

Clinical Document architecture (CDA) Development and Assimilation for Health Information Exchange Based on Cloud Computing System

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Abstract—Successful deployment of Electronic Health Record helps improve patient safety and quality of care, but it has the prerequisite of interoperability between Health Information Exchange at different hospitals. The Clinical Document Architecture (CDA) developed by HL7 is a core document standard to ensure such interoperability, and propagation of this document format is critical for interoperability. Unfortunately, hospitals are reluctant to adopt interoperable HIS due to its deployment cost except for in a handful countries. A problem arises even when more hospitals start using the CDA document format because the data scattered in different documents are hard to manage. In this paper, we describe our CDA document generation and integration Open API service based on cloud computing, through which hospitals are enabled to conveniently generate CDA documents without having to purchase proprietary software. Our CDA document integration system integrates multiple CDA documents per patient into a single CDA document and physicians and patients can browse the clinical data in chronological order. Our system of CDA document generation and integration is based on cloud computing and the service is offered in Open API. Developers using different platforms thus can use our system to enhance interoperability.

Keywords— Health information exchange, HL7, CDA, cloud computing, software as a service.

1 INTRODUCTION

Electronic Health Record (EHR) is longitudinal collection of electronic health information for and about persons, where health information is defined as information pertaining to the health of an individual or health care provided to an individual and it can support of efficient processes for health care delivery [1]. In order to ensure successful an operation of EHR, a Health Information Exchange (HIE) system need to be implemented [2]. However, most of the HIS in service have different characteristics and are mutually incompatible [3], [4]. Hence, effective health information exchange needs to be standardized for interoperable health information exchange between hospitals. Especially, clinical document standardization lies at the core of guaranteeing interoperability.

Health Level Seven has established CDA as a major standard for clinical documents [5]. CDA is a document markup standard that specifies the structure and semantics

of ‘clinical documents’ for the purpose of exchange. The first version of CDA was developed in 2001 and Release 2 came out in 2005 [6]. Many projects adopting CDA have been successfully completed in many countries [7], [8], [9]. Active works are being done on improving semantic interoperability based on open EHR and CEN13606 [10], [11].

To establish confidence in HIE interoperability, more HIS’s need to support CDA. However, the structure of CDA is very complex and the production of correct CDA document is hard to achieve without deep understanding of the CDA standard and sufficient experience with it. In addition, the HIS development platforms for hospitals vary so greatly that generation of CDA documents in each hospital invariably requires a separate CDA generation system. Also, hospitals are very reluctant to adopt a new system unless it is absolutely necessary for provision of care. As a result, the adoption rate of EHR is very low except for in a few handful countries such as New Zealand or Australia [12]. In the USA, the government implemented an incentive program called the Meaningful Use Program to promote EHR adoption among hospitals [13].

When a patient is diagnosed at a clinic, a CDA document recording the diagnosis is generated. The CDA document can be shared with other clinics if the patient agrees. The concept of family doctor does not exist in Korea; hence it is common for a patient to visit a number of different clinics. The exchange of CDA document is triggered in the following cases: when a physician needs to study a patient’s medical history; when referral and reply letters are drafted for a patient cared by multiple clinics; when a patient is in emergency and the medical history needs to be reviewed. It takes increasing amount of time for the medical personnel as the amount of exchanged CDA document increases because more documents means that data are distributed in different documents. This significantly delays the medical personnel in making decisions. Hence, when all of the CDA documents are integrated into a single document, the medical personnel is empowered to review the patient’s clinical history conveniently in chronological order per clinical section and the follow-up care service can be delivered more effectively. Unfortunately for now, a solution that integrates multiple CDA documents into one does not exist yet to the best of our knowledge and there is a practical limitation for individual hospitals to develop and implement a CDA document integration technology.

2 MATERIALS AND METHODS

In this section, we present the necessary techniques in detail for the design, and explain the implementation of our CDA generation and integration system based on cloud computing.

2.1 The CDA Document The HL7 Clinical Document Architecture Release 2 (CDAR2) was approved by American Nation Standards Institute in May 2005. It is an XML-based document mark up standard that specifies the structure and semantics of clinical documents, and its primary purpose is facilitating clinical document exchanges between heterogeneous software systems. A CDA document is divided into its header and body. The header has a clearly defined structure and it includes information about the patient, hospital, physician, etc. The body is more flexible than the header and contains various clinical data. Each piece of clinical data is allocated a section and given a code as defined in the Logical Observation Identifiers Names and Codes (LOINC) [15]. Different subcategories are inserted in a CDA document depending on the purpose of the document, and we chose the Continuity of Care Document (CCD) [16] because it contains the health summary data for the patient and it is also widely used for interoperability. Notable data included in CCD are listed in Table 1.

TABLE 1
Data Items in CCD Header and Sections in the CCD Body

CDA location	Data items
CDA Header	Document Information (creation time, template ID, language code, purpose) Patient's information (ID, name, gender, birth date) Author's information (ID, name, represented organization) Organization's information (name, address, phone number)
CDA Body	Payers Advance Directives Support Functional Status Problems Family History Social History Allergies Medications Medical Equipment Vital Signs Results Procedures Encounters Plan of Care

For the integrated CDA document, we chose the Korean Standard for CDA Referral and Reply Letters (Preliminary Version) format as the number of clinical documents generated when patients are referred and replies made, is large [17], [18]. It has the identical structure as the CCD and the types of data contained in the body are listed in Table 2.

2.2 Cloud Computing

Cloud computing refers to both the applications delivered as services over the Internet and the hardware and systems software in the data centers that provide those services [19]. The user pays fee depending on the amount of resources allocated, such as network, server, storage, applications and services. Currently, three major types of cloud computing service exist:

TABLE 2
Sections in the Korean Standard for CDA Referral and Reply Letters Body (Preliminary Version)

Sections in CDA body	CDA Referral letter	CDA Reply letter
Diagnosis	Yes	Yes
History of past illness	Yes	No
History of Medication Use	Yes	Yes
Laboratory studies	Yes	Yes
Radiology studies	Yes	Yes
Pathology studies	Yes	Yes
Function Status Assessment	Yes	Yes
Surgical Operation Note	Yes	Yes
Relevant Diagnostic Tests	Yes	Yes
Reason for referral	Yes	No
Special Treatments and Procedures	Yes	No
Subsequent Evaluation Note	No	Yes
Plan of Treatment	No	Yes

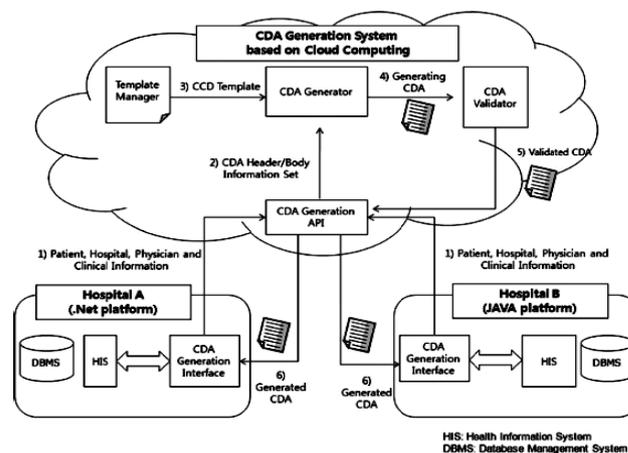


Fig. 1. The architecture of our CDA generation system based on cloud computing

- 1) Software as a Service (SaaS): This service model provides software.
- 2) Platform as a Service (PaaS): Cloud providers supply a computing platform to its clients where they can deploy applications of its own, program language of its own.
- 3) Infrastructure as a Service (IaaS): Vendor integrates basic infrastructure such as IT systems and database and then rents them to client.

In this paper, we chose a widely used cloud service, Amazon Cloud [20], and provide the CDA generation and integration system as SaaS.

2.3 CDA Generation System Based on Cloud Computing

Fig. 1 shows the overall architecture of how CDA documents can be generated on the health information systems of different hospitals by using our cloud computing-based CDA generation system.

Hospital A and Hospital B are demonstrated to show that it is easy to generate CDA documents on a variety of platforms if done via cloud. The purpose of each of the components is as follows:

- CDA Generation API generates CDA documents on cloud.

- CDA Generation Interface uses the API provided by the cloud and relays the input data and receives CDA documents generated in the cloud.
- Template Manager is responsible for managing the CDA documents generated in the cloud server. Our system uses CCD document templates.
- CDA Generator collects patient data from hospitals and generates CDA documents in the template formats as suggested by the Template Manager.
- CDA Validator inspects whether the generated CDA document complies with the CDA schema standard.

The DBMS at each hospital and the HIS are linked as follows. Hospital A, which uses a .Net-based system is connected via ODBC to connect to the DBMS while Hospital B, which uses a JAVA-based system, is linked with Hibernate.

At a hospital, the clinical information of patient, hospital, and physician is entered via CDA Generation Interface and sent to the cloud server via CDA Generation API. We utilize SOAP (Simple Object Access Protocol) as transmission protocol for the purpose of enhancing interoperability among different HIS when a hospital sends data to the cloud. CDA Generation API relays the data in the CDA Header/Body in the list type. The items included in CDA Header are: PatientID, BirthDate, Gender, GivenName, and Family- Name. In CDA Body, the following items are included:

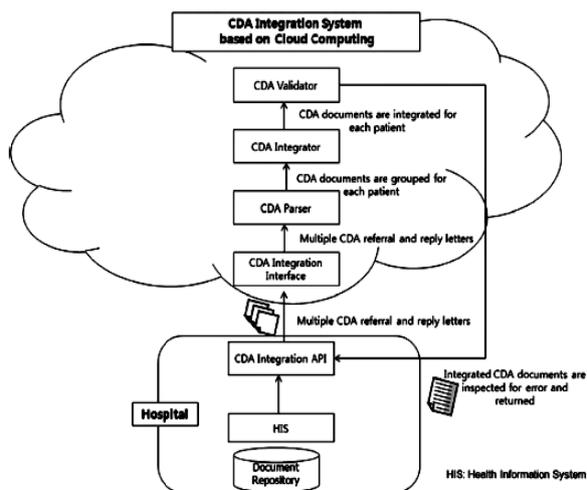


Fig. 2. The architecture of CDA integration system based on cloud computing.

Problem, Medication, Laboratory, Immunization, and so on. The data sent to the CDA Generation API are packaged in CDA Header Set and CDA Body Set and relayed to CDA Generator. CDA Generator retrieves a CCD template from Template Manager and fills in the appropriate fields of the CCD template with the data from the CDA Header/Body Sets. The generated CDA document is inspected by the CDA Validator whether the CDA standards are being satisfied. It is inspected whether there is any missing element or the format is adequately followed. If no error is found, a CDA document is returned to the recipient hospital. Hospitals A and B are presented to demonstrate that it is possible for different development platforms to extend to generate CDA documents via a cloud server.

2.4 CDA Integration System Based on Cloud Computing

Fig. 2 shows how multiple CDA documents are integrated into one in our CDA Document Integration System. The standard for this is Korean Standard for CDA Referral and Reply Letters (Preliminary Version). Templates which generate a CDA use CCD part of Consolidated CDA which is released by ONC and made by HL7. However, an actually generated CDA has a form of CDA Referral and Reply Letters. The rationale for CDA document integration is as follows [21]. When CDA-based HIE (Health Information Exchange) is actively used among hospitals, the number of CDA documents pertaining to each patient increases in time. Physicians need to spend a significant portion of their time on reading these documents for making clinical decisions. In Korea, physician's consultation time spent per patient is very short since the insurance model is fee for- service. Chronic patients especially are very likely to have been consulted by multiple physicians, in different hospitals. In this case, CDA documents may be scattered in different locations. Therefore, multiple CDA documents need to be integrated into single CDA document. If the medical history of a patient is available in a single CDA document, the physician's time can be more efficiently used.

This is evident when a patient is being referred to a different hospital or when a referral reply letter is sent. Our survey of physicians shows that displaying each section in chronological order helps improve the quality of care. This paper shows how we integrate CDA documents on a cloud server so that a variety of existing systems can be easily extended to generate integrated CDA documents.

At a hospital, the CDA documents to be integrated are processed through our CDA Integration API. The CDA Integration Interface relays each CDA document sent to the cloud to the CDA Parser, which converts each input CDA document to an XML object and analyzes the CDA header and groups them by each patient ID. The CDA Document Integrator integrates the provided multiple CDA documents into a single CDA document. In this process, the data in the same section in the document body are merged, following the LOINC values that set apart each section in the CDA document. The integrated CDA document is inspected for error in the CDA Validator, and the result is returned as string to the hospital that requested CDA document integration. This is because the CDA Integration System and the CDA Generation System are separate entities, and a new CDA document is made after document integration, hence it is necessary to determine whether the new document complies with the CDA document integration, especially whether there is any missing element, or the format is wrong. Error messages are returned if found. Then the received string is converted to a CDA document file and saved. The validation process by CDA Validator is based on the CDA schema. An error is generated when a required field has been left blank or the wrong data type has been used. Example: The CDA document generation time, 'effective Time,' needs to be set, at least, in the YYYYMMDD format such as 20140806.

3 RESULTS

In this section, we report the results concerning the implementation of CDA generation and integration system based on cloud computing

3.1 Construction of a Cloud Computing Environment and Deployment of CDA Generation and Integration System Based on It

We chose Amazon Elastic Compute Cloud (EC2) as the cloud platform for our CDA generation and integration system. Microsoft Windows Server 2008 Base was selected as its operating system. We chose Singapore as the server location. Java (JDK 1.6) was used for CDA document generation and integration system and Tomcat 6.0.26 was selected as the web server platform for service deployment. As discussed in Section 2, we developed the CDA document integration and integration system and deployed the system on the Amazon Cloud Server. Hospitals conveniently generate and integrate CDA documents by exploiting the API offered by our system.

3.2 Generation of CDA Documents on Different Developer Platforms through Cloud

To verify whether the system functions as designed, we requested CDA document generation on multiple systems implemented on different developer platforms via our API. For input data, we used the sample patient data offered by the US EHR Certification Program, Meaningful Use [22]. The data does not pertain to any actual person. It is fictional, and available for public access. The use case scenario and data for CDA document generation are shown in Table 3.

TABLE 3
The Use Case Scenario and Data for CDA Document Generation

Patient name	Isabella Jones
Date of birth	5/1/1947
Provider's name	Dr. Henry Seven
Provider's office contact information	555-555-1002, Get Well Clinic, 1002 Healthcare Dr. Portland, OR 97005
Reason for Visit/Chief Complaint	Mild Fever, 2 days Chills, 2 days Cough productive of greenish sputum, 2days
Smoking Status	Current every day smoker, Start: 1992
Medications Administered During Visit	Albuterol 0.09 MG/ACTUAT, 2 puffs once
Problems	Community Acquired Pneumonia Asthma
Laboratory Tests and Values/ Results	Hypoxemia HGB, 14.2 HCT, 45% WBC, 7.6 (10 ³ /uL) PLT, 220 (10 ³ /uL)
Immunizations	Tetanus - diphtheria adjuv, 1/4/2007 Influenza virus vaccine, 11/1/2009 Pneumococcal polysaccharide, 8/6/2012

We verified the validity of our CDA documents with the CDA document validation tool provided by US NIST (<http://cda-validation.nist.gov/cda-validation/validation.html>), which has the authority to certify CDA documents, to validate the CDA documents generated by using the API at our cloud server. The CDA documents generated by two clients developed with Java and C#, respectively, passed the validity test.

3.3 Integration of CDA Documents via Our Cloud Server

We integrated multiple CDA documents of patient referrals and replies by using the API at our server. The use case scenario and patient data used for integration are shown in

TABLE 4
The Use Case Scenario and Patient Data Used for Integration

Patient Characteristics	The patient is a 50-year-old White male with a history of asthma controlled by albuterol for breakthrough. He also has a history of type II diabetes and hypercholesterolemia controlled on NovoLog, Lantus, and Lipitor. 8/6/2012
Diagnosis History of Medication Use	pneumonia with mild hypoxemia albuterol, inhaled, Inhalant/Respiratory, 2.5mg/3ml NEB 3 times daily PRN wheezing/shortness of breath ceftriaxone, IV, 1 gram IV once daily 08/15/2012
Diagnosis Procedures Laboratory Studies	Costal Chondritis Pulmonary function tests CO2, 25 mmol/L 08/15/2012
Diagnosis History of Medication Use Procedures	Angina Aspirin 81 MG Oral Tablet, once daily
Functional Status Assessment	Electrocardiographic Procedure Intranasal oxygen therapy Memory impairment
Laboratory Studies	Dependence on walking stick Na, 140 mmol/L K, 4.0 mmol/L Cl, 100 mmol/L CO2, 25 mmol/L BUN, 20 mg/dL Cr 1.2 mg/dL Glu, 200 mg/dL Troponin T, 0.01 ng/ml

Table 4. We adopted sample patient data provided by the US EHR Certification Program, Meaningful Use. The data does not pertain to an actual person. It is fictional, and available for public access.

4 DISCUSSION AND CONCLUSION

Interoperability between hospitals not only helps improve patient safety and quality of care but also reduce time and resources spent on data format conversion [23]. Interoperability is treated more important as the number of hospitals participating in HIE increases. If one hospital does not support interoperability, the other hospitals are required to convert the data format of their clinical information to exchange data for HIE. When the number of hospitals that do not support interoperability, complexity for HIE inevitably increases in proportion. Unfortunately, hospitals are reluctant to adopt EHR systems that support interoperability, because changing an existing system adds cost for software and maintenance [24], [25]. The advantages of an API service as ours are at the amount of resources that hospitals need to allocate for interoperability is minimal [26]. Therefore, offering a system that supports interoperability with cloud computing is a good alternative for hospitals that have not yet adopted EHR because of cost issues.

The CDA document format a clinical information standard designed to guarantee interoperability between hospitals, a large number of HIE projects that use the CDA document format have been undertaken in many countries. Table 5 shows various HIE projects and whether they generate CDA documents or integrate multiple CDA documents. Our cloud computing based CDA generation and integration system has a few pronounced advantages over other existing projects. First, hospitals do not have to purchase proprietary software to generate and integrate

CDA documents and bear the cost as before. Second, our

TABLE 5
Comparison of Projects under Health Information Exchange

Project	Main object	Does the system (1) generate documents in the CDA format, and (2) does the system integrate multiple CDA documents?
The Standardization of Communication between Information Systems in Physician Offices and Hospitals using XML(SCPHOX) project in Germany [28], [29] XML technologies for the Onaha System in Italy [30]	The HIE project based on CDA Release1 and Release 2 To offer hierarchical structure for home healthcare in XML documents, and the developed model was designed to include CDA documents	No No
Generating standardized clinical documents for medical information exchanges[31], [32] in Taiwan	The research for CDA generation method for HIS	No
HL7 and DICOM based integration of radiology departments with healthcare enterprise information systems in Croatia [33]	The project to consolidate HIS and Image Information System based on HL7 CDA and Digital Imaging and Communications in Medicine (DICOM) standards	Only CDA and DICOM integration, but not using cloud computing
Implementation of reporting system for continuity of care document based on web service in Korea [34]	The service model that serves periodic PHR which is made by a medical specialist based on web service	Only CDA generation function, but not CDA integration
CDA integration and generation system based on cloud computing in our paper	The system that provide CDA generation and integration function independent from any specific platforms	Yes

service is readily applicable to various developer platforms because an Open API is to drive our CDA document generation and integration system. Regardless of the type of the platform, CDA documents can be easily generated to support interoperability. Third, CDA document generation and integration system based on cloud server is more useful over existing services for CDA document if the variety of CDA document increases. As of December 2013, there are 54 different types of CDA documents recognized by US NIST, and the number continues to grow year by year [45]. Among 54 CDA Document Templates, the approach suggested in this paper is being tested for CCD part of CCDA and Korean Standard for CDA Referral and Reply. Ordinarily, when a new type of CDA document format is established, hospitals have to upgrade or purchase proprietary software to accommodate files in that new format. With our API however, there is no need to change the software on the client-end; only the software at the server-end needs to be modified to adopt the new CDA document format. With the cloud-based architecture proposed in this paper, it becomes convenient to generate documents that comply with new document standards. Thus, the cloud server can readily provide documents that comply with CDA Release 3 if only the server adopts its model, data type, and implementation guidelines. As the number of HIE based on CDA documents increases, interoperability is achieved, but it also brings a problem where managing various CDA documents per patient becomes inconvenient as the clinical information for each patient is scattered in different documents. The CDA document integration service from our cloud server adequately addresses this issue by integrating multiple CDA documents that have been generated for individual patients.

The clinical data for the patient in question is provided to his/her doctor in chronological order per section so that it helps physicians to practice evidence-based medicine. In the field of document-based health information exchange, the IHE XDS profile is predominant [27] and our cloud computing system can be readily linked with the IHE XDS profile.

The approach employed in this paper is applicable in adopting other standards, too, such as the EHR Extract based on open EHR. If a hospital sends the content archetype, admin archetype, and demographic archetype to the cloud server, then the server extracts necessary information from each archetype. Next, it generates an Extract containment structure that fits with a designated template and returns the structure to the requested hospital. In addition, patients are enabled to use the CDA document integration service to obtain Personal Health Record (PHR)

[36], [37], [38], [39], which contains not only clinical documents but also Personal Health Monitoring Record (PHMR) [40] and Patient Generated Document (PGD) [41].

Patients can effectively generate and manage their PHR by using our cloud-based CDA document integration service. The following problems were encountered while developing our CDA document generation and integration system. First, the default language of the Amazon Cloud OS is US English and it did not adequately handle Korean language in the CDA documents. While the client handled the strings in Korean language without problems, the server did not, which was resolved by installing Korean language pack in the server OS. When SaaS is offered targeting hospitals of different languages, developers will need to pay extra attention to this issue. Second, the API parameter for our CDA document generation service was of the list type, but under the C# language environment, the parameter was converted to the string array type. This is suspected to have been caused by the IDE software of C#, which automatically makes this type conversion. Hence, the returned data needs to be as generic as possible to be applicable to as many platforms as possible.

In our future work, we will explore the following points. First, we will make a concrete estimation of the reduction in cost when the EHR system becomes cloud-based. Establishing a reasonable fee system is an important issue for cloud computing [20]. There is ample evidence that cloud computing is effective and efficient in cost reduction, and the medical field seems to be no exception [43]. Security and stability is top priority for cloud computing resources as it is used by many users [44]. Future work will attempt to enhance security while ensuring reasonable quality of service even with multiple users logged on the system at the same time.

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