Testing a New CDA Development Strategy in a Standardized Infrastructure for Continuity of Care in Chronic Kidney Disease Patients

Alberto Moreno, Alicia Martínez, Francisco Núñez, Carlos Parra

Virgen del Rocío University Hospital

Abstract

Objectives: In order to provide continuity of care for Chronic Kidney Disease (CKD) patients transferred to external outsourced centres, Virgen del Rocío University Hospital has developed an interoperability platform based on interoperability that enables the communication with the 8 different private providers. **Methods:** The development of this infrastructure has been based on IHE profiles and CDA documents. Specifications of this interoperability scenario will be made public to create different business models for Haemodialysis (HD) providers and IT health providers. **Results:** As part of this project, a set of CDA templates was created for the nephrology domain in Archetype Description Language format that also could be known as CDA archetypes. This new approach for developing CDA documents was able to create semantic structures that successfully define the relationship among different concepts based on the RIM that could be reused for nephrology domain. The results from our pilot experience will be the basis for a new implementation guide for CDA in the nephrology domain by HL7 Spain.

Keywords

Clinical Document Architecture, Interoperability, Electronic Health Records, Nephrology, archetypes, Integrated Healthcare Enterprise Profiles

Correspondence to:

Alberto Moreno Conde
Virgen del Rocío University Hospital
Av/Manuel Siurot SN. Edificio de Documentación Clínica Avanzada
41013 Sevilla (SPAIN)
E-mail: alberto.moreno.exts@juntadeandalucia.es

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1 Background

Nowadays, a large number of specifications can be applied to Electronic Health Record communication (EHR). This is a complex environment obtaining a perdurable infrastructure is important in order to align communications with the leading interoperability initiatives at international level.

At European level, epSOS project could currently be the most ambitious interoperability project at our continent since its large scope requires addressing many of the most elusive challenges that prevent meaningful sharing of information among systems [1]. This project aims to develop and pilot a cross border interoperability infrastructure capable to share Patient Summary (PS), ePrescriptions (eP) and eDispensations (eD) among a large number of member countries. The project implementation guide has defined three CDA documents fully structured for PS, eP and eD [2] that are shared based on profiles defined by Integrating the Healthcare Enterprise. Given the high impact of epSOS project, it is foreseen that the adoption of these specifications will increase.

1.1 ISO/HL7 27932 Clinical Document Architecture

Health Level 7 foundation has approved the ISO/HL7 27932 – Clinical Document Architecture Standard [3] in

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which is defined how clinical information can be structured and shared as documents based on the HL7 v3 Reference Information Model [4]. This specification defines the semantics for structure for XML documents.

1.2 Integrating the Healthcare Enterprise Profiles

IHE has defined a set of profiles that coordinate the application of communication standards such as DICOM, HL7, W3C and security standards in a scenario. IHE has defined a set of profiles for coordinating document and patient management tasks within the different systems in an Affinity Domain which are called Cross-Enterprise Clinical Documents Share Profile (XDS.b) and Patient Identifier Cross-referencing for MPI Profile (PIX) [5].

1.3 Clinical Information Modelling and harmonisation efforts

HL7 is working in the definition of templates [6] as specific documents or defined schemas specialised for a domain or use case. Templates definition is based on additional restrictions to the CDA model and they can be validated checking their results against a Schematron. They are able to promote the reuse of validated CDA or parts of them for a specific scenario.

In addition to the definition of CDA templates, there are other initiatives that aim to model clinical information such as HL7 Detailed Clinical Model [7], ISO/EN 13606 standard [8] and OpenEHR specification [9]. To facilitate the harmonisation among different approaches, representatives from leading organisations in semantic interoperability are collaborating in the Clinical Information Modeling Initiative (CIMI) [10] to provide a common format for semantically interoperable information. CIMI is committed to make these specifications initially in two formats: Archetype Definition Language (ADL) [11] and Unified Modelling Language (UML) [12]. Given that ADL is able to be applied to any reference model, this language could be applied for defining HL7 CDA templates. Although this strategy will not solve the interoperability among information defined in different standards, this harmonisation will facilitate the mapping process among them [13]. The adoption of ADL for defining CDA templates allows incorporating tools designed for the archetype approach in CDA development tasks and fosters the development of tools compatible with both approaches.

1.4 Haemodialysis scenario

When a patient is diagnosed with CKD in the Virgen del Rocio University Hospital (VRUH), he/she must follow a healthcare process including haemodialysis sessions, medical treatments, follow-up sessions and laboratory analysis. This public hospital is in charge of these chronic patients since the disease is diagnosed and transfers patient to outsourced external HD centres when the patient is stable.

The process starts when the patient is assessed in the Predialysis Unit, where a report is subsequently sent to the VRUH Nephrology Department. Based in this report, nephrologists generate a HD treatment plan. Also, they evaluate whether the patient is stable enough to be transferred to an external centre in order to undergoing a HD treatment, or must undergo it in the VRUH facilities otherwise. Afterwards, the Administrative Unit decides the external HD private centre where the patient will undergo his/her HD session. Once the patient is transferred to an external centre, a follow-up strategy for each patient takes place, leading to the generation of a session report every time the patient undergo a HD session. This report is then sent to the VRUH in order to be available for the nephrologists to be consulted in real time.

Once the patient is assigned to an external centre, he/she could be transferred again to the hospital whether his/her health condition become unstable. In addition, patient's mobility must be considered in this scenario, taking into account holidays and long-term displacements from his usual residence. This implies that the patient should be transferred from his/her usual HD centre to another closer to his/her new location. This issue is also managed by the Administrative Unit.

Furthermore, this scenario includes lab test information flow that needs to be shared among hospital and external centres because nephrologists from both health care providers need to keep control of patient response to HD treatment. Although there were EHR systems in VRUH and some of the external centres, the communication among them was paper based.

2 Objectives

This project aims to develop and test new interoperability approaches in a real scenario. This will be done in a platform able to be applied by the VRUH Nephrology department to provide care for CKD patients. Moreover, this platform has to be integrated with the regional architecture of the Andalusian Health Service and interoperable with external nephrology systems based on defined specifications. These specifications will be made public for all external HD private centres.

3 Methods

In order to achieve the continuity of care in CKD patients, in VRUH has been implanted the Nephrology Platform (NP). This platform is able to deploy new services and pilots projects focused on nephrology scenarios within the hospital environment. Nowadays, the NP allows communication and coordination among all the professionals involved in the CKD patients care (in our case, the hospital professionals and the external private HD centres).

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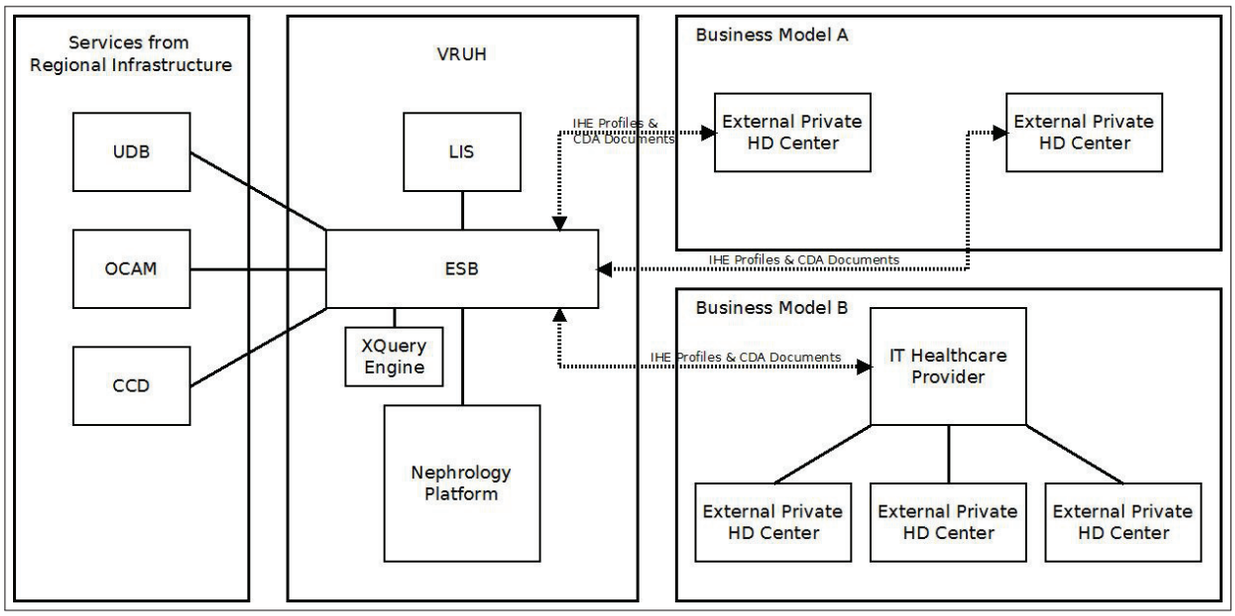

Figure 1: Defined Infrastructure

3.1 Open Business Model for Health and IT providers

The interoperability specifications in our nephrology domain are documented and it will be made public to allow any system to satisfy them. As a result, in our scenario there are the following business models depending on which type of client is presented (Figure 1):

- Business Model A. In this business model, the client is an external private HD centre that directly processes the messaging and handles the information according to its own needs.
- Business Model B. In this business model, must be an IT Healthcare Provider that offers to external private HD centres a system to address the functionality specified.

3.2 Integration with regional infrastructure

The NP is the EHR system for the nephrology professionals. This platform is a complement to other EHR systems in use. The NP is aligned with the Andalusian Public Health Regional SOA infrastructure through the following services:

- UDB. User Data Base. This is a central patient management system that includes their demographic data.
- OCAM. Operator Centralised Access Module. This system manages professional roles and passwords in order to allow other applications set different access levels.
- CCD. Centralised Clinical Data. This system is a registry that contains identifiers and pointers to clinical reports and general information about the patients (encounters, allergies, problems and treatments, etc.).

3.3 Interoperability with External Private Centres

The NP has been developed in order to be able to generate the following documents needed to support the CKD process. These documents have been defined as CDA documents and are able to establish a bidirectional communication among VRUH and the external centres. In order to perform the communication, these CDA are encoded in base64 to satisfy XDS profile.

- Referral CDA. This document is sent when the patient is included in the referral process. The document includes a patient summary and his/her evolution through previous HD sessions. When this document is generated, a communication channel between the centres involved in the health care for this patient is set up, enabling all the documents and information necessary to be shared.
- Prescription CDA. In this document the nephrology professionals specify the patient treatment plan including number of dialysis sessions, dialysis settings and medication list. This document guides nurses in preparation tasks of the sessions.
- Session CDA. This document contains the patient evolution through the session including vital sign evolution, weight, dialysis catheter, others accesses. Nurses must record patient vital sign every hour.

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Table 1: Number of times that Generic archetypes have been specialised

CDA Document	CDAHeader	SubstanceAdministration	Organiser	Observation
Referral	1	1	0	16
Prescription	1	1	29	121
Session	1	1	75	389

Additionally to these documents created by the health professionals and defined as CDA, the NP receives all the lab results from the Laboratory Information System (LIS) as HL7 v2.5 messages. Once the patient is transferred to an external private HD centre, NP sends notifications of all previous Lab Results from this patient to the system of the external HD centre which could request these documents at any time based on XDS profile.

4 Results

4.1 Platform implementation

The developed platform is based on the following technologies:

- ICEfaces framework [14] based on Java Server Faces (JSF) standard. This layer allows a separation between presentation and behaviour.
- Hibernate tools [15] as a productive persistence layer. These open source tools optimise the maintenance, performance and flexibility of databases.
- Spring tools [16]. This layer allows creating code with any lock-in.
- XQuery Engine. Our infrastructure incorporates a software solution called Saxon [17] which is able to execute the XQuery defined for creating CDA from the information generated in the Nephrology platform.

In the middleware layer, an Enterprise Service Bus (ESB) allows and manages the communication of the NP with centralised services of the regional architecture, external private HD centres and other systems from VRUH.

The infrastructure has defined an Affinity Domain among VRUH and external private HD centres. A Master Patient Index actor is in charge of the patient identification and a Document Registry actor will contain references to the patient clinical information. When a patient is assigned to an external private HD centre by the Administrative Unit of VRUH, his/her demographic data is sent to the receiver using the IHE PIX profile. At this time, notifications for all the previous documents that patient history contains are sent to the receiver using the IHE Register Document Set transaction, specifying the record identifier. When nephrologists at external private HD centres need the record, their external system requests it using the IHE Retrieve Document Set transaction and then NP sends the document.

4.2 CDA development

In order to develop these CDA documents, it has been applied the LinkEHR Ed tool [18] that is able to map information from any XML format to the most common EHR standards such as CDA, HL7v2 and ISO13606. This tool defines these mapping relationships as a XQuery file and this can be executed by any XQuery engine. Therefore, NP sends a simplified XML that is transformed to CDA by the XQuery engine and after it is sent to the external private HD centres.

In addition, LinkEHR tool is able to create archetypes based on the Reference Model of these specifications. As a result, archetypes were defined as CDA templates in ADL format for exchanging the nephrology documents.

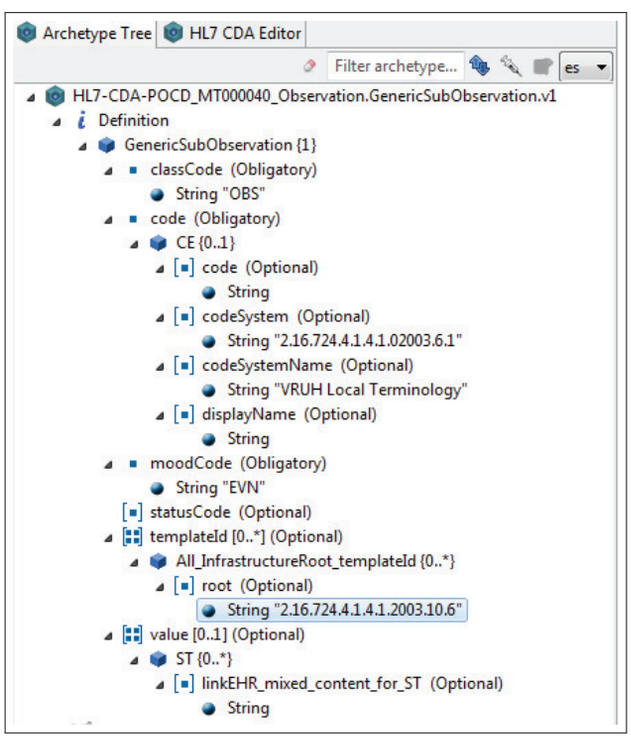

Figure 2: Definition of a Generic Archetype in the LinkEHR

To illustrate the extensive amount of information needed by the nephrology department, Table 1 details the required CDA structures. Based on this interoperability scenario it was possible to define a set of generic archetypes for CDA Header, Observation, Organizer and SubstanceAdministration entries that facilitated the de-

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velopment process (Figure 2).

These generic CDA archetypes could be specialised when they are applied in the resultant CDA document [19]. For instance, the Observation Entry Generic Archetype has assigned a TemplateId and also defines classCode, moodCode, statusCode, codeSystem, codeSystemName to be shared among all the entries. These generic CDA archetypes define only semantic structure CDA compliant and they facilitate the development stage since they can be combined as many times as required once they are specialised. As a result, defined generic archetypes specify the semantic structure for our local context without including clinical information. They are the basis for the specialised archetypes, which are conformant to the resultant CDA and include the clinical concepts specified by our nephrology department.

In addition, specialised archetypes were able to model the clinical information and incorporate complex relationship between concepts. For instance, Organizer Entry Archetypes define the relationship among different Observation Entries based on the requirements defined by domain experts. Given that the information contained in prescription and session record is very close related, they share most of their archetypes with a reusability ratio greater than 50%.

Based on reusing generic CDA archetypes, the management of mandatory components of the CDA model for a local organisation or IT infrastructure specific system is facilitated. In order to create additional CDA documents for new scenarios, the already defined generic CDA archetypes for our IT infrastructure context will reduce time and complexity for development tasks.

Furthermore, given that the LinkEHR tool is able to map the CDA archetypes to any data source in either XML or Database format, the defined archetypes for these three CDA documents can be applied by other systems in the same IT infrastructure. Mapping either databases or messages from legacy EHR systems already in use within the external HD private centres to these CDA archetypes would allow them to send their information in the CDA format specified. As a result, CDA archetypes could be successfully applied as a target specification for legacy systems facilitating their compliance with CDA standard.

5 Conclusions

The platform is currently being piloted by the nephrology department and the 8 external HD private centres through an IT Health provider. Nephrologists from external HD private centres receive demographic data, lab results, referrals and prescriptions for the 548 transferred patients. In a couple of months, it is expected to complete the bidirectional communications and it is planned to perform a cost-effectivity study about the impact that this new infrastructure has on clinical practice. The defined specifications have successfully opened a market for different health and technical providers. After the pilot stage, external private HD centres will be able to evaluate their preferred option for communication with the hospital either by their own developed system or an IT health provider.

The results from the development of these generic and specialised CDA templates based on archetypes provides a set of semantic structures that can be reused in future interoperability scenarios. These archetypes are expected to be the source for a new implementation guide for CDA in the nephrology domain which has just started within the HL7 Spain Technical Committee.

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