of the message. The reference structure of the message is obtained from the MSH-9 field.

The parser allows the caller to specify the desired validation level, the message profile to use, if necessary, and the name of the report file the `Validator` will produce in case of `STRICT` validation. It is also possible to specify a flag that makes the parser create groups and assign the segments as children of the group to which they belong, as stated in the message schema.

All the parser functions are called by the core classes in case of ER7 string assignment as shown in Listing 13.

```
m.msh.msh_9 = "ADT^A01^ADT_A01" # parse_field
m.evn = "EVN||20080115153000||AAA" \
  "|AAA|20080114003000" # parse_segment
m.evn.evn_5.xcn_1 = "AAA" # parse_component
```

Listing 13: Assigment of string as elements' value. The parser functions are called by the core classes in case of string assignment

3 Results

HL7apy supports the creation of HL7-compliant systems using the Python programming language. The library implements the following features.

- HL7 versions from 2.2 to 2.6 support
- Message Parsing
- Message Validation
- ER7 Encoding
- Custom Encoding Characters support
- Message Profile support
- Z-elements support
- Simple and Complex Datatype support
- HL7 tables support

With respect to the state of the art library (HAPI) we do not support HL7 v2.1 and XML encoding.

3.1 Testing HL7apy Message Types Coverage

In order to test HL7apy ability to parse different message types, we applied to a random sample of 1000 messages from IHE Gazelle [17]. We only used messages validated by Gazelle (marked as passed). We removed 4 messages from the set since they were using non ASCII/UTF-8 encoding characters, a feature currently not supported by HL7apy. The resulting dataset distributes messages within 12 different message types (e.g., ADT, QBP). Table 1 reports the results of message parsing using the two supported validation levels.

Table 1: HL7 messages coverage results. Abbreviations: v = valid, i = invalid, e = errors.

		tolerant			strict		
type	**tot**	**v**	**i**	**e**	**v**	**i**	**e**
QBP	74	74	0	0	31	43	0
ADT	425	420	0	5	240	183	2
SIU	4	4	0	0	4	0	0
OUL	24	24	0	0	16	8	0
ACK	47	47	0	0	28	19	0
ORU	22	22	0	0	9	13	0
ORR	16	16	0	0	3	13	0
OML	106	106	0	0	69	37	0
ORL	47	47	0	0	34	13	0
ORM	171	171	0	0	6	165	0
RSP	58	58	0	0	20	38	0
QCN	2	2	0	0	2	0	0

The errors reported on the ADT row derive from the fact that HL7apy does not currently support segment repetition outside of a group. It is interesting to note that some of these messages are rejected by `STRICT` before failing. All other messages are parsed without exception when setting the validation level to `TOLERANT`. The messages rejected by `STRICT` are correctly parsed when the parser is configured with the appropriate message profile. For instance, using the IHE ITI-21 message profile results in the acceptance of all the PDQ request messages (QBP^Q22^QBP_Q21).

3.2 Use Case Implementation

As a significant example of a real-world problem, we used HL7apy to implement the PDQ Supplier actor of the IHE ITI-21 Patient Demographics Query (PDQ) transaction [18, 19]. PDQ allows clinical systems to query a central patient demographics server with the purpose of retrieving patients' demographic information and it is one of the most used IHE transactions. As shown in Figure 3, the transaction involves two actors, PDQ Consumer and Supplier, with two exchanged messages: QPB_Q21 for requests and RSP_K21 for responses.

The PDQ Supplier receives query messages from one or more consumers and returns demographic information for all patients matching the query criteria. The module includes a network MLLP service for sending and receiving HL7 messages. All the PDQ Supplier components are shown in Figure 3. The module has been integrated in GNU Health [20], a worldwide used open-source Hospital Information System.

The module is structured as follows:

- the MLLP Server receives an HL7 PDQ request message (QBP_Q21) from a PDQ Consumer and redirects it to the Message Handler (MH);
- the MH parses and validates the message using the specific profile, extracts the query parameters and checks their compliance to the PDQ specifications. Query parameters are provided in one or more QPD_3 field repetitions. Each repetition has two components, the first indicating the parameter (e.g., name, surname, date of birth, etc) as coded by IHE, and the second specifying the value. For example, if the consumer wants to search all patients with name 'John' and surname 'Smith' the QPD_3 should be filled as '@PID.5.2^John~@PID.5.1.1^Smith';
- once the parameters are extracted, they are sent to the Data Access Object (DAO) which queries the demographic database to get the corresponding patient information and returns them to the MH;
- the MH creates the correct HL7 response message (RSP_K21) and sends it to the MLLP Server that forwards it to the PDQ Consumer.

HL7apy provides a standard MLLP server implementation through the MLLPServer class that needs to be specialized by providing the appropriate message handlers. Listing 14 shows the usage of the class in the PDQ module. In this case only one handler is necessary (PDQHandler).

```
from hl7apy.mllp import MLLPServer
from .pdq_supplier import PDQHandler

s = MLLPServer(host='localhost', port=6789,
               handlers={'QBP_Q21': PDQHandler})
s.serve_forever()
```

Listing 14: Usage of the MLLPServer class provided by HL7apy

When the server receives a QBP_Q21 message, forwards it to the PDQHandler class, whose implementation is shown in Listing 15. This class is the core of the module: it parses the request message, extracts the query parameters and gets patients information using the DAO. Finally it builds the response message and sends it back to the consumer.

```
import datetime, uuid

from hl7apy.v2_5 import DTM
from hl7apy.utils import check_date
from hl7apy.mllp import
    AbstractTransactionHandler
from hl7apy.parser import parse_message
from hl7apy.core import Message

from .dao import DAO
from .profiles import PDQ_REQ_MP, PDQ_RES_MP
from .parameters import PDQ_FIELD_NAMES

class PDQHandler(AbstractTransactionHandler):

  REQ_MP, RES_MP = PDQ_REQ_MP, PDQ_RES_MP
  FN = PDQ_FIELD_NAMES

  def __init__(self, message):
    self.dao = DAO()
    msg = parse_message(message,
                        message_profile=self.
                            REQ_MP)
    super(PDQHandler, self).__init__(msg)

  def _create_res(self, ack_code,
                  query_ack_code, patients):
    res = Message('RSP_K21',
                  reference=self.RES_MP)
    r, q = res.msh, self.msg.msh
    r.msh_5, r.msh_6 = q.msh_3, q.msh_4
    res.msh.msh_5 = self.msg.msh.msh_3
    res.msh.msh_6 = self.msg.msh.msh_4
    r.msh_7.ts_1 = DTM(datetime.datetime.now())
    r.msh_9 = 'RSP^K22^RSP_K21'
    r.msh_10 = uuid.uuid4().hex

    r, q = res.msa, self.msg.msh
    r.msa_1 = ack_code
    r.msa_2 = q.msh_10.msh_10_1

    r, q = res.qak, self.msg.qpd
    r.qak_1 = q.qpd_2
    r.qak_2 = ('OK'
               if len(patients) > 0 else 'NF')
    r.qak_4 = str(len(patients))

    res.qpd = self.msg.qpd

    g = res.add_group('rsp_k21_query_response')
    for i, p in enumerate(patients):
      g.add_segment('PID')
      g.pid[i].pid_1 = str(i)
      g.pid[i].pid_5 = "%s^%s" % (p[0], p[1])
    return res

  def _create_err(self, code, desc):
    res = self._create_res('AR', 'AR', [])
    res.ERR.ERR_1, res.ERR.ERR_2 = code, desc
    return res

  def reply(self):
```

```
params = dict(
   (self.FN[q.qip_1.value], q.qip_2.value)
   for q in self.msg.qpd.qpd_3
   if q.qip_1.value in self.FN)
if ('' in params.values() or
   (params.has_key('DOB') and
    not check_date(params.get('DOB')))):
  res = self._create_err(
       "100", "Invalid params")
else:
  p = self.dao.get_data(params)
  if len(p) > 0:
    res = self._create_res('AA', 'OK', p)
  else:
    res = self._create_res('AA', 'NF', p)
return res.to_mllp()
```

Listing 15: PDQHandler implementation

4 Conclusions and Future Work

In this paper we presented HL7apy, an HL7 v2 Python library whose main goal is to provide a pythonic way for handling HL7 messages.

The library is available at `https://github.com/crs4/hl7apy/tree/ihic2015` and it is released under the MIT License (MIT). Currently, it supports Python version 2.7.

In the near future we plan to add support for XML messages encoding, HL7 versions 2.7 and 2.8 and Python 3.

The website with the documentation can be reached at `http://hl7apy.org`.

5 Acknowldgments

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Model-based Analysis of HL7 CDA R2 Conformance and Requirements Coverage

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Abstract

Numerous national and regional projects around the world [23] are developing specifications for sharing electronic medical records. Many of them are basing their specifications on the HL7 CDA standard, extending it in order to meet the local requirements or medical practice. Many of these projects are illustrating the specifications with sample CDA documents and provide in addition tools [13] [14] [24] to check the conformance of CDA documents with their extensions. In this paper we provide the outcome of an evaluation of both the samples and the tools provided by these projects.

We looked at the conformance of the provided samples with the basic HL7 CDA requirements as specified within the "Clinical Document Architecture, R2 Normative Edition", and we looked at the capability of the tools provided to check those requirements. The outcome of the study shows that a large portion of the requirements specified by the standard are neither tested nor respected by the provided validation tools and samples.

Keywords

CDA, conformance, coverage, requirements, model-based, validation

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1 Introduction

Since the publication of the HL7 CDA R2 specifications [1], conformance checking of CDA documents has been a source of inspiration for multiple companies expert on healthcare IT standards. Since the CDA schema does not cover all the basic CDA requirements, several methodologies were developed and experimented in order to validate the content and the structure of the CDA documents [5] [14] [15]. The purpose of this paper is double. In a first part we have revisited the content of the CDA specifications in order to clearly identify and extract the requirements that are specified in the CDA standard but not covered by the CDA schema. Then, we evaluated the conformance of CDA documents published by various projects in Europe, with the extracted basic CDA requirements. And finally we checked the coverage of these basic requirements by different CDA validation tools.

2 State Of The Art

2.1 Introduction

The activity diagram described in Figure 1 summarizes the process used by most of the CDA validation tools.

The validation steps are as follows:

- The first step of the activity diagram checks that the CDA document is a well-formed XML Document [20]. This step checks that the syntax of the document is correct: the root element is present, all elements have a closing tag, elements are properly nested, attributes values are correctly quoted, etc.
- The second step is used to verify that the document is valid against the CDA schema [21].
- The third and final step is commonly used to verify the business rules related to the CDA standard and which are not expressed in the CDA schema.

Numerous tools are used to perform the last step of this validation process; this section describes the most used

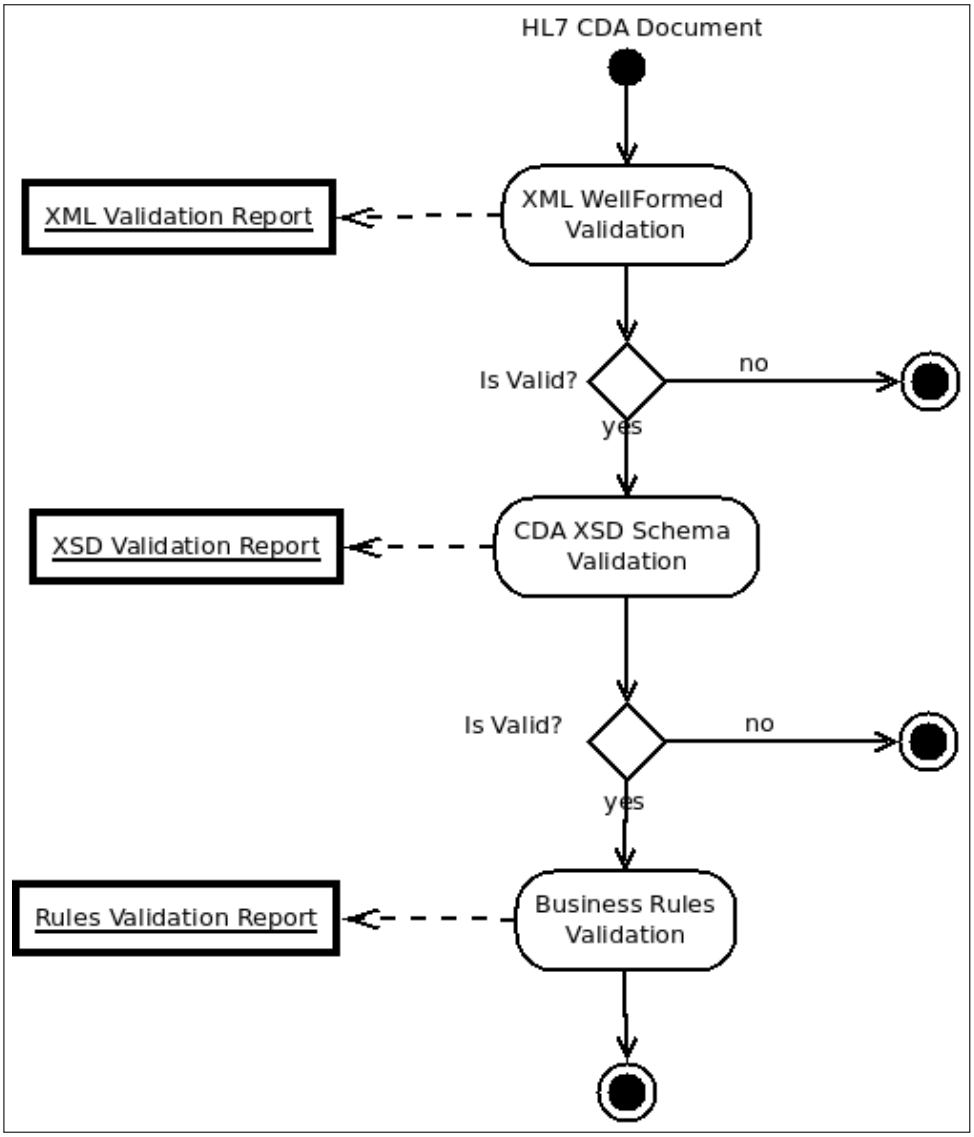

Figure 1: Validation process of CDA documents.

ones. Also, many studies were done to describe basic requirements in CDA standard; this section provides these analyses.

2.2 HL7 CDA R2 Validation Tools

This paragraph describes the most commonly used CDA validation tools.

Trifolia Workbench: Trifolia Workbench is developed by Lantana Consulting Group. It is a web-based application for standard development work, and it supports the generation of schematrons in order to test the conformance of CDA documents, based on requirements written within the tool [13].

MDHT: Model-Driven Health Tools (MDHT) is an open source tool developed and maintained by Open Health Tools[14]; the purpose of which is to validate CDA documents. It provides also a validation of basic CDA documents.

Eclipse Instance Editor (EIE): Eclipse Instance Editor is a tool used to create and edit CDA documents, and also to validate according basic CDA requirements. As described in [19], this tool is based on MIF and R-MIM description.

Art-Decor: Art-Decor is a tool developed by the ART-DECOR expert group [15]. It is a web-based application to record HL7 templates and reusable artifacts as value sets and templates. This tool allows the definition and generation of specification documentations. It also allows the generation of schematrons for checking the conformance to these specifications. This tool is largely used in Europe (ELGA from Austria, HL7 Deutschland, HL7 Norway, etc).

NIST validation tool: The NIST validation tool is released by the National Institute of Standards and Technology (NIST), an agency of the U.S. Department of Commerce, USA. This tool is a web-based application allowing the validation of CDA documents based on schematrons

developed by the NIST for the validation HL7 Continuity of Care Document (CCD) and IHE Patient Care coordination domain. The tool offers a web service to validate CDA documents. It is largely used within the IHE community.

Gazelle ObjectsChecker tool: The Gazelle ObjectsChecker tool is developed and maintained by IHE-Europe and it is part of the Gazelle project [11]. The tool provides a model-based validation of CDA documents, based on UML description of CDA requirements [5], including the CDA basic validation described in this paper.

Validation Tools Properties

The Table 1 summarizes the properties of each validation tool. From this table, we can remarks that there are two kinds of tools: tools oriented to specifications generation, and tools oriented to requirements validation. The tools oriented to specifications generation are MDHT, Trifolia and Art-Decor.

2.3 National and Regional Validation Materials

Many regional and national healthcare CDA-based specifications provide material to validate the conformity of CDA documents according to the national constraints; ASIP Santé (France) provides schematrons [25], eHealth Swiss provides an online validation tool based on schematrons [26], ELGA (Austria) provides an online validation tool and schematron resources used within the validation, KELA (Finland) provides online validation tools based on schematrons and the EVSClient tool[24]. Also, many US implementations provide schematrons to validate the conformity of CDA documents.

Many of these validation materials claim to be able to verify the conformity of the CDA documents according to their national or regional specifications; however multiple requirements related to the CDA standard could not be verified by these tools (see the requirement coverage paragraph for more information), and so these implementation materials may validate the requirements related to their specifications, but ignore an important number of basic requirements related to the CDA standard. This problem is due to the fact that there is no formal description of all the CDA basic requirements that the validation tools could refer to.

2.4 HL7 CDA R2 Requirement Studies

Previous studies were performed in order to describe the common requirements of CDA standard, which are not verified by the CDA schema [17] [18]. An important study is the one referenced [17], a white paper written by Rene Spronk and Grahame Grieve about the common issues found in the implementations of CDA, a description of the most common recurrent errors produced by implementers. This white paper was an important reference for this one, even if the subjects of those two papers are not the same.

3 CDA Basic Requirement Specifications

3.1 Introduction

The HL7 CDA R2 standard is based on:

- four specification documents [1] [2] [3] [4]
- a list of HL7 value sets
- the hierarchical descriptor of CDA standard
- the CDA Schema

All CDA documents SHALL conform to these specifications. Most of the requirements specified in the standard are expressed in the XSD schema, but not all of them. The paragraph below summarizes the requirements that are not expressed within the schema.

The complete list of the requirements missing from the schema was extracted and compiled by our team and published in the document 'HL7 CDA R2 Basic Requirements' [12]. The latter contains the interpretation of the requirements expressed in the CDA standard, which are formally listed and uniquely identified. More than 150 requirements not expressed in the schema were extracted, and the following sections describe these requirements.

3.2 HL7 CDA R2 RIM Requirements

Multiple requirements coming from the RIM model are not covered by the CDA schema, and are expressed in [2]. These requirements are especially related to the use of CNE value set (as it is the case for statusCode elements), and the use of the SET<T> data types.

3.3 HL7 CDA R2 R-MIM Requirements

There are multiple requirements missing in the CDA schema, and expressed in [1]. These missing requirements are extracted in [12], and they are mostly related to the following kinds of requirements:

- Requirements related to the use of the SET<T> data types (see paragraph 3.1, [3])
  - the SET<T> shall not contain null elements, when there are other elements which are not null
  - the SET<T> shall not contain equal elements
- Requirements related to the use of CNE value set on coded data type elements (as it is the case for statusCode, languageCode and interpretationCode elements)

Table 1: CDA validation tools properties.

	MDHT	Trifolia	Art-Decor	Gazelle Objects Checker	EIE	Nist Validation
Open source	yes	no	yes	yes	yes	yes
Rules editions GUI	yes	yes	yes	no	n/a	no
Generation of schematrons	no	yes	yes	no	n/a	n/a
Code generation	yes	yes	yes	yes	yes	n/a
Binding to value set repository	no	yes*	yes*	yes	yes*	yes*
Online validation service	yes	yes	unknown	yes	no	yes
Specifications generation	yes	yes	yes	no	no	no
Specifications output format	PDF DITA XHTML	Word XML HTML	HTML docbook XML	no	n/a	n/a

* The use of value sets is not from a repository but from file(s) containing all the value sets

- Requirements related to the behavior of the CDA elements, like the relationship between the narrative text and the statements, etc.

3.4 HL7 CDA R2 Data Type Requirements

The data type requirements in CDA standard which are not expressed in the CDA schema come from documents [3] and [4]. Multiple kinds of requirements are missing in the schema:

- requirements related to the use of nullFlavor with data types
- requirements related to the structure of the data type, like the structure of the telecom data, the UUID, the email, etc.
- requirements related to the use of fixed value set, like the use of UCUM for units.
- requirements related to the use of intervals; like for example the IVL<TS>, where the low value SHALL be lower or equal to the high value
- requirements related to the XML implementation: come especially from the data type ITS specification; like requirements related to the XML header definition

3.5 HL7 CDA R2 Narrative Block Requirements

Some requirements related to the narrative block description were expressed in the specification [1]. These requirements are especially related to the relationship between the narrative text and the coded elements, like the IDs references.

3.6 CDA Requirement Types

All the requirements missing in the CDA schema have been divided into two types, inspired from the RFC 2119 [22]. The ones that express an absolute requirement or prohibition belong to type 1, not respecting them will result in an error. The requirements that express a recommendation belong to type 2 and will raise a warning when not respected.

- Type1: the requirement is strong, and if the CDA document fails to implement it, then the document shall not be considered as a valid CDA document. The outcome of the validation raises an ERROR
- Type2: the requirement is not as strong as those of type1, and if the CDA document fails to implement it, then the document is still a valid CDA document. The outcome of validation against such requirement is a WARNING.

4 HL7 CDA R2 Conformance Analysis

To verify the conformance of the CDA documents, validation tools execute a list of checks in addition to the validation against the CDA schema. The outcome is a Boolean: the document does or does not conform to the CDA standard, with a list of positive and negative checks. From our point of view, the conformance of a CDA document could not be only described by a Boolean value, but with an indicator which states how conformable a CDA document is. As a consequence, we define the indicator of CDA validity.

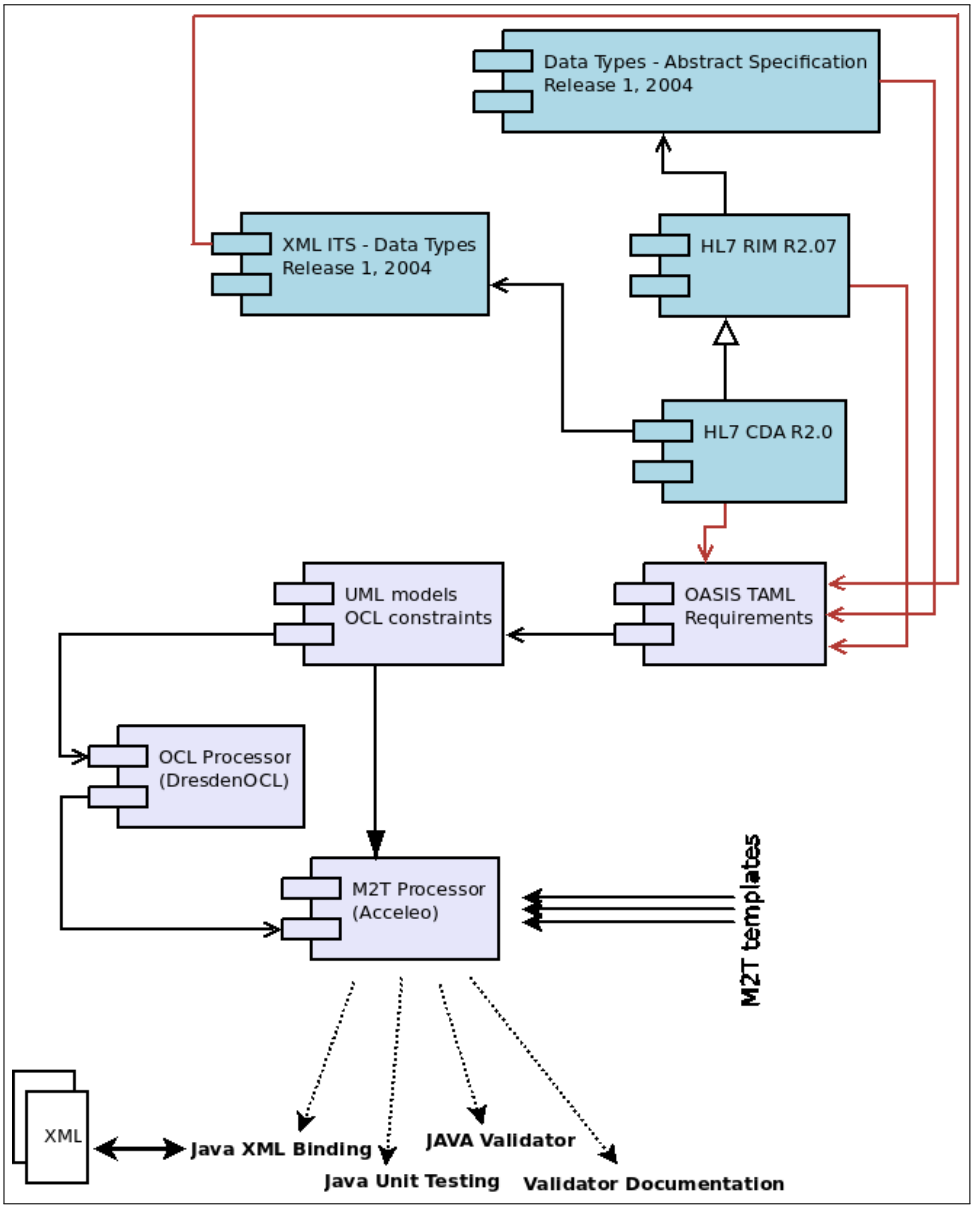

Figure 2: Principle of Gazelle ObjectsChecker.

4.1 CDA Validity

The CDA validity responds to the question: is the document valid according to the CDA standard? The indicator that describes the CDA document validity (I_v) is the number of errors found when checking the document against the CDA requirements.

$$I_v = N_{err} \quad (1)$$

Where N_{err} : Number of errors found

Another indicator, which is more significant from tool perspective, is the absolute indicator of validity (I_v^a), which describes only the number of different kinds of error found, and not the total number of errors found in the CDA document. Consequently, we remove the duplicated errors.

$$I_v^a = N_{err}^a \quad (2)$$

Where N_{err}^a : Number of kinds of error found

In addition to describing the document validity, this indicator mostly describes the degree of validity of the tool that has generated the CDA document.

5 Gazelle ObjectsChecker Methodology

Within the Gazelle Test Bed [11], we have developed a methodology for the conformance checking of XML content [5]. Figure 2 presents the principles of the method which is based on the UML description of the XML structure of the document, in our case the structure of CDA

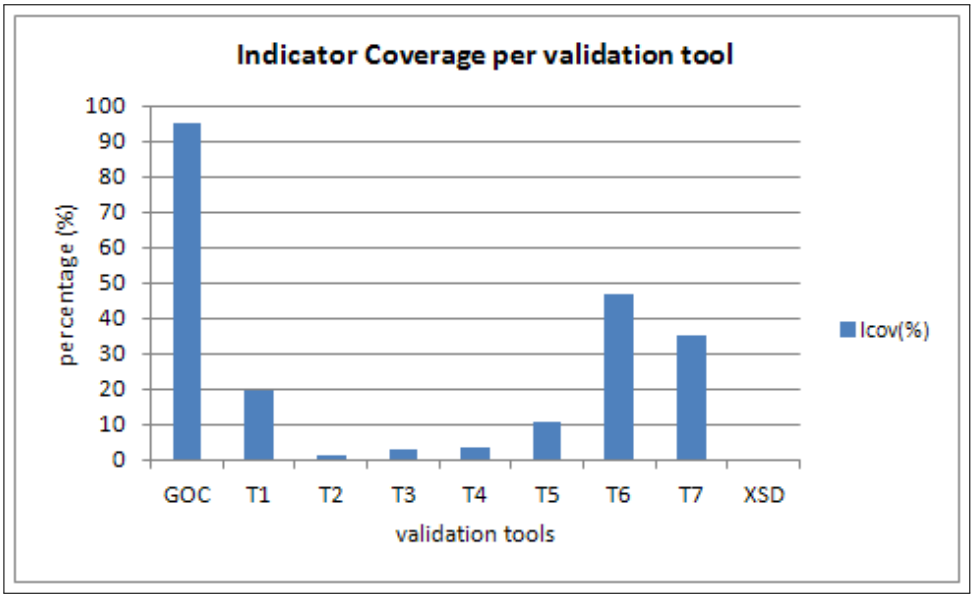

Figure 3: CDA basic requirements coverage indicator by CDA validation tool.

documents, and the description of the requirements based on the OCL language, which allows expressing formal requirements between UML classes and elements [6]. Once the model and the constraints populated, it is processed using a model to text (M2T) processor (acceleo)[7] and an OCL Processor (DresdenOCL) [9]. The outcome of the processing results in:

- First, Java code is generated for editing and modifying the CDA documents. This Java code allows the binding of Java instances to XML elements using JAXB API [8].
- The second output is a set of Java classes for validating CDA documents. This Java classes contain the OCL constraints processed and transformed into Java using the OCL processor.
- The third output is a set of HTML pages which documents the requirements written into the UML model.
- The last output is a set of unitary tests written in Java and based on the OCL constraints.

To manage requirements in a formal structure, we use OASIS TAML standard [10]. This technology allows to uniquely identifying each requirement from the specifications, which allows correlating each OCL constraint with a set of requirements.

For basic CDA validation, the OASIS TAML requirement structure is fulfilled using the requirements extracted from the normative description of CDA R2, RIM V2.07, and data types specifications, and described in [12].

All the UML requirements are hand written directly into the UML models using the OCL language and are tested and verified using unit tests.

The Java code generated using the Gazelle Objects Checker tool can be used for edition and for validation of CDA documents. In the same way, the generation and processing of unit tests result in a database of samples. This set of CDA documents is used for testing the requirements coverage of other CDA validation tools.

6 CDA Basic Requirements Coverage Analysis

6.1 Methodology

Requirement Coverage Indicator Specification

The requirement coverage is an indicator for validation tools. It describes the percentage of requirements covered and tested by the tool, compared to the total number of requirements.

$$I_{cov} = \frac{N_{cr}}{N_{tr}} \tag{3}$$

Where N_{cr} is the number of covered requirements, and N_{tr} is the total number of requirements related to the standard, in occurrence the CDA basic requirements, extracted and described in section 3.

This indicator provides information about the strength of the validation tool. When a document is validated against a tool with a low I_{cov}, the validation result is not relevant and the reliability of the tool decreases.

The indicator of validity I_v describes the validity of a document regarding a validation tool, and the indicator of coverage describes the validation tool itself; it is a constant value related to the tool and does not change per document validated. There are no direct link between the I_v and the I_{cov} except the fact that the couple (I_v, I_{cov})

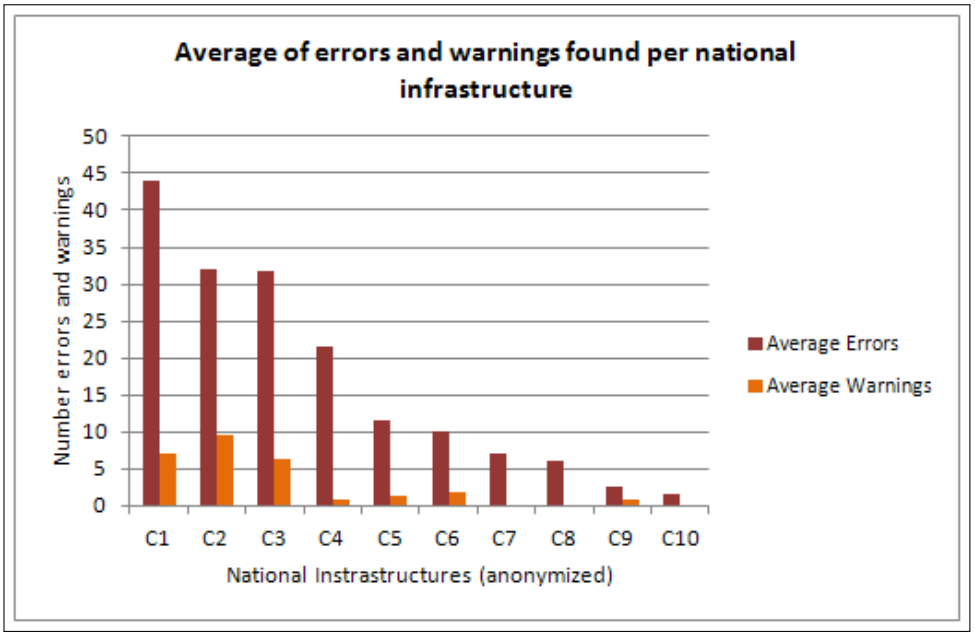

Figure 4: Validation of national specifications samples from Europe and North America.

describes the consistency of the CDA document regarding the basic CDA requirements.

Validation Tools: Requirements Coverage Indicator Calculation

To compute the requirements coverage of the different CDA validation tools, we developed a set of unit tests for each requirement. Each unit test consists of at least two CDA documents: one document that complies with the tested requirement (result will be 'passed', OK test), and one that does not (result will be 'failed', KO test); when the validation tool fails finding an error in a KO test ('passed' is returned whereas 'failed' was expected), we assume that the tool does not cover the requirement.

6.2 Results

More than 600 CDA were created to test the requirements expressed in [12].

Based on this methodology, we succeeded in generating a requirement coverage diagram (Figure 3). This diagram contains the requirement coverage for 7 tools, in addition to Gazelle ObjectsChecker validation service. The tools tested are especially those which provide basic validation of CDA documents, which are MDHT basic CDA validation, Eclipse Instance Editor, NIST web service validation for basic CDA documents, and some schematrons which are ART-DECOR basic validation, ASIP santé schematron for common validation, XSD-SD schematron and XD-LAB schematron from IHE. The weakness of this methodology is the fact that we are not able to apply it on schematrons based on templates, without modifying the original schematrons, and so the I_{cov} for the schematrons tested indicates the number of requirements detected and covered by the tool, but it does not indicate the number of requirements uncovered.

The purpose of this paper is not to compare the tools so we anonymized the results of the study.

None of the tools does cover 100% of the basic requirements and apart from Gazelle ObjectsChecker, all are ignoring more than 50% of the requirements that are not expressed within the CDA Schema.

7 Implementation

7.1 Application 1: National Infrastructures Samples Studies

Most of the national and regional infrastructures which restrict the use of the CDA standard to their national and regional use cases provide samples documents. Their purpose is to help the implementers of IT systems with creating and/or parsing the CDA documents. Multiple European and North American national healthcare IT do it, and most of them provide tools to validate the CDA documents according to the national specifications (some of them are described in the state of the art section). The samples provided with the national healthcare IT specifications are generally valid against the provided tools. As an application of the CDA basic validation using the Gazelle ObjectsChecker methodology, this paragraph studies the conformance to the CDA standard of the samples provided by some European and North American national entities; they are: ASIP Santé (France)[25], ELGA (Austria)[27], Kanta (Finland), HL7 Germany, HL7 Switzerland, region Emilia-Romagna (Italia), NICTIZ (Netherland), e-MS (Canada), HL7 Czech Republic[28], and some USA CDA imple-

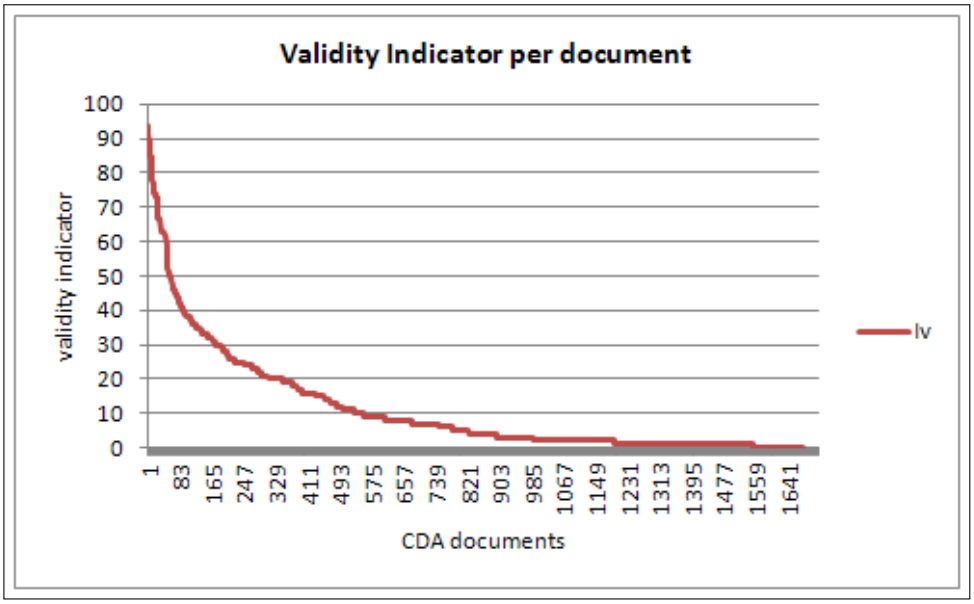

Figure 5: Basic CDA validation of already valid CDA documents according to IHE schematrons.

mentation specifications: CCD, C-CDA R1.1, CRS, and HIPAA. And, for security issue, we anonymized the results of validation, in Figure 4.

153 documents were used to generate this graphic. The average of errors indicator used in this graph desribes the average of the validity indicator I_v per document validated for each national infrastrure, and the average of warnings indicator describes the average of the number of warnings found per document. We can conclude from this diagram that a huge number of samples provided by national specifications are not conform to the basic specification of the CDA standard. We found an average of 14.97 errors per CDA document, which is an alarming number as it means that 2200 errors were found in official national and regional samples. The difference of the average of errors between the different national infrastructures may be explained by the difference of the level of complexity between their standards, and also could be explained by the quality of the national tool used to validate these samples.

7.2 Application 2: IHE Schematrons Validation Studies

The Figure 5 describes the number of errors (I_v) found using Gazelle ObjectsChecker for the conformance checking of basic CDA requirements, in 1700 CDA documents, which are valid according to the IHE schematrons. The samples were sorted by the number of errors found.

The first remark that we can do is about the number of errors found, which varies from 0 to 100, with 50 different kinds of error not detected. We conclude that only a few basic CDA requirements are validated by the schematrons. The average of errors found is 11.08 per document, which proves how important is the validation of basic CDA requirements.

By executing the basic CDA validation on 20,000 CDA documents coming from multiples sources (especially epSOS[16] and IHE), we found errors for only 60 out of the 160 requirements identified. This could be related to the fact that multiple requirements are rarely encountered; and this could explain why multiple validation tools do not check more than 50% of the requirements.

7.3 Application 3: Most Frequent Errors in CDA Documents

Based on the analysis done on the national CDA samples, and the IHE valid samples, we extracted the most frequent errors found in the CDA documents. The Figure 6 describes the frequency of errors found. We classified all the errors found in the validation of the documents by requirements, and the indicator used describes the percentage of errors found related to each requirement, regarding the total number of errors found.

50% of errors found are related to only five requirements, and 85% of errors found are related to only 10 requirements. These requirements are:

1. DTITS-007: the use of reference element under an ED data type (27% of errors found)
2. CDADT008 /CDADT-006: the use of attributes related to CD data type (nullFlavor, code, displayName, etc)
3. CDADT-011: the use of UUID structure
4. RMIM-078: the use of scope and player elements under a CDA role element
5. CDADT-013/CDADT-014: the specification of URL references

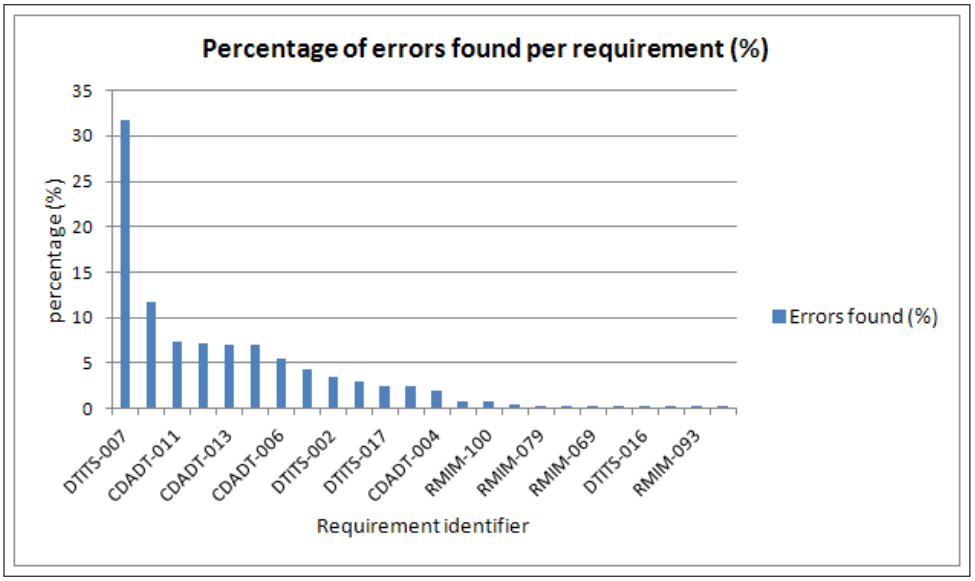

Figure 6: Most frequent CDA basic errors.

6. DTITS-017: bad declaration of a timestamp under TS data type

Other kinds of errors were also largely detected in the CDA documents, like the telecom structure, the use of schemaLocation attribute, and the misuse of CNE codes, like in Observation.interpretationCode element.

The errors found describe an inconsistency between the documents validated and the HL7 CDA R2 standard. However, these errors do not always deteriorate the clinical information included in the documents. Some of the errors found can create problems of interpretation of the clinical information, like the errors in the structure of the timestamp, or the misuse of codes from CNE value sets; on the other hand, a big number of the errors found does not create inconsistencies in the clinical information, but may create troubles for the software that will treat the document, like the structure of UUID used, the misuse of the reference element, or the use of a schemaLocation attribute.

8 Conclusion

Validation of CDA requirements presents a real challenge for national, regional and even cross enterprise infrastructures. In this paper, we have shown that error free CDA documents are rare and that there is a clear need for better validation tooling. The Gazelle ObjectsChecker based on UML model and OCL presents a good coverage of the basic CDA requirements and could be used as a common tool. Its methodology has proven to be highly effective in detecting non-conformity in the tested documents. The validation of national infrastructure material samples using this methodology detected hundreds of inconsistencies, which proves that the basic requirements are rarely respected. The analysis of the pool of IHE CDA documents showed that schematrons lack validation rules and that combining schematrons business rules to the Gazelle ObjectsChecker tool might be necessary. Finally, the analysis of coverage of the different validation tools has proven the fact that most of them are far from covering 100% of the requirements. This raises the question of coverage reporting. When a tool provides an evaluation of the conformance of a document to some specifications, it is a good practice to provide information about the coverage of the specification.

Several extensions to this paper could be done, like a possible conjunction between the Gazelle ObjectsChecker tool and some CDA graphical specifications editors like Trifolia or ART-DECOR, to allow the automatic generation of validation materials. This methodology could also be extended to other healthcare XML based technologies, like for example for the HL7V3 messages or FHIR resources, which could improve the interoperability between healthcare systems, and avoid inconsistencies.

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Applying FHIR in an Integrated Health Monitoring System

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Abstract

The continuous monitoring of vital signs has become an important supplement to traditional medical treatment to ensure the success of a therapy. Integrated health monitoring solutions based on existing health standards provide interoperability and enable healthcare providers and patients to exchange and access their data across institutional borders. This paper shows an integrated monitoring solution based on Continua and Integrating the Healthcare Enterprise, which has been tested by more than 130 patients and 14 healthcare institutions. According to user feedback, one recurring problem is the low battery life of smartphones due to high data traffic. Since the recently developed HL7 standard FHIR offers a resource efficient handling of web service connections, a possible approach to extend the monitoring solution to support FHIR.

Comparing both solutions using data collected by 68 patients, it can be concluded that there is a significant decrease in data traffic when relying on a RESTful architecture in combination with FHIR. For productive use of the FHIR-based approach shown in this paper, security related concerns have to be taken into account in future work to ensure authenticity and authorization.

Keywords

Fast Healthcare Interoperability Resources; Integrating the Healthcare Enterprise; Continua Health Alliance; Telemonitoring; Electronic Health Record

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1 Introduction

People suffering from chronical diseases have to measure their vital signs like blood pressure, heart frequency, blood sugar and weight regularly. Especially in rehabilitation, for example after cardiologic surgery, the continuous monitoring of vital signs has become an important supplement to traditional medical treatment to ensure the success of a therapy [1]. Most available personal health monitoring solutions are isolated applications, which provide results only to the person conducting the measurement, i.e. the patient, or rely on proprietary protocols concerning the exchange and access to measured data. Thus, healthcare providers often lack access to the monitoring results. Integrated health monitoring solutions based on existing health standards provide interoperability and enable healthcare providers and patients to exchange and access their data across institutional borders [2], see Figure 1. This paper shows an integrated health monitoring solution, which has been developed for several use cases, e.g.:

- Monitoring of patients in cardiologic rehabilitation to examine, whether the monitoring of vital signs can support the rehabilitation process, while enhancing the compliance of patients.
- Monitoring of patients with defined medical indications in hospital environments
- Monitoring of elderly people suffering from chronic diseases, especially patients/customers in care centres who regularly measure blood pressure, weight and blood sugar, to find out if telemonitoring supports medical care by providing physicians with detailed information of their patient's health status.

The presented solution has been evaluated in several small test settings over the last five years. From Jan. to Sept. 2014 it has been tested by more than 130 patients and 14 healthcare institutions consisting of medical practitioners, hospitals, rehabilitation centres, nursing homes as well as care centers. It is still in development and is being constantly refined.

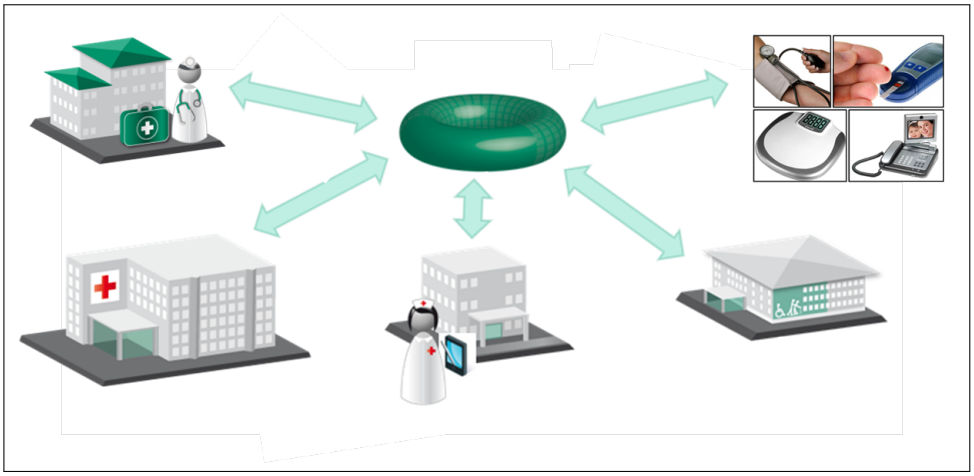

Figure 1: Integrated health monitoring solution used by medical practitioners, hospitals, rehabilitation centres, nursing homes and patients.

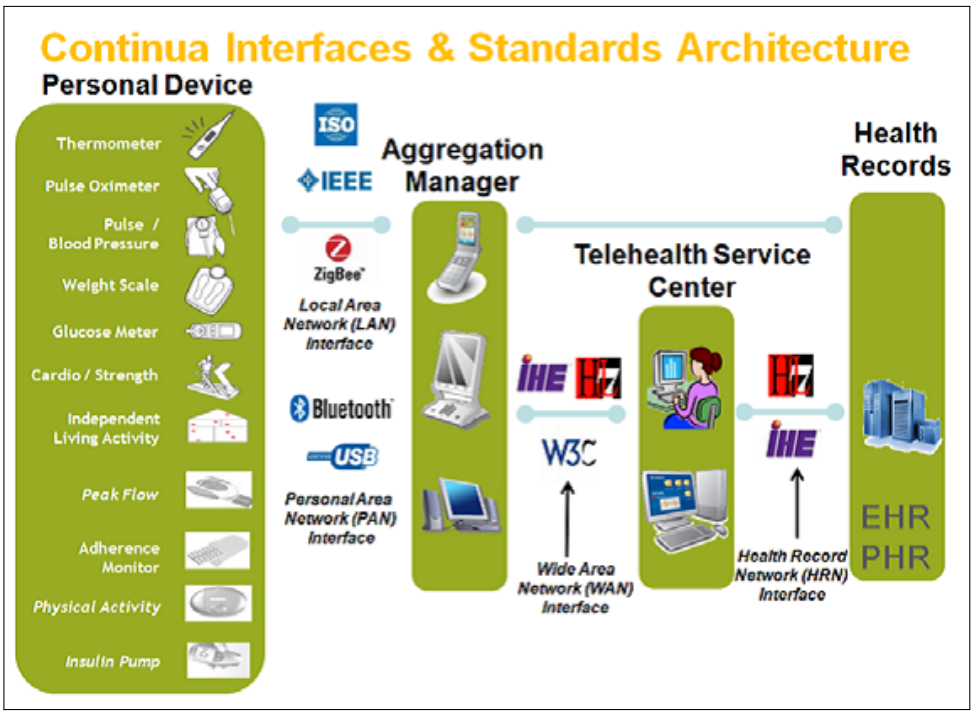

Figure 2: Continua Interfaces and Architecture define use of IHE and HL7 for interoperability [6].

According to user feedback, one recurring problem is the low battery life of smartphones due to high data traffic. Since the recently developed Health Level 7 (HL7) standard Fast Healthcare Interoperability Resources (FHIR) [3] offers a resource efficient handling of web service connections while still preserving the stipulated interoperability through the use of standards connected to HL7, the application of FHIR in context of an integrated health monitoring solution seems worth investigating. Hence, this paper shows a possible approach to extend a health monitoring system to support FHIR.

2 Methods

2.1 Integrated Health Monitoring System

Since the health monitoring system has to be developed as a medical device, it is based on guidelines defined by the Continua Health Alliance (Continua), which require the use of Integrating the Healthcare Enterprise (IHE) and HL7 to provide interoperability between medical devices and other healthcare systems (see Figure 2). The exchange of data monitored by patient care devices (PCD) is based on the ISO/IEEE 11073 and implements the IHE Device Enterprise Communication (DEC) profile. According to IHE and Continua, a measurement

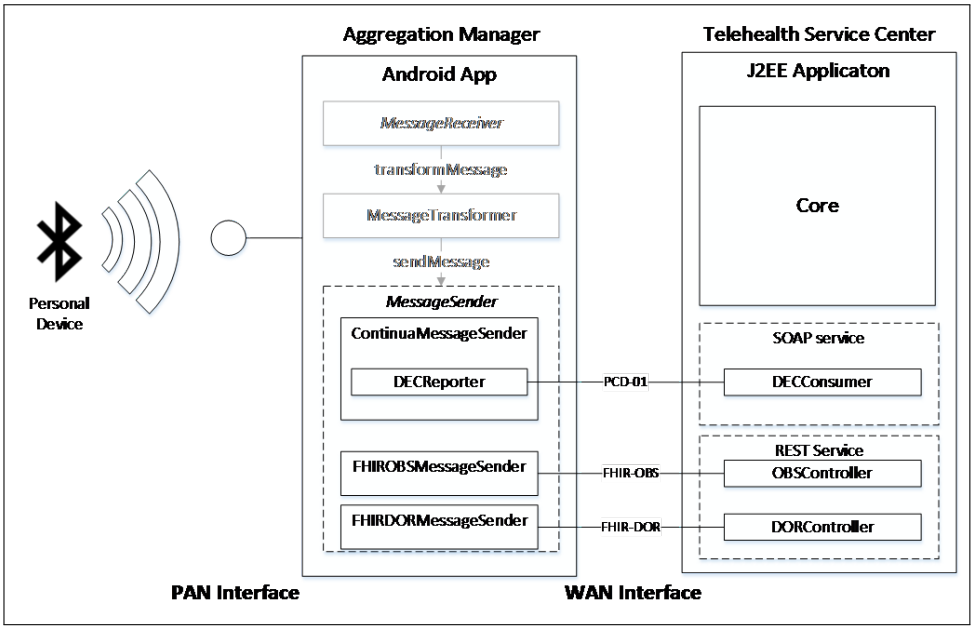

Figure 3: Continua Interfaces and Architecture define use of IHE and HL7 for interoperability [6].

recorded with a telemonitoring solution, is processed as follows [4, 5] (see Figure 2): A personal device, e.g. a scale, sends each measurement to a device, which acts as aggregation manager. The MessageReceiver is responsible for establishing, maintaining and releasing connections to associated personal devices. As a next step, any received data is forwarded to a MessageTransformer that decodes measurements into a human readable format. Finally, the results are transferred using the MessageSender, which acts as DEC Reporter. Hence, it is responsible for, encoding the measurements according to the defined requirements, and sending them to the Telehealth Service Center via a PCD-01 transaction. For transmission, PCD-01 uses a HL7 V2.6 Observation Result Unsolicited (ORU)^R01 message in combination with Simple Object Access Protocol (SOAP). The message contains information on the measurement, the device and the demographic data which enables to establish a link between the information and a patient (realized through extending DEC with Patient Identity Binding, ITI-21 [5]).

As a prerequisite, the patient has to be identified during the measurement, usually done using a unique identifier. Patients using a personalized smartphone, which is linked to the PID, can be assigned directly. To identify patients measuring in a multi-user environment, for example a station in a nursing home, the user is assigned a QR-Code printed on a personal ID-Card.

The Telehealth Service Center acts as DEC Consumer and receives the measurement data. Using Cross Enterprise Document Sharing (XDS), it checks if a Personal Health Monitoring Report (PHMR) has already been registered in the Electronic Health Record (EHR) for the defined patient. The THSC then either creates a new PHMR or it extends the existing document. To avoid large CDA documents, a new version of a PHMR is created every month or depending on a configurable amount of maximum measurements within onereport. Each PHMR document is stored in the EHR, i.e. in an XDS repository. Authorized practicioners and other health personnel can request the PHMR for their patients. The documents are transformed using an extended EXtensible Stylesheet Language Transformations (XSLT) based on the Autrian Electronic Health Record (ELGA) stylesheet.

2.2 Applying FHIR

To apply FHIR to the solution described above, it was necessary to extend the WAN-Interface located between the Aggregation Manager and the Telehealth Service Center (see Figure 2). The HL7 message used in connection with the PCD-01 transaction consists of a patient identification, measured data (e.g. weight) and the unit of measure encoded in a HL7 ORU^R01 message. The FHIR resources Observation and DeviceObservationReport were chosen since they are a suitable alternative to the HL7 ORU^R01 message in FHIR. Hence, two additional MessageSenders were created, as depicted in Figure 3

1. FHIROBSMessageSender responsible for transferring measured data as FHIR-Observations (FHIR-OBS) resources

2. FHIRDORMessageSender responsible for the transport of FHIR-DeviceObservationReports (FHIR-DOR)

An Observation resource contains measurements and simple assertions made about a patient, devices and other subjects [8]. Devices are administrative resources that track individual devices of all kinds and their location [9]. In order to send multiple observations at once, the FHIR

```
<Device id="bathroomScale_1">
    <type>
        <coding>
            <system value="urn:std:iso:11073:10101"/>
            <code value="46264-8"/>
        </coding>
    </type>
    <manufacturer value="Tanita"/>
    <model value="BC-1000"/>
    <lotNumber value="080520"/>
</Device>
```

```
<Observation id="o1">
    <name>
        <coding>
            <system value="http://loinc.org"/>
            <code value="3141-9"/>
            <display value="MDC_MASS_BODY_ACTUAL"/>
        </coding>
    </name>
    <valueQuantity>
        <value value="86.3"/>
        <units value="kg"/>
```

Figure 4: Example for a Device and a simple Observation resource in (XML-format).

```
{
  "resourceType": "DeviceObservationReport",
  "text": {
    "status": "generated",
    "div": "Device observation report"
  },
  "contained": [
    {
      "resourceType": "Observation",
      "text": {
        "status": "generated",
        "div": "<div>Jan 30 2014: Body Weight = 80 kg</div>"
      },
      "name": {
        "coding": [
          {
            "system": "http://loinc.org",
            "code": "3141-9",
            "display": "MDC_MASS_BODY_ACTUAL"
          },
        ]
      },
      "valueQuantity": {
        "value": 80,
        "units": "kg",
        "system": "http://unitsofmeasure.org",
        "code": "kg"
      },
      "status": "final",
      "reliability": "ok"
    }
  ],
  "instant": "2008-12-11T14:45:00",
  "source": {
    "reference": "device/d1"
  },
  "subject": {
    "reference": "Patient/ihe-pcd"
  },
  "virtualDevice": [
    {
      "channel": [
        {
          "metric": [
            {
              "observation": {
                "reference": "#o1"
              }
            },
          ]
        }
      ]
    }
  ]
}
```

Figure 5: Example of a DeviceObservationReport (JSON-format).

specification offers a bundle concept, which allows grouping of several observations together. Bundles can be used for transactional storing of data [8], e.g. a blood pressure measurement consisting of three observations, the systolic, diastolic and pulse observation. For a simple weight observation, bundling can be omitted (see Figure 4).

The resource DeviceObservationReport describes a set of observations produced by a device at a certain point in time (i.e. the measured data). This resource is based on ISO 11073 and only used for devices which report data [9]. Each DeviceObservationReport contains the measurement, a reference to the patient, the device used for the measurement and a list of observations supplied by the device [8], see Figure 5.

The FHIR-based approach was evaluated using data generated during the evaluation of the Continua-based monitoring system. The data collected from 68 patients monitoring their weight for the duration of 5 months, was used to generate the FHIR resources. Only measurements which have been processed by the system successfully were taken into account and used to simulate the extended approach based on real-world user behavior and patient data.

3 Results

Conducted surveys, which are described in Table 1, showed, that users (age 29-89) claimed to be pleased or very pleased with using the system. Especially the graphical overview of the measured data (see Figure 6) was considered helpful and important. Particular problems concerning the hardware could be identified. They include poor battery life of the smartphones due to high data traffic, problems using the touch screen of the smartphone and problems in using the measurement devices.

Table 2 shows the average amount of data contributed by PCD-01, FHIR-DOR and FHIR-OBS for weight scale devices over an evaluation period of five months for PCD-01 (the Continua compliant system), FHIR-OBS and FHIR-DOR. The data traffic using PCD-01 is 3.2 times higher compared to FHIR-OBS and 2.6 times higher compared to FHIR-DOR.

4 Conclusion and Outlook

The presented method shows a possible extension of an integrated interoperable health monitoring system using

Table 1: Overview over conducted surveys.

USE CASE 1 *Cardiologic Reha*	**USE CASE 2** *Monitoring via hospital*	**USE CASE 3** *Monitoring of elderly people*
Patients were monitored over 2.924 d	Patients were monitored over 1.582 d	Patients were monitored over 1.726 d
Evaluation during the project Telephone-interviews (N=7)	**Evaluation during the project** Telephone-interviews (N=7)	**Evaluation during the project** Tel/personal interviews/discussions in the user environment (N=11)
Summative evaluation Questionnaire for patients (N=20)	**Summative evaluation** Questionnaire for patients (N=9)	**Summative evaluation** Partially standardized discussions in the user environment (N=11+3 discussion rounds)
Questionnaire for phycisians (N=74, n=10)		

Table 2: Overview over conducted surveys.

	users	measurements	total data (bytes)	estimated data (bytes)
	68	1959		
PCD-01			354196	944505
FHIR-DOR			138811	370159
FHIR-OBS			112290	299435

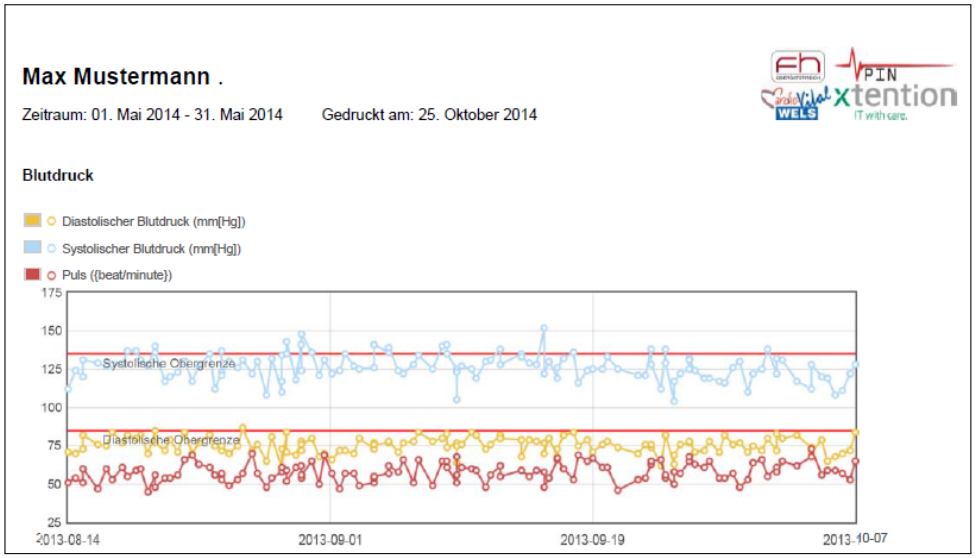

Figure 6: Graphical overview of measured data.

a FHIR-based approach. FHIR uses a RESTful approach concerning efficient exchange of its resources. Thus, it is offering a lightweight alternative to the existing IHE and CHA compliant system, which uses SOAP-based web services. Due to the overhead needed to consume a SOAP-based web service from a mobile device [3] the implementation of a SOAP-based web service client results in increased mobile data traffic and can lead to poor battery life [10]. Comparing both solutions using data collected from 68 patients, it can be concluded that there is a significant decrease in data traffic when relying on a RESTful architecture in combination with FHIR. Furthermore due to the decreased amount of data transferred between the Aggregation Manager and the Telehealth Service Center it can be assumed that the battery life of the Smartphones used for transmitting the measurements can be increased, which is confirmed by findings of [3]. This might lessen or eliminate altogether one of the major problems shown during the evaluation of the former solution. Early tests confirm this assumption and show that the extension of battery life seems to provide better user experience and thus acceptance for the patients. Nevertheless, further evaluation of battery life extension is still in progress. Evaluations of the original approach show that such an integrated monitoring system can enhance the personal health competence of a patient. Furthermore, it supports medical personnel by providing a periodic overview of a patient's health status, thus enabling better adjustment of a (medical) therapy. It can also help to detect potential risk situations. Hence, it is necessary that the system is implemented as a medical device and adheres to legal regulations that are in place. To enable productive use of the FHIR-based approach shown in this paper though, security related concerns have to be taken into account to

ensure authenticity, authorization and authority [1]. Any additional standards from WS-* specifications can be integrated into a CHA (thus IHE)-compliant system, when implementing a SOAP-based approach [4]. It remains to be seen in future work if a comparable and sufficient solution for the FHIR-based approach can be found, e.g. a combination of Oauth6 for user authorization with the decentral authentication system OpenID7.6.. Although the proposed solution enables to reduce data footprint on devices with limited resources, it no longer fully complies with the CHA guidelines. However IHE which CHA refers to is currently working on the application of FHIR as stated in [11].

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Converging Patient Summaries: Finding the Common Denominator between the European Patient Summary and the US-Based Continuity of Care Document

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Abstract

Having the administrative and clinical information concerning the patient presented in a comprehensible format, language, and terminology is valuable for any healthcare provider. In Europe, this type of information is represented by the Patient Summary Guideline and on the other side of the Atlantic by the Continuity of Care Document (CCD). Trillium Bridge is a project co-funded by the European Commission that "compares specifications of EU and US patient summaries with the aim of developing and testing common and consistent specifications and systems enabling interoperability of electronic health records across the Atlantic." The objective of this article is to summarize the findings of the comparison between these two Patient Summaries. Both documents are using the same syntax, namely Clinical Document Architecture (CDA), making the comparison easier. The documents were compared from a clinical, syntactic, and terminological point of view focusing on semantic interoperability. A common denominator was found in terms of sections, data elements, and value sets. Comparing the value sets led the project team to assess available official maps such as the SNOMED CT and ICD-10 and determine their applicability. In some cases, such as the National Cancer Institute Thesaurus and the EDQM standard terms, no maps were found and the team proposed associations. The common denominator thus identified allows for significant parts of the data to be exchanged, setting the baseline for the transatlantic exchange of a meaningful set of patient summary data and establishing a springboard for an international patient summary standard.

Keywords

Semantic interoperability, code system maps, EU-US MoU, Patient Summary guideline

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1 Introduction

1.1 Patient Summaries Initiatives in Europe and the United States

Concise, unambiguous health information is of paramount importance for the healthcare provider administering care to his or her patient. This becomes even more important in cases of cross-border care, where the patient might not speak the language or understand the subtleties of the local culture. The information that is most useful to a healthcare provider is of administrative, demographic, and clinical nature.

Most often this information is present in what is known as a Patient Summary and is available in various formats in the Member States (MS) of the European Union, leading to a variety of regional and national Patient Summaries. The information is represented by discrete data elements, which were harmonized by the European Patient Smart Open Services (epSOS) [1], a large scale eHealth pilot project co-funded by the European commission (EC) focusing on issues related to the communication of patient summary data in situations of emergency or unplanned care, in a cross-border context. The epSOS Patient Sum-

Table 1: Section Comparison between the epSOS PS, EU PS Guideline, and CCD.

epSOS/EU Directive	**EU PS [2] Guidelines**	**epSOS PS** [7]	**CCD** [8]	**CCD**
Section	*Optionality*	*Optionality*	*Section*	*Optionality*
Allergy	R	R	Allergies	R
List of current medicines	R	R	Medications	R
List of current problems/diagnoses	R	R	Problem	R
Surgical Procedures prior to the past six months	R	O	Procedures	O (R only for inpatients)
Major Surgical Procedures in the past six months	R	R	Procedures	O (R only for inpatients)
Medical Devices and implants	R	R	Medical Equipment	O
Vaccinations	O	O	Immunizations	O
Social History Observations	O	O	Social History	O
Pregnancy history (Expected date of delivery)	O	O	Social History (Pregnancy Observation)	O
Physical findings (Vital Signs Observations)	O	O	Vital Signs	O
Diagnostic tests (Blood group)	O	O	Results Section	R
Treatment Recommendations	R	O	Plan of Care	O
Autonomy/Invalidity	R	O	Functional Status	O
Not matched			Advance Directives	O
Not matched			Family History	O
Not matched			Payer	O
Not matched			Encounters	O
List of resolved, closed or inactive problems (History of Past Illness)	O	O	Not matched	

mary services were further incorporated in the European Guideline on Patient Summary minimum/non exhaustive data set for electronic exchange under the cross-border directive 2011/24/EU [2, 3] in May 2013 during the 3rd meeting of the of the eHealth Network [4]. These guidelines support the objective of continuity of care and patient safety across borders, focusing on emergency or unplanned care in a cross-border context and indicate the minimum data set to be used in the cross-border exchange of patient summaries in the pan-European space. The guidelines also make non-binding recommendations on the syntax (CDA) and the various terminologies and value sets to be used in the electronic documents to be exchanged.

On the other side of the Atlantic, the US Department of Health & Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC) defines certified Electronic Health Records technology through a series of "Meaningful Use" regulations, the current one being the Meaningful Use 2 (MU-2) that are next linked to provider incentives [5]. Part of these regulations applies to electronically-produced medical documents also based on a CDA compliant syntax. For example, MU-2 refers to C-CDA specifies the data elements, syntax and terminologies for several document types, i.e. Consult Note, Diagnostic Imaging Report, Discharge Summary, History and Physical, Operative Note, Procedure Note, Progress Note, and Continuity of Care Document (CCD). Among these, the Continuity of Care Document (CCD) is defined as a "core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare" allowing the aggregation of all of the pertinent patient data to be forwarded to another practitioner, system, or setting so as to support the continuity of care.

1.2 EU/US Cooperation and the Trillium Bridge Project

A Memorandum of Understanding [6] between the United States Department of Health and Human Services and the European Commission on cooperation surrounding health related information and communication technologies (ICT) was signed in 2010. The main objectives of this MoU, namely the "...cooperation on topics directly pertaining to the use and advancement of eHealth/health IT, in pursuit of improved health and health care delivery as well as economic growth and innovation..." and "...the development of internationally recognized and utilized interoperability standards and interoperability specifications for electronic health record systems that meet high standards for security and privacy protection..." are reflected in the aims of the Trillium Bridge Project.

The Trillium Bridge Project co-funded by the European Commission, compares from a semantic point of view the epSOS Patient Summary and the CCD documents investigating if a common area of exchange is possible and what is necessary to accomplish the baseline exchange and shared understanding of the relevant patient summary data.

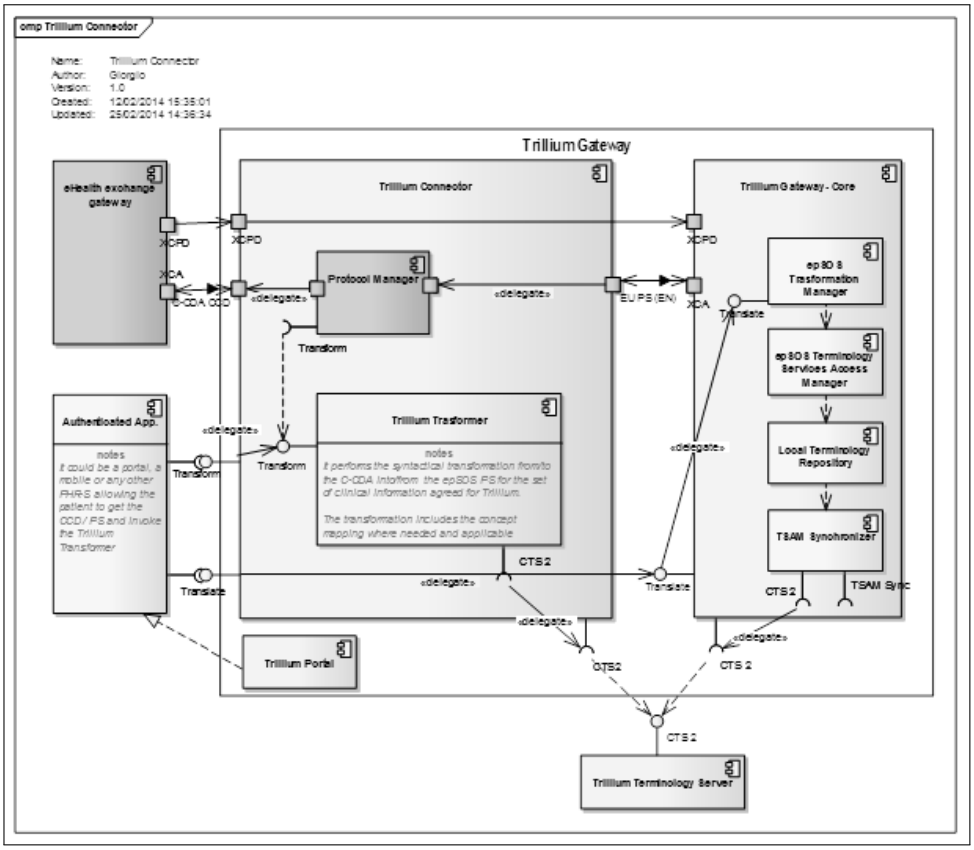


Figure 1: Trillium Gateway: transformation, terminology, and translation componentss.

2 Methods

The two patient summary specifications from each side of the Atlantic were compared with several lenses: their intended used, consisting sections, data elements, syntax and value sets. A common intersection area was identified.

The intended use of the two documents, the epSOS Patient Summary (epSOS PS) [7] and the Consolidated CDA Continuity of Care Document (CCD Release 1.1, hereafter simply indicated as CCD) [8] and the detailed composition of their respective sections were studied. Corresponding sections were investigated from a functional definition perspective. Within each section there are several data elements. Particular attention was paid to the data elements that contained value sets and to the functional rules concerning the syntactic transformation that had to be applied. In case of different value sets, the code systems were identified and official mappings were sought. The official mapping were further investigated in terms of their applicability to the content of the value sets. Where no official maps were found, mapping was done by the Trillium Bridge Project team. The code systems, value sets and the mappings were uploaded in a Common Terminology Services Release 2 (CTS2) terminology server and its contents are available online. A transformer currently under development, uses the CTS2 web service (http://extension.phast.fr/STS_UI) in mapping structure and semantics in actual patient summaries.

3 Results

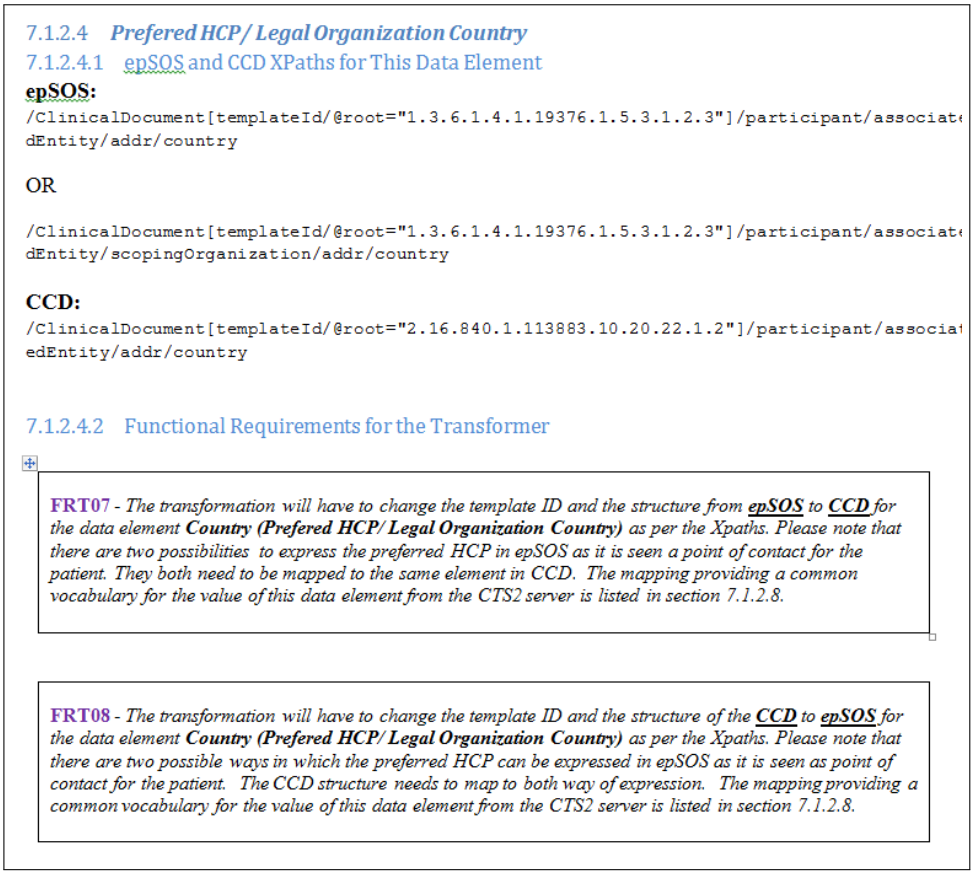
3.1 Comparison at the Document Level

The intended clinical meaning of the epSOS PS and CCD were listed in the introduction. Although CCD has a much wider scope and is intended to facilitate the patient transfer from one healthcare provider to another, it can be safely concluded that in principle, both documents contain the same type of information: clinical, demographic and administrative data at one particular point in time.

3.2 Comparison at the Section Level

The content of the documents is compared in Table 1. Although, to our knowledge, there are no implementations of the European Patient Summary (EU-PS) Summary guideline, it has been included as it is the future direction of implementation in Europe under the Connecting Europe Facility (CEF), which aims to support large scale eHealth deployment. However, it must be noted that since there are no implementations of the EU Patient Summary, the epSOS PS implementation guide has been used throughout the rest of the project and is referenced in all the results and discussions.

There are three common sections which are required in both documents – they are deemed as the common intersection between the two documents which will always


7.1.2.4 *Prefered HCP/ Legal Organization Country*

7.1.2.4.1 epSOS and CCD XPaths for This Data Element

epSOS:

/ClinicalDocument[templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.2.3"]/participant/associat
dEntity/addr/country

OR

/ClinicalDocument[templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.2.3"]/participant/associat
dEntity/scopingOrganization/addr/country

CCD:

/ClinicalDocument[templateId/@root="2.16.840.1.113883.10.20.22.1.2"]/participant/associa
edEntity/addr/country

7.1.2.4.2 Functional Requirements for the Transformer

FRT07 - *The transformation will have to change the template ID and the structure from **epSOS** to **CCD** for the data element **Country (Prefered HCP/ Legal Organization Country)** as per the Xpaths. Please note that there are two possibilities to express the preferred HCP in epSOS as it is seen a point of contact for the patient. They both need to be mapped to the same element in CCD. The mapping providing a common vocabulary for the value of this data element from the CTS2 server is listed in section 7.1.2.8.*

FRT08 - *The transformation will have to change the template ID and the structure of the **CCD** to **epSOS** for the data element **Country (Prefered HCP/ Legal Organization Country)** as per the Xpaths. Please note that there are two possible ways in which the preferred HCP can be expressed in epSOS as it is seen as point of contact for the patient. The CCD structure needs to map to both way of expression. The mapping providing a common vocabulary for the value of this data element from the CTS2 server is listed in section 7.1.2.8.*

Figure 2: Example of transformation rules concerning the healthcare professional role [10].

be present as they are mandatory on both sides of the Atlantic (first three lines in Table 1). There are nine sections that are required in one document but are optional in the other, as well as sections that are optional in both documents – there are considered as the possible common intersection between the two documents (next nine lines in Table 1). There are two sections that are present as text only (next two lines in Table 1) such as the Treatment Recommendations and the Autonomy/Invalidity. These are mentioned for completeness, but are not included in the analysis. Lastly, there are four sections that are present in one document, but not present in the other document – these sections are not considered to be part of the common ground between the two documents (last four lines in Table 1).

Some additional information concerning several sections is necessary. Both the Surgical Procedures prior to the past six months and the Major Surgical Procedures in the past six months, use the Coded List of Surgeries section. The only indication differentiating them is the Date. The History of Past Illness section in the epSOS PS it is rarely used and only by a few MS. Furthermore, it does not have a direct correspondence in the CCD. Although CCD is an open document template and any of the section templates can theoretically be added to it, the chances of this section being present in a routine clinical document originating from the US side are very slim, hence it is not considered as having an equivalent. With these consideration in mind, there are 11 sections out of the 15 present in the epSOS PS have correspondence in the US CCD, and 11 sections out of the 15 present in the CCD have correspondence in epSOS. A detailed analysis of the comparison is available in [9].

3.3 Transformable Coded Data Elements

Within the common sections, there are common data elements conveying the same semantic meaning using two types of content: structural elements and terms bound to specific value sets. Trillium Bridge uses a set of XSLT transformations to ensure their correct interpretation. The structural elements will be transferred as they are between the two sides of the Atlantic with the understanding that the template identifiers will be changed. In case that a structural element is not present, the default value from the recepient specification will be used. The value elements will be transformed according to well-specified functional rules and contextual mappings of their value sets. Figure 1 shows the information flow, the transformation process, and the integration with the CTS2 server, while Figure 2 shows an example of the transformation rules used [10, 11].

Table 2: Mapping between the value sets epSOSAdverseEventType and CCD Allergy/Adverse Event Type.

epSOS Code	epSOS Display Name	CCD Code	CCD Display Name
419199007	Allergy to substance	419199007	Allergy to substance (disorder)
416098002	Drug allergy	416098002	Drug allergy (disorder)
59037007	Drug intolerance	59037007	Drug intolerance (disorder)
414285001	Food allergy	414285001	Food allergy (disorder)
235719002	Food intolerance	235719002	Food intolerance (disorder)
420134006	Propensity to adverse reactions	420134006	Propensity to adverse reactions (disorder)
419511003	Propensity to adverse reactions to drug	419511003	Propensity to adverse reactions to drug (disorder)
418471000	Propensity to adverse reactions to food	418471000	Propensity to adverse reactions to food (disorder)
418038007	Propensity to adverse reactions to substance	418038007	Propensity to adverse reactions to substance (disorder)

Table 3: Mapping between the value sets epSOSRoleClass and CCD INDRoleclassCodes.

epSOS Code	epSOS Display Name	CCD Code	CCD Display Name
ECON	emergency contact	ECON	RoleClass
NOK	next of kin	NOK	RoleClass
	no match	PRS	RoleClass
	no match	CAREGIVER	RoleClass
	no match	AGNT	RoleClass
	no match	GUAR	RoleClass
	no match	ECON	RoleClass

3.4 Comparison of the Value Sets

The value sets used in the coded data elements present in the two documents are referenced in the same usage context. Thus, when comparing value sets two cases can be distinguished: value sets whose concepts are based on the same code system and value sets that are based on different code systems. Below each case is explained in turn.

Value sets that are based on the same code system

Within the value sets that are based on the same code system there are cases where there is a perfect match between the concepts of the value sets. Table 2 presents such a case for the value sets of Adverse Event Types related to Allergies in epSOS and CCD.

These cases are unfortunately rare since requirements are typically formulated differently by the healthcare professionals on the two sides of the Atlantic. In most cases, where the code system is the same, there is usually a partial overlap between the two value sets. Table 3 and 4 present such examples.

[1] For more information please see the document Mapping SNOMED CT to ICD-10 Technical Specifications that comes with the SNOMED CT distribution [12].

Value sets that are based on different code systems

Alternatively the value sets bound to corresponding can be based on different code systems. In some cases there are official maps that are available for use, such as the maps provided by IHTSDO between SNOMED CT and ICD-10 and by the National Library of Medicine (NLM) between SNOMED CT and ICD-10-CM [12] as well as RxNorm, NDF-RT and ATC. The official maps had to be studied in order to determine their applicability to the contents of the value sets. Within the maps supplied by IHTSDO and NLM between SNOMED CT and ICD-10, not all the terms have an unambiguous mapping – some are context-dependent or rule-based. For example, the target term may depend on gender and age of onset. Trillium Bridge selected from the official mappings only the ones where:

- mapRule is equal "TRUE" and "OTHERWISE TRUE", independent of context[1],
- mapAdvice indicates ALWAYS a code
- mapCategoryValue indicates that Map source concept is properly classified
- mapTarget contains always an ICD-10 code.

Table 4: Mapping between the value sets epSOSTelecomAddress and CCD Telecom Use (US Realm Header).

epSOS Code	epSOS Display Name	CCD Code	CCD Display Name
WP	work place	WP	work place
MC	mobile contact	MC	mobile contact
HV	vacation home	HV	vacation home
HP	primary home	HP	primary home
PG	Pager	Not matched	
H	Home	Not matched	
EC	emergency contact	Not matched	
AS	answering service	Not matched	

- The ICD-10 codes are included in cases that a code was ALWAYS listed with the additional recommendations:
  - possible requirement for an external cause code
  - consider additional code to identify specific condition or disease
  - descendants not exhaustively mapped
  - consider raterality specification
  - addtional codes may be required to identify place of occurrence
  - possible requirement for causative disease code
  - consider trimester specification.
- The ICD-10 codes were excluded when:
  - Use as primary code only if site of corrosion unspecified, otherise use as supplementary code with categories T20-T25 (Burns)
  - This is an external cause code for use in a secondary position
  - This is a manifestation for use in a secondary position
  - This is an infectious agent code for use in a secondary position

Although this is an oversimplyfication, it is necessary as there are no means to select the appropriate term based on contextual rules in Trillium Bridge. Moreover, after eliminating rule-based associations according to the guidance provided above, there are still one-to-many mappings as shown in the example of Table 5. Such one-to-many mappings had to be excluded from the Trillium Bridge association maps as they would have put the healthcare provider at the receiving end into a dilemma as to which one to chose without any background information. This decision to exclude one-to-many mappings reduced dramatically the size of the maps.

The last consideration regarding the official mappings is their applicability to the concepts present in the value sets. Not all the concepts present in the value sets are included in the official maps. In the case of the other set of official maps supplied by NLM between RxNorm (describing the clinical drug name and the brand name) and the NDF-RT (drug class) and ATC the synonyms in the mappings were excluded – a code was used only once. The statistics on the official maps and the percentage of coverage they provide to the Trillium Bridge Project are presented in table in Appendix 1.

In some cases, where the value sets are based on different code systems no official mapping was found. In these cases the mapping between the various concepts belonging to the value sets were done by the project team and need a rigurous quality assurance by subject matter experts. The mappings cover concepts in the following code systems:

- ISCO-08 – NUCC (International Standard Classification of Occupations 2008 and The National Uniform Claim Committee)
- EDQM Standard terms – NCI thesaurus (National Cancer Institute Thesaurus)
- SNOMED CT – CVX (Vaccine Administered)
- UNII – SNOMED CT (Unique Ingredient Identifier from FDA)

The results of all the value set mappings are summarized in table in Appendix 1.

4 Discussion

A considerable amount of work went into the analysis of the semantic components of the epSOS Patient Summary and the Continuity of Care (CCD) document specifications. Sections were compared based on data elements contained by the sections, followed by the value sets. Although the documents are different and were originally intended for slightly different purposes (CCD for is intented for planned and unplanned care and epSOS PS for unplanned care), there is a considerable amount of overlap in the clinical information present. However, the way the structure is expressed brings forth the need for syntactic transformation. The epSOS Patient Summary and likewise the EU PS guidelines are based on IHE content profiles. CCD is a document type in Consolidated CDA (CCDA), which is the result of harmonization of CDA implementation guides developed independently by IHE, HealthStory and HL7. This can explain the differences in

Table 5: Example of one-to-many mappings in the official files from IHTSDO and NLM that were excluded.

SNOMED CT code	SNOMED CT designation	ICD-10-CM code	ICD-10 designation
193003	Benign hypertensive renal disease	I12.9	Hypertensive renal disease without renal failure
193003	Benign hypertensive renal disease	N18.9	Chronic kidney disease, unspecified
2355008	Rud Syndrome	Q80.3	Congenital bullous ichthyosiform erythroderma
2355008	Rud Syndrome	F79	Unspecified intellectual disabilities
2355008	Rud Syndrome	Q87.1	Congenital malform syndromes predom assoc w short stature

the way the clinical information is syntactically expressed. A transformer can help with this syntactic conversion in the short term, but in the long term, a formal consolidation process would be necesary.

However, syntax represents only half of the semantic components. The value sets that are used in the data elements of the CD data type also need to be mapped. In some cases, only some of the value sets have equivalence on both sides. The difference between the uses of the value sets can be attributed to the different clinical needs identified by the healthcare professionals who contributed to the development of the specifications in Europe and the US.

Trillium Bridge performed a feasibility study consisting of comparing the two document specifications and their associated vocabularies and value sets. It is important to acknowledge that this exercise does not claim to solve all interoperability and terminology issues, nor is a finite, one-time endeavor. A first attempt to mapping is put forth to establish the baseline for testing and implementation and provide evidence for policy decisions. However, it is expected that quality assurance will continue throughout the reminder of the project and well afterwards, once the proper processes and infrastructure are in place. Our study laid the basis for a feasibility study answering the question: Can an exchange of documents take place between the Europe and USA, and can there be any meaningful information transferred between the two sides?

Mapping between terminologies is a complex activity, which needs to be continued with the proper subject matter experts on board. It is important that the subject matter experts include not only medical personnel, but also academic and research representatives as well as experts from governments and the industry. Most importantly, the presence and participation of Standards Development Organizations such as IHTSDO and WHO, is necessary.

The results of the feasibility study so far indicate that there are value sets that are much richer in content and granularity on either side of the Atlantic and that a common denominator must be found to establish the basis for the exchange patient information. However, this common denominator results in loss of clinical information as it is neither specific nor granular enough. The original code and original document must be always sent as to preserve the original intended meaning. The transformed/transcoded information should be used for information purposes only by the patient and the receiving clinicians.

In retrospect, there is clear value in the efforts undertaken by the Trillium Bridge project because working to establish a baseline for interoperability has advanced cooperation and mutual understanding among experts in the two sides of the Atlantic. Moreover, the information and knowledge gained can initiate harmonization in the syntax and the terminologies used in the patient summary specifications and hopefully lead to the development of an international patient summary standard.

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Appendix 1: The Trillium value set mappings with % covered (concents with correspondence/concepts present)

epSOS Value Set	epSOS Code System	epSOS %covered	CCD Value Set	CCD Code System	CCD % covered
epSOSAdministrativeGender	HL7 AdministrativeGender	3/3 (100%)	Administrative Gender (HL7)	HL7 AdministrativeGender	3/3 (100%)
epSOSCountry	ISO 3166-1 Country Codes	43/43 (100%)	CountryValueSet	ISO 3166-1 Country Codes	43/244 (18%)
epSOSEntityNamePartQualifier	HL7 EntityNamePartQualifier	10/11 (91%)	EntityNamePartQualifier	HL7 EntityNamePartQualifier	10/10 (100%)
epSOSHealthcareProfessionalRoles	ISCO-08	30/39 (77%)	Provider Type	NUCC	104/232 (45%)
epSOSConfidentiality	HL7 Confidentiality	3/7 (43%)	HL7 BasicConfidentialityKind	HL7 Confidentiality	3/3 (100%)
epSOSLanguage	ISO 639-1	35/35 (100%)	Language	ISO 639-1	35/184 (19%)
epSOSPersonalRelationship	HL7 RoleCode	39/39 (100%)	Personal Relationship Role Type	HL7 RoleCode	39/104 (38%)
epSOSTelecomAddress	HL7 AddressUse	4/8 (100%)	Telecom Use (US Realm Header)	HL7 AddressUse	4/4 (100%)
epSOSRoleClass	HL7 RoleClass	2/2 (100%)	INDRoleclassCodes	HL7 RoleClass	2/6 (33%)
epSOSReactionAllergy	SNOMED CT	6/9 (67%)	Problem	SNOMED CT	6/16,443 (0.04%)
epSOSAdverseEventType	SNOMED CT	9/9 (100%)	Allergy/Adverse Event Type	SNOMED CT	9/9 (100%)
epSOSActiveIngredient	ATC	606/5592 (6%)	Medication Drug Class	NDF-RT	1365/10699 (13%)
epSOSActiveIngredient	ATC	2836/5592 (51%)	Medication Brand Name	RxNorm	3329/13885 (24%)
epSOSActiveIngredient	ATC	2836/5592 (51%)	Medication Clinical Drug	RxNorm	9642/31214 (31%)
epSOSAllergenNoDrugs	SNOMED CT	79/112 (71%)	Ingredient Name	UNII	5315/63996 (8%)*
epSOSRoutesofAdministration	EDQM Standard Terms	55/73 (75%)	Medication Route FDA	NCI Thesaurus	57/118 (48%)
epSOSDoseForm	EDQM Standard Terms	28/457 (6%)	Medication Product Form	NCI Thesaurus	99/153 (65%)
epSOSUnits	UCUM	77/77 (100%)	UCUM Units of Measure	UCUM	77/557 (14%)
epSOSUnits	UCUM	6/77 (8%)	AgePQ_UCUM	UCUM	6/6 (100%)
epSOSIllnessesandDisorders	ICD-10	1775/9525 (19%) IHTSDO maps	Problem	SNOMED CT	7204/16443 (44%) IHTSDO maps
epSOSIllnessesandDisorders	ICD-10	1147/9525 (12%) NLM maps	Problem	SNOMED CT	6914/16443 (42%) NLM maps
epSOSCodeProb	SNOMED CT	7/7 (100%)	Problem Type	SNOMED CT	7/8 (88%)
epSOSStatusCode	SNOMED CT	3/8 (38%)	HITSPProblemStatus	SNOMED CT	3/3 (100%)
epSOSResolutionOutcome	SNOMED CT	7/8 (88%)	HealthStatus	SNOMED CT	7/7 (100%)
epSOSProcedures	SNOMED CT	102/102 (100%)	no specific value set, whole code system	SNOMED CT	N/A
epSOSMedicalDevices	SNOMED CT	70/70 (100%)	no specific value set, whole code system	SNOMED CT	N/A
epSOSVaccine	SNOMED CT	27/31 (87%)	Vaccine Administered	SNOMED CT	87/163 (53%)
epSOSSocialHistory	SNOMED CT	8/8 (100%)	Social History Type Set Definition	SNOMED CT	8/9 (100%)
epSOSPregnancyInformation	LOINC	3/3 (100%)	no specific value set, whole code system	LOINC	N/A
epSOSBloodGroup	SNOMED CT	12/12 (100%)	no specific value set, whole code system	SNOMED CT	N/A
epSOSBloodPressure	LOINC	2/2 (100%)	HITSP Vital Sign Result Type	LOINC	2/12 (1.7%)