Application of HL7 CDA R2 and V3 messaging for national ePrescription in Finland

Jari Porrasmaa[a)], Juha Mykkänen[a)], Timo Tarhonen[b)], Marko Jalonen[c)], Petri Kemppainen[c)], Antero Ensio[d)] and Vesa Pakarinen[e)]
[a)] University of Kuopio, IT centre, PO BOX 1627, 70211 Kuopio, Finland, [b)] Tietotarha Oy,
[c)] The Social Insurance Institution of Finland (Kela), [d)] Ensitieto Oy, [e)] VTT Information Technology

***Abstract*- This paper presents an overview the national efforts on ePrescribing in Finland. The main focus is on the utilization of HL7 standards, but an overview of main functional requirements, development and deployment plan is also presented.**

I. INTRODUCTION

The foundation for ePrescribing (eRx) in Finland has been laid out by legislation in 2007 and 2008 [1,2]. Another important component has been an earlier eRx pilot which led to changes to the original approach [3].

The Social Insurance Institution of Finland (Kela) has mandate on the information content of both paper-based and electronic prescriptions. Kela is also responsible for building the National ePrescription Centre and several other services to implement the national eArchive for patient records. The law sets a transition period until 2011 1st of April when eRx is required to have been implemented and deployed nationally.

An initial set of functional and data requirements for the eRx system were defined by consultants and Kela through several iterations. HL7 technical specifications were developed in parallel – multiple iterations and national ballots were required to achieve the version for the first development and deployment phase. A consortium of companies was selected for the implementation of the eRx service in May 2007 and the service will be online before the end of 2008.

The eRx service is related to several components that are beyond the scope of this paper. These include the national PKI solution, the national pharmaceutical database, the code sets and classifications provided by the national code server, patient's browsing system, decision support applications and the certification criteria for the applications related to the eRx service [4].

II. OVERVIEW OF FUNCTIONALITY AND ARCHITECTURE

Kela has created the high level specifications for the eRx service. Most of the specifications focus on the use cases and requirements for EPR systems (or eRxing apps) and pharmacy systems which use the service, respectively, but a shared overview and unified information content is provided.

A. Main use cases

Table I gives an overview of the use cases that have been defined. In addition to the this functionality, general supporting use cases for login and authorization, logout, user rights management have been defined. Technical use cases include sending and receiving documents between eRx service and the different systems.

TABLE I
USE CASES FOR MAIN FUNCTIONALITY

EPRs/ eRxing systems use cases	***Pharmacy systems use cases***
Browse prescriptions, dispenses and renewal requests	Update prescription status information (hold, lock, …)
Write prescription	Dispense a prescription
Send signed prescriptions and corrections	Correct a dispense
	Repudiate a dispense
Release a held prescription	Select prescriptions for dispense
Shared use cases	
Repudiate a prescription	
Correct a prescription	
Print overview of prescriptions	
Print patient instructions for a prescription	
Add and process renewal requests (simplified, includes other use cases)	

B. Overview of the prescription and dispense process

Fig. 1 displays the most significant information flows of the prescription process, numbered in their typical occurrence order. When a prescription is sent to the eRx service, patient receives an optional paper instruction which includes a barcode containing the document id. The patient or a representative can use this document in the pharmacy to indicate which prescription is to be dispensed. If no document is presented, the pharmacist can use the national person id number to fetch undispensed prescriptions. Dispense document is sent to the eRx service. The patient can ask for renewal in a healthcare facility or a pharmacy and receive the result of renewal process via an SMS message. The patient can access the prescriptions securely on the web. Authentication is done with online banking passwords or by a citizen PKI card.

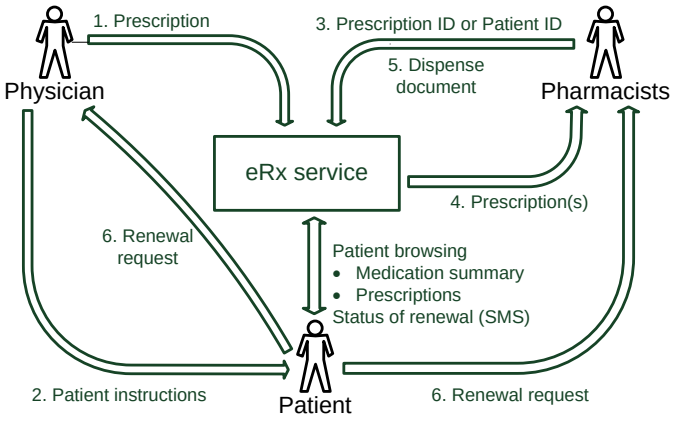

Figure 1. Information flows of prescribing, dispensing and renewing

C. Architecture and technology

The architecture is based on a centralized repository service for ePrescriptions and messaging. The solution employs service-oriented principles and synchronous web service interfaces to transfer HL7 V3 messages. HL7 Web services transport profile has been applied. The transferred data is encrypted using two-way authenticated SSL/TLS connections. If third-party service providers mediate messages, Web Services Security X.509 token profile is required for the authentication of the user organization [5].

The internal structure of the centralized solution consists of the messaging interface, a BPEL process engine and a content management platform. The latter contains a database for metadata management and WORM (Write Once Read Many) capable data store for storing the actual documents as mandated by the retention period of each document type. Data security tools for monitoring the use of the eRx service and 'vaulting' the sensitive data as well as redundancy for the data storage are provided. The architecture is kept similar to the national EPR archive service while taking the functional differences into account.

III. HL7 Solution and Implementation Guidelines

D. Background and rationale for selecting CDA R2 and V3

Prescriptions need persistence and authentication, and are also archived after 30 months. HL7 Finland has created several implementation guidelines for CDA R2 and R1. Vendors are also quite familiar with CDA documents. The paper-based prescribing approach also fits quite closely to the document-oriented paradigm of HL7 CDA. V3 messaging has been used in earlier projects related to scheduling and death notifications. CDA R2 was chosen as the basis for prescription and dispense information. HL7 V3 Medical Records DSTU was approved shortly after the HL7 Finland work started on eRx and it was selected for communication. Pharmacy messages were also considered, but eventually it was decided that eRx content was to be specified using CDA R2.

E. HL7 Finland implementation guidelines (IGs) for ePrescribing

The HL7 Finland eRxing specification package consists of the following IGs: overview, eRx CDA R2 header, eRx CDA R2 body, eRx Medical Records messages and related schema files [6]. The national HL7 V3 messaging IG is also utilized.

The CDA R2 header guide specifies the required header fields and local extensions, multiple document signature and document relationships between the 18 different CDA R2 document types of eRx. The digital signatures are used according to W3C XML DSig recommendation, except the multiple document signature which has a wrapper layer to allow each document to have an independently verifiable signature.

The CDA body guide defines the content of 18 different documents used. Prescription and dispense documents are the most complex ones. Documents related to renewal requests are very simple with only a few structured entries.

The medical records (MR) domain document management is modeled so that there are two almost identical message types, which are used in 30 interactions. The eRx service is modeled to reflect the business names of the operations (e.g. add prescription document, lock prescription).

IV. Discussion, Issues and Conclusions

In the body portions of the ePrescribing documents is was rather difficult to express the structure of medication and structured dosage with CDA R2. This was solved by using a general organizer entry. In comparison to the RIM and some pharmacy models, CDA R2 RMIM is non-optimally constrained for ePrescription. The narrative block of CDA leads to some redundancy, as all systems are expected to use the fully structured entries. The narrative block is still mandatory, but little focus is given to its layout and content.

In CDA R2 header the document relationships are used to express broader document relationships than the original standard. CDA R2 restricts parent document to a single type code or a combination of either transform and replace or transform and append. However, in the eRx document relationships there is a need to use combinations which are not allowed, such as replace and append in a single document.

The MR approach to interactions suits the eRx approach well. The same data model is used in all interactions and primarily only the interaction name varies. All interactions are localized. Interactions returning metadata have been extended to include information from the prescription and dispense content. The MR domain has no application level acknowledgements which had to be added to all interactions.

XML digital signatures seem easy to add on top of CDA. However, the details can be problematic. The CDA XML schema does not have XML IDs in all the potential elements you might want to sign (e.g. structuredBody). XPath filtering works even if IDs are not available, but requires careful consideration for correctness of the filter expression.

In conclusion, despite some of the problems encountered, HL7 V3 and CDA R2 have provided a valuable blueprint for the specification of national ePrescribing solutions.

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