Standard Document Development for Health Information Exchange in Korea

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Abstract

Background Health information exchange (HIE) allows healthcare providers to access a patient’s medical information to improve patient care continuity. The standardized data realize the HIE values. Since the Health Level 7 Clinical Document Architecture (CDA) is flexible, implementation guides (IG) are needed for use cases. Although many CDA IGs have been developed, they did not describe how these CDA IGs were developed. A national CDA IG that meets the local requirements is demanded since the data differs according to the digital divide and social-cultural background of the country that wants to establish HIE. Due to their localized contents, other countries cannot directly adopt the published CDA IGs.

Objectives We developed the national CDA IG, namely, Korean (K)-CDA IG that meets the local requirement, including reusable structured templates, value sets, and object identifiers (OIDs). We present a detailed description of the development process and the technical methods of the national CDA IG in the Korean context.

Methods The K-CDA IG was developed in the following stages: analysis, development, and evaluation. First, we investigated the health information environment and electronic health record (EHR) systems and conducted a gap analysis with published CDA IGs. Second, a templated CDA approach was taken for designing modular. Lastly, we consulted a technical advisory group for comments on the validity of the K-CDA IG.

Results A total of 35 CDA templates were developed. We improved 28 value sets of which 13 were Korea specific and 15 were based on the ones used in other IGs, and made a set of rules to establish the OID structure.

Conclusion We presented the development process and the technical specifications of K-CDA IG. We explored how the results can be used as interoperability criteria in the national EHR systems certification program. Finally, we provided recommendations that could guide other entities planning their HIE programs.
Background and Significance

Health information exchange (HIE) allows healthcare providers and patients to access and share a patient’s medical information to improve patient care continuity, quality, safety, and cost. The HIE can improve the completeness of a patient’s records, as past history, current medications, and other information are jointly reviewed during visits. Appropriate, timely sharing of patient information can better inform decision-making at the point of care and allow providers to avoid medication errors, improve diagnoses, and decrease duplicating tests. The HIE has many benefits regardless of how it is transmitted, but realizing the HIE value is to standardize data. The standardized data are seamlessly integrated into the data recipients’ electronic health record (EHR) systems and used variously, such as clinical research and big data analytics.

The Health Level 7 (HL7) Clinical Document Architecture (CDA) is an international standard for document-based communication. HL7 CDA Release 2 has been applied in various interoperability studies since its publication in 2005. Since the CDA specification is richly expressive and flexible to create clinical documents, templates and implementation guides (IGs) are needed to represent specific use cases. Many CDA IGs have been developed over the past few years, such as the U.S. Consolidated CDA (C-CDA), European Union eHealth Digital Service Infrastructure (eHDSI) International Patient Summary (IPS), ePrescription of Integrating the Healthcare Enterprise (IHE) profiles, Australia’s Shared Health Summary and Advance Care Planning, and Canada’s pan-Canadian CDA Header. These CDA IGs are not only used to implement used cases but also to adapt the interoperability criteria of certification programs. For example, the C-CDA IG has been adopted as interoperability criteria of the U.S. Office of the National Coordinator Health Information Technology Certification Program. However, the CDA IGs did not provide a detailed description of how these CDA IGs were developed.

A national CDA IG that meets the local requirements is demanded since the collectible data differs according to the digital divide and social–cultural background of the country that wants to establish HIE. Due to their localized contents, other countries cannot directly adopt the published CDA IGs. The national CDA IG also can be used as interoperability criteria in the national certification program for an EHR system. Although several studies implemented the CDA standard in Korea, they did not provide a CDA IG for the national HIE.

In 2017, Korea’s Ministry of Health and Welfare (MoWH) launched an HIE initiative. As of February 2022, approximately 6,837 hospitals and clinics are exchanging medical records and images. The conceptual architecture of the initiative is shown in Fig. 1. The HIE framework is based on the IHE Cross-Enterprise Document Sharing-b (XDS.b) profile with some variations. Target documents for the HIE initiative are a referral note, transfer note, care record summary, and diagnostic imaging report. When a patient needs a referral or transfer, a healthcare provider generates CDA documents using the data from patient visits and stores it in a regional document repository that a tertiary hospital typically hosts. Healthcare providers can also opt for a public document repository hosted in a government-managed cloud service called G-Cloud. Document metadata are stored in the shared document registry that is also hosted in G-Cloud. Typical

Fig. 1  A conceptual architecture for the National Health Information Exchange Initiative in Korea. HIE, health information exchange; MPI, master patient index.
document-sharing transactions follow the XDS.b profile. In addition, security and privacy, patient consent procedures, value sets, and object identifiers (OIDs) are included in the HIE guideline distributed by MoHW. As an add-on service, patients can search their referral and transfer history using a portal service called “My Chart.”

Certain factors are driving the improvement of the current HIE initiative’s guidelines as described here. First, templates provided by the HIE initiative were not designed according to the templated CDA approach which uses a library of modular CDA templates. The templates cannot be reused if the CDA document type is extended. Second, some templates were semantically misused and did not conform to the CDA standard. And Third, the OIDs are essential for the HIE were not officially registered but arbitrarily used.

In this study, we developed the national CDA IG, namely, Korean (K)-CDA IG that meets the local requirement and improves the HIE initiative guideline including reusable structured templates, value sets, and OID structure. We also present a detailed description of the development process and the technical methods of the national CDA IG in the Korean context. By providing the K-CDA IG in Korea, it is expected that the exchanged data will be more standardized and structured, thereby improving the value of HIE. We also expect other countries or communities that can gain insights from our experience for their own HIE projects.

**Methods**

**Korean Clinical Document Architecture Implementation Guides Development Process**

The K-CDA IGs were developed in stages, as shown in Fig. 2: analysis, development, and evaluation. In the analysis stage, we surveyed the health information environment and EHR systems deployed in Korea. We conducted gap analysis with previously published international/national IGs such as U.S. C-CDA IG, eHDSI IPS IGs, and Korea HIE guidelines. In the development stage, a templated CDA approach was taken for the modular, reusable building block. In the evaluation stage, we consulted a technical advisory group that consisted of healthcare information experts, health information technology (IT) specialists, and clinicians for comments and feedback on the validity of the K-CDA IGs. Moreover, the K-CDA templates were registered in the Trifolia workbench for management and creating a Schematron.

**Consulting a Technical Advisory Group**

The K-CDA IG contains all essential information for Korea’s HIE initiative that complies with the level of the EHR systems deployed in Korea and conforms to the CDA standard. The “essential information” refers explicitly to the “minimum” criterion for the dataset in the HIE initiative. The K-CDA IG was developed by diligently incorporating stakeholders’ feedback such as government agencies, hospitals, research institutions for health IT standards, and EHR system vendors. By design, the technical advisory group consisted of government officials, health IT standard experts, EHR system developers, and healthcare providers. The health IT standard experts reviewed the K-CDA IGs based on the CDA standard. The EHR system vendors reviewed whether the data were stored in the EHR system and if that were essential data for the HIE. The healthcare providers reviewed the data required for continuity of care. The results of the consultation and the progress status were reported to the Korea Health Information Service which is a public sector organization responsible for managing the IGs, templates, value sets, and OIDs.

**Validation and Management**

The K-CDA templates were published in the Trifolia workbench for management, as shown in Fig. 3. The Trifolia workbench is an open-source tool for creating the CDA
templates and generating Schematron, a rule-based language for validating CDA documents. It also prevents human errors, maintains consistency, and improves developers’ productivity.

Results

Overview

The templates included in the K-CDA IG were developed to be compatible with HIE initiatives. The HIE initiative did not initially provide a CDA general header, so we developed a reusable general K-header template for other types of document templates defined in the future, including the four document types. The example of the referral note document template is shown in Fig. 4. The HIE initiative’s section and entry templates also were included in the K-CDA IG for compatibility. Instead, templates that semantically misused and did not conform to the CDA standard were revised. Some entry templates were added to standardize and structure the narrative text in the section template. As presented in Table 1, a total of 35 CDA templates were developed for the K-CDA IGs: 5 document templates, 14 section templates, and 16 entry templates. In K-CDA IG, every template and data element has three kinds of optionality: R refers to “mandatory,” R2 for “recommended,” and O for “optional.”

We improved 28 value sets for semantic interoperability of which 13 were specific to Korea and 15 were based on the ones used in the other IGs, such as C-CDA IG, and IPS IG. We adopted value sets, such as chief complaints and immunization medication, using Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) since Korea became the 39th official member of SNOMED International in 2020.

The Document, Section, and Entry Templates

We developed five document templates as follows: (1) the general K-header, (2) referral note, (3) transfer note, (4) care record summary, and (5) diagnostic imaging report. The general K-header template was newly defined to represent administrative and demographic data for CDA documents in Korea. The general K-header template contains document metadata, including the id, type, title, date, recordTarget, author, custodian, informationRecipient, authenticator, and componentOf which are extensible markup language tags defined in the CDA standard. The recordTarget represents patient information. The informationRecipient represents a consumer of document. The componentOf represents the type of encounters, such as ambulatory, inpatient, or emergency. The headers of document templates follow the general K-header constraints. In the general K-header template, the optionality of informationRecipient was assigned as O. However, since document recipient was mandatory in the referral note and transfer note, the optionality of informationRecipient was constrained as R. The general K-header template could be reused for other types of document templates defined in the future.

The general K-header template did not include some elements specified in the CDA standard. The elements were informant, dataEnterer, inFulfillmentOf, documentationOf, legalAuthenticated, and authorization. The informant refers to a person who provides relevant information, and the dataEnterer represents a participant who enters the data into an EHR system. Both the informant and dataEnterer were not collected in the EHR system in Korea. The contents of inFulfillmentOf and documentationOf, which are related to events, were described in section or entry templates of the K-CDA IG. The legalAuthenticated, which represents a provider that legally authenticates the CDA document, was...
inapplicable in the HIE since CDA documents have no legal effect in Korea. The authorization, which represents whether patients consent to participate in the HIE, was not included to avoid duplication since the HIE separately collects consent.

The other document templates, including referral note, transfer note, care record summary, and diagnostic imaging report, consisted of the general K-header template and a combination of section templates. Table 2 shows the optionality of section templates in the document templates. The referral note, transfer note, and care record summary document templates contained the Diagnosis, Medication, Result, Procedure, and Allergies and Intolerance section templates of which the Diagnosis is mandatory. The diagnostic imaging report document template contained the Finding section which was assigned as mandatory.

We developed 14 sections and 16 entry templates that are reusable across multiple CDA document types. The section templates are shown in Table 2, and the entry templates are Problem Concern Act, Problem Observation, Medication Supply Order, Medication Information, Result Organizer, Result Observation, Procedure Activity Procedure, Allergy Concern Act, Allergy-Intolerance Observation, Immunization Activity, Immunization Medication Information, Vital Sign Observation, Social History Organizer, Social History Observation, and Smoking Status. We assigned section codes using the Logical Observation Identifiers, Names, and Codes.

### Table 1: The document, section, and entry templates in K-CDA IG

<table>
<thead>
<tr>
<th>Level of templates</th>
<th>Templates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document templates (5)</td>
<td>General K-header, referral note, transfer note, care record summary, and diagnostic imaging report</td>
</tr>
<tr>
<td>Section templates (14)</td>
<td>Problem, medication, result, procedure, allergies and intolerances, assessment, reason for referral, plan of treatment, history of past illness, immunization, vital sign, social history, infection disease, and finding</td>
</tr>
<tr>
<td>Entry templates (16)</td>
<td>Problem concern act, problem observation, medication supply order, medication information, result organizer, result observation, procedure activity procedure, allergy concern act, allergy intolerance observation, immunization activity, immunization medication information, vital sign organizer, vital sign observation, social history organizer, social history observation, and smoking status</td>
</tr>
</tbody>
</table>

(LOINC) to provide the intended use of sections. In the K-CDA IG, since the Medication section was used to describe medication orders, the section code was 57833–6: Prescription for Medication.

**Code Systems and Value Sets**

We selected code systems for value sets in K-CDA IG using Korea specific and international terminologies. The Korea specific terminologies, such as the Korean Standard Classification of Disease (KCD); for diagnosis, the Korea Drug (KD) codes for medications, and the claim codes for the tests, were adopted. International terminologies, such as SNOMED CT and LOINC, were adopted for the problem type, chief complaint, vaccine, vital sign, result type, and social history. The Anatomical Therapeutic Chemical classification (ATC) was adopted for drug ingredients, and the International Classification of Disease-Ninth Revision-Clinical Modification (ICD-9-CM) was adopted for procedures.

We defined 28 value sets for the entry templates: Problem, Observation, Vital Sign Observation, and Immunization Medication Information. The value set for the Problem Observation was developed to represent diagnosis and chief complaint using the KCD and SNOMED CT. The value sets for the Vital Sign Observation were developed to represent vital sign type and measurement units, including height, weight, body temperature, blood pressure, body mass index (BMI), and oxygen saturation using the LOINC and Unified Code for Units of Measure. The value set for the Immunization Medication Information was developed using SNOMED CT and vaccine administered (CVX) code set. The CVX code was used only for the Hantavirus vaccine which is relevant for Korea; however, the vaccine was not included in SNOMED CT.

The value set for Allergies Intolerance Observation was under development since the allergy was recorded in text in Korea. With the growing importance of allergy, we designated an element for the allergy code to be mandatory. Currently, the element was set at a fixed value with no information (NI). We also designated an element for the allergy name to text.

**Object Identifier**

We made a set of rules to establish the OID structure for HIE in Korea. The OID structure consisted of healthcare provider, system, organization, terminology, template, and value set, as shown in Fig. 5. The root node of the HIE, the OID for Korea, was registered at the OID repository, and the rest were locally managed. The OIDs for healthcare providers had two subnodes—doctor and nurse—which were represented by the national license number. The OIDs for patients used master patient index managed by the MoHW and patient ID managed by hospitals. The OIDs for organizations used hospital ID that was derived from national insurance claims. The OIDs for templates were divided as follows: document, section, and entry.

**Discussion**

**Principal Results**

We have developed a national CDA IG, the K-CDA IG, that meets the local requirements in Korea. By combining reusable templates from the K-CDA IG, new document templates can be developed, and by adding section and entry templates to the K-CDA IG, sharable data can be extended. Data elements were considered for what data could be collected in the Korean context and whether they could be standardized and structured. Some data elements that do not standardize were developed to enable binding a value set to be defined soon. They are increased semantic interoperability. All templates and data elements were constrained by

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**Table 2** The optionality of section templates in different document templates

<table>
<thead>
<tr>
<th>Section templates</th>
<th>Referral note</th>
<th>Transfer note</th>
<th>Care record summary</th>
<th>Diagnostic imaging report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergies and Intolerances</td>
<td>R2</td>
<td>R2</td>
<td>R2</td>
<td>N/A*</td>
</tr>
<tr>
<td>Assessment</td>
<td>R2</td>
<td>R2</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Problem</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>N/A</td>
</tr>
<tr>
<td>Finding</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>R</td>
</tr>
<tr>
<td>History of past illness</td>
<td>N/A</td>
<td>R2</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Immunization</td>
<td>N/A</td>
<td>N/A</td>
<td>R2</td>
<td>N/A</td>
</tr>
<tr>
<td>Infectious diseases</td>
<td>N/A</td>
<td>N/A</td>
<td>R2</td>
<td>N/A</td>
</tr>
<tr>
<td>Medication</td>
<td>R2</td>
<td>R2</td>
<td>R2</td>
<td>N/A</td>
</tr>
<tr>
<td>Plan of treatment</td>
<td>R2</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Procedure</td>
<td>R2</td>
<td>R2</td>
<td>R2</td>
<td>N/A</td>
</tr>
<tr>
<td>Reason for referral</td>
<td>R2</td>
<td>R2</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Result</td>
<td>R2</td>
<td>R2</td>
<td>R2</td>
<td>N/A</td>
</tr>
<tr>
<td>Social history</td>
<td>N/A</td>
<td>N/A</td>
<td>O</td>
<td>N/A</td>
</tr>
<tr>
<td>Vital signs</td>
<td>N/A</td>
<td>N/A</td>
<td>R2</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Abbreviation: N/A, not applicable.

Note: Every section has three kinds of optionality. R refers to “mandatory,” R2 “recommended,” and O “optional.”

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optionality and cardinality. We configured the OID structure to easily assign OID to new participants in the HIE initiative.

The national IG can make a virtuous cycle that improves the EHR systems and the certification program, as shown in Fig. 6. The EHR systems were built by reflecting the requirements, such as opinions of the healthcare professionals, policies, new technologies, and standards. The certification program was created by reflecting the EHR systems.

The EHR systems can be improved by reflecting the certification criteria. For example, the requirements of policies related to interoperability were reflected in national IGs, such as K-CDA IG, to improve the EHR systems.

We expect it to be adopted in the interoperability criteria of the EHR system certification program since the care record summary IG, one of four document types in the K-CDA IG, was accepted by the Korean Industrial Standards, the
national standards. The EHR system certification program has been in operation since 2020. The program has three categories, such as functionality, interoperability, security, and B6 certification criteria for EHR systems. The requirements of interoperability are based on HL7 CDA.

A governance model is required to maintain the national CDA IG and OID structures such as processes, systems, and organizations. Processes and support systems to manage versions of K-CDA IG, value sets, and OIDs are needed. Conformance tools for verifying CDA documents should be developed. An authority to manage the value sets, such as the value set authority center in the United States, should be established. Incorrect value set binding does not guarantee semantic interoperability and may affect patient safety. An OID repository should be provided where OIDs can be retrieved and assigned to new entities anytime, anywhere. A newly established Korea Health Information Service (KHIS) is expected to manage and oversee the processes and systems.

The HL7 Fast Healthcare Interoperability Resource (FHIR), a next-generation HIE standard, has become the most actively studied. The FHIR is a standard describing data formats and elements, known as “resources,” and an application programming interface (API) for exchanging electronic health information. The FHIR is easier to implement because it uses a modern web-based suite of API technology, including an HTTP-based RESTful protocol and a choice of JSON, XML, or RDF for data representation. Due to these benefits, there are attempts to map CDA to FHIR, such as C-CDA on FHIR. Nevertheless, CDA and FHIR can coexist for the time being, at least in Korea, as 6,837 hospitals and clinics have already participated in the CDA-based national HIE initiative and much has been invested in the infrastructure. In addition, Korea is in an early stage of FHIR adoption, and no healthcare provider has been reported to be FHIR ready. In the long term, however, FHIR is expected to be prevalent for HIE in Korea.

Recommendations for Other Entities Planning Their Own HIE Programs

Although the K-CDA IG that meets Korea’s local requirements was developed, it cannot be directly adopted in other countries due to localized contents. This study provides recommendations that could be helpful to other entities planning their own HIE programs. First, the national health IT infrastructure and standardized data in EHR systems currently deployed should be considered to establish the national HIE. It is necessary to understand the EHR systems deployed in the country, including what data are being collected and whether the data are recorded as coded data. For example, the allergy data are collected as text, not as coded data, in an EHR system in Korea. Since it is expected to adopt a value set for allergy in the near future, the K-CDA IG allows both code and textual input.

Second, all elements and entities constituting the national HIE, including templates, value sets, doctors, nurses, organizations, and terminology systems, should be assigned to OID. It is necessary to register OIDs in repository, so that anyone can search at anytime and anywhere. The OID structure should be defined to manage entities. In the OID structure for the K-CDA IG, the MoHW node has six subnodes as follows: (1) healthcare provider, (2) system, (3) organization, (4) terminology, (5) template, and (6) value set.

Third, terminologies for the national HIE should be considered under national policies. It is also necessary to understand terminologies currently used in the country. In the K-CDA IG, the KD codes were used to represent medication rather than RxNorm, a standardized nomenclature for clinical drugs in the United States, used in C-CDA IG. In addition, KCD-8 was used to represent diagnosis rather than the International Statistical Classification of Disease (ICD)-11th Revision or SNOMED CT. KCD-8 is a translation of the concept and term used in Korea based on ICD-11 and subdivided according to the situation.

Fourth, value sets should be considered along with the socio-cultural and environmental situations of the country. Value sets such as gender and language do not change significantly, depending on the region or country, and hence, the value sets developed in other countries or organizations can be used. However, value sets, such as diagnosis and immunization, are required to be localized according to region or country. For example, the Hantavirus vaccine code is needed for K-CDA’s vaccine value set, but it may not be necessary for other countries. Additionally, a set of naming conventions for value sets is needed to provide consistency. In the K-CDA IG, the naming convention for value sets is “Management Agency + Purpose of Use + Name,” for example, MoHW HIE KCD 8.

Fifth, an identification system for HIE patients, such as patients, healthcare providers, and organizations, should be established. The patient ID can be used to identify patients within the organization but the national HIE needs the master patient index to identify a patient nationwide. Healthcare providers also need national identification. In the United States, a national provider identifier (NPI) is used to identify individuals and organizations, and the Provider Enumeration Systems NPI registry allows us to search an NPI. In Korea, the MoHW issues and manages the licenses of healthcare providers, and the license number is applied to the HIE.

Conclusion

We presented the development process and the technical specifications of K-CDA IG. We subsequently explored how the results can be used as interoperability criteria in the national certification program for EHR systems. Finally, we provide recommendations that could guide other institutions or entities planning their own HIE programs.

Clinical Relevance Statement

Continuity of care related to the quality of care over time is facilitated by applying standards to electronic health record (EHR) systems for interoperability. This study describes the development process and technical methods of the national clinical document architecture (CDA) implementation guides and draws implications.
Multiple Choice Questions

1. Which of the following statements is not correct about the virtuous cycle of the electronic health record (EHR) systems and the certification program?

   a. The EHR systems were built by reflecting the requirements, such as opinions of the healthcare professionals, policies, new technologies, and standards.

   b. The certification program was created by reflecting the EHR systems.

   c. The EHR systems can be improved by reflecting the national implementation guides (IGs).

   d. The EHR systems can be improved by reflecting the certification criteria.

   **Correct Answer:** The correct answer is option c. The EHR systems can be improved by reflecting the national IGs. The EHR systems were built by reflecting the requirements, such as opinions of the healthcare professionals, policies, new technologies, and standards. The certification program was created by reflecting the functionality, interoperability, and security of the EHR systems. The certification program can be improved by adopting the newly developed national IGs.

2. When planning their own health information exchange (HIE) programs, which of the following statements is correct?

   a. The national health information technology (IT) infrastructure and information level of EHR systems should be considered.

   b. Terminologies for the national HIE are necessary to understand terminologies used in other countries.

   c. Value sets developed in other countries such as diagnosis and immunization can be used.

   d. An identification system for HIE patients must be made newly.

   **Correct Answer:** The correct answer is option a. The national health IT infrastructure and information level of EHR systems should be considered. Terminologies for the national HIE are necessary to understand terminologies used in other countries. Value sets developed in other countries such as diagnosis and immunization can be used.

References


Protection of Human and Animal Subjects

This paper described the development process and lessons learned from national implementation guides for healthcare information exchange; therefore, informed consent was not required.

Conflict of Interest

None declared.