A Set of Preliminary Standards Recommended for Achieving a National Repository of Clinical Decision Support Interventions

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Abstract

We are investigating the development, implementation and evaluation of clinical decision support (CDS) projects to advance our understanding of how best to incorporate these interventions into the delivery of healthcare. Our overall goal is to explore how the translation of clinical knowledge into CDS and its incorporation into practice can be routinely achieved to improve the quality of healthcare delivered in the U.S.A. Toward this end, we have developed a 7-step model that provides a framework for clinical decision support-related standards that are necessary if we wish to achieve these goals. We believe that if all commercially available EHR systems had the features and functions described in these recommendations, many more healthcare organizations could begin to develop and implement the basic CDS features that are necessary to radically transform the quality, safety, and cost of the current healthcare system.

Introduction

Electronic health records (EHRs), when used effectively, can improve the safety and quality of medical care. For maximum benefit, however, EHRs must be paired with clinical decision support (CDS) systems to effectively influence physician behavior [1] and impact healthcare processes and outcomes. CDS includes a variety of techniques designed to facilitate and guide doctors' decision making toward evidence-based practice. For example, Osheroff et al. identified six specific CDS intervention types: clinical documentation forms and templates, relevant data presentations, order creation facilitators, time-based checking and protocol support, reference information and guidance, and reactive alerts and reminders[2]. We believe all of these CDS types are critical if we are to achieve the vision of transforming the quality and manner in which healthcare is delivered.

The present set of recommendations focuses mainly on the data, tools, features, and functions necessary to allow EHR implementers to create any of these CDS intervention types. In addition, we focus mainly on the use of rule-based alerts and reminders, time-based checking, and reference information. Common examples of these types of CDS include computerized checks for drug interactions and electronic reminders for screening tests like mammograms and Pap smears, and the ability to access reference information within the order entry workflow (i.e., InfoButton-type activities).

While the evidence that CDS can be effective is clear, current use and adoption of CDS is limited. In fact, most of what we know about CDS comes from only four academic medical centers and integrated delivery networks[3]. Wider adoption of decision support has been held back by a variety of issues, including:

- Difficulty translating medical knowledge and guidelines into a form usable by EHRs.
- Technical challenges in developing a standard representation for CDS content that could be shared across sites.
- Absence of a central knowledge repository where human readable and executable guideline knowledge can be shared and stored.
- Challenges integrating decision support into clinical workflow and other barriers to IT adoption
- Limited capabilities for CDS in commercially available EHRs.

On March 1, 2008, the Agency for Healthcare Research and Quality (AHRQ) funded two research teams to develop Clinical Decision Support Demonstration Projects: The Guidelines Into Decision Support (GLIDES) project based at Yale, headed by Richard Shiffman, MD, and the Clinical

Decision Support Consortium (CDSC), based at the Brigham and Women's Hospital, and headed by Blackford Middleton, MD. The goal of these projects was the "development, implementation and evaluation of demonstration projects that advance understanding of how best to incorporate clinical decision support (CDS) into the delivery of healthcare…with the overall goal to explore how the translation of clinical knowledge into CDS can be routinized in practice and taken to scale in order to improve the quality of healthcare delivery in the U.S."[4]. A major objective has been identification of clinical decision support-related standards that will be necessary if we are to achieve these goals.

Methods

Over the past year the Knowledge Management Lifecycle Assessment team of the CDSC has conducted site visits to study current practices for CDS and knowledge management in all five member organizations (Partners Healthcare in Boston, Wishard Health System / Regenstrief Institute and Roudebush VA in Indianapolis, the Mid-valley IPA in Salem, OR and the University of Medicine and Dentistry of New Jersey (UMDNJ) in New Brunswick, New Jersey). In addition, we conducted an extensive survey of CDS types and knowledge management activities at each site. We also reviewed the 2008 Certification Commission for Health Information Technology (CCHIT) ambulatory system criteria looking for clinical decision support-related criteria and met with members of the GLIDES team to get their input. Finally, the recommendations were reviewed by the Technical Expert Panel for the AHRQ contract that funded this work. Our goal was to develop a set of recommendations for standards activities that are complementary to and build upon what already is known or exists.

Using our Rapid Assessment Process[5] we sent 5 or 6 researchers for each site visit. Upon arriving for our 3-day visit, we split into teams and began holding discussions with key stakeholders (i.e., clinician leaders and IT leadership) and conducting observations of ambulatory clinicians as they used their CDS-enabled EMR system in the routine care of their patients. Following the site visit we analyzed all the data collected using a grounded approach[6].

Seven-Step Model of CDS-related Standards

Based on these analyses, we have developed the following 7-step model that provides a framework for the standards that we feel are required to complete this journey. Specifically, we must have:

Step 1: Access to high-quality, standardized, syntactically and semantically encoded patient data.

Step 2: A standard for encoded clinical knowledge that is both human-and machine-readable.

Step 3: A set of standard CDS intervention types (drug-drug interaction alerts or condition-specific order sets).

Step 4: A set of standard locations within clinicians' electronically enabled clinical workflow at which CDS interventions can be presented to clinicians, and the requisite EMR functionality for the CDS intervention. For example, when selecting a medication from a list, the clinician is told that the current patient has an allergy to a particular medication.

Step 5: A standard method for either requesting patient data in a standard format, or having this data automatically sent to an application that is separate from the EMR (perhaps as a service on the internet, for example).

Step 6: A validated, open-access, CDS knowledge base that contains at least a starter set of standard, high-quality, clinically evaluated CDS interventions that can be downloaded and utilized, or perhaps accessed over the internet as a service, by any CCHIT-approved EMR system.

Step 7: Agreement on, and development of, a set of clinical quality measures that can be used to measure and monitor the effectiveness of the CDS interventions described above.

Unfortunately, to our knowledge, none of the standards and approaches suggested in steps 2-7 has yet been developed. If we are successful over the course of our CDS projects, we will be able to offer some insight into these issues over the next few years. With that said, we offer the following recommendations based on our research over the first year of our CDS demonstration projects.

Specific CDS-related Recommendations

Recommendation 1: Define Standard Triggers. Triggers are defined as "events that cause a decision support rule to be invoked. Triggers are critical to providing event-driven, action-oriented, real-time, point of care clinical decision support and represent the initiating condition for many different types of clinical decision support interventions. Examples of triggers include prescribing a drug, ordering a laboratory test, or entering a new problem on the problem list."[7]. All of these data items need to be captured and stored in a structured and coded data

field meaning that both the syntax, or format, of the data conforms to a pre-defined (and if available standards-based) structure and that the semantics, or meaning, of the data are based on a pre-defined standard. Otherwise, they are not usable by current CDS systems that rely on such coded data.

Recommendation 2: Define Standard Input Data. Nearly all decision support rules require patient-specific, coded data to make their inferences. The following types of data should be available as input data for use by the clinical decision support intervention logic to make inferences regarding suggested clinical actions or alerts: laboratory test results, patient demographics, and the patient's problem list, for example.

Triggers and input data elements represent the input arm of decision support. Interventions, by contrast, are efferent. The best decision support systems tailor their interventions based on the severity of clinical situation and the user's workflow[8], so offering a broad palette of interventions is important.

Recommendation 3: Define Standard Interventions. For the possible actions a decision support module can recommend, enable the system to automatically route these actions to the appropriate person, based on logic included with the CDS intervention. Examples include such actions as sending a message to a clinician, showing a guideline, or simply logging that an event took place.

Recommendation 4: Define Standard Offered Choices. Choices or options should be made available to clinicians following a CDS intervention, with explanation. Such choices are usually offered alongside, or following a system notification event and represent the actions a user of the clinical information system can take based on the clinical decision support intervention, or reasons why it may be rejected. For example, a rule that fired because a physician entered an order for a drug the patient is allergic to might allow the clinician to cancel the new order, choose a safer alternative drug, or override the alert and keep the order as written but provide an explanation[9].

Recommendation 5: Utilize Continuity of Care Document (CCD) standard[10]. While we realize that the HITSP process has already endorsed the CCD as a system interoperability standard for the exchange of clinical summary documents[11], we are recommending that its use be expanded. Specifically, we would like to see clinical decision support applications that are potentially separate from the underlying EHR system, be able to request, or receive a copy of a current CCD at various points in the clinical workflow through a programmatic interface. This would enable CDS applications that are external to the EMR to use the patient's data in their logic.

Our reasoning for this recommendation is that if we are to achieve the widespread transformation of the healthcare delivery system through use of state-of-the-art clinical information systems, we must make it easier and less expensive for healthcare organizations to implement, test, and maintain the vast amounts of clinical decision support logic required. Our research to date indicates that only a very small number of leading academic medical centers have been able to design, develop, implement, test, and maintain even a fraction of the clinical knowledge required to truly revolutionize the practice of medicine. We believe that by making it easier for external applications to access the patient's clinical data right in the clinical workflow, that existing (as well as many new) clinical content development organizations will begin to make available actionable, real-time, clinical decision support interventions on a widespread scale.

Recommendation 6: Specify Relevant Controlled Vocabularies. HITSP should continue its support for and promulgation of the various controlled clinical vocabularies that are required to fully characterize the patient's clinical condition. Specifically, we believe that if controlled vocabularies were in routine use to encode the patient's medication list [12] (RxNorm for medications and NDF-RT for medication classes), allergies (SNOMED-CT for reactions and severity), clinical problems and diagnoses (SNOMED), clinical laboratory results [13] (LOINC + SNOMED CT), etc., that much more robust clinical decision support, that is sharable across implementations, would be possible.

Recommendation 7: Define Logical Rules. All EMRs should provide a general purpose facility for creating logical rules. The facility should support triggering, allow for access to coded data, allow a variety of intervention types, and especially support offering actionable choices with explanation to users. It should not limit end users to any specific type of CDS.

Recommendation 8: The CDS rule engine should support basic mathematical (e.g., MAX and MIN values), temporal (e.g., FIRST - earliest time a data element was stored in the patient's record and LAST –most recent time a data element was stored in the patient's record), and logical (e.g., AND, OR, NOT, XOR) operators. We believe the need for semantic reasoning is just around the corner.

Recommendation 9: Allow selective filtering or tailoring of rules (i.e., to turn off some rules) that apply to particular contexts: specific practices, physicians, specialties, clinical situations (e.g., bone-marrow transplant patients, terminally ill or comfort measures only, pregnant women, etc.), patient types (e.g., day surgery, out-patients), time of day, physician performance patterns, or locations within a practice or hospital setting.

Recommendation 10: Support Randomization of CDS interventions at the patient, provider, and practice level to facilitate experiments regarding different aspects of these interventions. We believe this is necessary to allow any organization to test the effectiveness of the CDS interventions within their own environment.

Recommendation 11: Support commercially-available CDS knowledge-based (drug-drug interaction checking, drug-allergy checking, reminders, order sets and templates) out of the box, and support various commercial content types. Make it as easy as possible to incorporate this knowledge along with updates (CCHIT 08 - FN 12.09 [14)] within the EMR. The EMR system should allow appropriately trained personnel at the local site to customize any and all CDS logic and/or content.

Recommendation 12: Log the results (include date, time, location, name of provider, and patient) of all inferences and rule firings and user responses / override reasons and provide a facility for viewing, exporting and analyzing these logs.

Recommendation 13: Allow appropriately trained personnel at the local sites the ability to access and configure, or customize, the appearance or functionality of selected data entry or review screens, and the knowledge underlying CDS. We recommend that all vendors provide the ability for the end user to tailor or configure the presentation layer, and the associated knowledge elements, to fit their setting.

Recommendation 14: Support the HL7 InfoButton standard [15] for at least: problems, medications, and laboratory tests.

Recommendation 15: Export the clinical knowledge used in all CDS interventions in a human-readable form so that any interested person can easily review the clinical logic used in any CDS intervention.

Recommendation 16: Provide a user interface that allows template-based design of data collection with integrated prompting and flexible display of relevant information. Radio button and checkboxes should be supported as well as free text comments about why decision support may have been ignored. Audit of these functions should be straightforward.

Recommendation 17: Support import and export of standard knowledge artifacts, e.g., order sets encoded using the emerging HL-7 standard.

Recommendation 18: Support service-based decision support modules. If the capability to support these types of CDS modules existed, it would allow disparate clinical information systems and clinical decision support systems to share a reference knowledge-base over a network according to a defined set of interfaces and protocols[16].

Recommendation 19:, Describe the preferred means of expression or use for each CDS intervention within the target clinical application; e.g. an order-set requires order entry functionality; a drug-drug alert requires a drug order entry environment and knowledge of patient medication list; etc.

Discussion

Over the course of the next several years, we will have more recommendations based on the lessons we expect to learn as we get more deeply involved in the demonstration pilot projects. Specifically, we hope to address several of the issues raised in steps 2-7 above. For example, our knowledge representation team is currently working to develop a (step 2) high-quality knowledge interchange format that is both human- and machine-readable. Therefore, we are specifically NOT making a recommendation regarding the adoption of any of the existing clinical knowledge representation formalisms (e.g., Arden, GLIF, GELLO, etc.). At this time, our research indicates that none of these standards has achieved widespread acceptance or been implemented by more than a few clinical information system vendors. Until it becomes clearer which if any of the existing, or under development, knowledge representation formalisms are shown to be superior, we would recommend waiting to adopt any standard.

The CDSC knowledge management lifecycle assessment team is developing a (step 3) survey of over 50 different CDS intervention types which we hope to field with physicians across the USA. The results of this survey will help us to better understand what is currently possible within existing commercially-available EMR systems. Our CDS pilot demonstration teams are working on (step 5) a service-oriented approach to creating CDS interventions that can be used across existing EMR systems. The CDSC Knowledge Portal project is developing a first iteration of a clinical knowledge

base that will include a starter set of CDS interventions that we will be sharing amongst members of our CDS Consortium. Finally, we are working on development of a clinical decision support dashboard that will display the results of the measurements (step 7) made of the CDS interventions that we are developing.

In the near future we envision that CDS interventions will be available to healthcare organizations via an open-access, CDS knowledge base that contains at least a starter set of standard, high-quality, clinically evaluated CDS interventions (step 6). These interventions will consist of a "knowledge pack" that includes:

1) The data standards (steps 1 & 5) required to syntactically and semantically describe the data necessary to drive the clinical logic as well as measure the clinical outcome of the intervention; 2) The clinical logic specification (step 2) that describes the intervention logic; 3) A functional specification of the HIT system feature(s) necessary to carry out the intervention including the position in the clinical workflow at which it will be delivered (steps 3 & 4); and 4) A reporting specification that contains a description of the method for measuring the impact of the CDS intervention (step 7).

If we are successful, the results of all these teams' work will push our understanding of the issues in all of these areas much further ahead.

Conclusion

We believe that if all commercially available EMR systems had the features and functions described in these recommendations that many more healthcare organizations could begin to develop and implement the basic clinical decision support features that are necessary to radically transform both the quality and safety of the current healthcare system.

Acknowledgement This research was funded in part by a contract from the Agency for Healthcare Research and Quality HHHSA29020080010.

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