Design and implementation of a standards-based interoperable clinical decision support architecture in the context of the Korean EHR

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\textbf{Abstract}

\textbf{Background:} In 2000 the Korean government initiated efforts to secure healthcare accessibility and efficiency anytime and anywhere via the nationwide healthcare information system by the end of 2010. According to the master plan, electronic health record (EHR) research and development projects were designed in 2005. One subproject was the design and implementation of standards-based interoperable clinical decision support (CDS) capabilities in the context of the EHR system.

\textbf{Objective:} The purpose of this study was to describe the challenges, process, and outcomes of defining and implementing a national CDS architecture to stimulate and motivate the widespread adoption of CDS services in Korea.

\textbf{Methods:} CDS requirements and design principles were established by conducting a selective literature review and a survey of clinicians, managers, and hospital and industrial health information technology engineers regarding issues related to CDS architectures. The previous relevant works of the American Medical Informatics Association, the Healthcare Information and Management Systems Society, and Health Level Seven were used to validate the scope and themes of the service architecture. The Arden Syntax, Standards-Based Sharable Active Guideline Environment, First DataBank, and SEBASTIAN approaches were used to assess the coverage of the application architecture thus defined. A CDS prototype of an outpatient hypertension management system was implemented and assessed in a simulated experimental setting to evaluate the feasibility of the proposed architecture.

\textbf{Results:} Four CDS service features were identified: knowledge application, knowledge management, audit and evaluation, and CDS and knowledge governance. Five core components of CDS application architecture were also identified: knowledge-execution component, knowledge-authoring component, data-interface component, knowledge repository, and service-interface component. The coverage and characteristics of the architecture identified herein were found to be comparable with those described previously. Two scenarios of deployment architecture were identified in the context of Korean healthcare. The preliminary feasibility test revealed that the architecture exhibited good performance and made it easy to integrate patient data.
1. Introduction

Clinical decision support (CDS) is not only a good idea but also an essential and core function of electronic health records (EHRs). The current widespread use of EHRs emphasizes the potential for improving the quality of healthcare by providing timely access to patients’ health information, tracking patients over time to ensure that they receive guideline-recommended care, and offering decision support mechanisms to reduce treatment errors. Institute of Medicine reports published in 2001 and 2003 strongly recommended the development of automated information systems that provide clinicians with immediate access to CDS tools [1, 2]. One recent statewide survey in the United States concluded that to use the CDS services, and so relevant medical knowledge is not always available or used when making many healthcare decisions.

Several studies have demonstrated that decision support delivered via EHRs can improve the quality of care, especially in specific domains such as preventive care and the care of certain chronic conditions. However, there has been limited adoption of effective CDS capabilities, including in the United States [4]. Zhou et al. [3] reported that the usage of decision support among EHR users was quite low, at only 23.5% in 2005, compared to its availability, which was 65.0% among those with an EHR. Greenes [4] pointed out the difficulties of implementing robust and sustainable CDS services from a long-term maintenance and update perspective, which relate to (1) frequent changes in the knowledge assets underlying CDS, (2) the various forms used to represent the knowledge, and (3) the lack of tools to support the sharing and leveraging of medical knowledge.

Korea has had more than 20 years of experience in health information technology (HIT), but only a few tertiary teaching hospitals utilize home-grown CDS services [5, 6]. These systems are embedded in a computerized physician order entry (CPOE) and/or an electronic medical record (EMR, an institutional EHR) system that is ultimately customized and highly dependent on the specific applications, which makes it difficult to share CDS capabilities between applications and institutions. Moreover, there is a degree of redundancy in development cost and efforts, as well as limitations to those who are able to access hospital CDS services due to them having insufficient resources or experience in developing CDS systems (CDSSs). As a result, they do not even attempt to use the CDS services, and so relevant medical knowledge is not always available or used when making many healthcare decisions.

The Korean Ministry of Health and Welfare (MOHW) developed the master plan for National Healthcare Information and Communication Technology (NH-ICT) between 2000 and 2010. The vision of this program was to secure healthcare accessibility and efficiency anytime and anywhere via the nationwide healthcare information system by the end of 2010. Based on this program, a center of interoperable EHR (CiEHR) was established, which directed the long-term research and development plans to support the NH-ICT initiatives both technically and strategically [7]. We have worked to develop CDS service architecture and components in harmony with other EHR activities by defining an EHR architecture at the national level, developing a common clinical content model and healthcare terminologies, and identifying a health information exchange infrastructure under the vision of the CiEHR. The purpose of the present paper is to describe the process, challenges, and outcomes of defining the CDS architecture at the national level in order to stimulate and motivate the widespread adoption of CDS services in Korea. This process ultimately led to the implementation and evaluation of a prototype CDS service for hypertension management in ambulatory care settings. This process has been followed by several pilot demonstration projects in three hospitals in Seoul and the Gyeonggi province. These projects aimed at systematically assessing the feasibility of implementing the CDS architecture outside of the CiEHR, which could drive improvements in health outcomes and allow the process to be readily deployed in diverse healthcare settings.

2. Background

In 2005, Health Level Seven (HL7) initiated the Healthcare Services Specification Project (HSSP) together with the Object Management Group to standardize the functionality and interfaces of software services that are considered important to the healthcare industry. One of the HSSP services is a CDS service that uses patient data to make machine-interpretable inferences regarding patients. The HSSP CDS service project aims to define a common service interface to fulfill a core functional requirement shared by all CDSSs. The American Medical Informatics Association (AMIA) released “A Roadmap for National Action on Clinical Decision Support” [8] to realize the vision of a United States healthcare system in 2006. The report identified core pillars for realizing the promise of CDS. Kawamoto and Lobach [9] proposed a service-oriented architecture (SOA) framework based on the HSSP approach and AMIA recommendations, and identified core elements.
Greens et al. [10] proposed a client–server architecture for an external rules engine from the perspective of knowledge management. The architecture had a centralized rule base and rule engine in order to allow rules to be shared by different application/entities interacting within the system, and authored and maintained or updated more readily by domain experts. On the client side, clinicians and front-end applications access the server to store and retrieve information. The server side comprises a rule base, databases with patient information, knowledge bases, rule engine, event monitor, and rule activator. Huang et al. [11] of BJC HealthCare introduced the migrating approach for a next-generation CDS application. They built a CDS rule-engine service with a standards-based format for rule representation to simplify the maintenance of existing functionality and deployment of the patient-specific assessment and interventions that they have used since the early 1990s. They used Java Rule Engine API as a CDS application, virtual medical record as a patient data model, extensible markup language (XML)-based language as an executable format, and SOA principles. For CDS implementation, Osheroff et al. [12] proposed a guideline of six steps that healthcare organizations might use to implement CDS, beginning with identifying stakeholder goals and available clinical systems, and continuing by selecting CDS interventions, building them, deploying them, and analyzing their effects, with the results in turn being fed back into the process in order to refine interventions.

As concrete examples of how medical knowledge can be integrated into clinical applications, Arden Syntax [13,14] with Medical Logic Modules, Standards-Based Sharable Active Guideline Environment (SAGE) [15], commercial medication knowledge resources such as First DataBank approaches [16], and SOA are frequently cited in the literature. The knowledge resource is maintained in a separate knowledge base in the Arden Syntax and SAGE architectures. However, Arden Syntax is limited to single-step decisions with atomic modularity, while SAGE utilizes knowledge resources that dictate most aspects of CDS generation and delivery. Commercial medication knowledge resources and SOA approaches do not dictate when the knowledge resource is used, how the required data are obtained, or how the conclusions generated by the resource are communicated to end-users. Instead, the knowledge resource simply defines the process of inference generation, with the other processes being the responsibility of the application environment.

In summary, these current efforts to increase the adoption of a CDS service can be divided into two levels: (1) the enterprise level, which addresses architectural issues within the organizational aspect, including political strategies and knowledge management approaches; and (2) the clinical application level, which focuses more on design elements or components as a unit of software that services as a CDS module. The AMIA's roadmap and Healthcare Information and Management Systems Society (HIMSS) guidelines [8,12] suggest that key features such as knowledge management, widespread strategies, and outcome-driven focus would facilitate realization of the full potential and adoption of CDS. Greens' client–server architecture [10], Arden Syntax, SAGE, commercial medication knowledge, and SOA approaches emphasize the knowledge integration process inside a CDS module. Therefore, based on these previous works we sought to elicit and synthesize CDS architecture at two levels, enterprise and application, in order to facilitate the realization of benefits of CDS in the context of the national EHR in Korea.

3. Methods

The vision of the CiEHR is to improve the accessibility to EHRs and decision support systems. The first specific goal of the CiEHR is to achieve widespread adoption of EMRs by healthcare organizations to improve the quality, safety, and efficiency of care. The second specific goal is to establish a sharable lifetime EHR system to improve the quality of care and reduce healthcare costs incurred by care redundancy in Korea. Based upon these visions, the aim of the CiEHR CDS service is to ensure that providers can access a sustainable and robust CDS wherever and whenever they need it. The specific goals are to define the architecture for CDS services in the EHR context, to develop a sharable and reusable medical knowledge base, and to identify the core components of a CDS module.

To achieve these three goals, we began to identify the core components of CDS at the enterprise level. This was achieved by extracting EHR-related data from the literature and developing a survey to be administered to potential users that would assess their related needs. We reviewed the AMIA roadmap and HIMSS guidelines to extract common key concepts in order to identify those tasks that would enable achievement of the full benefit of a CDSS; this can be described as a “To-Be” model. A structured survey was also applied to the 167 attendees at a symposium on medical informatics technologies on December 11, 2008. The symposium was designed to introduce research and development projects funded by the Korean MOHW. The attendants were key informants such as managers and clinicians within their organizations who were involved in implementing clinical information systems (CISs). Of the 167 survey respondents, 25 (14.5%) were clinicians, 55 (32.9%) were HIT engineers, and 87 (52.1%) were other personnel such as medical record administrators and students. The purpose of this survey was to gain a better understanding of what potential users expect out of a CDS, thus enabling the development of better design and implementation strategies for addressing practical drivers and barriers. Accordingly, only the data of the clinicians and HIT engineers were analyzed.

A structured set of questions was developed by the research team, grouped depending upon whether or not the respondent was a clinician. The clinicians were asked if they had already implemented a CDSS. If they had, they were asked questions regarding the type of CDS they used, how satisfied they were with it, whether they had any implementation problems, and what drove them to implement CDS. If they had not implemented a CDSS, they were asked open questions regarding why not. Those who were not clinicians were asked if they had any experience or difficulties with CDS implementation. The engineers were asked open questions about the user requirements for CDS services and whether they would use standards-based shareable CDS services if they were available via a common, public EHR system. The depth of the participants’ perceived
knowledge regarding CDS services was measured with a visual analogue scale.

Collected data were analyzed with descriptive statistics using Windows SAS version 9.1 (SAS Institute, Cary, NC). The free-text answers to the open questions were analyzed qualitatively. Two of the authors developed themes independently as they reviewed the answers, making notes as they read and reread the various texts that were assembled. The resulting theme lists were compared and discussed by the study team in order to ultimately summarize the data and divide them into several main themes. Finally, the architecture design principles were derived from the requirements reported by the users in the survey.

The structural aspects of the inside of a CDS module were considered next. The initial approach for an application architecture was formulated by adopting Greenses’ conceptual model of CDS design components as a framework, which is an idealized model of how a CDS module should be created [4]. Greenses identified five design elements based on the tasks that must be performed to provide CDS: (1) a decision model/execution engine, (2) knowledge content resources as the knowledge base, (3) an information model, (4) result specification, and (5) the application environment. We used the CDS conceptual model and the identified design principles to define the CDS application components and the relationships between them. The components were covered by reviewing CDS approaches that are frequently cited in the medical informatics literature. We used a snowball method that concentrated on references cited in relevant papers rather than performing a systematic search. The snowball method is an efficient way to find relevant studies dealing with specific topics, such as those related to CDSS architectures. The search was performed in April 2008. We began from the current issues found from keyword searching using the following databases: “architecture” AND “clinical decision support”; and “architecture” AND “decision support service”.

The included publications were all original research reports or literature reviews that discussed the CDSS architecture at the enterprise level and had been published after 2000. We selected Arden Syntax [13,14] with Medical Logic Modules; which was adopted as an American Society of Testing and Machinery standard in 1992. SAGE [15] and First DataBank approaches [16] were selected as a multi-institution collaborative effort and an example of a commercial market adaptation; respectively. SEBASTian; which was first described in the literature in 2005; was also reviewed as a Web service using XML [9]. It has already been well established that these approaches are capable of integrating medical knowledge and can be integrated into clinical applications. We analyzed and compared these approaches with our application architecture in terms of following architectural issues:

1. Role of the knowledge resource.
2. Scope of supported institutions.
3. Scope of supported CDS application types.
4. Use of an information model and terminology standards.
5. Use of a knowledge-module execution engine.
6. Use of knowledge formalism and authoring environments.

The feasibility test for the initial architecture was performed in a simulated experimental setting involving 201 real cases with essential hypertension as a primary diagnosis at a public secondary hospital in Seoul. Two general physicians and one physician specializing in family medicine from a tertiary teaching hospital participated voluntarily. We developed a prototype of an outpatient hypertension management system, called Lightening Pressure with Computer-Implemented Guidelines on Hypertension Treatment (LIGHT), since hypertension is a chronic disease with a morbidity rate of 27.9% in Korea. The medical knowledge for LIGHT was captured from Korean hypertension treatment guidelines [17], World Health Organization international guidelines [18], European guidelines [19], and the Seventh Report of the Joint National Committee [20]. The knowledge regarding hypertension treatment was represented and encoded using SAGE guideline ontology and Protégé v3.4 [21]. For this test we selected the medication recommendations regarding absolute contraindications and compelling indications. The evaluation scheme was established with a matrix of the four categories of add, maintain, increase, and remove, and the six medication classes of thiazide, dihydropyridine calcium-channel blocker (CCB), other CCBs, angiotensin-converting enzyme inhibitor, beta blocker, and angiotensin-receptor blocker. LIGHT was designed as a Web service that communicates with a CIS using XML messages transmitted over the Internet. For evaluation, we integrated LIGHT with a simulated EMR database that was designed to follow a real hospital’s database schema. We asked two physicians to apply LIGHT independently to the cases, presuming that these were patients in outpatient clinics and that they were looking at patients’ data captured in EMRs. The physicians’ medication order was noted and compared with the system’s medication recommendations. If there is discrepancy between the physicians’ responses and LIGHT recommendations, the physician with internal medicine specialty determined which one was correct. The log values of engine execution time and access time to patient data were also recorded.

4. Results

4.1. Survey results

The survey participants held various positions, such as the chief or manager of a department of medical information, members of informatics committees [e.g., quality improvement (QI), EMR, and patient safety committees], user coordinator, system developer, and end-user of CDS services (Tables 1 and 2). Eighteen of the clinicians (72%) and 20 of the engineers (40%) came from tertiary hospitals; the remaining participants were from secondary hospitals or were vendors. The clinicians and HIT engineers scored their knowledge about CDS services on a visual analogue scale ranging from 0 to 10 (where 0 implies no knowledge at all and 10 implies total knowledge) as 5.6 and 5.7, respectively. Fourteen of the clinicians (56%) had used EMR and CDS functionalities previously, of which 10 (71.4%) responded that they were not satisfied with their CDS service due to the current abilities of CDSSs being inadequate to meet their
Table 1 – Needs assessment for clinicians regarding clinical decision support (CDS) services (n = 25). QI, quality improvement; CPOE, computerized physician order entry; CiEHR, center of interoperable electronic health record.

<table>
<thead>
<tr>
<th>Category</th>
<th>Subcategory</th>
<th>Frequency (%)</th>
</tr>
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<tbody>
<tr>
<td>Role in the hospital</td>
<td>Chief or manager in a department of medical information</td>
<td>3 (12.0)</td>
</tr>
<tr>
<td>Use of CDS functions</td>
<td>Implemented in existing systems</td>
<td>14 (56.0)</td>
</tr>
<tr>
<td>Drivers of CDS implementation in the hospital (multiple responses, n = 35)</td>
<td>To meet users’ needs</td>
<td>10 (28.6)</td>
</tr>
<tr>
<td>Types of CDS use (multiple responses, n = 26)</td>
<td>CPOE relevance</td>
<td>9 (34.6)</td>
</tr>
<tr>
<td>Requirements for CiEHR CDS services (multiple responses, n = 18)</td>
<td>Knowledge governance</td>
<td>6 (38.9)</td>
</tr>
<tr>
<td>Intention to use CiEHR CDS services</td>
<td>Yes</td>
<td>22 (88.0)</td>
</tr>
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needs. This inadequacy manifested in various ways, such as in the use of nonsystematic development approaches without links to their organizational goals and lack of knowledge interventions that could be delivered by CDSSs. Some clinicians stressed that current CDS functions seem to be focused on simply alerting the clinicians to possible errors, whereas CDS is capable of much greater functionality. Some clinicians expressed concerns that the government would act as a “Big Brother” regarding cost regulation. However, they did recognize the potential usefulness of CDS services, such as in preventing errors, delivering useful knowledge to the workflow, and educational opportunities.

In addition to the user’s requirements, one of the most prominent current drivers for CDS functions was hospital accreditation. Other internal needs, such as QI, evidence-based practice, and process standardization, were weighted

Table 2 – Needs assessment for HIT engineers regarding CiEHR CDS services (n = 55).

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<tr>
<th>Category</th>
<th>Subcategory</th>
<th>Frequency (%)</th>
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<tr>
<td>Role in the hospital (multiple responses, n = 59)</td>
<td>Manager in a department of medical information</td>
<td>18 (30.5)</td>
</tr>
<tr>
<td>Experience with CDS implementation</td>
<td>Yes</td>
<td>19 (34.5)</td>
</tr>
<tr>
<td>Difficulties with CDS implementation (multiple responses, n = 20)</td>
<td>Definition of service content (lack of agreement between physicians)</td>
<td>10 (50.0)</td>
</tr>
<tr>
<td>Requirements for CiEHR CDS services (multiple responses, n = 42)</td>
<td>Knowledge governance</td>
<td>18 (42.9)</td>
</tr>
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similarly. As for the preferred type of CDS service, CPOE supports were the most popular, such as antibiotic assistance, prophylactic use of antibiotics, and screening for redundant prescriptions or laboratory tests. These were closely related to the appropriateness criteria of care enforced by the Korean Health Insurance Review and Assessment Services. Specific disease-focused clinical pathways, guidelines, and protocols were followed. Knowledge governance was the main theme for the requirements for CiEHR CDS services. We grouped the concerns according to the accuracy, authority, consensus, and responsibility of medical knowledge delivered by CDS services into the governance theme. The other themes, such as applying data standards and terminologies, integration with legacy systems, privacy and data security, and ease of use were addressed with similar frequencies. Eighty-eight percent of clinicians reported they would use any sharable CDS service provided to their hospitals.

Only 19 (34.5%) of the HIT engineers had experience with CDS implementations (Table 2). Some of the difficulties they encountered were related to the discrepancy between current and optimal CDS implementations: the definition of the CDS service content, communication with clinicians, and leverage of users’ motivation to use CDS. Specifically, they highlighted CDS governance issues such as legal rights on the knowledge and accreditation of a CDS service. As to the requirements for CiEHR CDS services, the concerns of HIT engineers regarding knowledge governance, data standards, and system integration were similar to those cited by the clinicians. However, the engineers suggested broader political approaches, including financial support, incentives, and reimbursement to encourage clinicians to become actively involved in the development of a CDSS. They also addressed the issue of data security; specifically, when data are transmitted from local EMR systems to the CDS module. Most (89.0%) of the HIT engineers stated that they would use sharable CDS services.

4.2. Identifying CDS service features

Our review of the literature and the survey results identified four business components required for an effective and harmonized CDS service at the enterprise level: knowledge application, knowledge management, audit and evaluation, and CDS and knowledge governance (Fig. 1). First, knowledge application—which refers to realized knowledge services and interaction directly with clinicians via software applications—can take various forms, such as templates for documentation, specialty data review flow sheets, order sets for protocol-driven care management, reports for feedback, automatic alerting, and suggesting recommendations. The mode of CDS interventions may be classified into different paths according to different views of point. We classified interventions systemically based on accesses to a CDS server to store and retrieve information. We defined two modes of application: synchronous and asynchronous. The synchronous mode includes physician orders of medication or procedures and the physician’s actions, which should be directly coupled with actions/responses from the system. In contrast, CDS interventions designed with time-driven and request-driven applications can be classified into the asynchronous mode; for example, when a laboratory result is generated by the corresponding entity with no actual interaction with a user, or a background process is running to look for potential adverse drug events.

Second, the knowledge management feature can be understood as support for knowledge acquisition, representation, validation, revision/update, and deployment. The goal of this function is to reduce the cost and accelerate the rate of acquisition of the decision support knowledge that drives the quality and safety of care. The framework of knowledge management comprises the integrated set of knowledge-authoring environments, knowledge repository, knowledge engineering, and the management process that supports the knowledge lifecycle of creation, integration, and dissemination. The authoring environment is a software component that could support authoring and aligning knowledge assets with existing and emerging industry, national, and international terminology standards and quality regulations, as well as with supporting collaboration processes. The repository contains formalized knowledge modules and supplementary documentation in a standardized format so as to promote reusability and shareability.

Third, the audit and evaluation feature is a mechanism for obtaining feedback on knowledge application from systems and users. This feature includes reporting statistics, cost-effectiveness analysis, and outcome analysis, which could be referred back to the knowledge management functions. Therefore, this function is considered a sort of data-driven learning process by leveraging the quality data warehouse to support a closed-loop learning cycle of enterprise-wide knowledge discovery and performance improvement. This feature also supports knowledge discovery via a well-designed ana-
lytic data repository. It provides the clinical research process of analyzing data for the purpose of understanding performance and for reporting, predicting, and harvesting new knowledge on how to improve.

Finally, CDS and knowledge governance address the roles and responsibilities of the participants, including political, legal, and financial issues. At an organization level, the governance provides guidelines as to the questions of who should be involved in the CDS committee to set service goals and knowledge management processes, what should be the relationships with other relevant committees such as QI and safety committees, who is responsible for knowledge validation and deployment, who is accountable for evaluation and feedback regarding the outcome of CDS initiatives, and who is responsible for knowledge validation and deployment, who is accountable for evaluation and feedback regarding the outcome of CDS initiatives, and what are the mechanisms for encouraging participation in CDS governance and adoptions. The governance also addresses the approaches of standards that facilitate knowledge sharing and customization and tools that incorporate these standards. The strategy for CDS deployment and concerns on organizational culture are also governance subjects. Therefore, all CDS stakeholders should be involved in the governance structure and make alliances with several organizations, including healthcare academia and societies and Korean industry standards institutions.

4.3. Identifying the application architecture

To define the application architecture, we identified the following CDS design principles:

1. Component-based approach to ensure integration with legacy systems.
2. Separate knowledge from execution environments.
3. Encode knowledge in both human- and machine-interpretable formats in a consistent manner.
4. Allow users to easily customize knowledge modules for deployment.
5. Define generic CDS engines (which serve as a rule engine and a workflow engine).
6. Reconcile with information model and terminology standards.

Fig. 2 shows the components that are defined in the CDS application architecture and how these components interact to create a context-specific actions or recommendations. We identified five components: (1) inference server, (2) authoring environment, (3) interface server and interface repository, (4) knowledge repository, and (5) service interface. The inference-server component contains the knowledge engine that integrates the process and rule engines, plus the function and class libraries for executing the medical knowledge. Time-related functions (e.g., last, first, average of $x$ months, and maximum of $x$ intervals) are examples defined in the libraries for health care. The authoring environment has several features: a CDS framework to support the authoring process, a guideline browser, a guideline converter to conform to the specific representation of an engine, a guideline simulator for logical verification before deploying the knowledge, and guideline deployment tools [22,23]. The knowledge repository contains
three kinds of knowledge: (1) knowledge modules and documents, (2) a test case, and (3) a CDSS quality database. Knowledge modules are executable knowledge, and knowledge documents contain specifications produced during the knowledge engineering process. The knowledge repository can store knowledge resources in four formats: free-text, and ontology, terminology, and data models. These documents help knowledge engineers to understand the available information. Test cases should be used to verify the correctness and completeness of knowledge. We managed test cases since the information therefrom could be reused for knowledge localization.

The interface server generates run-time data-request queries with information stored in the interface repository, and accesses the local information system using queries. Finally, the service-interface component is an event listener designed to catch triggers from a local CIS and contains a route by which to deliver clinical data in the standardized format. Fig. 3 illustrates the relationships between the CDS application architecture components. The client application triggers a CDS service via an XML-based standard interface as a Web service. Before triggering the CDS service, the client application obtains the initial patient information from the database and constructs the XML interface, which contains two kinds of information: (1) a service description to identify the CDS service and (2) patient information for executing the knowledge. The patient information is not specific to the particular situation, but it can reduce both the time required to access storage and the number of queries, so it helps to speed up the knowledge-execution time. The service interface invokes the knowledge engine, which retrieves the precise knowledge module from the repository and executes it to create actions or recommendations. At that time, if necessary, the service interface delivers the initial patient data to a knowledge engine in XML format. In cases where the engine needs more patient data due to the knowledge-execution flow, it sends a data request to a data-interface component, which is a kind of adaptor that generates the data-access query using predefined data mapping profiles for each hospital. For the mapping profiles, we used the Systematized Nomenclature of Medicine–Clinical Terms (SNOMED-CT) as a terminology and the extended virtual medical record (eVMR) as a standard data model [24]. The eVMR was defined by the present authors by adding 7 classes and 19 attributes from the virtual medical record (VMR) suggested by Johnson et al. [25]. Two classes (DrugInfo and Diagnosis) with new definitions and slots were created due to the need to link external local drug databases and to explicitly designate the medical diagnosis in an EMR. Three specialized classes (2Encounter, 2Alert, and 2Observation) were derived from the original Encounter, Alert, and Observation classes by adding new slots. For example, we assumed that this eVMR model will support different types of CDS service, which led to five slots (cdssType, recType, subRecType, notification, and reasonCode) being added in the 2Alert class. Two specialized classes (LabResult and ImageResult) were derived from the Observation class by adding slots of specimenType, first readingResult, second readingResult, and third readingResult. Executing the knowledge in a local hospital requires the knowledge to be localized. In our research context, this can be achieved by mapping between standards used in the knowledge and in the terminology and schema of an EMR. We developed a mapping editor that displays the terminology hierarchy of SNOMED-CT but with only some parts included in the knowledge. The manager of the local hospital information system uses the mapping editor to select one term from the terminology and in the terminology and schema of an EMR. We classified the terminology mapping algorithm into two categories related to the mapping cardinality and hierarchy. Our mapping direction is from the standard system to the information system of the local hospital. We defined four kinds of mapping algorithm in both the mapping-cardinality category (1:1, 1:N, M:1, and M:N) and the mapping-hierarchy category (leaf node to leaf node, nonterminal node to leaf node, leaf node to nonterminal node, and nonterminal node to non-terminal node). An eVMR is mapped to an EMR in the same
Fig. 4 – Two scenarios of a CDS service delivery model. (a) Scenario 1: a centralized knowledge source but where each instance of the architecture is realized at each local hospital. (b) Scenario 2: a centralized CDS service but where localized knowledge is available for each local hospital. KM, knowledge management.
providers, such as government-sponsored organizations in the case of Korea.

4.4. Outpatient hypertension management system

The knowledge engine designed to execute knowledge modules for LIGHT was implemented using Java technology so it could be executed on diverse platforms. The service-interface components for a .Net framework and J2EE platform were also implemented. The performance of the architecture was evaluated based on service delivery by simulating the client application using JavaServer Pages/Servelt technology. First, the ease of integration of the legacy hospital information system and the CDS service architecture was evaluated. The only thing required for a client application is to add a new invocation expression to the CDS service with the initial patient information system using the provided service-interface component. The client application is not affected by what platform the CDS architecture operates on. The returned result is provided in XML as a Web service indicating what contents to show and the CSS (cascading style sheets) for what visual layouts to display. It is thus simple to integrate the CDS architecture into legacy systems. Second, the knowledge-execution performance was evaluated. Since in real clinical settings there is time pressure, users are greatly concerned about the system response time. In the simulated research setting, the mean response time was less than 750 ms (SD = 119.3 ms), including accessing the patient information resources to obtain additional patient information during knowledge execution. The properties of the test environment were set for 10 concurrent users and a throughput of seven requests per second. The simulation test produced average correspondence rates of 85.1% and 100% for compelling indications and absolute contraindications, respectively. A review of discrepancy cases by one physician revealed that the other two physicians had not recognized the two conditions of absolute contraindications. Five percent of the discrepancy cases were due to a missing rule in LIGHT, which was reflected in the associated encoding algorithms. There is also a special feature in the service-interface component that manages the request and response time. If the CDS architecture does not respond before the user-specified limit time, the service-interface component disconnects the service session on the Web server and reports this to the client application so that it can skip the next step. The evaluation data showed that knowledge modules can be portable and that the knowledge execution in CDS is stable.

5. Discussion

In this study, the enterprise architecture of a CDSS was defined by reviewing advanced works/guidelines and focus-group survey results. Through this process, the core business components for the operation of CDS services at the enterprise level were identified. Further application and deployment architectures have been suggested based on this architecture. The feasibility of the application architecture was also evaluated by implementing and verifying an outpatient hypertension management system of LIGHT. Although LIGHT was implemented as a stand-alone prototype system, the demonstration revealed that the accuracy and execution performance of the architecture were acceptable and quite good, respectively.

The focus-group survey revealed that regardless of technology issues, only 56% of clinicians had any CDS experience and they showed a high degree of dissatisfaction with the CDSS. The respondents indicated that this dissatisfaction was due to the nonsystematic approaches and limitations of service. This implies that the current embedded system was not flexible in maintaining and expanding services. The HIT engineers and vendors had less experience of CDS than did the clinicians. Some engineers with CDS development experience noted that defining the CDS service content was the greatest barrier. Most participants reported that they were representatives of informatics-relevant committees, but that they may not have been able to deal with CDS service and knowledge governance issues such as knowledge accountability and participation incentives. For the requirements of CiEHR CDS services, both the clinicians and HIT engineers had issues with not only the challenges related with this information technology, but also those related to CDS services and knowledge governance, workflow, and organizational processes. These results support the findings of Jenders et al. [26], who conducted round-table interviews for medical directors of information systems. CDS has been viewed simply as something driven by the availability of information technology rather than as a set of techniques to fulfill the strategic goals of an organization and to meet QI initiatives. One interesting finding was the concern expressed by some clinicians that the government would act as a “Big Brother” regarding cost regulation. Little is known about the clinical usefulness and impact of CDS applications in Korea. Choi et al. [27] and Park et al. [28] reported their experiences of implementing and utilizing CDS services in tertiary hospitals, but a clinical-impact analysis was either not performed or had a very limited scope.

The process of deploying a CDS must be grounded in sound governance that involves all stakeholders and matches the technology to an organization’s clinical goals in the CDS business architecture. Based on the governance, knowledge management, and service evaluation, the infrastructure should facilitate and mediate the use of CDS in practice by using outcome-driven approaches. The deployment architecture was derived from a specific healthcare system in which there are common national health insurance programs. This commonality implies that CDS knowledge sources are easily shared between facilities, such as drug-utilization review regulations.

Differences and similarities between this CiEHR CDS service and well-known CDS architectures were determined by comparing its architecture with those of Arden Syntax, SAGE, First DataBank, and SEBASTIAN approaches according to certain comparison criteria. Knowledge resources of CiEHR CDS were designed to define the entire knowledge-integration task using the SAGE formalism and the Protégé platform. We found that the SAGE formalism can be used to express single rules and rule chains with multiple-step processes, and that the Protégé platform can support table-based rules using predefined Java technology. However, most of the existing architectures have been designed to support specific types of CDS application, such as event-based alerting systems, CPOE systems with CDS functionality, and interactive consultation systems.
In contrast, the CiEHR CDS was designed to support various types of CDS services ranging from simple rules to complex protocols, guidelines, and pathways. The Arden Syntax and First DataBank approaches do not provide explicit mechanisms by which to integrate the information model and terminology into a knowledge source. The SAGE and SEBASTIAN approaches provide relevant standards such as the VMR or the HL7 Reference Information Model (RIM) and standard vocabularies for representing clinical concepts. SAGE provides the so-called SAGE workbench as a knowledge-execution service, but this engine is not currently available outside of the SAGE project. Arden Syntax requires the infrastructure to author and execute Medical Logic Modules, and this infrastructure is only available within several commercial CIS products. The First DataBank approach also needs a specific commercial environment, while SEBASTIAN is said to support various formalisms using predefined Java and XML technologies. However, The CiEHR CDS adopted the VMR that conforms to the HL7 RIM and SNOMED-CT. The application architecture also supports different formalisms and authoring environments depending on the knowledge.

The suggested application architecture comprises essential functions of CDS services. The architecture developed in the present study may represent a good reference architecture for organizations that do not as yet have a CDS service but who need to extend their information system. With these architectures, knowledge can be shared across different organizations, since knowledge is based on standards and can be localized to individual hospitals. Also, the present research core components were implemented to share and realize our architecture. These components were verified and showed good performance in the feasibility testing of the hypertension management service. The knowledge engine was implemented in the internal repository as a file system so that the new CDS server can be added easily and cheaply so as to optimize the response time and throughput when new knowledge modules are added or the number of concurrent users increases. It is true that time and effort are required to localize the knowledge, since our knowledge model is based on VMRs. Even though additional efforts are needed to deploy the knowledge for individual hospitals, knowledge sharing is very important to leveraging the adoption of CDSSs. We could identify the intentions of clinicians and HIT engineers using the focus-group survey; however, the potential users and developers had little experience of knowledge authoring. To overcome these barriers, sharable knowledge and interoperable knowledge services should be easily accessible and understandable. The SAGE authoring environment that we adopted has notable innovative features, including a graphical form and annotated links, as described by Tu et al. [29]. However, since these features made it appear overly complex and confusing for clinical users, we simplified the interface of the guideline ontology that displayed classes used in the hypertension guideline encoding by hiding unrelated classes. We believe that the successful promotion of CDS services in Korea will require the provision of knowledge-authoring and management tools because knowledge-authoring places high demands on labor and intellect, and it is expensive. It is expected that the approach described herein will prove useful to others involved in delivering CDS at the point of care.

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<tr>
<th>Summary points</th>
<th>What was already known on the topic</th>
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<td>• The quality of care cannot be improved simply by implementing electronic health records (EHRs); EHRs need to be coupled with other systems, such as a clinical decision support (CDS) system.</td>
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<td>• Only a few institutions worldwide currently have effective CDS capabilities, including in the United States and Korea.</td>
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<td>• Korea has been using health information technology for over 20 years, but there remains limited understanding and experience of CDS capabilities and infrastructure, and in particular in harmony or alignment with EHRs.</td>
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What this study added to our knowledge

• We have identified CDS requirements and service features that will enable the Korean EHR to contribute to improvements in the quality of care.
• In the context of Korea healthcare and EHRs, an enterprise CDS delivery architecture and application architecture were suggested as infrastructures for the adoption of a CDS service in Korea.
• We have described our experiences and shown how the CDS architecture would be designed and customized to reflect a specific healthcare system and context.

One potential limitation of the present study is the selective literature review and the use of convenience sampling for the focus group from which the architectural requirements were derived. While it is possible that the selected literature and group may not be entirely representative of related studies and all organizations interested in developing a CDSS in Korea, the lessons from previous works and the opinions of the survey participants were useful in the present study at stimulating the adoption of CDSSs to improve clinical care. Another limitation is that the usefulness we suggested has not yet been validated outside the CiEHR and for several important types of CDS applications, such as CPOE systems with CDS capabilities. Our plan for the future is to implement and validate the architectures for several typical CDS applications in real settings. It is expected that further demonstrations will reveal the flexibility and clinical usefulness of CDS services in Korea.

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