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Structured Representation for Core Elements of Common Clinical Decision Support Interventions to Facilitate Knowledge Sharing

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Abstract

At present, there are no widely accepted, standard approaches for representing computer-based clinical decision support (CDS) intervention types and their structural components. This study aimed to identify key requirements for the representation of five widely utilized CDS intervention types: alerts and reminders, order sets, infobuttons, documentation templates/forms, and relevant data presentation. An XML schema was proposed for representing these interventions and their core structural elements (e.g., general metadata, applicable clinical scenarios, CDS inputs, CDS outputs, and CDS logic) in a shareable manner. The schema was validated by building CDS artifacts for 22 different interventions, targeted toward guidelines and clinical conditions called for in the 2011 Meaningful Use criteria. Custom style sheets were developed to render the XML files in human-readable form. The CDS knowledge artifacts were shared via a public web portal. Our experience also identifies gaps in existing standards and informs future development of standards for CDS knowledge representation and sharing.

Keywords:

Clinical Decision Support, Knowledge Representation, Information and Knowledge Sharing, Standards.

Introduction

Studies have shown that appropriately implemented computer-based CDS can reduce medical errors and improve quality of care. Nevertheless, many healthcare delivery institutions lack resources, content or expertise to effectively realize these potential benefits. The lack of universally adopted, comprehensive standards for the representation of CDS interventions and their core structural elements has led most institutions to implement CDS in different ways. This lack also slows the implementation of CDS in institutions because they cannot easily leverage interventions developed elsewhere. A roadmap was proposed for improving CDS capabilities and its use through the U.S. health sector [1]. One fundamental step is to represent best available clinical knowledge and CDS interventions in standardized formats and provide knowledge sharing services from which users can readily access the material they need and deploy it into their own environment.

The Office of the National Coordinator for Health Information Technology (ONC) Advancing Clinical Decision Support (ACDS) project, led by the RAND Corporation and Partners Healthcare, was intended to accelerate the effective use of computer-based CDS interventions to facilitate evidence-based clinical practice and the meaningful use of health IT. This paper describes a subtask of this effort that aimed to identify key requirements, outline core parameters and elements, and propose an approach for the representation of structured and shareable CDS intervention artifacts, which can be subsequently transformed to a machine-executable format and consumed by clinical information systems, or accessed as web-services. In order to develop a structured representation for core elements of common CDS interventions, our approach was divided into several main steps, which moved from requirements identification, to comparison of approaches, solution proposal, validation, and finally distribution.

Requirements Analysis

As the first step in identifying how CDS interventions should be represented in a format that could enable widespread sharing, we identified (a) commonly used CDS intervention types that would be valuable to share and (b) core structural elements within those CDS intervention types.

1. CDS Intervention Types

Based on an extensive literature review [1-10], we identified five key CDS intervention types that are central to CDS knowledge sharing: 1) ***Alerts and Reminders***: an alert is a proactive warning or notification generated by a clinical information system as it monitors system inputs and evaluates outcomes triggered by those inputs for inappropriate values or situations that need attention. Examples include alerts for abnormal laboratory test results, drug-drug interactions, drug-allergy contraindications, etc. A reminder is similar to an alert, but it is a system-generated message triggered by the existence of conditions or the passage of time that makes specific actions desirable. For example, a reminder may be generated to prompt women over 50 years of age to get an annual mammogram. 2) ***Infobuttons***: an infobutton is defined as a point-of-care information retrieval application. It automatically generates and sends queries to on-line health information resources ('e-resources') using patient data extracted from the electronic health record (EHR) and background information ('context') that is captured from the interaction between a clinical user and a clinical information system (e.g., user role, patient age and gender, and task being performed by the user). 3) ***Order Sets***: an order set is a predefined and approved group of orders relating to a particular clinical condition (e.g., hypertension treatment and monitoring) or stage of care (e.g., hospital admission to Coronary Care Unit). Often the order set consists of both diagnostic (i.e. laboratory tests and procedures) and therapeutic (i.e. medication or procedures) orders. Order sets implemented

in Computerized Provider Order Entry (CPOE) systems can provide real-time CDS for adverse drug interactions, calculated dosages based on patient characteristics (e.g., age or weight), and other aspects of standardized care delivery. 4) ***Documentation Templates and Forms***: a documentation template is a structured form for recording clinical information about a patient into a set of pre-defined data slots. Documentation templates and forms provide a passive CDS intervention by reminding clinicians about particular data elements to be included, the format of the input, the allowable values or ranges, and other related information. They can also have an active component if the documentation items vary based on patient characteristics or facts already documented on the form. Examples of forms are History and Physical Exam forms or Tobacco Use forms. **5)** ***Relevant Data Presentation***: it optimizes decision making by ensuring that the most pertinent data are considered and organized in a way that facilitates decision making. For example, flowsheets of relevant lab test results, vital signs, and concurrent medications can be displayed when administering a medication.

2. Core Structural Elements of CDS Interventions

We further identified core structural elements shared across all five intervention types and classified these elements into five groups: 1) ***General Metadata*** provides information about the CDS artifact as a whole or about its components (e.g., modules, applicable clinical scenarios and recommendations) within the resource. Metadata encompass elements such as identifier, title, description, author, supporting evidence, and so on. 2) ***Applicable Clinical Scenarios*** define the clinical scenarios for which a knowledge resource or the knowledge resource component (e.g., knowledge module or recommendation) applies. For example, a particular alert may apply to the outpatient care of an adult patient who has diabetes. 3) ***CDS Inputs*** are the data obtained from clinical information systems in order to trigger and inform the CDS intervention. Sources of such input data include EHR systems or practice management systems. Typical input data include patient encounter, medication list, practice site, etc. 4) ***CDS Outputs*** are the CDS information provided to relevant clinical information systems and CDS systems through the analysis of the input data. CDS outputs include patient-specific assessments, care recommendations (e.g., an encounter request or a procedure request), and the like. Within the five broad CDS intervention types, CDS outputs can be conceptualized to include patient-specific alerts and care recommendations; user-specific and context-specific information obtained through infobuttons; context-appropriate order sets; documentation templates tailored to the needs of a specific clinical context (e.g., outpatient primary care encounter for patient with hypertension); and the content and formatting of relevant data to display for a given clinical situation. 5) ***CDS Logic*** represents how CDS inputs are analyzed, how inputs and outputs are associated, and how CDS outputs are inferred. For example, CDS logic may entail how a patient's age, gender, past breast cancer screening history, past mastectomy history, past breast cancer-related diagnoses, and relevant family history are associated and analyzed to provide a patient-specific recommendation on whether breast cancer screening is currently indicated.

Comparison of Approaches

We conducted both a "horizontal" review on alternative approaches to representing the core structural elements that serve as building blocks for the CDS interventions included in this study and a "vertical" review on relevant work related to the representation of the individual intervention types. Relevant work reviewed includes the HL7 Arden Syntax standard [4], the ASTM GEM model [5], the HL7 Order Set specification [6], the HL7 Infobutton standard [7], the HL7 Virtual Medical Record (vMR) project [8], OpenEHR [9], OpenCDS [10], GELLO [11], the AHRQ Structured Care Recommendation approach [12], the CDS Consortium (CDSC) approach [13], etc. Due to space limitations, we only present a summary of our findings here. Our assessment is that there are no universally adopted, comprehensive standards for the representation of CDS interventions and their core structural elements. However, there are many relevant existing efforts, and these existing efforts share many similarities that are amenable to harmonization. Therefore, we proposed an approach to the representation of CDS interventions that leverages these existing efforts and merges them into a coherent, unified specification.

Proposed Approach

We propose here an approach that focuses primarily on the core structural elements and provides a unified representation framework for the five identified CDS intervention types. We believe that this approach will facilitate the development, sharing, use, and maintenance of these various CDS intervention types. The proposed approach leverages and extends the previous work of the CDS Consortium [13], particularly with regard to the Structured/L3 representation of CDS knowledge resources. In the CDSC project, a four-layered knowledge representation framework was developed to translate narrative guideline recommendations into structured input for a CDS system [14]. Such a layered approach was also used in previous work [15]. 1) ***Unstructured (Level 1)***: any human readable knowledge in any document format. 2) ***Semi-structured (Level 2)***: knowledge is deconstructed and encapsulated as individual recommendations. These knowledge specifications are primarily authored by clinical domain experts. A schema is developed for this layer, but knowledge is not codified. 3) ***Structured (Level 3)***: this layer defines and specifies the structure and semantics of all the data elements and logic needed to make the knowledge interpretable by computers. These specifications are typically authored by knowledge engineers and have the following major characteristics: a) The knowledge is independent of implementation in a particular type of CDS tool or a particular clinical setting, to maximize its ability to be shared; b) Unified Modeling Language (UML) models and XML schemas are developed for this layer; and c) Data elements are codified as necessary. 4) ***Executable (Level 4)***: this layer is dependent on the specific CDS tool employed and clinical setting. Programmers implement the knowledge into specific rule engines or clinical systems. The knowledge is not easily sharable across disparate implementations.

The initial work of the CDSC focused on building Level 3 (L3) specifications for alerts and reminders. The ACDS effort expanded upon the CDSC work by exercising the L3 XML schema to support additional CDS interventions as identified in the requirements analysis.

Overview of the Approach

The proposed schema models knowledge contained in a clinical knowledge resource as a collection of unsequenced recommendations to be made in various clinical contexts, which is unlike other guideline representations that model knowledge as a flow of activities. These recommendations are organized into modules. Each recommendation consists of metadata, applicable scenarios and clinical advices (actions). Certain data elements (e.g., metadata and applicable scenario) are reusable at different levels of this schema (e.g., at the knowledge resource level, module level or recommendation level). The XML Schema Definition (XSD) and Extensible Stylesheet Language (XSL) files can be downloaded from a public web portal (http://cdsportal.Partners.org/RelatedResources.aspx?pageId

=3). The overview of the schema is shown in Figure 1, and component elements that correspond to the core structural elements are detailed below.

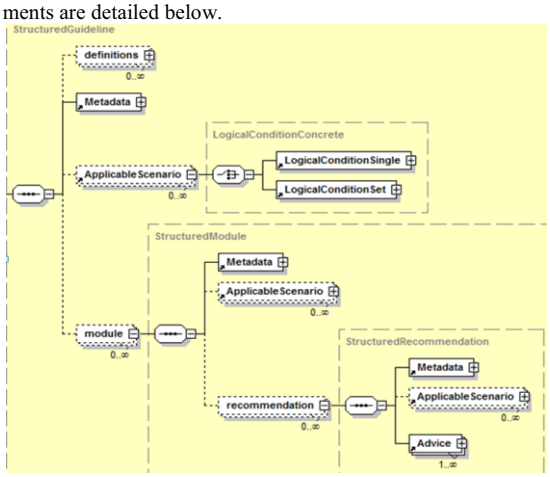

Figure 1- Overview of the Schema

1. Representation of General Definitions and Metadata

Based on our review of relevant standards and research studies, including Arden Syntax, HL7 Order Sets, GEM, and several others, we found that the metadata identified in these efforts are similar with slight differences. We collected and analyzed the metadata from these efforts and proposed general definitions and a common set of metadata that may be applicable for all intervention types. Definitions provide a structural description about the clinical knowledge resource, including title, description and identifier. The metadata contain general information about the knowledge resource as well as modules and recommendations within the resource, including a unique identifier, contributor, coverage, evidence basis, development approach, knowledge type, testing information, and versioning and life cycle management information.

2. Representation of Applicable Clinical Scenarios

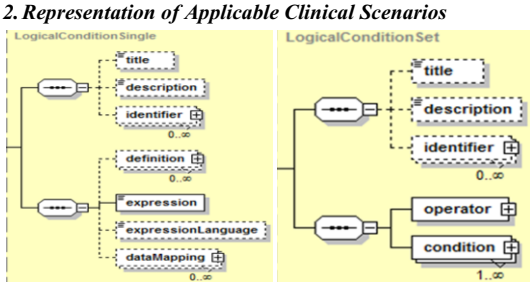

Figure 2 - Overview of Logical Conditions

Applicable clinical scenarios are proposed to consist of a single logical condition or a set of logical conditions (Figure 2). Each logical condition includes the identification, definition, expression, and data mapping to the patient data model. The applicable scenario can be reused at the guideline level, module level or specific recommendation level. For example, at the guideline level, the applicable scenario may be the outpatient care of a patient who is >= 18 years old.

Within a logical condition, the "definition" can be used to specify the meaning of a term that exists across recommendations or guidelines. For example, a definition could specify the term "poorly controlled diabetes" in terms of serum hemoglobin A1c test results. The "expression" is used to define a precise meaning of the term. It can be written in GELLO [11] or other rule expression languages. The "dataMapping" provides a link to a patient information model (described below) which specifies the data items that are referenced in the logical expressions. The "operator" defines how the logical conditions should be combined, i.e., conjunction, disjunction, negation by using *and*, *or*, or *not* operators respectively.

3. Representation of CDS Inputs

At the core of CDS inputs is patient data. We propose a patient data model (Figure 3) that is based upon the Clinical Statement model from the Health Information Technology Standard Panel (HITSP)'s Summary Documents Using HL7 Continuity of Care Document (CCD) Component, i.e., the C32 specification [16]. We further recommend that this model be harmonized with the emerging HL7 vMR standard, and that the HL7 vMR standard be used for the representation of CDS inputs once available.

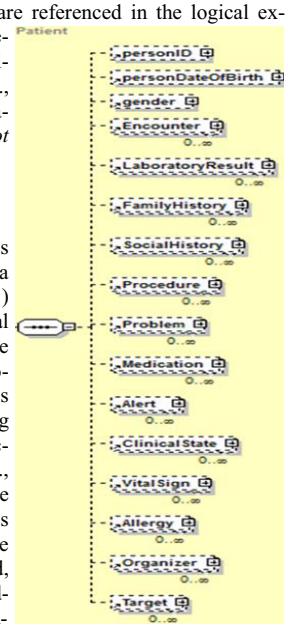

Figure 3 - Overview of Patient Data Model

4. Representation of CDS Outputs

Figure 4 provides an overview of the proposed representation of CDS outputs. Similar to the patient data model, the proposed approach draws from the CCD clinical statements model with the overlaid HITSP constraints. Concrete actions can be message request, event request or any other types of request and organized by the action organizer using logic operators (*and*, *or*, *not*). An override or exception reason can be added to any action. It is an option in the display of a recommendation that allows the user to indicate to the CDS system why they are choosing to not execute the recommended action. In addition, priority of the request (high, medium, low), request type (e.g., instruction), selectionCriteria (i.e., action preference), and severity of the clinical condition request are also represented.

5. Representation of CDS Logic

As noted in the overview to our approach, we propose that the CDS logic be represented as an unsequenced collection of decisions, so as to simplify and broaden sharing and reuse of the knowledge assets. In this approach, a CDS intervention consists of one or more modules (Figure 1). Each module consists of a specification of module-specific metadata, module-specific applicable scenarios (e.g., "no blood pressure within last 12 months"), and zero or more recommendations. In turn, each recommendation consists of a specification of recommendation-specific metadata, recommendation-specific applicable scenarios, and one or more CDS advices. Finally, within a given advice, there are concrete actions (ActionConcrete) that represent the CDS outputs (Figure 4).

Within the specification of applicable scenarios for a specific CDS advice, logical expressions may be constructed using various expression formalisms, such as GELLO, Arden Syntax, and pseudocode. Of note, the applicable scenarios are founded on the patient information model. Thus, the proposed approach is to represent CDS logic as a pairing of applicable scenarios based on the CDS input model to recommended actions encapsulated in the CDS output model.

6. Representation of Value Sets

Central to the specification of both CDS inputs and outputs is

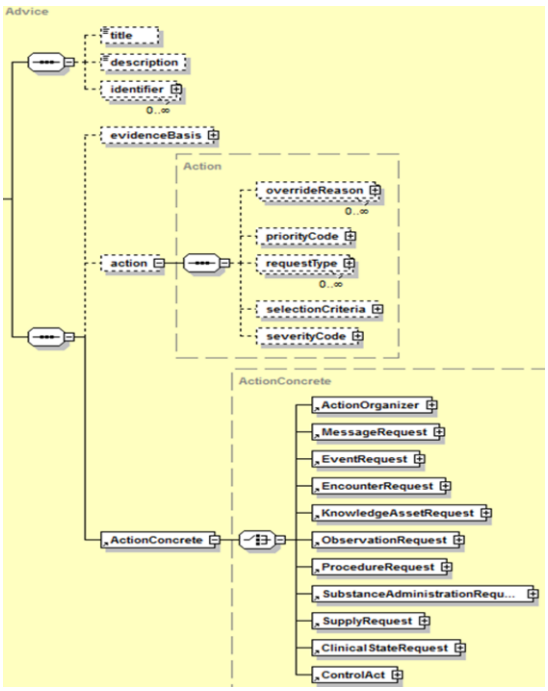

Figure 4 - Overview of CDS Output Model

the use of standard terminologies and value sets that are bound to the various data elements of the relevant information models. For example, for a patient's clinical problems, the set of permissible codes needs to be clearly defined. We recommend that such terminology and value set bindings be maintained separately as independent resources that can be re-used across CDS interventions. For example, we identified 29 different SNOMED concepts (e.g., 8801005-Secondary diabetes mellitus) to identify patients who have diabetes mellitus. An information model was developed for representing these value sets (Figure 5). The codes in the value set have a set of attributes (e.g., code and coding system) and zero or more qualifiers that increase the specificity of the primary code. The codes can be translated to other coding systems or tied to other related work (e.g., NQF eMeasures Value Sets).

Validation and Distribution

We validated the XML schema by building a set of CDS interventions targeted toward guidelines and clinical conditions called for in the 2011 Meaningful Use criteria, which have

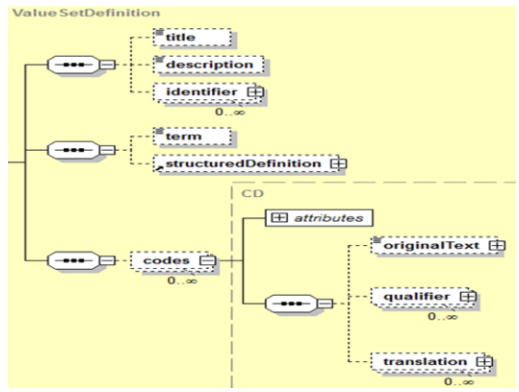

Figure 5 - Overview of Value Set Model

been implemented at Partners Healthcare and informed by related CDS projects, especially the NQF eMeasures [17]. The process of building the CDS artifacts and validating them against the schema was iterative. We developed three custom stylesheets appropriate for clinical Subject Matter Experts, Knowledge Engineers and Developers, to render the logic in human-readable form. They were extremely useful during the artifact review and refinement process, because each stylesheet offered a different level of detail for the various team members and they helped us identify inconsistencies and discrepancies. Clinical elements including clinical states, labs, and procedures in these artifacts were defined by linking to the NQF eMeasures using the OIDs defined in the NQF spreadsheets. Twenty-two CDS artifacts and 16 value sets were developed that cover the five CDS intervention types [18]. We reviewed our approach with EHR vendors. Allscripts conducted a demonstration of transformation by importing ACDS artifacts and firing the rule logic in their local test environment [18]. The ACDS artifacts, the custom stylesheets, and key supplemental files were deployed to our web portal (http://cdsportal.partners.org/). Figure 6 illustrates an example of ACDS L3 stylesheet for the smoking cessation order set.

Discussion

In this study, we proposed a structured representation for core elements of common CDS interventions to facilitate knowledge sharing and improve the standard of care. This extends the large body of work to date in number of ways. First, rather than propose a model for all CDS, we focused on five of the most commonly implemented modalities of CDS. The proposed XML schema adequately supports the development of CDS artifacts of the five different intervention types and facilitates the CDS sharing via a knowledge-sharing framework,

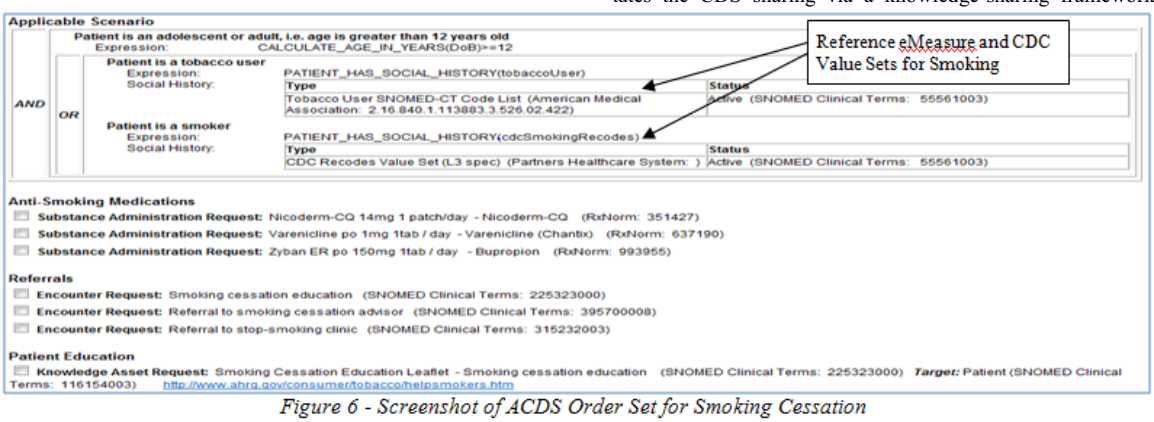

Figure 6 - Screenshot of ACDS Order Set for Smoking Cessation

repository and service. The ACDS and CDSC efforts have demonstrated that it is possible to interface a CDS knowledge sharing framework with EHR vendor systems.

CDS Data Model: There is a lack of a standard model for representing data items, including patient and provider information, clinical actions and workflow information, that are referenced in the logical expressions. Rather than developing another proprietary model, our approach was to remain standard-based. The patient data model in the proposed schema is based on the HL7 Clinical Statement in the HITSP's C32 specification (i.e., Summary Documents Using HL7 CCD Component). The CCD is a medical summary. It provides a practical but not ideal transport mechanism for the clinical data when calling the CDS Service. The HL7 vMR is intended to be "a data model for representing clinical information inputs and outputs that can be exchanged between CDS engines and local clinical information systems, through mechanisms such as CDS services."[8] Although vMR could be an appropriate standard for representing the needed data elements, it is currently in the draft stage.

Rule Languages and Formalisms for Logic Expression: It is important to have a well-defined and easily adaptable rule expression language to create queries to retrieve and manipulate EHR data and to construct logical expressions to reason about particular data features and values. Although many efforts have been made to develop methods, models, and algorithms for manipulating the underlying data elements associated with CDS interventions as well as constructing and exchanging rule logical expressions, significant gaps still exist which prevent us from recommending a specific standard in this particular area at this stage. For example, The GELLO expression language [11] was noted by some EHR system vendors to be "too complex for most programmers to utilize, especially without an easily accessible compiler." Although we have utilized GELLO in our artifacts, because of the lack of standards in this area, our proposal supports a variety of logic formalisms, such as Arden Syntax and even pseudocode.

Quality Measures: While quality measurement retrospectively reports care quality using EHR data at the population level and CDS improves quality at the point of care for individual patients, both quality measurement and CDS are built upon clinical guidelines and other best evidence, and the underlying data processing involved is similar. Therefore, quality measurement and CDS should align with each other. Our approach supports the references to published quality measure value sets, but more work is needed to make these measures interoperable with CDS logic in a more automated fashion, as we relied on manual identification, review, and curation.

Terminologies and Value Sets: The CDS intervention data elements need to be encoded using standard terminologies and value sets in order to be sharable and reusable. There are significant challenges of mapping standard terminologies to local codes, classifying specific problems or medications into generic categories, and identifying a clinical state for CDS (e.g., checking if the patient is on a specific therapy using a class of concepts). Because of the diversity in the terminology field, multiple parties need to be involved and a tremendous amount of effort is needed to integrate all the pieces. This is the area where the biggest benefit lies in sharing, rather than continually re-creating similar artifacts locally.

Conclusion

We have undergone a process to define a comprehensive, shareable representation of CDS interventions and their core elements by leveraging previous efforts, and validated the model to some extent within our own system and with commercial EHR systems. Next steps will include further extension and validation of the proposed approach, and make reference to the Health eDecisions work [19].

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