15th International HL7 Interoperability Conference

Proceedings

Concept, Models and Implementations for innovative interoperable eHealth Solutions

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Health level Seven is an international community spreading its knowledge and wisdom by excellent worldwide standards. HL7 provides standards for interoperability that improve care delivery, optimize workflow, reduce ambiguity and enhance knowledge transfer among all of stakeholders, including healthcare providers, government agencies, the vendor community and patients. HL7 exhibits timeliness, scientific rigor and technical expertise without compromising transparency, accountability and practicality.

International HL7 Interoperability Conference (IHIC) has been a natural part of the HL7 life as a scientific forum for a long time. IHIC series was inaugurated in 2000 by Board of HL7 Germany. The first event in Dresden, Germany was entitled “Advanced Healthcare Information Standards”. To date we saw 14 meetings all over the world extending topics to concepts, models, testing, certification processes and in last resort to a Show me Your CDA practical session.

World-wide adoption of HL7 standards generates unbelievable large pool of people with a practical experience. In addition, there are more than 4000 officially certified HL7 experts. These people are not scientists anymore. Should we neglect their non-scientific knowledge? Can they bring innovations to HL7 standards?

On the other hand the number of contributions to IHIC slowly decreases from 33 in Kyoto (2009) to 22 in Vienna (2013). It proves my feeling that HL7 evolved to a next stage of its life cycle – mature enough to be a source of truth more than a field of research.

In such situation we decided to extend the topics of IHIC to strengthen the interaction between science and enormous practical experience. This year we, for the first time, directly invite implementers to share their experience.

In many cases people from industry are not able to follow the structure of a scientific paper (IMRAD). To overcome this typical barrier between scientists and industry originated in a different style and methodology, we asked implementers to write an implementation report or (at least) to submit an abstract of such report.

To date we received 28 submissions – 16 scientific papers, 2 practice reports and 10 abstracts of a practice report. Each scientific paper or practice report was reviewed by two reviewers; each abstract was reviewed by one reviewer. Three submissions have been withdrawn, two have been rejected. Eight scientific papers have been selected to be published in the special issue of European Journal for Biomedical Informatics (EJBI, Volume 11, Issue 2). At this point I would like to express many thanks to EJBI Special Issue guest editor Bernd Blobel for his excellent work and help he provided to me.

I expect that such a great mixture of practical and scientific experience can bring great discussion, enhance your points of view and in some cases may bring innovations on both sides – in industry as well as in medical informatics research.

Last, but not least I would like to thank the International Council of HL7 Int., HL7 Austria, HL7 Germany and HL7 Switzerland for a financial support and backup.

Libor Seidl
President of HL7 Czech Republic
January 20, 2015
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I would like to express many thanks for endless support and time I got from everyone above, even in a rush Christmas time and by the end of the year. Without such support the IHIC 2015 would never happen.

Thank you!

Libor Seidl
20th January 2015
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Providing Interoperability to a Pervasive Healthcare System
Through the HL7 CDA Standard

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Abstract

Background: Pervasive healthcare is a new paradigm of healthcare services where the patients are active participants on their own well being. The development of Pervasive Healthcare Systems (PHSs) consists on approaching monitoring solutions into the hands of the patients, and has been reported as a key to minimize the healthcare costs due to the aging of population. However, interoperability is a technological challenge not taken into account in most of the existing implementations of PHSs.

Objectives: This paper focuses on how we provide interoperability to a PHS for the management of the gestational diabetes mellitus (GDM) by using the CDA standard. In this monitoring system an Android application sends CDA documents to the server side of the system, so that the health information reported by the patient is transmitted over the Internet in an interoperable way.

Methods: The generated CDA documents report on three different aspects related with GDM that are: physiological parameters, symptoms and medications. Each one of them is encoded as a section in the body of the CDA. To build these CDA documents, different pre-installed XML templates are combined and filled by using XPath.

Results: Doctors using this system want that patients report both: the dose quantity taken and the dose prescribed for the insulin bolus. As a consequence we had to extend the SubstanceAdministration class with a new element to encode all the semantics.

Conclusions: This paper illustrates how the CDA document has been adopted to report on the health status of a GDM affected patient, and can be taken as a model to provide interoperability to other PHSs.

Keywords
Pervasive healthcare, CDA Document, Standard Vocabularies, Gestational Diabetes Mellitus (GDM), Multiagent systems

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1 Introduction

Pervasive healthcare is a discipline involving the use of the ubiquitous computing technology in the healthcare environment [1]. As defined by Varshney [2], pervasive healthcare is the "healthcare to anyone, anytime, and anywhere by removing locational, time and other restraints while increasing both the coverage and the quality of healthcare". This new paradigm of healthcare services tries to modify the healthcare service delivery model, by moving it from a centralized approach focused on doctors to a decentralized one based on the patients [3].

The development of Pervasive Healthcare Systems (PHSs) has the potential to provide better healthcare services to an increasing number of people, and to reduce the long-term cost of the healthcare services [4]. However, when developing this kind of systems some technological challenges must be taken into account such as interoperability, scalability and security.

Interoperability is defined by the IEEE as "the ability of two or more systems or components to exchange information and to use the information that has been exchanged" [5]. However, as stated in [3] interoperability is not taken into account in most of the PHSs implementations, resulting in segmented solutions that are highly specific in nature, often known as the so called "closed" systems. These systems are not able to communicate with other components in order to support a collaborative behavior, and to achieve interoperability between different
PHSs is mandatory the use of standards such as the ones developed by the HL7 organization.

This paper focuses on the Gestational Diabetes Mellitus Management System (GDMMS) [7] is a PHS based on multiagent systems to continuously monitor women affected by Gestational Diabetes Mellitus (GDM). The multiagent platform of the system analyzes the physiological data from the patients and provides alerts when potentially dangerous situations are detected. In [5] we described how the security of the system is addressed, while in [9] we provided a study on the scalability of the system. In this work we describe how we have achieved the interoperability of this system through the compliance of the HL7 standard.

In particular, the main contribution of this paper is to show how we have used the Clinical Document Architecture (CDA) to record the monitoring status of the patient and send this healthcare-related information from the client side to the server side of the system. By doing this we extended the current functionality of the GDMMS, enabling it to collaborate with other heterogeneous systems already using the CDA standard.

1.1 GDMMS Pervasive Healthcare System

The aim of the GDMMS system is to help with the treatment of GDM, a type of diabetes affecting 3%–10% of all pregnant women due to an increased resistance to insulin. GDM can increase the risk of health problems developing in an unborn baby, so it is important that the glucose levels in the pregnant woman blood are under control.

Figure 1: Architecture of the GDMMS PHS.

With GDMMS, pregnant women affected by GDM are monitored by means of using an Android smartphone, which allows them to introduce health data related with GDM such as physiological parameters, symptoms and medications. The healthcare professionals can also log on to the system to visualize and analyze data form patients. The system allows both, patients and their caretakers, being informed with historical values and receive alerts when dangerous situations are detected.

Figure 2: Main screen of the Android application.

The Web server layer is composed by a web entry gate which takes care about the http requests, and the certificates of the clients and a web server containing the presentation layer, which is responsible for handling the requests from the doctors and interacting with the business layer to implement the requests.

The Application server has four main components. The i) security proxy generates and sends a security token for the clients on its first request. In the following requests checks the validity of the token (i.e. it has not expired). The ii) services checks whether the requests have the right arguments, and forwards them to the business layer. The iii) business layer implements the core functionality of the system. Finally the iv) data access layer provide access to the data that is hosted on the database server.

The GOLEM monitoring system has three main components. The i) GOLEM balancer is a web service that receives notifications from the business layer, consisting on the health data from the patient. The ii) GOLEM environments are containers which contain the monitoring agents. There is one agent per patient that is in charge of generating alerts about hypoglycemia, repeated hyperglycemia and hypertensive states, by analyzing patients’
data according to a set of abductive and deductive rules. The iii) GOLEM database stores the inactive monitoring agents.

Finally, the Database stores all patients’ information: demographics, health values and alerts. We refer the interested reader to [10] for more detailed description of the system.

2 Interoperability in the GDMMS

The client side of the GDMMS PHS for the patient consists on an Android application in which the patient can enter a series of health data related with GDM. Figure 2 shows the main screen of the application with the different categories that the patient can report about. Table 1 shows the elements that can be reported in each category. The application also allows a patient to check and eventually correct the data she has entered. All data are stored encrypted in the phone and sent to the server side for further processing if the phone has network connection.

Table 1: Health data related with the GDM encoded in the body of the CDA document.

<table>
<thead>
<tr>
<th>Physiological Parameters</th>
<th>Blood pressure</th>
<th>Heart rate</th>
<th>Blood sugar</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms</td>
<td>Chest pain</td>
<td>Edema</td>
<td>Blurred vision</td>
<td>Headache</td>
</tr>
<tr>
<td>Medications</td>
<td>Insulatard</td>
<td>Huminsulin basale</td>
<td>Levemir</td>
<td>Novorapid</td>
</tr>
</tbody>
</table>

We have encoded all the health information from Table 1 using the CDA standard to send the data from the phone to the server side in this standard format. The client side application creates a CDA document with all the unsent health values entered by the patient, and sends it to the server side when there is network connection. In order to do this we added a package to the source code containing all the necessary classes to create the CDA (Figure 3 shows a UML diagram of the classes). The CDADocument class corresponds to the clinical document intended to send, and it contains all the necessary methods to build it. In addition, each one of the rest of the classes is linked to an XML template file already formatted according to its representation in the CDA standard. When building the document all the necessary XML templates are collected, their variable values and attributes are selected using XPath expressions, and the missing values are filled with its corresponding string representation. Figure 4 shows the XML template used for a blood glucose entry, and the XPath expressions used to fill the elements of this template.

Sending the data from the client side of the system in a standard way implies changes in the server side, in order to properly handle the connections. On the other hand, a CDA document is persistent in nature and maintained by an organization entrusted with its care [11]. These facts are reflected by the change of the relational database by a XML database using BaseX, which allows to store the clinical document in its original format. This also implies the use of XQuery to query the information on the CDA documents. Next we explain the structure of each part of the CDA document.

2.1 CDA Header

The header part of the CDA implementation contains only the mandatory elements required by the standard. The optional elements are not used in order to minimize the amount of data sent through the network interface of the mobile phone.

Every header part establishes the default context for the contents of the clinical document. The set of minimum mandatory elements to set this context includes the following:

- The identification of the document, which is defined with the <id> element. This XML element has two attributes: root and extension. The root attribute identifies the universe of the clinical document, and the extension provides the uniquely identification for the clinical document.

- The type of document, specified with the <code> element. We use the LOINC code *51855-5* with name "Patient Note", as it describes well the type of clinical document we want to generate because

---

1http://www.basex.org
2http://s.details.loinc.org/LOINC/51855-5.html
it states "A patient authored note is generated by a patient, or a patient agent, acting in a non-clinical role to provide clinically relevant information".

- The creation time of the document, defined with the <effectiveTime> element.
- The confidentiality of the document, defined with the <confidentialityCode> element.
- The patient (or patients) whose document belongs to. All the patients’ information is inside the <recordTarget> element. It can include the name, gender, address and other information, but the only mandatory field is its identification specified with an <id> element.
- The author of the document, can be someone or some device with the role of author. The author is defined with the <author> element, and its child <assignedAuthor>. Again, the author can be specified by providing its name, address, phone, email, but the only mandatory field is its identification specified with the <id> element. In our case the patient and the author of the document are the same person.
- The organization that is in charge of maintaining the document, defined by the <custodian> element. Although the name, address, telephone and other information about the organization can be specified, the only mandatory element is the <id> element.

Table 2: LOINC codes used to identify each section of the body.

<table>
<thead>
<tr>
<th>Section</th>
<th>Code</th>
<th>Display name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physiological Parameters</td>
<td>8716-3</td>
<td>Vital signs</td>
</tr>
<tr>
<td>Symptoms</td>
<td>10164-2</td>
<td>History of present illness</td>
</tr>
<tr>
<td>Medications</td>
<td>10160-0</td>
<td>History of medication</td>
</tr>
</tbody>
</table>

2.2 CDA Body

The body part of the CDA implementation is a XML structured body divided in three different <component> elements each one with one <section> element. Each section encodes one of the following groups: physiological parameters, symptoms, and medications. In addition, each section has <entry> elements encoding the medical information from the second column of the Table. Furthermore, the sections are identified by a LOINC code using the <code> element using its corresponding code and display name attributes (see Table 2). Other standard vocabularies used in the body are SNOMED CT to encode physiological parameters, ICD-10 for symptoms and ATC for medication.

2.2.1 Physiological Parameters

The section corresponding to the physiological parameters can have four different kind of entries wrapped by <entry> elements, each one coding a different physiological parameter. These parameters can be the blood pressure, the heart rate, the blood sugar, or the weight. All of these physiological parameters are encoded as observations using the <observation> element. An observation is an act which can be though as a "non-altering" procedure that results in a value. In the case of this section a value is a physical quantity of a physiological parameter, although it can be virtually anything.

Table 3: SNOMED CT codes used to identify the physiological parameters.

<table>
<thead>
<tr>
<th>Physio. param.</th>
<th>Code</th>
<th>Display name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood pressure</td>
<td>251076008</td>
<td>Cuff blood pressure</td>
</tr>
<tr>
<td>Systolic blood p.</td>
<td>271649006</td>
<td>Systolic BP</td>
</tr>
<tr>
<td>Diastolic blood p.</td>
<td>271650006</td>
<td>Diastolic BP</td>
</tr>
<tr>
<td>Heart rate</td>
<td>3640759005</td>
<td>Heart rate</td>
</tr>
<tr>
<td>Blood sugar</td>
<td>302789003</td>
<td>Capillary blood glucose measurement (procedure)</td>
</tr>
<tr>
<td>Weight</td>
<td>363808001</td>
<td>Body weight measure</td>
</tr>
</tbody>
</table>

Each physiological parameter is identified by its corresponding SNOMED CT code using the <code> element (see Table 3), specifies its measure units in the unit attribute of the <value> element, and has associated metadata such as the time of the measurement specified in the value attribute of the <effectiveTime> element. Figure 5 shows the encoding of the blood pressure. The class code attribute of the <observation> element defines the kind of the act that is, while the mood code attribute describes its placement in time. In this case the value of the mood attribute is "Body weight measurement".

Figure 4: XML template for the blood glucose entry and XPath expressions to select components.
code of all physiological parameters is "EVN" as it defines an act that has already occurred.

The encoding of the blood pressure differs from the other physiological parameters as it consists of two different parameters, the systolic and the diastolic blood pressure. This relationship is encoded with two different <entryRelationship> elements inside the <observation> element. The encoding of the heart rate also differs from the other physiological parameters as it is measured in beats per minute (bpm). This fact is expressed with a <denominator> element which is a child of the <value> element.

Table 4: ICD-10 codes used to identify the symptoms.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Code</th>
<th>Display name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest pain</td>
<td>R07.4</td>
<td>Chest pain, unspecified</td>
</tr>
<tr>
<td>Edema</td>
<td>O12.0</td>
<td>Gestational oedema</td>
</tr>
<tr>
<td>Dyspnoea</td>
<td>R06.0</td>
<td>Dyspnoea</td>
</tr>
<tr>
<td>Blurred vision</td>
<td>H53.8</td>
<td>Other visual disturbances</td>
</tr>
<tr>
<td>Headache</td>
<td>R51</td>
<td>Headache</td>
</tr>
<tr>
<td>Epigastric pain</td>
<td>R10.1</td>
<td>Pain localized to upper abdomen</td>
</tr>
</tbody>
</table>

2.2.2 Symptoms

The section corresponding to the symptoms can have six different kind of entries, each one coding a different symptom. The symptoms, as the physiological parameters, are encoded as observations with the <observation> element. The identification of the symptom is done using the ICD-10 vocabulary (see Table 4 for the codes). In each symptom entry the child <code> element of the <observation> provides the identification of the symptom. Every symptom has associated metadata corresponding to the time in which the symptom occurred. Figure 6 shows an example encoding the headache symptom.

2.2.3 Medications

The section corresponding to the medications can have six different kind of entries, each one coding a different medication. All the medications of this section are kinds of insulin as the PHS is focused on the management of the GDM. In this section the medications are encoded using the <substanceAdministration> element. This element is intended to represent the administration of a particular substance, e.g. a medication, immunization or other substance to a patient [11].

Table 5: ATC codes used to identify the medication.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Code</th>
<th>Display name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulatard</td>
<td>A10AC01</td>
<td>insulin (human)</td>
</tr>
<tr>
<td>Huminsulin basale</td>
<td>A10AD01</td>
<td>insulin (human)</td>
</tr>
<tr>
<td>Levenir</td>
<td>A10AE05</td>
<td>insulin detemir</td>
</tr>
<tr>
<td>Novorapid</td>
<td>A10AB05</td>
<td>insulin aspart</td>
</tr>
<tr>
<td>Humalog</td>
<td>A10AB04</td>
<td>insulin lispro</td>
</tr>
<tr>
<td>Metformin</td>
<td>A10BA02</td>
<td>metformin</td>
</tr>
</tbody>
</table>

Each medication is identified using its ATC code (see Table 5). In addition the <name> element provides the name of the medication as it appears in the mobile application. Figure 7 shows an example of the encoding of one drug. The metadata associated with the medication entry are: i) an optional comment related with the entry that the patient can write into the mobile application wrapped with the <text> element, ii) the time when the medication was taken encoded with two <effectiveTime> elements, and iii) the dose amount taken by the patient and the dose amount prescribed by the doctor, both expressed as insulin units (IU).

In the mobile application the time at which a medication was taken is specified with two elements: a time stamp, and a text specifying when was the dose taken e.g. before breakfast, after breakfast, etc. Besides, the <substanceAdministration> element of the CDA specifies the dose frequency with <effectiveTime> elements using the General Timing Specification (GTS) data type. The GTS data type allows to express complex timings as

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CoICVApAPCM
anpAPCD
Meaning
anA PCV
10
Brugués
use the
taken. To encode the insulin dose taken by the patient we
take. From the type and amount of meals
which is the right dose of insulin she needs, as the blood
taken. To encode the insulin dose taken by the patient we
sugar levels depends on the type and amount of meals
taken. To encode the insulin dose taken by the patient we
the doctor and the insulin dose really in-
application the patient can type both, the insulin dose
fixed by the HL7 standard. Table 6 shows the ones we have used in our application.
The <substanceAdministration> element only allows the codification of one dose. However, in the mobile
application the patient can type both, the insulin dose
prescribed by the doctor and the insulin dose really in-
exposed. This is because diabetes is a self-managed disease,
so the patient has certain degree of autonomy in deciding
which is the right dose of insulin she needs, as the blood
sugar levels depends on the type and amount of meals
taken. To encode the insulin dose taken by the patient we
the <doseQuantity> element defined by the standard,
and we added the <dosePrescribed> element to encode
the dose prescribed by the doctor. This is the only XML
element we have defined in the whole CDA in order to be
able to encode all the health-related data specified into
the mobile application. The addition of locally defined
XML elements is something allowed by the standard as
in the Section 1.4 it states "Locally-defined markup may
be used when local semantics have no corresponding rep-
representation in the CDA specification."

Table 6: Event related timing codes used to identify times of the
day.

<table>
<thead>
<tr>
<th>Time of the day</th>
<th>Code</th>
<th>Meaning (from lat.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before breakfast</td>
<td>ACM</td>
<td>ante cibus matutinus</td>
</tr>
<tr>
<td>After breakfast</td>
<td>PCM</td>
<td>post cibus matutinus</td>
</tr>
<tr>
<td>Before lunch</td>
<td>ACD</td>
<td>ante cibus diurnus</td>
</tr>
<tr>
<td>After lunch</td>
<td>PCD</td>
<td>post cibus diurnus</td>
</tr>
<tr>
<td>Before dinner</td>
<td>ACV</td>
<td>ante cibus vespertinus</td>
</tr>
<tr>
<td>After dinner</td>
<td>PCV</td>
<td>post cibus vespertinus</td>
</tr>
<tr>
<td>Later</td>
<td>ICV</td>
<td>inter cibus vespertinus</td>
</tr>
</tbody>
</table>

The addition of the <dosePrescribed> element has
some implications with respect the interoperability with
other systems. In particular, the validation of a CDA
containing extensions must be done in stages [11]. The
first stage should validate the extension content, by using
W3C Schema or ISO Schematron that must be provided
to the rest of applications. Once the extensions are
validated, these must be removed before other validations
occur. This is something that can be done using a XSLT
stylesheet.

3 Discussion

Interoperability has been taken into account in previous
research on PHSs [12, 13, 14]. We also can find in the
literature research projects which have already used the
CDA standard to provide interoperability. All these sys-
tems already using the CDA can interoperate with ours
by combining them in different ways. Although these in-
tegrations are not straightforward, the use of the CDA
standard can minimize the efforts to achieve them.

In [15] the authors report a Home Telecare System
(HTS) consisting of a patient database and a report sys-
tem. The database stores parameters extracted from raw
signals of vital signs, whereas the report system takes the
data from the database to perform analysis on it. The
report system is also in charge of generating the clinical
document of the patient by first converting the informa-
tion stored on the database to XML format. Whereas
in this system the CDA report only contains vital signs,
in GDMMs the CDA report contains information about
symptoms and medications too. Furthermore, in GDMMs
the use of the mobile phone allows the mobility of the pa-
tient while being monitored. Thus, the GDMMs could
complement that system by extending its capabilities.
To achieve that inclusion relationship the information about
symptoms and medications could be sent to the database,
and the report system should include these sections in the
generated CDA reports.

A smart home healthcare system is presented in [16].
This system is for monitoring Alzheimer patients in their
homes, while GDMMs is for monitoring GDM patients
everywhere. In this smart home the data about different
activities are collected through motion sensors, preprocessed
using different algorithms (sensory based, video based, lo-
ocation tracking), and stored in XML format. Each activity
includes information about type of activity, sensor infor-
mation, name of the person, activity name, identification
of the sensor location, and occurrence time of the activity.
A CDA document is generated reporting the activities of the
Alzheimer patients, which can be transmitted to all
registered healthcare systems with the smart home. This
system and GDMMs monitors different kind of diseases.
Thus, they could have a comorbidity relationship by com-
bining the functionalities of both systems.

In [17] the authors propose a novel framework fo-
cused on medication treatment manager, to provide safety
with respect the medication by coping with Adverse Drug
Events (ADEs). Their architecture is composed of two
subsystems the patient site and the medical site. Patient
site has a body area network with sensors measuring the
blood pressure and the heart rate, and a Mobile Base Unit

Figure 6: Headache symptom encoded in the CDA.
(MBU) which coordinates the sensor network and notifies the monitoring to the medical site. The medical site is in charge to store the sensed parameters at the patient site and to send to the MBU information related with the prescription such as treatment goals in terms of monitored signs, important ADEs that may occur, and ADE detection patterns. From the medical site to the patient site the drug prescription information is encoded using an own schema, while in the reverse channel like in GDMMS the reports of the monitoring are provided by using the CDA. The functionality related with ADEs of that system could be included in the GDMMS, and complementing it with an inclusion relationship.

All the reviewed systems address the interoperability by generating CDA documents, which report the monitoring state of the patient. However, none of them provides information about how they have followed the standard nor the structure of the generated CDA reports.

On the other hand, the industry sector is more concerned with interoperability. In particular HL7 in conjunction with Continua have published the Personal Healthcare Monitoring Record (PHMR), an implementation guide for the CDA which constrains the elements of the CDA header and body. The PHMR is intended to represent measurements captured by monitoring devices such as glucometers, blood pressure cuffs, etc. to transmit the information about the measurements in a standard way. In fact this implementation guide has a required section on the sensors used for the measurements. Our proposal differs from the PHMR in the sense that is more oriented towards the patient. This is reflected in the fact that the PHMR has no symptoms section as these are subjective, and therefore can be only reported by the patient. So that we decided to use the CDA as it is more general and already comprises what the PHMR models.

4 Conclusions and Future Work

Most of the PHSs we can find in the literature do not consider the interoperability as a concern [6]. In this paper we have described how we have implemented the HL7 CDA standard in a particular PHS in order to achieve interoperability. We used the CDA to produce a clinical document which states in three different sections the physiological parameters, the symptoms and the medication taken by the patient. We believe our work can be taken as a model to provide interoperability to further implementations of PHSs.

Furthermore, we conclude that there is a need to extend the CDA specifications in order to consider patients’ involvement in the monitoring process. For example, in GDMMS we have two types of insulin doses, the one taken by the patient and the one prescribed by the doctor, and in the CDA standard there is only one attribute to encode specific dosages. Thus, we added the <dosePrescribed> element to model the insulin dose prescribed by the doctor and we used the <doseQuantity> element of the standard to specify the insulin dose taken by the patient. We also assume that in a real scenario, a code for the organization owning the document should be requested to the HL7 organization in order to identify it with a unique ISO Object Identifier (OID).

As a future work we plan to move the multiagent platform from the server side to the client side of the system. Thus, the alerts generated by the monitoring agents can be encoded as a new section inside the CDA document already generated by the mobile phone.

Acknowledgments

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References


Figure 7: Levemir medication encoded in the CDA.


A model for realizing interoperable EHR systems in Italy

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Abstract

Background: The Italian Constitution delivers autonomy to each Region about healthcare, thus fostering the proliferation of heterogeneous healthcare information systems. In this scenario, realizing interoperable regional EHR systems, and at the same time, satisfying all the complex requirements and constraints indicated by a recent Italian law, is very challenging.

Objectives: This paper describes the process undertaken in Italy to implement a nationwide interoperable EHR system by supporting the development of homogeneous regional solutions in order to improve healthcare efficiency and reduce costs.

Methods: An architectural model has been designed i) by respecting a shared ISO/HL7 EHR-S FM-based functional model defined at the national level, ii) by specifying a topology both at the regional and national level able to ensure technical interoperability and security, and iii) by identifying solutions for an unambiguous exchange of clinical documents and data through HL7 CDA Rel. 2 and LOINC standards.

Results: A federated architectural model which aims at enabling both technical and semantic interoperability among various regional healthcare information systems has been devised. The model has been approved by the Agency for Digital Italy, the Ministry of Health, governmental institutions, Regions and Autonomous Provinces.

Conclusions: This work represents an important first step into the process of digitalizing the Italian health record system. The proposed model is turning out to be successful for both Regions that have already started an e-health process and Regions that are still at the starting line. Further technical details are still to be defined along with the implementation process.

Keywords

Electronic Health Record; Italy; Interoperability; Architectural Model; LOINC

1 Introduction

The Electronic Health Record (EHR) is a "longitudinal collection of health data and documents about an individual’s lifetime with the purpose of supporting continuity of care, education and research, and ensuring confidentiality at all times" [1]. Clinical information produced in healthcare facilities is collected by using an EHR system (EHR-S), in order to make it available to healthcare professionals. Thus, such systems allow to obtain a considerable amount of health information, which could be used to improve both quality and efficiency of medical care.

Nowadays patient mobility is substantially increasing, as more and more patients receive medical treatments in areas that are different from where they live [2]. This has imposed the urgent need to integrate healthcare systems of different regional domains, hence realizing the abstraction of a unique virtual EHR.

At the European level, the development of EHR-Ss has been slow if compared to the development deriving from the use of ICT in other sectors. In 2008, the EU Commission set 2015 as the target year for EHR interoperability [3], therefore, many European countries have been studying how to address issues related to the realization of national EHR-Ss [4][5].
In Italy, so far, each Region has autonomously started the realization of its own EHR-S, thus providing some EHR services to citizens, or at least laying the foundations for their provision. The heterogeneity of such systems has resulted in an interoperability issue. Thus, in the last few years, a lot of work has been done by governmental institutions, regional administrations, and public research centers aiming at creating a cooperative network to define regulations for health data management, acquiring both International Standard Board guidelines and EU recommendations. Among these efforts, the InFSE project [6] aimed at proposing a technological infrastructure for making heterogeneous health information systems mutually cooperate among each other. Such a proposal has been approved by the “Tavolo di lavoro permanente per la Sanità Elettronica” (TSE), including representatives of the 19 Italian Regions and 2 Italian Autonomous Provinces. The feasibility of the proposed solution has been proven through experiments that involved 10 different regional systems, namely the national IFSE project (part of the European epSOS project). At the end of the InFSE project, it was possible to identify the main requirements and challenges for realizing a national EHR solution.

Between 2012 and 2013 two government laws (L. 221/2012 [7] and L. 98/2013 [8]) urged Regions to implement their own EHR-Ss by June 2015 according to specific technical interoperability requirements, subsequently defined in March 2014. In order to accomplish the numerous and complex requirements and constraints, the Agency for Digital Italy and the Ministry of Health have established a dedicated Technical Board, including representatives of Italian Regions, the Ministry of Economy and Finance, and the Italian National Research Council, which has elaborated a set of guidelines for the homogeneous realization of the regional EHR-Ss [9].

With regards to such an effort, this work describes: i) a federated architectural model approach, at both national and regional levels, for the realization of interoperable EHR-Ss by satisfying shared functional requirements, and ii) a methodology for ensuring a semantic meaningful frame by the use of standardized terminologies and data logical organization.

The organization of the rest of the paper is as follows. Section 2 outlines the main interoperability requirements for the realization/adjustment of regional EHR systems. Section 3 describes the reference architectural model for the regional systems, both at regional and national levels. Section 4 details the main security issues and proposed approaches. Section 5 is dedicated to the description of the methodology proposed to manage clinical documents and data content in order to assure semantic interoperability. Section 6 presents some working scenarios. Finally, Section 7 concludes the paper.
the objective of defining a common functional model for EHR-Ss and their meaningful use. The functional model, obtained by localizing the HL7/ISO EHR-S FM standard, allows defining, in a structured and integrated way, a set of business functions for the EHR, delegating implementation details about the realization of interoperable EHR-Ss. The profile, published by HL7 Italy, has been defined through an analysis of the existing laws, rules, work processes, and actors involved in the use of an EHR-S.

3 The proposed architectural model for EHR-S interoperability

The proposed architectural solution is based on a federated model, as shown in Figure 1, which focuses on the cooperation of local nodes.

Specifically, the nationwide EHR-S is based on a system of systems approach, where each regional system is realized by taking into account local needs. In order to do this, each system has to expose a set of specific services, which provide all the functionalities needed to manage, search, and consult data and documents. The main components that have to be realized in a regional EHR-S are shown in Figure 2.

3.1 Topology of the regional architectural model

The architecture of the regional EHR-Ss consists in a set of different subsystems, as the information systems of the Local Health Offices, hospitals, pharmacies, clinic laboratories, physicians’ offices, etc. Thus, regional systems have to i) allow searching and retrieving of clinical data and documents to all the authorized users, and ii) provide the functionalities for managing both clinical documents and data and their associated meta-information. In addition, to control data access, the systems have to both authenticate healthcare professionals and identify their patients, which is why it is necessary to manage a Master Data of both healthcare professionals and patients.

Management of clinical documents and data

As abovementioned, an EHR-S has to interact with several information systems that generate clinical documents and data. In general, there are two possible architectural models that can be adopted to collect such information. The first one is based on a centralized approach, meaning that each time that clinical information is produced, this has to be forwarded to a centralized system. The second solution involves the use of distributed repositories in the regional area, where clinical documents and data are stored. The latter solution is the most suitable in large regional domains, because it allows healthcare facilities to keep under their own responsibility data and documents they generate. The regional system must so arrange a service for:
• clinical data and documents publication in the EHR;
• retrieving clinical data and documents.

Management of meta-information

Documents and data have to be described by opportune meta-information (i.e. metadata), to be easily retrievable even if distributed in different regional healthcare facilities. The chosen approach lies on the adoption of the registry/repository paradigm, which consists in managing documents in repositories and their meta-information in one or more index registries. Meta-information comprises a set of data that describe clinical documents, thus allowing document indexing (e.g. author name, document type, document production date, repository reference, etc.). Some meta-information can identify each document, namely the healthcare facility code and the document identifier. Querying the regional registry (centralized at the regional level) allows locating and then retrieving a clinical document. Obviously, the larger and more exhaustive the set of meta-information is, the higher the expressiveness of queries can be. For such a reason, the regional system must establish a service for:

• submitting meta-information to the regional registry whenever a new document is generated;
• querying the regional registry, to obtain the metadata related to the documents satisfying the searching criteria.

Master Data management

Accessing an EHR-S has to be preventively authorized by the regional system. In particular, access authorization depends both on the user who is requesting access and the patient who required clinical information and who the documents refer to. For this reason, healthcare professionals have to be first authenticated and then authorized. Moreover, the patient has to be identified to assure that the required information is related to the correct patient.

Thus, the system should be able to consult a Master Data system for healthcare professionals enabling the certain identification of the professionals and pinpointing the possible roles that the professional can assume in the system. A possible solution is to centralize a Master Data for the healthcare professionals, and similarly manage a patient Master Data. To this aim, a national centralized service aiming at containing certain information about patients is being devised. This system therefore has to offer a service for:

• querying the healthcare professionals Master Data;
• querying the patient Master Data.

Access user interface

Each regional EHR-S has to provide access to the offered functionalities to both healthcare professionals and patients. To this aim, it is possible to offer either a cen-
3.2 Topology of the national architectural model

The topology of the national architectural model of the EHR-S aims at enabling interoperability among different regional systems and allowing the exchange of clinical data and documents. In this scenario, the first need is allowing users to locate clinical information that can be distributed on the entire national territory, i.e. patients’ clinical documents and data can be archived in different regional information systems. This makes the retrieval task quite complicated. The simplest solution consists in querying all the regional registries; this, however, would lead to an all-time high in search, which could be fatal for the whole system. The chosen approach lies in the identification, in each regional domain, of a node in charge of managing all the meta-information about a patient. Specifically, the health care assistance Region of the patient is responsible for managing meta-information associated to his/her clinical documents, even if they are produced in another regional domain. Thus, in order to consult a document located outside a regional domain, it is first necessary to identify such a Region and then to interrogate its regional system in order to locate the specific healthcare facility in which the document is stored.

Business processes

The business processes identified at the national level involve three kinds of actors: provider nodes, consumer nodes, and support nodes. A provider node is a system that offers a service; a consumer node is a system that requires a service; whereas, a support node is a system that provides support services. The main business processes defined are:

- **Search for documents and data:** it allows a user (consumer node) to contact an appropriate provider node (the system of the health care assistance Region) to search for documents and data. The provider node will give back, if present and if the user is authorized, the meta-information to retrieve the searched documents.

- **Create new documents or data:** it allows a user (consumer node) to create new documents or data related to a patient assisted by another regional domain (provider node). For this reason, the system manager of the document or data has to send the meta-information to the patient’s health care assistance Region.

- **Retrieve documents and data:** it allows the consumer node to send a request to the provider node (which manages the documents or data of interest) for retrieving specific clinical information.

- **Change health care assistance Region:** it permits to transfer all the meta-information related to the documents and data of a given patient to a new health care assistance Region.

The formalization of the main business processes allowed the identification of the most important interoperability services that each regional system has to offer.

3.2.1 Interoperability services

To realize an interoperable federation of the regional EHR-Ss, all local nodes have to cooperate according to a federated model, by exposing a set of services with a standardized interface. The most important services to be offered in an interregional context are:

- **Searching service:** it allows the retrieval of meta-information for locating documents and data that meet proper searching criteria. Each regional system has to be able to invoke the service offered by the patient’s health care assistance Region.

- **Retrieving service:** it permits the retrieval of clinical documents or data, after the searching service has been invoked. Each system has to be able to invoke the service offered by the system in charge of maintaining the documents or data to be retrieved. This information can be obtained by consulting the meta-information provided by the searching service.

- **Indexing service:** it is in charge of sending and receiving a set of metadata related to a document that is created in a regional domain different from the health care assistance Region of the patient who the document refers to.

Furthermore, regional systems have to arrange other supporting services, such as those related to security, as described below.

Implementation details

The proposed architecture is based on a Service-Oriented Architecture, by adopting the Web Services technology. The definition of technical specifications according to consolidated international standards for the development of the services and the provision of the message formats is a work in progress.

4 Security aspects

This section describes the EHR-S security requirements and presents the security model proposed to satisfy such requirements on both regional and national levels.
4.1 Regional security requirements

The main security requirements that must be satisfied at the regional level are:

- Consent management.
- Visibility policies and obscuration.
- Access control.
- Patient identification.

Consent management

Italian law states that a patient has to provide both "uploading" and "consultation" consents. Each regional system has thus to be able to collect and store its patients’ consents and manage them in a way that they can be automatically verified whenever there is an access request to the EHR-S. For example, a new document will be entered into the system only if the patient has given an explicit uploading consent; when searching for a document, it will be localized if the patient has provided a consultation consent to the healthcare professional role that is performing the search. A possible solution for handling patient consents is storing consent information in the centralized registry or a related repository at the regional level.

Visibility policies and obscuration

Patients have to be able to specify the level of privacy they want to associate to their documents and data, according to specific visibility policies, and to "hide" their documents and data to specific or all healthcare practitioners. The security model proposed, according to the indications of the Italian Data Protection Authority, allows patients to indicate the set of healthcare professional roles that can have access to each clinical document type of their EHR and also to obscure (making inaccessible) their documents and data to specific healthcare professional roles, including not letting them known that those documents and data exist (that is, obscuring the obscurity).

Access control

The security model is based on an Access Control (AC) mechanism consisting in two phases: i) authentication of professionals and patients, and ii) verification of the authorization for accessing clinical documents and data. The AC mechanism must meet the patient’s privacy wishes, as the clinical data and documents can be managed by the EHR-S only if the patient has given his/her consents and the request satisfies the policies provided by the patient. During the authentication phase, the security subsystem must verify the identity of healthcare professionals and patients (through the interaction with a Master Data) and associate them to their appropriate role. If a user holds more roles, he/she has to specify the role assumed in the current context.

Patient identification

When a healthcare professional searches for clinical data or documents, it is crucial that the patient is preliminary identified. This is because the healthcare professional has to be sure that the clinical information that he/she will receive in response is related to the patient for whom he/she carried out the search. The solution used so far consists in providing a Region with one or more patient Master Data. Nevertheless, the national centralized patient Master Data, currently under development, should replace the regional ones.

4.2 National security requirements

The security model at the national level meets the following main requirements:

- Access control (authentication/authorization).
- Patient identification.
- Secure message exchange.

Obviously, the fulfilment of the security requirements at the regional level is a prerequisite to assure security at a national level.

Access control (authentication/authorization)

Access control at the national level, consisting of an authentication and an authorization phase, is realized according to a federated approach.

The authentication phase aims at verifying the identity of the healthcare professionals and has to be realized by the consumer system (which owns the Master Data of its healthcare professionals). The authorization phase, instead, allows evaluating whether a user can or cannot access required services and data, and it has to be realized in the provider regional system. For this reason, it is necessary to establish a proper single-sign-on mechanism at the national level. In the proposed solution, the consumer system, after verifying the correct authentication of a healthcare professional, has to generate an appropriate portfolio of assertions that contains a series of attributes related to the healthcare professional, which has to be sent to the provider system. The provider system must first verify the validity of the received portfolio (e.g. digital signatures) and then may or may not authorize the healthcare professional to access the requested resources.

As the management of consents and clinical information in the EHR-S is under the responsibility of the health care assistance Region, for each access request it has to check the effective presence of the given consents and the satisfaction of the visibility policies provided by the patient.
5 Information management

Managing information of the EHR-S is not only a matter of retrieving and exchanging documents, but it is especially related to mutually understanding what is in them. Not everything which is called with the same name necessarily refers to the same thing. Ambiguity deriving from language can only be overcome by using standards. In this proposal, standards for both defining document structure and encoding its content have been identified. In both cases, also by looking at some European experiences, they have not been introduced as they are, but progressively localized to the Italian scenario for the parts they allow to customize. Further details about the usage of HL7 CDA Rel. 2 and coding systems are described in the paragraphs below together with some use case scenarios.

5.1 Document management and format

According to the Italian legislation, only PS and Laboratory Reports are mandatory in the first EHR implementing phase. Step by step, all the other kinds of clinical documents will be introduced. To the aim of semantic interoperability, exchanged clinical documents have to be structured by using HL7 CDA Rel. 2 (ISO HL7 27932:2009) and clinical information embedded in them has to be encoded by using specific national and international classification systems and specialized terminologies [9]. HL7 CDA is an XML-based document architecture for the exchange of clinical information. It has been strongly recommended by the Italian government since 2009 through different guidelines released by TSE in cooperation with representatives from the Italian Regions and Autonomous Provinces. Because CDA is built on XML, it is flexible enough to cover different needs such as having narrative blocks without mark-up. Even if they constitute a limitation to the full interoperable use of CDA documents, they have been allowed as a temporary compromise in the CDA implementation process. As clinicians hardly give up their aptitude at free-text narrative reporting, it has been a chance to become more familiar with the new technology before using it at operating speed. Even if clinical content is not codified, documents are highly structured and this allows finding data in them. This smooth transition from unstructured to highly structured documents turned out to be a productive solution in a mostly "paper-based healthcare". Moreover, CDA has the advantage of being "invisible" to the user as documents are human-readable. European experiences of success in adapting HL7 CDA to national contexts and needs [15] show how efficiently integrating internationally standardized elements and nationally or locally customizable parameters is the strong point of the standard.

5.2 Clinical data encoding

The national and international classification systems and specialized terminologies defined by law for encoding clinical content in PS and Laboratory Reports are: the International Classification of Diseases 9th revision — Clinical Modification (ICD9-CM); Logical Observation Identifiers Names and Codes (LOINC) for both document type identification and tests encoding; AIC (Autorizzazione all’Immissione in Commercio) and ATC (Anatomical Therapeutic Chemical classification system) codes for drugs identification. With specific reference to LOINC, it is a standardized system of clinical and laboratory observations codes. HL7 CDA document types and sections
are identified by LOINC codes and, moreover, they convey unique identification for laboratory tests and clinical exams into structured clinical records. The chance to have LOINC fully specified names in Italian – in 2010 the CNR started the translation as the official Italian partner of the Regenstrief Institute (RI) [16] – has facilitated the use of both document types and section codes and laboratory observation codes. Some of the LOINC names did not need to be merely literally translated but adapted to the Italian context of use often because of semantic shifts in their meaning. Sharing the same terminology for document identification is an essential first step towards interoperability across institutions, and it should not be taken for granted. LOINC Document Ontology is a great help in this process even if it is to be noticed that things are not always given the same name and finding synonyms or possible alternative names is not immediate to who is accustomed to a specific set of terms. Previous works have analyzed LOINC codes coverage of local document names [17] and have proposed efficient mapping techniques [18].

6 Working Scenarios

6.1 An example of business process

This section illustrates an example of business process related to searching documents and data in an interregional context. The process enables a healthcare professional, working in a regional domain different from the health care assistance Region of the patient, to research patient documents and data. Figure 3 shows the interactions between the consumer node (the healthcare professional system) and the provider node (the health care assistance Region system). The process allows requesting a list of documents and data that meet both specified search parameters and policies for accessing the provider node.

Process activities shown in the figure above are described in Table 1.

6.2 An example of CDA and LOINC use

During the implementation phase of the above-mentioned InFSE project, healthcare professionals have been continuously supported in the course of the process of creating well formed HL7 CDA documents. Eight laboratories (6 in the Calabria Region and 2 in the Campania Region) have been involved in the testing phase. As it was found that laboratories were not quite aware of the standards and coding systems, preliminary educative training sessions were organized.

Figure 3: Business process related to searching documents and data at national level.
Table 1: Activities of the searching documents and data business process.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>professional authentication</td>
<td>It requires the healthcare professional to correctly authenticate himself/herself in the local system.</td>
</tr>
<tr>
<td>patient identification</td>
<td>It allows sending information for patient identification. This activity invokes a service offered by a support node (where the system of the national patient Master Data is located).</td>
</tr>
<tr>
<td>patient master data</td>
<td>It allows identifying the patient by the citizen identifier or a subset of personal data.</td>
</tr>
<tr>
<td>patient identified</td>
<td>It receives the results of the patient identification phase and allows the process to continue properly.</td>
</tr>
<tr>
<td>generation assertions for search</td>
<td>It allows the construction of the security assertions to perform the search operation.</td>
</tr>
<tr>
<td>request a list of documents and data</td>
<td>It builds the message for documents and data search. This message has to be forwarded to the searching service in the health care assistance Region of the patient and it must contain both the assertion generated in the previous step and the search criteria.</td>
</tr>
<tr>
<td>patient control</td>
<td>It i) assesses whether the patient is assisted by the regional system invoked, and ii) determines whether the patient has given the consultation consent. If both checks are passed, the activity allows searching documents and data.</td>
</tr>
<tr>
<td>assertions validity</td>
<td>It checks the validity and correctness of the assertions. error generation</td>
</tr>
<tr>
<td>display error</td>
<td>It aims to generate an appropriate alert message, when an error occurs.</td>
</tr>
<tr>
<td>generate list of documents and data</td>
<td>It provides in output the list of metadata for the documents satisfying both the search criteria and the access policies previously defined by the patient.</td>
</tr>
<tr>
<td>display answer</td>
<td>It aims to obtain the list of documents from the previous activities and shows them to the healthcare professional.</td>
</tr>
</tbody>
</table>

It was decided to start from structuring Laboratory Reports, as laboratories are organized in branches and this allows a progressive and per se coherent implementation. It was discovered that laboratories use their own codes and names to identify tests, and in some cases they even do not have data management software applications, thus disadvantaging interoperability. Seminars were firstly aimed at introducing LOINC and explaining mapping strategies to be used in the Regenstrief LOINC Mapping Assistant (RELMA®) was developed.

Once laboratory professionals had mapped their own local tests to LOINC standards, mapped codes were manually double checked to validate them. In many cases, the result was a good mapping percentage, meaning that a LOINC code was identified no matter if right or wrong, and most of them were correctly mapped to LOINC codes. Results positively acknowledge the training phase, regarding tutorials and guided mapping as adequate to fully understand how to manage the standard. Furthermore, LOINC was positively perceived because once having completed mapping operations, laboratories can continue to use names which they are accustomed to and LOINC codes are automatically output in the CDA Laboratory Report.

The next step was structuring CDA Laboratory Reports including mapped LOINC codes. Almost all the laboratory data management software applications were able to implement the automatic output of CDA documents, thus speeding up the process. Subsequent automatic transmission to the patient EHR was only virtually tested because of the current unavailability of the regional EHR infrastructure.

7 Conclusion and future work

This work presents a nationally shared architectural model aiming at supporting technical and semantic interoperability among regional EHR systems, which have to be developed or revised according to recently issued specific Italian laws.

The work represents an important first step in the process of digitalizing the Italian EHR system. The proposed model is turning out to be successful for both Regions that have already started an e-health process and Regions that are still at the starting line. The efforts which have been made so far in conjunction with central and regional administrations help Regions to overcome the main difficulties still linked to the use of paper, highlighting the
benefits that automated processes could bring in terms of time consuming and quality of care. The solutions described in this paper are quite flexible as, on the one hand, they provide a standardized approach to ensure regional EHR-S interoperability and, on the other hand, they enable Regions to define their own technical specifications for the realization of regional EHR-Ss.

Future work will regard the definition of further technical details, which will be performed along with the following phases of the implementation process. Continuous collaboration among all the actors involved in the process will allow defining shared technical specifications in more detail, pursuing the efficient pathway which is already being taken to successfully implement interoperable EHR-Ss.

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CDA HL7 document for use in Czech radiology practice

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Abstract

Objectives: The Clinical document architecture (CDA HL7) standard is not commonly used in the Czech Republic. The exchange of clinical reports is conducted mostly on paper; in some cases proprietary formats are being used. The aim of this article is to assess usability of CDA HL7 standard in the field of radiological examination, especially in mammography screening programme which is established from the year 2002 in the Czech Republic.

Methods: Implementation guidelines for imaging reports was analyzed (IG), conformance requirements were examined one after one and compared with common practice in mammography centers.

Results: Results of this analysis are comments to individual requirements. Problem parts that would need special care upon implementation are emphasized.

Conclusions: Mammography screening practice is not in direct contradiction to IG but more detailed information about CDA elements and XML examples are needed for successful implementation of standards such as CDA.

Keywords
Clinical document, CDA HL7, radiology, mammography screening

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1 Introduction

In 2002, the Czech Republic has joined other states with national prevention programme of breast carcinoma, which consists mainly of mammography examination of women older than 45 years in 2-years intervals. Women are sent to mammography examination either by their practitioner or gynecologist. He then receives radiological report about the results of the examination. If the result is positive, woman is sent to oncology centre, otherwise the whole process repeats in two years. Currently there are 70 accredited mammography centers providing mammography examinations in the Czech Republic [1].

Examination reports are being entered into information systems both as free text and at the same time in mandatory data structure that has to be filled for each examination. Transfer of reports to referring physicians is conducted almost solely on paper. Parametric data are being sent for statistical analyses to the Institute of Biostatistics and Analyses (IBA MU) every six months. A simple custom data interface was developed for this transfer. Aside from central database management and statistical processing of the screening data, IBA MU has developed locally installed software that can be used either as a full-featured ambulatory information system or it can cooperate with existing ambulatory IS and provide specific services for mammography screening. Having this experience, IBA MU as an academic institution has conducted an analysis aimed to find out if it is possible to implement the CDA HL7 standard in Czech radiology. The Czech Republic is an HL7 affiliate but use of HL7 in the Czech Republic is limited. The term CDA document is largely unknown in practice and is discussed only in academic field. This poses even more challenge to compare common radiology practice with requirements of the standard.

2 Methods

We chose the Implementation guide for imaging reports (IG) [2] as input for the analysis. This guide specifies in detail common requirements of the HL7 DCA release 2 standards for radiology. This IG specifies the form of the report used by radiology department to store and transfer information about conducted examination or set of examinations to referring physician or in case of mammography screening.

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screening to subsequent oncology department. IG defines 171 requirements (Conformance requirements) for a CDA document. Each requirement was assessed with respect to common practice in the Czech Republic according to the authors’ experience. For each requirement, the degree of difficulty for bringing the requirement to practice was assessed.

3 Results

The result of the analysis is separated for the CDA document header and the body of the document.

3.1 Header of CDA

IG requirements for the header of the document are summarized in Table 1.

3.2 Body structure

According to IG (conformance requirement 74), the body of the report should be structured to sections where at least one “Findings” section is mandatory. Another important section described in IG is DICOM Object Catalog, used to attach references to imaging information on given examination. Utilization of this section is limited in Czech environment. Although most mammograms are digital machines with its own PACS archive, in most cases the results are given back to practitioner who does not utilize the imaging information. In case of positive result the situation is different – the report is sent to a specialized oncology healthcare facility. The imaging information transfer is very important here and is being conducted using CD-ROMs in most cases. Selected healthcare facilities are connected on-line and transfer is conducted using the DICOM standard. Other sections of the body part in the IG document that could be utilized in Czech mammography screening include "REQUESTED IMAGING STUDIES INFORMATION" containing static information on mammography screening, PRIOR IMAGING PROCEDURE DESCRIPTIONS and RADIOLOGY COMPARISON STUDY – OBSERVATION for comparing prior images in subsequent cycles of the program, CONCLUSIONS for the final conclusion and RADIOLOGY STUDY – RECOMMENDATION for recommendations given to the patient.

Other conformance requirements for the body of the CDA document are summarized in Table 2.

3.3 Specific requirements

Breast cancer screening program has its own specific parameters that should be contained in the CDA document and which are missing in the analyzed IG. These include the assessment of results in BIRADS categories, assessment of mammary gland density in Tabar categories and eventually specification of tumor found. Suitable elements for these parameters would be Clinical Statements, especially observation statement when using a suitable coding system. In case of BIRADS categories that would probably be SNOMED-CT concept Mammography assessment finding (Concept ID: 397137005) and other concepts included in Mammography finding (Concept ID: 129714008).

4 Conclusions

Although the CDA HL7 standard is mostly unknown term in the Czech Republic, common radiology practice is able to cover requirements specified in IG. Our analysis did not find any significant discrepancy which would prevent the use of the standard. The most notable problem can be the complexity of the standard. For the needs of developers of health information systems, it will be necessary to further extend the guidelines and prepare examples of final CDA documents for different types of mammographic centers including both small specialized ambulances and big healthcare centers. Great help for developers would be to differentiate static parts of the document and actual information being transferred.

The big question is whether implementation of standards such as CDA to specific healthcare programs like mammography screening should be internationally coordinated so that the main idea of HL7 CDA is maintained, which is interoperability in healthcare. Possible ways could go through IHE iniciative or expert guidelines.

Acknowledgements

Our thanks go to Dr. Bartonkova a Dr. Mutina, heads of two mammographic centers, for consultations on this topic from clinical perspective.

References


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Practical Implications of Value Set Definitions: an Example

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Abstract

Data Exchange as the foundation of interoperability consists of two major components: the grammar and the vocabulary. This paper analyzes the implications of value set definitions on interoperability using an example from practice.

Keywords

Interoperability, Value Sets, Code Systems

1 Introduction

The utilization of communication and document standards in healthcare environments like HL7 v2, V3 and/or CDA [1, 2, 3] are a prerequisite to achieve interoperability. However, a communication standard can be seen and treated as a language combining a grammar and the appropriate vocabulary and being derived from its specific ontology. Both grammar and vocabulary enable data and information exchange, but do not guarantee semantic interoperability. Despite the aforementioned preconditions, i.e. the existence of communication standards, applications are not directly enabled to "speak" or "understand" this language. But even if the applications are programmed to use such an interface language, no matter whether it is a real communication standard or not, it has some influence on the internals of applications. This paper analyses the implications using a scenario from practice.

2 Methods

At the abstract level of an architectural model, the development process dimension is represented by viewpoints defined in ISO/IEC 10746 "Information technology – Reference Model – Open Distributed Processing (RM-ODP)" [4]. Herewith, the information viewpoint is responsible for providing the underlying concept models that specify the interrelationship of the data elements in question. These elements either allow for entering free text or are reduced to a specific terminology. For this paper, the impact of terminology usage onto applications expressed by value set definitions referring to codesystem is analyzed.

3 Results

A very good example leading to endless discussions is the gender of a patient. Usually persons with different background will contribute mixing different aspects:

- administrative gender
- biological gender
- genetic gender
  - hermaphrodites
    - pseudohermaphrodites
    - psychic hermaphrodites
  - aneusplioidites
    - monosomy
    - trisomy
  - Klinefelter syndrome
  - Poly-X syndrome
  - XYY syndrome
- transgender
- transsexual
- hormonal or gonodales gender
- genital gender

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This paper should not provide a detailed introduction into the differences of the aforementioned list. This is left to the interested reader.

During the nineties, HL7 International has changed the term "sex" to "administrative gender" to eliminate confusion and prevent from diverging interpretations. The new term should delineate how an individual person would like to be treated administratively. Thus, only the following values are allowed and are sufficient:

3.1 Non Administrative Gender Details as Observations

From the impressive list provided above, and given the details about administrative gender in Table [1], it became obvious that a clear distinction between administrative gender and other gender details should be made. Having this said, the table for administrative gender is reasonable (also for its use in veterinary medicine), complete and sufficient.

3.2 Code Systems

The aforementioned extended list should lead to detailed specifications of code systems with appropriate codes and associated concepts. Clear guidance combined with official publications should then stop the never-ending discussions about what is meant by "gender". A simple reference to the correct codesystem will solve the problem.

3.3 Interpretations

The German Cancer Association in combination with some workgroups from ADT [7] and GEKID [8] has released an XML-based specification [9] for exchanging cancer related information. The details on sex (gender) are as follows:

The first two codes are clear. The third entry should also not cause any discussions. But for the fourth entry, there is no guidance on how it should be used. So this is left to the implementer, of course leading to non-harmonized messages. In other words, under the same circumstances, different application will report different gender codes for a specific patient. The discussion around "other" reveals two aspects:

a) This code can be used to report arbitrary concepts from the aforementioned list.

b) This code is most probably used for transgender issues according to interpretations of one of the leaders writing this specification.

3.4 Implications

The implications from a) will lead to a list of patients whose data is rendered unusable because the patient will neither have a clear gender nor is determined which concept is represented. However, this does not matter because the associated details are not communicated at all. If the interpretation is reduced to b), the outcome may be handled by some sophisticated applications. Nevertheless, even this interpretation will require some modifications of the application and the associated interfaces themselves because it has an impact on the overall set of codes. Most of the applications can only manage values as

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>male</td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>female</td>
<td></td>
</tr>
<tr>
<td>U</td>
<td>unknown</td>
<td></td>
</tr>
<tr>
<td>O</td>
<td>other</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>ambiguous</td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>not applicable</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Gender Definition from ADT/GEKID for Cancer Reporting.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>male</td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>female</td>
<td></td>
</tr>
<tr>
<td>U</td>
<td>unknown</td>
<td></td>
</tr>
<tr>
<td>S</td>
<td>Other</td>
<td>what exactly is meant?</td>
</tr>
</tbody>
</table>
Table 3: Enhanced Transgender Definition for Cancer Reporting.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>ADT/GEKID</th>
<th>Standard</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>male</td>
<td>M</td>
<td>M</td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>female</td>
<td>F</td>
<td>F</td>
<td></td>
</tr>
<tr>
<td>FM</td>
<td>Male, formerly female</td>
<td>S</td>
<td>M</td>
<td>Newly introduced</td>
</tr>
<tr>
<td>MF</td>
<td>Female, formerly male</td>
<td>S</td>
<td>F</td>
<td></td>
</tr>
<tr>
<td>U</td>
<td>unknown</td>
<td>U</td>
<td>U</td>
<td></td>
</tr>
</tbody>
</table>

listed by Table 1. Enhancing this would fulfill the requirements as listed by b), so that Table 3 must be established and implemented. It contains two additional new rows for the necessary concepts:

The two columns in the middle of Table 3 demonstrate the mapping to all concepts as requested by either ADT/GEKID for their specification or the standard communication scenario for most applications. Without such a mapping, either the new requirements cannot be fulfilled or the already up and running interfaces will not operate any more.

### 3.5 Value Sets

Table 2 and 3 also introduce another discussion: If a list of values is provided, does this also imply to support all listed codes? This discussion with the folks from ADT/GEKID is silent on this point. But if the answer is yes, then it will introduce a lot of problems onto the underlying systems. On the other hand, if the answer is no, then there is no real requirement to provide values if no system will ever support them.

### 4 Discussion

The list of different concept sets provided above and the implications explained aforementioned should introduce the idea of providing codesystems and value sets publicly. In order to achieve agreement this must be done by independent institutions. In Germany, the DIMDI would be an ideal candidate.

### 5 Conclusion

Specifying a list of values to be used in communication scenarios without any relationship to running systems will cause problems. This is another indication why vocabulary must be defined with care.

### Acknowledgements

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### References


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Developing a Common Health Information Exchange Platform to Implement a Nationwide Health Information Network in South Korea

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Abstract

Objectives: We aimed to develop a common health information exchange (HIE) platform that provides integrated services for implementing the HIE infrastructure in addition to guidelines for participating in an HIE network in South Korea.

Methods: By exploiting Health Level 7 (HL7) Clinical Document Architecture (CDA) and Integrating the Healthcare Enterprise (IHE) Cross-Enterprise Document Sharing-b (XDS.b) profile, we defined the architectural model, exchanging data items and their standardisation, messaging standards, and privacy and security guidelines, for a secure, nationwide, interoperable HIE. We then developed a service-oriented common HIE platform to minimise the effort and difficulty of fulfilling the standard requirements for participating in the HIE network. The common platform supported open APIs (application program interfaces) for implementing a document registry, a document repository, a document consumer, and a master patient index. It could also be used for testing environments for the implementation of standard requirements.

Results: As the initial phase of implementing a nationwide HIE network in South Korea, we built a regional network for WC hospitals and their collaborating clinics to share referral and care record summaries to ensure the continuity of care for industrially injured workers, using the common HIE platform and verifying the feasibility of our technologies.

Conclusions: We expect to expand the HIE network on a national scale with rapid support for implementing HL7 and IHE standards in South Korea.

Keywords

Health Information Exchange, Electronic Health Record System, Service Oriented Architecture, Health Level 7 Clinical Document Architecture, Integrating the Healthcare Enterprise

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1 Introduction

In South Korea, most hospitals and clinics still refer patients using paper documents; only a few tertiary hospitals have implemented an electronic referral system, that is, a web portal that enables access to patients’ lab test results by network clinics. This referral system has the limitations of offering only one-way information, limited scalability and expandability, and limiting information access to only a specific hospital. Additionally, because the system depends on a specific vendor and organisation, it is difficult to compile and access patients’ longitudinal data, which are stored in scattered silos.

Thus, there have been growing demands for a health information exchange (HIE) between hospitals and clinics to reduce healthcare costs and improve quality by shar-
ing patients’ clinical information and preventing duplicate testing; this exchange would require a number of standards for interoperability. Prior studies have found that HIE has benefits in improving coordination of care [1], improving the accuracy of diagnosis, preventing hospital readmissions and medication errors [2], enhancing public health surveillance [3], and increasing the efficiency and quality of public health reporting [4], with higher patient satisfaction [5, 6].

In this study, as a Korean HIE initiative, we began creating a nationwide HIE network early this year, in a first step towards exchanging clinical information on industrially injured workers between workers’ compensation (WC) hospitals and their collaborating clinics. Our final goal is to extend the coverage of HIE across the nation in stages. To accelerate the adoption of interoperable technologies for implementing a nationwide HIE network, we developed a common HIE platform that provides standard terminology, documents, and messaging tools to support hospitals and vendors in easily participating in the network. The implementation guidelines and tools will be able to mitigate some technical barriers and challenges to engage in the exchange of health information [6].

This paper describes the common HIE platform and our architectural and security strategies for implementing the HIE network in WC hospitals and their collaborating clinics using the platform.

2 Objectives

Our final goal is to implement a nationwide HIE network in South Korea to enable sharing patients’ referral documents and care record summaries among hospitals and clinics. Based on Health Level 7 (HL7) and Integrating the Healthcare Enterprise (IHE) standards, we began the initial phase of developing the architectural model, the implementation guidelines for clinical documents, the common terms, and privacy and security guidelines.

This study aimed to develop a common HIE platform that would provide integrated services for implementing the HIE infrastructure and guidelines for participating in our HIE network. In cooperation with Korea’s Workers’ Compensation & Welfare Service (COMWEL), we also aimed at verifying our concepts and platform by sharing clinical information on industrially injured workers between two WC hospitals and their six collaborating clinics.

3 Methods

We defined the architectural model, the exchange’s data items and their standardisation, messaging standards, and privacy and security guidelines for a secure, interoperable HIE across South Korea. In essence, we used the HL7 Clinical Document Architecture (CDA) [7] standards for generating clinical documents and the IHE Cross-Enterprise Document Sharing-b (XDS.b) profile for the communication infrastructure.

3.1 HIE Architecture Models

Based on the IHE XDS.b profile, we defined four architecture models that would be feasible for an HIE network in South Korea (Figure 1). The models depend on the location of each registry and repository, focusing on security issues at the physical locations where health information will be shared.

The Integrated Registry - Repository model is a central architecture in which all shared clinical documents (the repository) and the metadata (the registry) for searching them are stored in a central cloud server. The One Registry - Multiple Repositories model is a distributed architecture in which the repository is located within each healthcare organisation or in its EHR vendor’s server, with a registry for linking documents between locations maintained in a central server. The Federated Registry - Multiple Repositories model supports information exchange through communication between the regional registries. Finally, the Peer-to-Peer model is based on direct exchange between healthcare organisations using socket communication or secure email.

In this study, we focused on developing a common HIE platform that would support the Integrated Registry - Repository and the One Registry - Multiple repositories models. The architecture models would depend on the EHR infrastructure, the healthcare environment, and the cultural environment.

3.2 The Common HIE Platform

Based on the IHE XDS.b profile, we derived common HIE functions and services for each actor, including a document repository, document registry, and document consumer. Based on service-oriented architecture (SOA), we developed a common HIE platform that provides these functions and services to minimise the effort and difficulty in implementing the IHE XDS.b profile, CDA standards, and common terminology set.

The common HIE platform supports open APIs (application program interfaces) for implementing the document registry, document repository, document consumer, and master patient index. The document registry receives the metadata from clinical documents generated by healthcare organisations, stores the metadata, and supports searches for the documents. The document repository stores clinical documents, requests indexing in the document registry, and provides the documents when they are requested by other healthcare organisations. The master patient index (MPI) maintains patient identifiers and patient consent information. In addition to providing the services needed for sharing documents, we also included supportive HIE services that allow for standardising local terminologies to international terminologies, managing master data of participating healthcare organisations and departments, and regulating transaction logs.

To design the common HIE platform, we derived atomic services based on the IHE XDS.b profile and then...
We developed a number of services for CDA documents with open APIs, for example, CDA Viewer, which displays CDA documents in readable format by applying the XSLT style sheet. The 'CRS and Referral Generate’ API supports the automatic generation of CDA documents based on the corresponding values of data elements that were extracted from the EHR system. The terminology mapping can be used to generate CDA entries by automatically mapping local terms to structured coded terms.

### 3.3 CDA Contents

As a standard for clinical documents to be exchanged among healthcare organisations, we adopted HL7 CDA Release 2 (R2) Level 3. Based on CDA R2 and some of the IHE CDA content modules, we defined the data elements and templates for the referral and care record summaries to support collaborative care.

In this study, the referral summary was defined as a document created to support collaborative care by referring patients from a clinic or hospital to a specialist. It is used for referrals and replies between two healthcare organisations. The care record summary (CRS) was defined as a document that summarizes hospital visits and hospitalizations; it is automatically created and stored for the purpose of the continuity of patient care.

Table 1 shows the major CDA data items in the headers and bodies of two types of documents, including coded entries with standard terminology for ensuring semantic interoperability.

Regarding the data items for problems, medications, and test results, we created coded entries for each data item with the international terminologies. We used the International Classification of Disease (ICD-10) (translated, and known as KCD-6 in Korea) and Logical Observation Identifiers Names and Codes (LOINC) for the diagnoses and the examination names, respectively. For medications, we allowed for the use of multiple code sets, including the Korean Electronic Data Interchange (EDI) drug codes used for insurance claims and the international Anatomical Therapeutical Chemical (ATC) codes. In South Korea, the government has developed Korea Standard Terminology of Medicine (KOSTOM) in which their terms were mapped to the international terminology, such as ICD and LOINC. Therefore, we also adopted KOSTOM in addition to ICD and LOINC for the secondary use of data for both domestic and international purpose.

Because most hospitals and clinics do not use LOINC codes for tests, manual mapping from the local test codes to the LOINC codes was necessary for creating the CDA entries. Thus, we included a terminology mapping service and tool in the common HIE platform.

### 3.4 Master Patient Index

In South Korea, there is no unique patient identifier that can be used only for medical purposes. Although all Koreans have their own social security numbers (SSNs), there have been increasing issues with the use of SSNs for HIE because of privacy and security concerns.

Because most hospitals and clinics have their own local patient identifiers, we created and assigned universal unique identifiers (UUIDs) to each patient who agreed to participate in the HIE using a master patient index (MPI) based on the IHE PIX (Patient Identifier Cross referencing) and PDQ (Patient Demographic Query) profiles.

We used HL7 V3 ADT messaging to transmit each hospital’s local patient identifier to the MPI system, enabling searches for patients and their UUIDs. Using the MPI system, we managed patient demographic information, including SSN, name, birth date, and address.

### 3.5 Security Architecture

To support the implementation of a secure HIE network, we provided required security guidelines after investigating the current security conditions and the solutions that were being used at the participating healthcare organisations. The security guidelines in essence comprised both technical and administrative security. Technical security considered medical information, (e.g., life cycles of data) and storage (e.g., passwords and access control). Administrative security focused on integrated management (e.g., organisational policies, backup and restore and documentation) and auditing (e.g., audit record policies and reports).

We considered security with regard to accessing devices, the network, the platform, and the content necessary for implementing a nationwide HIE network using our common platform.

### 3.6 Pilot Implementation of the HIE Network

As part of a nationwide initiative, our first phase was to implement an HIE network for WC hospitals and their collaborating hospitals and clinics because industrially injured workers typically require long-term collaborative care and their medical costs are covered by industrial accident insurance; we found that HIE outcomes can be used to evaluate insurance reimbursement to promote HIE participation.

In our pilot implementation of the network, two WC hospitals, one each in Incheon and Ansan, participated. The hospitals are located in the metropolitan area and have approximately 500 beds, and there were six collaborating clinics near the WC hospitals. The two hospitals...
had recently adopted an EHR system developed by a domestic EHR vendor. The six participating clinics used two different EHR systems. The WC hospitals are public healthcare organisations that provide rehabilitation for workers, but their medical service is not limited to injured workers.

4 Results

4.1 HIE Network Implementation Results

Our participating WC hospitals and clinics had different IT infrastructures and environments. The WC hospitals had their own network infrastructures and managed their EHR systems through an IDC centre of Korea COMWEL. However, the clinics’ EHR systems were connected through a broadband network, indicating the weakness of security.

Therefore, as shown in Figure 3, we chose a hybrid architecture of, physically, the Integrated Registry-Repository model and, logically, the One Registry - Multiple Repositories model. Using the common HIE platform, we implemented the HIE registry, repository, and MPI system components in Korea COMWEL’s IDC centre, called the HIE IDC Centre; there were one registry and distributing repositories for each EHR vendor in the centre. Both WC hospitals and the clinics communicated with the HIE IDC centre through their gateway servers and encrypted network connections. The gateway server for clinics, located on a DMZ network, provided open APIs and bridged service between the healthcare organisations.

Our security guidelines required that each doctor’s PC have a vaccine program, a PC firewall, and a data loss prevention solution. Regarding network security, a virtual private network (VPN), a secure sockets layer (SSL) protocol, an intrusion prevention system (IPS), a web firewall, and server dualisation were applied to prevent hacking and system errors. Server security was reinforced by installing a secure OS, a server vaccine program, a database encryption solution, and a storage backup solution.

4.2 Workflow for Exchanging the Health Information of Injured Workers

The common HIE platform was used to support the transfer of referral summaries from a clinic to a WC hospital and vice versa and the sharing of patients’ care record summaries among the participating healthcare organisations. Figure 4 shows the workflow and scenarios implemented in our HIE network for injured workers.

Regarding the transfer of referral summaries, when a patient visits a clinic near his or her workplace and the patient needs to be transferred to a WC hospital, a doctor creates a referral summary using the clinic’s EHR system. The referral summary is automatically generated in CDA format and stored in the repository, and its metadata are entered into the registry. The WC hospital will be automatically notified of the referral. After the referred hospital confirms the referral and checks the CDA document, a specialist views the referral summary during the patient’s visit. The doctor can then also send the reply documents to a clinic on completion of the patient’s treatment through the HIE network (Figure 4 (a)).

To share care record summaries (CRS), a CDA CRS is automatically generated in the event of a patient’s hospital visit and discharge and is stored and entered into the repository and the registry. When the patient requires emergency treatment or receives treatment from multiple hospitals and clinics, the CRS can be used to share that patient’s health information among the facilities, supporting continuity of care (Figure 4 (b)).

Since HIE system should be incorporated into organizational and doctor’s workflow in order to be successful, the HIE service scenarios were developed by analyzing intra- and interorganizational workflows of patient’s care.

4.3 Packaging the Common HIE Platform

To accelerate the interoperability between different EHR systems, we adopted international standards, such as HL7 CDA and HIE profiles, and developed a common HIE platform that supports implementing the standards, thus enabling participation in the HIE network and connection between EHR systems. We packaged together the components of the common HIE platform that were required for the registry, repository, and MPI servers. In addition to the HIE system packages, we packaged useful tools that support CDA content generation, standard terminology management, and master data management.

In our HIE network, we installed the registry server and MPI server packages in a Korea COMWEL IDC centre and built repository servers for each hospital and clinic using the repository package. These packages allowed for addressing changes in management authority and physical server location because they are simple to install and remove.

5 Discussion

One of the greatest barriers to the adoption of HIE by more health organisations is the lack of an HIE business model. This study addressed that problem by choosing WC hospitals for industrially injured workers as our test sites for the initial implementation of a nationwide HIE network. Most patients in WC hospitals have rehabilitation needs and require collaborative care at other hospitals. As our business model, we plan to provide HIE data to patients to allow them to check their health information using smartphones, with various mobile health services to improve their rehabilitation and treatment and self-monitor their health. The data will be able to be utilised for various applications, creating new value for the HIE system.
Common concerns for HIE include the safety and confidentiality of electronic information exchange and the reliability and quality of the data [10]. In this study, we aimed to separate patients’ demographic information from their medical information, and we created UUIDs for the purpose of identifying patients in the medical domain. We also distributed the medical information into multiple repositories. By creating a separate repository for each hospital or EHR vendor, we reinforced the security and disaster recovery. Based on the IHE ATNA (Audit Trail and Node Authentication) profile, all access and retrieval logs were recorded.

Through this study, we aimed to accelerate the adoption of HIE using a common HIE platform. We have been implementing the regional HIE network in two WC hospitals and their six collaborating clinics, thereby enabling the exchange of referral and care record summaries in a standardised way. We plan to share medical images by adopting the IHE XDS.b-I (Cross-enterprise Document Sharing for Imaging) profile and to increase the number of participating hospitals and clinics in our HIE network next year.

6 Conclusions

The benefits of HIE systems are known, including preventing medical errors; reducing paper document use and duplicate, unnecessary examinations; collecting and monitoring outcomes through sharing medical information among healthcare organisations; and improving care quality, efficiency, and patient safety.

In this study, we developed a common HIE platform to promote and diffuse the adoption of the interoperability standards that are required for implementing a nationwide HIE network in South Korea. As our first phase, we applied a packaged platform solution to securely share patients’ health information among WC hospitals and their collaborating clinics.

We expect to expand the HIE network on a national scale with rapid support for implementing the HL7 and IHE standards in South Korea.

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References

Electronic Medical Record (EMR) to EMR CDA Data Transfer and Conversion Specification – Conformance Testing and Design Physician Information Technology Office (PITO), British Columbia, Canada

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Abstract

Background: The E2E-DTC is a comprehensive set of EMR-to-EMR Data Transfer and Conversion specifications which supports standardized exchange of patient information for referral/consult and visit reports, chart transfers and conversion to a new EMR. A structured conformance framework was pivotal to the successful implementation of this specification across 7 EMR vendors.

Objective: The objective of this paper is to provide an overview the key aspects of the conformance framework and highlight the lessons learned from its application for the E2E-DTC implementations. The findings were gathered through consultation with the conformance team and participating vendors as part of post-implementation evaluations.

Key Findings: The structure of a “modular” conformance process was well received by clinicians and vendors because it allowed them to develop and conformance test their system for specific use case(s) either sequentially or simultaneously.

The level of vendor knowledge of underlying HL7v3/CDA standards correlated with the amount of individual vendor support required. Example files and a “help desk” service were critical to support all vendor implementations. Early implementer feedback led to the pre-engagement between vendor and Conformance Team Technical Resources in advance of formal conformance test. Clear documentation of issues or changes to the specifications and communication of errata to implementing vendors was critical to the optimal progression of the conformance testing processes.

Conclusion: In conclusion, the use of a structured conformance framework was pivotal to the implementation of this specification across 7 EMR vendors, but its application highlighted areas for efficiency improvements for future CDA implementations.

Keywords
Conformance Framework, CDA, EMR, Data Transfer, Data Conversion

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1 Introduction

The Physician Information Technology Office (PITO) EMR-to-EMR Data Transfer & Conversion Standard (E2E-DTC) specifications support the standardized exchange of patient information between disparate electronic medical record (EMR) systems in support of various business processes including single patient chart transfers, conversions of multiple patient charts from one EMR to another as well as the exchange of episodic documents.

The scope of exchange includes supporting various non-specific episodic events in the care of the patient; transfer of the (materially) complete patient chart as a single patient transfer; or in support of conversion of an entire EMR system.

The specification includes a consolidated set of HL7 Clinical Document Architecture (CDA) document templates:

- EMR Conversion Document Specification
- Patient Transfer Document Specification
• Generic Episodic Document Specification
• Unstructured Document Specification
• Generic Unstructured Referral Document Specification
• Generic Structured Referral Document Specification

It is aligned with key specifications and HL7 standards – both version 2.x and CDAR2 leveraging key terminologies adopted in BC including: SNOMED CT®, ICD and LOINC.

This specification has been implemented by seven EMR vendors in the province of British Columbia, Canada. A structured conformance framework and process was used to evaluate vendor adherence to the standard and assist in overall adoption of the standard.

2 Objectives

The objective of this paper is to provide an overview the key aspects of the conformance framework and highlight the lessons learned from its application for the E2E-DTC implementations.

3 Methods

The findings were gathered through consultation with the conformance team and participating vendors as part of post-implementation evaluations.

4 Conformance Framework Overview and Findings

4.1 Conformance Framework

The Conformance Framework is built on one or more use cases and adds business and technical requirements and/or rules to provide a suite of artifacts that can be tested. A

A Conformance Profile defines what is testable for a computer application. For this project, the conformance profiles were scoped by the following:

• Applied equally to an Electronic Health Record (EHR) or other Point of Service (POS) application
• Each Conformance Profile established a specific marketable conformance capability (e.g. E2E-DTC Conversion)
• Each profile referenced one or more versions or series of versions of one or more target specifications and clearly outlines the expectations for the specifications.

Roles: The E2E-DTC conformance profiles are document-oriented and are therefore focused on “CDA” document exchanges. Each ‘CDA or interoperability focused’ Conformance Profile includes one or more roles. Such roles are either defined within the profile or reference the following common roles:

• Originator or Sender: The system creating, originating or sending a particular document or message.
• Recipient or Receiver: The system receiving and processing a particular document or message.

4.2 Conformance Process

The Conformance Process was developed for use in the validation that a particular product meets applica-
The process is generic in purpose to support the validation of any PITO specification. At the time of development only conformance to the E2E-DTC Specification was in place.

The audience for the conformance process includes stakeholders seeking to create, sell or acquire EMR products and who wish to either formally validate the conformance of a particular product and version place in the market or to confirm the status of conformance for a particular product considered for acquisition.

The process defines the overall approach to asserting conformance to an in-scope specification and for conformance testing of EMR systems that assert such conformance (See illustration below). The key sub-processes include:

1. Registration
2. Vendor Review and Development
3. Conformance Test Request
4. Conformance Test (and Conformity Assessment)
   - Multiple steps including web-conference to visually inspect vendor system after import
     - Includes Conformance Technical Resources and Clinical Jurors
4. Deployment

5. Deployment

The Conformance Testing sub-processes is divided into multiple parts and varies based on E2E-DTC conformance profile. They include:

- Part 1 - Planning
- Part 2 – Export of patient data
- Part 3 – Import of clinical document(s)
- Part 4 – Export of clinical document(s) with modified content
- Part 5 – Evaluation

The following sections further describe each of the 5 parts.

### 4.2.1 Part 1 – Planning

The objective of Part 1 – Planning is to ensure clear understanding of roles and processes by all participants. The vendor is provided with the conformance test process, test chart scenario data and instructions. A planning teleconference is held with Conformance Team and Vendor to review the process, discuss the use of patient data provided to create patient chart and to schedule conformance dates.

### 4.2.2 Part 2 – Export of Patient Data

The objective of Part 2 – Export of Patient Data is to test the system’s ability to export conformant documents containing all appropriate/required clinical content. The vendor creates a patient chart based on the clinical data provided within their system using their system user interface. They are typically provided data to create 2 patient charts to allow testing of all sections that could be included in the export document. The vendor exports files/documents and provides to Conformance Team for validation. The Conformance Team validates files/document against the CDA Schema and Schematron validation rules and does a visual inspection of clinical content.

### 4.2.3 Part 3 – Import of Clinical Document(s)

The objective of Part 3 – Import of Clinical Document(s) is to test the system’s ability to import all clinical content and make it available to system users according to requirements of the specifications and appropriate clinical practice. Once Part 2 files have been successfully validated, the Conformance Team provides the vendor with files/documents to import into their system and schedules a web conference. There is a manual inspection of vendor system to ensure that data was imported and has not been lost. This includes technical and clinical conformance jurors.

### 4.2.4 Part 4 – Export of Clinical Document(s) with Modified Content

The objective of Part 4 – Export of Clinical Document(s) with Modified Content is to test the system’s ability to re-export patient record containing specific clinical...
content changes. The vendor is provided with changes to make to imported data using the system’s user interface at the end of the Part 3 visual inspection. For example, add allergy, medication or change content on allergy or medication. Clinical documents are exported and validation is completed by the Conformance Team through automated and visual inspection of the exported files/document.

4.2.5 Part 5 – Evaluation

The objective of Part 5 – Evaluation is to assess overall conformance to the specification and documentation of any outstanding issues or concerns. The Conformance Team completes validation of all documents provided and documents results in Conformance Test Script workbook. This is provided to the vendor.

4.3 Findings and Lessons Learned

Seven EMR vendors completed the conformance process above. Post-implementation evaluations with both the Conformance Team and the vendors revealed the following findings and lessons learned:

1. Modular conformance process was well received by clinicians and vendors

   (a) Allowed vendors to develop and conformance test their system for specific use case(s) either sequentially or simultaneously

2. Knowledge of overarching HL7 CDA requirements was key

   (a) Vendors were familiar with E2E-DTC specification but had limited familiarity with underlying HL7 CDA Specification – particularly for level 3 specifications

   (b) Use of the existing CDA framework allowed to mitigate CDA knowledge gaps and speed up the development

3. Errors, omissions or clarifications were identified in the specification during the vendor implementation

   (a) Clear documentation of issues or changes and communication of errata as soon as they are found to the implementing vendors.

   (b) This was a source of complexity – and sometimes frustration – for vendor participants

4. Review process was time intensive and various process improvements were suggested by participants

   (a) Implemented a pre-engagement between vendor and Conformance Team Technical Resources in advance of formal conformance test

   (b) Applied advanced schematron files to identify structural and terminology errors, which are not picked up by schema validations and hard to identify manually (e.g. valid template ids, section codes)

5. Amount of individual support varied by vendor but all required some effort of support during their development work and during the conformance test

6. Example files and a “help desk” service were critical to support vendor implementations.

7. Conformance testing needed a pragmatic approach in the review of the import and export of clinical data

   (a) Specification supports the conversion and transfer of all clinical data that is in an EMR

   (b) Each EMR is different and support different modules and structured data to different extents

   (c) Step by step review of data imported and exported with significant input from the vendor to determine where the data as imported and/or exported

5 Conclusions

In conclusion, the use of a structured conformance framework was pivotal to the implementation of this specification across 7 EMR vendors, but its application highlighted areas for efficiency improvements for future CDA implementations.

Acknowledgements

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References

Medical image exchange and sharing between heterogeneous picture archiving and communication systems based upon international standard: pilot implementation

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Abstract

Background: Because medical imaging costs a large amount of expenses and may expose patients to repetitive radiation, its exchange or sharing is required from patients. However, in reality, electronic medical image exchange is not widely available.

Objectives: This study is aimed to execute pilot implementation of medical image exchange and sharing system between heterogeneous picture archiving and communication systems (PACS) based upon international standard.

Methods: This study included 3 different PACS solutions; INFINITT, TechHeim and Medical Standard. Each of them was operated on the basis of DICOM and customized according to the user environment of medical organizations. Ten medical institutes were included in this study; 5 primary hospitals, 2 secondary referral centers, 1 tertiary referral center and 2 public healthservice centers. Among them, 8 hospitals used INFINITT PACS solution, 1 hospital TechHeim PACS solution and 1 hospital Medical Standard PACS solution. A centralized network architecture was adopted. Transactions in the architecture were implemented on the basis of Integrating the Healthcare Enter-prise (IHE) cross-enterprise document sharing for image (XDS-I.b) profile. An image exchange center was established and it contained registry, repository and image storages.

Results: Our system was developed to enable direct upload of medical images onto a PACS of a central server. Radiology reports were uploaded into a document repository in the clinical document architecture (CDA) format. The images in the central PACS could be viewed using a hypertext markup language 5 (HTML5)-based medical image viewer. Administration of patient identifiers issued from different medical institutes were carried out using IHE PIX profile. The document registry executed management and inquiry of patient metadata and was set up using web service description language (WSDL). A document repository stored DICOM KOS files and its web services were set up using WSDL. An online patient agreement process was developed. The cell-phone based short message service (SMS) was used for identification. Exchanging or viewing of medical images were enabled only after patient agreement was obtained. The network between the image exchange center and hospitals was secured using virtual private network (VPN).

Conclusions: Through our medical image exchange system, different levels of hospitals using different PACS solutions could exchange imaging data on the basis of DICOM standard, showing its interoperability. Even if there are still concerns on system security and patient identification, a larger scale of studies in the future will be facilitated by utilizing our pilot implementation study.

Keywords

Medical Image Exchange, DICOM, Integrating the Healthcare Enterprise, Cross-enterprise document sharing for image, Picture Archiving and Communication Systems

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1 Introduction

Health information exchange has been developed to make patient medical information available when and where it is needed. It is useful to improve quality, efficiency and safety of patient healthcare in a community. Medical imaging is also one of medical information and its exchange or sharing can also have similar beneficial effects [9, 10].

Picture archiving and communication system (PACS) has been widely used for storage, transmission, reporting and retrieval of medical imaging. Because most of PACS from multiple manufacturers are based on the standard file format and network communication protocol, digital imaging and communications in medicine (DICOM), medical image exchange can be considered to be more feasible rather than medical document exchange [1, 2, 4, 5].

Furthermore, because medical imaging costs a large amount of expenses and may expose patients to repetitive radiation, its exchange or sharing is required from patients. However, in reality, electronic medical image exchange is not available in South Korea and it is still transferred from a hospital to another hospital on a compact disk by the patients themselves [7, 8, 9].

2 Objectives

This study is aimed to execute pilot implementation of medical image exchange and sharing system between heterogeneous PACS solutions based upon international standard. A master patient index based upon a standard will also be developed to administer patients with different identifiers from different healthcare organizations in the present study.

3 Methods

3.1 PACS

This study included 3 different PACS solutions; INFINITT (80% of domestic market share), TechHeim (10%) and Medical Standard (5%). Each of them was operated on the basis of DICOM and customized according to the user environment of medical organizations. The structure of each system was analyzed.

3.2 Medical organizations

Ten medical institutes were included in this study: 5 primary hospitals, 2 secondary referral centers, 1 tertiary referral center and 2 public health service centers. Among them, 8 hospitals used INFINITT PACS solution, 1 hospital TechHeim PACS solution and 1 hospital Medical Standard PACS solution.

3.3 Architecture of image exchanging system

In the present study, a centralized network architecture was adopted instead of distributed or point-to-point model because it was considered to have advantages in network security, cost effectiveness and availability. Transactions in the architecture were implemented on the basis of Integrating the Healthcare Enterprise (IHE) cross-enterprise document sharing for imaging (XDS-I.b) profile. An image exchange center was established and it contained registry, repository and image storages (Figure 1).

4 Results

4.1 Upload of images

The system was developed to enable direct upload of medical images onto a PACS of a central server. The location of each image was recorded in a XDS repository. A DICOM agent was designed to process both DICOM images and XDS metadata. Transmission of images was supported by a standard DICOM method, C-Store. A DICOM Sender was developed to send DICOM images from local PACS according to XDS protocol. A DICOM Receiving Agent tool was also developed to receive DICOM images and played a role as an image document source. The DICOM Receiving Agent tool also worked as a validation filter to fit the images into a DICOM standard (Table 1).

4.2 Radiology report

Radiology reports were uploaded into a document repository as Base64-encoded clinical document architecture (CDA) documents. A CDA document generator was developed in each institute and each document was linked with the corresponding images.

4.3 Viewing the images

The images in the central PACS could be viewed using a hypertext markup language 5 (HTML5)-based medical image viewer. The viewer was developed to work regardless of the operating system or networking browsers. Therefore, it could be operated without installation of middlewares such as ActiveX, Plugin or Java. For viewing, the user should be certified outside the viewing system and was able to view the images using a study instance unique identifier (UID) interfaced by XDS.b-based key object selection (KOS).
4.4 Patient identifier cross-referencing (PIX)

Administration of patient identifiers issued from different medical institutes were carried out using IHE PIX profile. The PIX manager collected patient metadata and generated a universally unique identifier (UUID) using a simple object access protocol (SOAP)-based webservice in the form of Health Level (HL7) v3. The patient metadata was recorded in the PIX manager in the form of HL7-defined PRPA-IN201301UV02. A standard metadata was generated to execute Patient Identity Feed, a patient registration traction (ITI-44). Image exchanges were enabled after patient agreement was obtained.

4.5 Document registry

The document registry executed management and inquiry of patient metadata and was set up using web service description language (WSDL). It could receive metadata from the document repository. Retrieval of documents from different hospitals was enabled using a registry stored query technique. The metadata was described using the IHE electronic business using extensible markup language (ebXML).

4.6 Document repository

A document repository stored DICOM KOS files and its web services were set up using WSDL. Both documents and its metadata were uploaded and stored after their validity was checked. When the documents were stored in the repository, their unique ID in the repository was stored in the registry along with the metadata. This unique ID was shared by all of the actors inside the affinity domain (Figure 2).

4.7 Patient agreement process

An online patient agreement process was developed. The cell-phone based short message service (SMS) was used for identification. PIX metadata was generated from patient information and registered in MPI. UUID was generated and used for transaction between registry and MPI. As soon as the patient images were uploaded to the central server, image registration was notified to the patient. Retrieval of patient images in the central server could be enabled only after patients receive and identify a certification number through SMS.

4.8 Security of system

The system could be accessed only by certified personnel and system entry log was stored. Exchanging or viewing of medical images were enabled only after patient agreement was obtained. The network between the image exchange center and hospitals was secured using virtual private network (VPN).

Figure 1: Image source.
5 Discussion

While medical document exchange should address difficulties in standardization, there are few issues on standardization for medical image exchange due to presence of widely-used image standard, DICOM. However, many hospitals are known to customize PACS solutions for optimization in their user environment. Furthermore, online standard-based image exchange between different PACS solutions has not been available in South Korea. The present study was aimed to enable medical image sharing between different PACS solutions based on healthcare standards such as IHE, DICOM and HL7.

The present study showed that medical image exchange has worked irrespective of PACS solutions and hospitals. The system users could directly upload images from their hospitals to the central PACS or download images from the central PACS to their hospitals on condition that patient agreement was obtained. It was also possible to simply view the images in the central PACS without download of images. All of the processes were operated based upon a unique patient ID instead of 13-digit Korean Residence ID.

System expansibility was also an important component for development to involve as many hospitals as possible. The user hospitals needed to log on the web portal and simply download the software for exchange interfaced by XDS.b engine, MPI and PACS. Furthermore, the agreement process for patients was enabled on the web portal. Therefore, this system is featured by enhanced usability (Figure 3).
Our system is also featured by combination of XDS.b module and PACS. Medical images were uploaded to central PACS and its location reference information was stored in XDS repository. For this purpose, the DICOM agent was designed to deal with both DICOM images and XDS metadata. The DICOM download tool enabled the medical institutes to download the patient images, store in their own PACS and utilize them whenever they are needed for diagnosis and treatment.

6 Conclusion

Through our medical image exchange system, different levels of hospitals using different PACS solutions could exchange imaging data on the basis of DICOM standard, showing its interoperability. Even if there are still concerns on system security and patient identification, a larger scale of studies in the future will be facilitated by utilizing our pilot implementation study.
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References

Organ transplantation: Exchange of laboratory results for organ allocation in Switzerland

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Abstract

**Background:** Human Leukocyte Antigens (HLA) are the primary source of immuno-rejection after an organ transplantation. Luminex-Technology allows for detecting donor specific HLA antibodies in potential recipients but increases the number of lab results to be compared drastically. Handling with forms is no longer feasible.

**Objectives:** In order to make handling of lab results in transplantation allocation more efficient and in particular safer, the Swiss Office of Public Health took effort in the implementation of an electronic lab data exchange from donor sites to the Swiss Organ Allocation System (SOAS).

**Methods:** A joint HL7 – IHE working group developed in collaboration with FAMH (The Medical Laboratories of Switzerland) an implementation guideline for lab data exchange in the context of organ transplantation. After consultation with relevant stakeholders the guideline is recommendation as a national standard by eHealth Suisse.

**Results:** The implementation guideline relies without exception on HL7 CDA R2 and IHE profiles, in particular the IHE Laboratory (LAB) Technical Framework and the Sharing Laboratory Reports (XD-LAB) Content Profile respectively. Most lab results are coded with LOINC. HLA testing with Luminex technology is however not covered by LOINC neither by another established coding system; it was therefore necessary to define new codes which were derived from the serological nomenclature of HLA antigens.

**Conclusion:** Software implementation of lab results according to our guideline is under way and a first operational release is to be expected end of year. The authors are looking forward to report the benefits of the practical use at the IHIC conference.

Keywords

Organ Transplantation, CDA, Laboratory Results, Implementation Guideline

References


Healthcare Light Sensor

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Abstract

Objectives: The objective of this work is the integration of a system of ambient light sensors with patients’ biometric data in the actual hospital room environment through ISO/IEEE 11073 (X73) and HL7 protocols of Healthcare Informatics, allowing lighting information to be part of the patients’ Electronic Health Records (EHR).

Methods: Many studies have demonstrated strong evidence for therapeutic effects of visible (natural and artificial) and non-visible light in human wellness and health, but exact mechanisms remain unknown. In hospital studies, light and lighting have not always been properly measured and characterized, making light customized and optimized treatment procedures difficult to establish. Light for the visual task has to be also clearly differentiated from light for the biological processes (like circadian rhythms).

Results: This novel system measures and analyzes light and lighting quality and quantity in real time through different metrics and specific parameters, such as spectral power distribution, illuminance and geometry (glare). All the signals are time-stamped for accurate analysis, processing and correlation. The information will be handled under the “big data” IT platform.

Conclusion: The first generation of the sensor subsystem will be integrated with the existing hospital biometric sensors (mainly heart rate, blood pressure and body temperature). Future generations might include additional biometric sensors to measure, record, and process advanced parameters like heart rate variability, galvanic skin response, EEG and pupilometry (eye tracking, saccades and micro-saccades, task-evoked pupillary response). Metabolic hormones (like cortisol and melatonin) might be also considered.

We are developing this system with a highly recognized hospital in NY state (to be disclosed if accepted).

Keywords

Radiation, Visible, Illumination, Medical Informatics
Lessons Learned from the Transition of the Polish National Draft Implementation Guide for HL7 CDA Standard into DECOR Format

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Abstract

Background: The key ongoing national eHealth project in Poland includes development of national implementation guide (IG) for HL7 CDA [1]. In the current draft version 0.9.10 it covers 7 types of clinical documents: drug prescription, referral, medical equipment prescription, consultation note, diagnostic study note, laboratory report and hospital discharge summary.

Objectives: iEHR.eu which had developed all the previous versions of the IG has been commissioned to perform its transition to DECOR format [2], which is now the official HL7 Templates DSTU.

Methods: Development environment of ART-DECOR has been set up including reference to the base HL7 CDA building block repositories. Several new value sets from existing external Polish code systems have been defined. OID Registry for Polish eHealth agency has been designed using ISO-13582 conformant XML syntax and new code system for Polish HL7 V3 qualifiers in ClIaML format has been defined. Total number of 194 templates including 17 document-level templates have been created.

Results: Observations from performed work regard unclear DECOR relationships between templates and its influence on consistent national level IG maintenance, differentiation of abstract and non-abstract templates and support for definition of business rules. The process of IG publishing has been modified to meet national needs.

Conclusion: DECOR proved to be very useful format for HL7 CDA implementation guide on national level. Comments and suggestions for the future have been collected and communicated to the ART-DECOR team.

Keywords
eHealth, HL7 CDA, ART-DECOR

References


Abstract

Background: As far as HL7 CDA standard is concerned there are many implementation guides already created on the national or regional level, due to specific local regulations and requirements. Since rapid development of the DECOR specification which is now official HL7 DSTU for V3 templates, it is possible to perform transition from local implementation rules to automatically generated, constrained programmable objects to be part of software components for EHR systems.

Objectives: The main objective was to design the framework for rapid and standardized development of clinical document editor software component, generating HL7 CDA documents, conformant to the specific implementation guide.

Methods: The ART-DECOR environment is the center pillar of the framework. For each component instance there is a specific DECOR project containing templates and value sets with a reference to local or external building block repositories. The second major component of the framework is the set of C# libraries build on the top of ASP.NET technology stack, being the code base for every form and control used in the component instance and implementing input and context data processing, data binding and RESTful API for clients. The MARC-HI Everest Framework is used for serialization and deserialization of CDA documents.

Results: Having repeatability in mind we have designed Definitions Database containing constrained CDA R-MIM classes, data bindings, input and context data schemas and stylesheets for further reuse.

Conclusion: As a conclusion, the DECOR specification should not be only treated as a format for definition of implementation rules, but also as a supportive tool in software development process.

Keywords

HL7 CDA, CDA Editor, DECOR, ART-DECOR, Everest Framework, EHR

References


Implementation Report on HL7 Infobutton in the Czech Republic

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Abstract

Background: HL7 Infobutton facilitates medical knowledge search and retrieval by user directly from a clinical application (EMR). The query initiates in the EMR by hitting an 'Info' button displayed side-by-side particular medical term. Consecutive query describes the context of the click – who is performing the click, the task in the application (context), particular medical term and many more. Appointed knowledge manager (KMgr) server represents institutional set of medical knowledge sources (MKS). The KMgr distributes the query and collects all answers from MKS in form of Atom feeds.

Objectives: Easy search and access to medical knowledge in right context of the user can speed up new knowledge turnover from scientific articles and academia to daily medical practice. Our objective is to support such knowledge turnover in the Czech healthcare by involving Czech medical knowledge sources [1].

Methods: To support Infobutton service dissemination we should provide working Infobutton KMgr loaded with useful medical knowledge sources in the Czech language. To support adoption by EMR vendors as well as a query ability of Czech MKS (libraries, patient portals, governmental institutions) we should provide meaningful demonstration of the system. Implementing such system, we expect to uncover problems related to national terminologies, aspects of Czech medical informatics environment and Czech language related issues.

Results: We built complete demonstration setup. As the Infobutton KMgr we involved the OpenInfobutton - an open source implementation.

To demonstrate info-button usefulness in the EMR we selected university-based Electronic Labor Book [2]. This EMR is in daily use at Obstetrics and Neonatology department of Brno Hospital. We identified several GUI spots where info-buttons can be placed. All info-buttons produce an ICD10 based search query.

To demonstrate ease of MKS implementation as well as a gain in publicity and visibility of the source, we selected university-based Czech Catalogue of Clinical Practice Guidelines [3]. This website system holds more than 500 links to guideline documents published by Czech medical chambers. The catalogue has already been equipped by ICD10 search index.

Conclusion: Existence of working implementation of Infobutton KMgr with preconfigured English MKS (OpenInfobutton) gave us good starting point. Loose coupling provided by the Infobutton architecture inhibits any interdependency of EMR and MKS development.

EMR extension proves to be not quite complicated even when parsing Atom feed without any third-party library. It opens many possible features dealing with user behaviour and intrahospital education management.

Having ICD10 indexed database the MKS Infobutton responder implementation was easy task.

We identified problem with Czech disease names in ICD10 (MKN10): First, the MKN10 XML definition originated in DASTA protocol provides names with some abbreviations. The EMR thus does not know full name and is unable to put it in the Infobutton query. This
effectively inhibits the full text search in any MKS.

EMR vendors can overcome the problem by providing alternative full text search criterion for each info-button appearance.

At the end, we have solid background for national Infobutton service.

**Keywords**

HL7 Infobutton, implementation, EMR, knowledge source

**References**


Abstract

Background: IHE profiles can significantly speed up the process of interconnecting compliant information systems. In the Beroun Hospital, two non-compliant systems were running – EuroMISE Organize scheduling system (SCHS) and Akord hospital information system (HIS). Upgrading the HIS to achieve IHE compliancy or at least to include support for HL7 messaging was not a feasible way to go.

Objectives: The hospital owner requested to inhibit double patient data entry and keeping the HIS as a master source of patient demographics. We aimed at a setup that allows keeping both systems updated immediately.

Methods: We studied the Master Patient Index (MPI) concept in general, then the IHE PAM and IHE PIX profiles to fulfil the hospital requirement. To overcome the passivity of the HIS, we access patient data directly in its SQL database involving trigger events on a table insert/update/delete. To isolate the IHE implementation of the scheduling system apart from the SQL strategy at HIS side we plug the Mirth integration engine in the middle.

Results: We decided for IHE PAM based on HL7 v2.5. The SCHS included HAPI library. The integration of the HIS is done by Mirth database connector to MSSQL, isolated database tables used for data exchange and table triggers to facilitate data propagation in both communication directions. Such isolation guarantees transparent SQL access to original HIS database. This was required not to break a HIS vendor’s service level agreement (SLA).

At startup, the setup synchronized more than 150 thousand patients in about 2.5 hours.

Conclusion: The setup included a challenge of integrating a system that does not support foreign IDs while the customer requested this system to act as an authoritative master and to support integrating records originating from the scheduling system.

The HAPI really eases the Java implementation of the HL7 messaging at SCHS side.

To our surprise, the IHE PAM does not mention any strategy for first synchronization. It involves the same HL7 messages but special behavior of applications such as a pseudo-creation of each patient. In addition, the IHE PAM does not mention any strategy for resynchronization in case of interconnectivity failure.

Keywords
Integration, IHE PAM, hospital information system, HAPI, implementation
Transmission of laboratory infection prevention data according to German legal specifications using IHE XD-LAB

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Abstract

Objectives: According to German legal specifications each resident physician, hospital and laboratory is obliged to transmit data about notifiable diseases or agents to the relevant health authority. In case of reasonable suspicion, affection or death by infectious diseases specific information is differently communicated by laboratories and physicians. Proprietary ways of transmission inherit threats like deficient or incomplete availability of data. At least these circumstances imply non-predictable health-related hazards for the population.

Methods: As the carrier of the information, HL7’s Clinical Document Architecture (CDA) will be tested by designing appropriate CDA templates to define the contents of the notifiable disease documentation. These templates are derived from the IHE Sharing Laboratory Reports (XD-LAB) Integration Profile specification. IHE XD-LAB provides an electronic format for the laboratory report, which is human and machine readable. This double capacity is achieved by leveraging the HL7 CDA standard. IHE XD Lab defines a root section called “specimen act” which encapsulate entries for specimen collection, specimen reception, laboratory and isolate organizer and the more important notification organizer which contains the report.

Results: The international established medical terminology SNOMED CT can contribute semantic interoperability and a highly specific description of laboratory findings. The applicability of SNOMED CT shall be tested in the domain of laboratory findings respective notifiable infectious agents. Also LOINC standard shall be tested for identifying medical laboratory observations which are used for the laboratory test.

Conclusion: Very similar work has been done in Austria and Switzerland. These approaches also make use of IHE XD-LAB. Because viruses don’t know any national borders it should now be a purpose to harmonize this work for Europe. This work can be used as a basis for any future work.

Keywords

Infection prevention, HL7 CDA, IHE XD-LAB, SNOMED CT, LOINC
Semantic interoperability in eHealth Switzerland based on HL7 CDA

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Abstract

The eHealth strategy Switzerland bases on IHE for technical and semantic interoperability. Therefore multiple implementation guides were published. Using these implementation guides Switzerland becomes interoperable across institutions, regions, cantons and even countries. Not only technical interoperability but also semantic interoperability is given by the usage of international codesystems and the detailed description of value sets.

An open source project "eHealth Connector (eHC)" has been established to increase the number of implementations. Vendors using the eHC will benefit in costs and development time and become able to sell an even more interoperable and harmonized product.

Planned agenda for this presentation:

• Short overview over the Swiss eHealth strategy
• Their key elements for a technical and semantic interoperability
• Main advantages and benefits of the "eHealth Connector", an open source initiative for a convenience API for software vendors (see also http://sourceforge.net/projects/ehealthconnector/)
• Existing and planned CDA implementation guides
  − CDA-CH-EDES - Emergency Department Encounter Summary
  − CDA-CH-LRPH - Laboratory Reports for Public Health
  − CDA-CH-LRTP - Laboratory Reports in the Transplantation Process
  − CDA-CH-MSET - Medical Summary for Emergency Treatment
  − CDA-CH-SMCP - Social medical care plan
  − CDA-CH-SMTL - Shared Medication Treatment List
  − CDA-CH-VACD - eVACDOC (Vaccination card, Immunization request and recommendations)
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