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Dynamic Creation of Patient Summaries: A CDA and IHE XDS Based Approach for Regional EHRs

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Abstract

Cooperative healthcare is regarded as one of the major goals for providing adequate health related information to physicians. To achieve this goal, national authorities and large hospital organizations are introducing large scale, standard based transactional EHR systems. Those systems record and distribute a significant amount of medical related data. This raises the concern of information overload for the intended users. The objective is to elaborate on an architecture and consequently a workflow that allows the generation of an automatic patient summary in a standard based IHE XDS environment. A literature review evaluating the current state of research is conducted. Current eHealth projects, laws and technical background are analyzed. An architecture is suggested, prototyped and compared using SAAM (Software Architecture Analysis Method) against alternative approaches. A technical workflow built on IHE XDR and HL7 FHIR observations is suggested introducing two new services within an IHE XDS product for extracting observations from CDA documents and storing the data on domain level scope. The information is published as an OnDemand Document in the IHE XDS infrastructure.

Keywords:

Electronic Health Record, Information Management

Introduction

For information systems and software products operating in the professional domain of eHealth, one major goal is providing health related information to physicians and patients adequately and timely [1]. Providing medical practitioners with comprehensive electronic health records (EHRs) and information is intended to contribute to an optimized treatment process and essentially improve continuity of care [2]. Therefore, this is seen as a prerequisite to a more efficient and cooperative healthcare [3]. The definition and quality aspects of EHR systems have been evaluated and published according to several approaches over the last years [4]. Subsequently, national states as well as the EU are focusing on introducing regional/nationwide and connected EHRs [5; 6]. As a current example, Austria introduced ELGA "Elektronische Gesundheitsakte" (ELGA) [7]. It is a nationwide, standards-based EHR infrastructure which went online officially in December of 2015. ELGA is regarded as a virtual EHR system for all Austrian citizens connecting all hospitals and a patient portal in several phases [5]. Due to their nature, such large scale EHR systems are expected to record and distribute more medical information and reports than conventional electronic medical records (EMRs) in isolated data silos. Benefiting from this vast information overflow is a challenge for physicians and systems [8]. However, doctors' acceptance of EHR systems is one major, critical success factor [9]. Presenting the patient's vital information in a summarized view, extracted from the information stored in the EHR, could lead to a reduction inworkload and an improvement inquality of care [10]. This set of data is referred to as a patient summary, a standardized set of medical data including facts that are necessary for a safe and efficient patient treatment. On a European level the epSOS project outlined a special form of such a patient summary [11]. This electronic patient summary is referred to as a "Consolidated Continuity of Care" (C-CDA) document. It has been defined by HL7 and required by the US-driven "Meaningful Use Stage 2" in the HITECH Act [12]. The objective of this paper is to elaborate on and conceptualize the ELGA implementation as an architectural validation of implemented IHE profiles to generate automatic patient summaries. The suggested approach respects currently established interoperability standards and workflows of large-scale EHR systems.

Methods

Focusing on recent work, a literature review of research onthe extraction of data and creation of patient summaries wasconducted. The research supporting this paper focused on recent publications found in Pubmed and the ACM Digital Library. Only documents published after 2003 were considered. For the identification of relevant papers, the following keywords and combinations were used: "ehr data summary", "ehr data extraction", "cda data extraction", "cda patient summary"" "clinical document data extraction". Relevant references from already included papers were also included. In addition to the analysis of relevant academic papers, current market leading standardization organizations and the technologies of current eHealth projects were identified. National data privacy and health telematics laws as a basis of regional/national EHRs [13] and the technical background of the implemented architectures were analyzed. The newest developments from the standardization units and organizations, whose technology and standard definitions were identified asbeing used in current eHealth projects, were analyzed.

Using this information, a technical concept intended to seamlessly integrate into a standardized eHealth architecture wasdeveloped. In order to validate the feasibility of the concept, a prototype was implemented and integrated into a demo installation of a major eHealth EHR product (sense® by ITH icoserve GmbH, a Siemens company). The product was selected because it is deployed in major parts of the Austrian

ELGA EHR and thus fulfills all requirements defined for the national project [7].

As a final step the architecture was compared with two other approaches discovered in the literature review executed in the initial step. The Software Architecture Analysis Method (SAAM) [14] was used for comparison. The compared architectures are described in [15] and [16].

Results

The following set of standards and technologies were identified as crucial:

- IHE IT Infrastructure Framework (IHE XDS, XDS-I, PIXPDQ, XDR, ATNA and related profiles)
- HL7 Clinical Document Architecture (HL7 CDA)
- HL7 V2, V3 and Fhir as Data- and Communication Model
- Logical Observation Identifiers Names and Codes (LOINC)

The literature review also confirmed the initial assumption concerning the need of a summarization of patient information stored in an EHR infrastructure. Electronic medical records (EMR) and EHR systems still primarily operate on the basis of documents as atomic information entities [17]. For users, this is in strong contrast to the requirements for the EHR to grant fast access to discrete data [18] as well as an adequate and scalable retrieval of information [19]. As the patient summary is intended to be part of an EHR system, this requirement is also mandatory for the proposed architecture. Another aspect is that EHR systems are required to strictly enforce a tight and well defined access control system limiting the user's rights and abilities. This also impacts the data included in a patient summary since users with different rights may have access to different data presented in the summary. The contained data is also dependent on the treatment context in which the user is accessing the EHR. We concluded that it is necessary to generate a patient summary on demand. In order to fulfill the previously mentioned requirement of the access performance, we suggest a system that uses a database of previously extracted information. This database is populated in the workflow of registering documents in the distributed infrastructure such as defined by IHE XDS [17].

In such an environment the registration workflow is executed by three services implementing the following IHE profiles: Document Source, XDS Repository and XDS Registry, as depicted in Figure 1. The system by definition does not analyze the documents content, the nature of the documents is reflected by the document metadata.

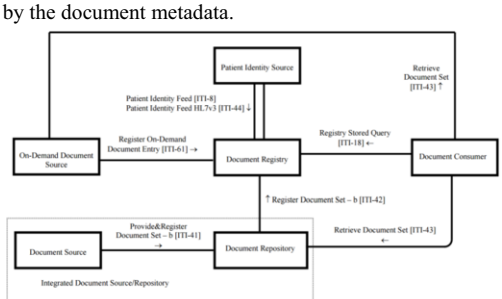

Figure 1– IHE XDS-b Architecture Overview [17]

To overcome this document based approach we introduce two new services: Observation Extraction Service (OES) and Observation Broker Service (OBS). The OES is intended to operate within the scope of the local institution; the OBS is operating on scope of the IHE affinity domain. The deployment scenario and overview of the architecture is depicted in Figure 2.

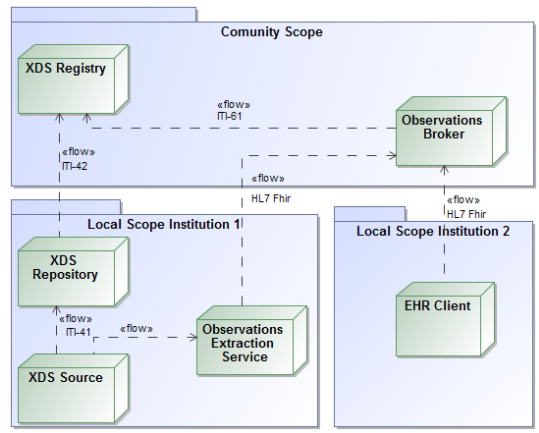

Figure 2– Deployment Overview of an Observations Enhanced IHE XDS Infrastructure

The main task of the OES is to extract data from the CDA documents intended to be registered in the EHR system. To assure standard based communication it is expected to provide an IHE XDR Recipient compliant interface [17], accepting the ITI-41 (Provide and Register Document Set-b) transaction. Using this interface, a standards based XDS Source can submit the data triggering a second ITI-41 transaction to the OES in addition to registering it in the infrastructure. Medical information is expected to be represented in a structured and coded format within the CDA documents, e.g. in the context of the Austrian national EHR ELGA data is coded using the LOINC (Logical Observation Identifiers Names and Codes) Standard. LOINC is a database which provides a universal code system for reporting laboratory and other clinical observations [20]. Using this information, the OES can extract discrete data. To make the data available to all authorized users and systems accessing the affinity domain the data is submitted to the OBS using a REST based HL7 FHIR transaction [21]. The OBS is intended to collect discrete data of the patient. These include, but are not limited to, the data extracted from the previously extracted documents. It is also possible, using the HL7 FHIR transactions to submit directly the discrete values that were collected in the process of progress monitoring of a patient, laboratory data, vital signs from home monitoring, or other [21]. For publishing the data to the affinity domain, the OBS registers an On-Demand Document to the affinity domain using the IHE Transaction ITI-61 [22]. This document, which is assembled at the time of access using the data registered in the OBS service, allows XDS based clients to retrieve the data wrapped in a CDA L3 document using the standard ITI-43. In addition, it is also possible to access the data using an HL7 Observations Query, if the client wants to avoid processing an XML based documents (e.g. on mobile devices, where REST based API calls are preferred [23]). The workflow of the registering and retrieval process is outlined in Figure 3.

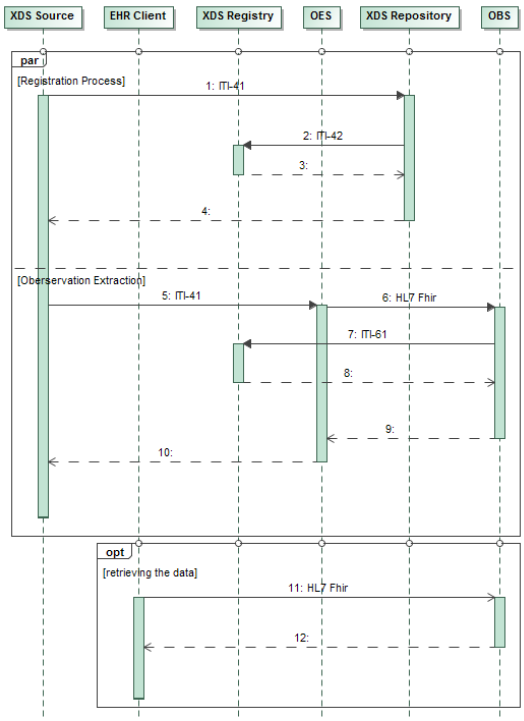

Figure 3– Workflow of the Registering and Retrieval of Observations extracted from CDA Documents.

Another aspect that needs to be considered is the management of data that is needed from the extraction process. Using this workflow, the OES receives the whole document metadata in the initiating ITI-41. Using this information, the service is capable of deciding which documents are relevant for the extraction process and which are not. Additionally, in the document analysis process, the service can decide which information is sent to the OBS and which is not. This, however, is likely to be definied by the scenario the services operate in. This avoids the unnecessary duplication of irrelevant data.

Discussion

The objective of this paper was to elaborate on a conceptual architecture on a technical level of how patient summaries can be generated on the fly in an IHE standard based infrastructure. Starting off with a literature review,the need for an architecture solving this problem could be confirmed. The literature review– although the queries were conducted using broad search terms - resulted in only three relevant approaches. An explanation for this circumstance might be that standard based XDS EHR systems just started to be widely established in the last years.

In contrast to the other approaches, the workflow suggested in this paper tries to integrate into the registering process of medical documents. Capturing the data in the phase of registering allows the extraction of concrete data from the documents without executing automated transactions that do not involve human actors. Automated non-user-based, transactions are always regarded as suspicious and hard to explain to the patient who will see the automated access in the audit logs of the EHR, a functionality of EHR systems that is crucial for patient acceptance and in many countries required by law. [5]. In addition, using this approach, quality requirements addressing performance and feasibility can also be addressed. The direct extraction of the information from the EHR system would require the client to retrieve all relevant documents of the patient at runtime. Depending on the amount and size of the documents, this would take a significant amount of time and therefore result in negative impact on the usability of the solution. This drawback is avoided by designing a service containing pre-extracted and processed observation information.

The approach integrates seamlessly into standards-based EHR systems using the IHE XDS infrastructure. Using the directed submission functionality of the IHE XDR profile, documents can be directly sent to the service extracting the medical data from the document. This OES Service is within the scope of a local installation, e.g. of a hospital network infrastructure. The approach is also expected to scale well under high load since the extraction process itself is not carried out on a central infrastructure. The data itself are stored in a centralized service, the Observation Broker. This service is able to generate the patient summary itself. The output will either be an On-demand document [22] or a HL7 FHIR based query interface. The implemented prototype proves that it could seamlessly fit into a standard based IHE compliant product and does not require major additions to already existing workflows and standards as they are recommended in large eHealth projects like ELGA [24].

Despite these advantages, there has to be some additional work executed concerning the context and access rights. EHR systems, especially in the IHE XDS environment, are commonly built on an access control system focusing on restricting user access according to rules referencing the XDS document metadata, the role of the user, and the presence of a relationship or association between the user and the patient. As the referenced approaches within this architecture separate the discrete medical data from the document container, a concept needs to be elaborated, to efficiently establish a connection between the document metadata based access control system and the extracted discrete data segments. Another open topic is the auditing requirement of accessing the patient summary. While audit requirements for access toclinical documents is quite clearly defined by standardization units such as IHE or national laws such as ELGA, the audit specification for access toextracted discrete data elements or generated values are less clear. This concerns the pure information of the access to the information as well as what information is shown, when the data are accessed by a certain user.

Conclusion

Providing a summarized and aggregated view of the patients most essential information is an important feature for users of large scale EHR systems. To achive this, discrete values to information must be provided in addition to achieving this in document-based EHR systems implementing the IHE XDS standard. This information can be extracted from the structured CDA document. Establishing this extraction process in the workflow of registering documents allows the processing of the documents without triggering automated, consuming side transactions, which are regarded as sucspicious by patients and users. Additionally, extracting the information in the registration process has a positive effect on the performance, since the information is already present as discrete values and must not be gathered on the fly while the user is waiting for the information. It is, however, still an open challenge on how to restrict the access to the extracted information. Due to the document based nature of IHE XDS EHR systems the access control system of such deployments also work on a document

level. Solving this problem needs addidional research and will be the focus of future work.

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