A Conceptual Architecture for National Standards-based Clinical Decision Support Integration and Syndication*

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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 behavior¹ and impact healthcare processes and outcomes. CDS includes a variety of techniques designed to facilitate and guide clinicians' decision making toward evidence-based practice. 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 reminders². 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.

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 networks³. 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.
- A shortage of experienced, well-trained knowledge engineers capable of transforming currently available clinical guidelines into highly structured, controlled clinical terminologies and computer-interpretable logic required by state-of-the-art EHRs.
- 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

The goal of this research project was to develop a conceptual architecture that describes the key socio-technical elements (i.e., people, processes, technology, and organizations)⁴ required

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for the production, implementation, use, and evaluation of standards-based clinical decision support that can be integrated into existing EHRs and syndicated nationwide.

Background

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 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."⁵.

CDS has been shown to improve the quality of patient care and increase adherence to evidence-based guidelines^{6,7}. In addition to being well-integrated into existing hospital systems and designed to smoothly fit into provider workflow, high-quality decision support also depends on a substantial knowledge base that must be regularly maintained by clinical informatics staff, a process known as *knowledge management*.

Effective knowledge management requires an ongoing investment of time and resources and an experienced and knowledgeable IS staff. High-quality CDS content must continuously incorporate the newest research and clinical practice guidelines in order to be of value to endusers. This process depends especially on *knowledge engineers*, who must possess sufficient expertise in both clinical practice and computer science to act as an effective conduit between domain experts and IS programmers. This makes the process of clinical knowledge management especially challenging and resource-intensive.

Despite the accomplishments of a small number of clinical sites, the local development and implementation of CDS content remains a daunting task. Given the investment of time and resources necessary to produce high quality decision support content and the shared need for high-quality clinical content, local development of CDS remains a sub-optimal solution to the problems we currently face. In order to generate and disseminate high-quality content, to mitigate the substantial investments required and to realize the full potential of CDS, the sharing of CDS content, management, and services is necessary on a national scale.

Methods

Over the past 2 years the Knowledge Management Lifecycle Assessment (KMLA) team of the CDSC has used our Rapid Assessment Process (RAP)⁸to study current practices for CDS and knowledge management in all five member organizations (Partners Healthcare in Boston, MA; Wishard Health System / Regenstrief Institute and Roudebush VA in Indianapolis, IN; Mid-valley Independent Physicians' Association in Salem, OR and the University of Medicine and Dentistry of New Jersey (UMDNJ) in New Brunswick, New Jersey). For each site visit, we deployed five or

six researchers to conduct interviews and observe physicians in the clinical environment. 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 EHR systems in the routine care of their patients. Following the site visit we analyzed all the data collected using a grounded approach⁹.

We also used a modified version of our RAP (i.e., 3 researchers for a 1-day site visit to interview key employees) to study several commercial, clinical content vendors (Zynx Health in Los Angeles, CA; First DataBank in South San Francisco, CA; and UpToDate in Waltham, MA)¹⁰.

In addition, we conducted an extensive survey of CDS types and knowledge management activities at each site¹¹. 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.

Results

Model for CDS Syndication

Figure 1 provides a conceptual model for how a national clinical decision support repository that supports widespread syndication could be integrated into the current CDS landscape. The model begins in the upper left hand corner with the *clinical guideline developers*. These organizations rely on the evidence gleaned from the scientific literature and their experience to create the evidence-based clinical guidelines. They must work closely with knowledge engineers who create and maintain the metadata associated with these text-based guidelines that facilitate their retrieval from existing guideline repositories.

Before the clinical knowledge contained in these guidelines can be incorporated into existing EHR systems, *knowledge engineers must identify and transform key concepts* into computer-executable logic statements. In addition, the data used to trigger and evaluate these logical expressions must be mapped to existing controlled clinical terminologies. Finally, the metadata used to catalog these standards-based CDS interventions must be created. Then, they can be stored in the national CDS repository.

Local knowledge engineers are now able to browse the national CDS repository looking for specific interventions identified by the local clinical content governance committee as priorities for their institution. Once they identify potentially suitable content, they can download it to the local systems and begin the process of assessing whether their existing EHR system has the features, functions and data required to implement the interventions identified. If it passes this

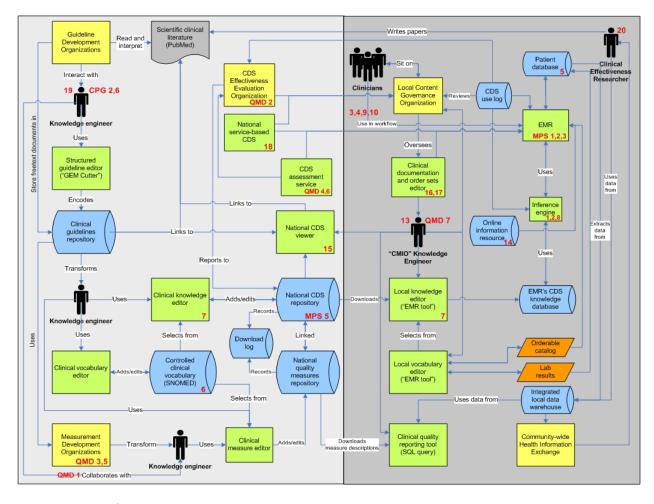


Figure 1. Diagram of the CDS landscape.

test, then they can begin *mapping the required data elements and recommended actions to the local controlled vocabularies* (i.e., local laboratory coding vocabulary and orderable items).

The customized CDS interventions are then uploaded into the organization's EHR, tested, and moved into routine clinical use. All user actions related to content use (e.g., medications and procedures ordered directly from CDS functionality, override rates, and patient outcomes) should be logged in the organization's clinical data warehouse and reported out to local CDS oversight committees. In addition, organizations should use existing clinical quality measures to track the use, effect, and potential adverse events related to CDS use. These measures should be reported to local community health information exchanges where they can be aggregated and eventually fed back to clinical effectiveness researchers for further analysis. Finally, reports of the overall CDS use, safety, and effectiveness should be examined by clinical guideline developers so they can refine their clinical guidelines.

Based on this conceptual model, we identified the following key features, functions, processes, policies, and procedures that need to be designed, developed, implemented, and evaluated if the nation is to achieve the widespread adoption of CDS and the resulting transformation of the current healthcare delivery system.

Recommendations

We have grouped the recommendations into broad groups based on the model in figure 1. Namely, we have identified CDS producers, implementers, consumers, and evaluators. The following sections outline our recommendations for each of these stakeholders.

Producers - people and content

CDS producers include those groups that generate basic CDS content such as guideline developers (e.g., American Academy of Pediatrics), governmental task forces (e.g., US Preventive Services Task Force), and commercial clinical content vendors (e.g., Zynx, Thomson Reuters, Elsevier). Especially important to this process are *professional and medical specialty societies*, which play a vital role in shaping practice guidelines.

For these guidelines to be adopted by CDS implementers and incorporated into state-of-the-art EHRs, producers of clinical decision support content should observe the following practices during the guideline development process:

Producers should define standard CDS 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 CDS and represent the initiating condition for many different types of CDS interventions. Examples of triggers include prescribing a drug, ordering a laboratory test, or entering a new problem on the problem list." For these data to be available to trigger CDS in existing EHRs they 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 predefined (and if available standards-based) structure and that the semantics, or meaning, of the data are based on a pre-defined standard.

Producers should 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 CDS 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 clinical 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 workflow¹³, thus, offering a broad palette of interventions is important.

Producers should increase clarity and internal consistency of all clinical logic included in guidelines. Focus should be put on reducing the ambiguity of recommendations in guidelines (e.g. refrain from saying "if the patient's blood pressure is high then..."; rather state "if the patient's systolic blood pressure is > 140 mmHg then...") ¹⁴. Explicit threshold values for input data and associated recommendations should be provided for all cases of a rule resulting from a guideline. When precise recommendations are not possible due to lack of evidence or consensus, producers should indicate their uncertainty by providing an acceptable range or

simply stating that this recommendation is not very specific. Such clarity is necessary if the logic is to be incorporated in a computer executable form.

Producer groups should include well-trained and experienced clinical informaticians on all committees. By including these individuals, the resulting guidelines should be easier to transform to computer executable forms. In addition, it may be possible that these informaticians could actually create the computer executable forms (i.e., for several of the leading commercially available EHRs) for review by the committee prior to release of the guideline.

Medical specialty societies should develop a specialty-specific, EHR assessment process that is based on requirements that are specific to their members' needs [see, for example, references¹⁵, ¹⁶, and ¹⁷]. In addition, each society should periodically publish their evaluations of all the leading Office of the National Coordinator (ONC)-approved EHR vendor products along with those EHRs that have been widely adopted by members of their specialty^{18,19}.

Medical specialty societies should include creation and/or implementation of state-of-theart, point-of-care CDS that is designed to improve the efficiency, safety, or quality of the care they deliver in their Quality Improvement programs²⁰ or other re-certification requirements.

Medical specialty societies should encourage and provide opportunities, such as trainings, for members who are interested in learning more about the application of health information technology, in general, and CDS, in particular, to gain additional education. For example, the American College of Emergency Physicians and the American College of Physicians have partnered with the American Medical Informatics Association to create courses designed to transition interested emergency and internal medicine physicians into thought leaders in their respective specialties related to clinical informatics [see: ²¹, ²²]. As the adoption and use of electronic health records (EHRs) with advanced CDS capabilities increases, there will be a substantial need for more clinicians trained in clinical informatics to help create the next generation of this system and incorporate the latest research developments into practical tools and techniques for practicing clinicians.

Medical specialty societies should begin or continue developing and testing specialty-specific CDS interventions that members can easily download, customize and incorporate into EHRs [see references ²³ and ²⁴]. Further, this content should be developed in a standards-based manner. In addition, professional societies should make sure that all of their endorsed clinical practice guidelines include CDS content that can be readily incorporated as CDS interventions into existing EHR systems.

Developers and Implementers

CDS developers and implementers include the informaticians, knowledge engineers, terminologists, and analysts who work to translate the clinical guidelines into computer-executable CDS interventions, such as, alerts, reminders, order sets, documentation templates, information resources, and complex patient care protocols [ref Morris and Methodist sepsis]. To facilitate this knowledge translation and encoding process we offer the following recommendations.

EHR vendors should define standard intervention routing mechanisms. For all possible actions a decision support module can recommend, create a set of all possible routes these actions can use to send the information 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, displaying an alert, or simply logging that an event took place.

A standard set of offered choices or options should be developed. Using these options clinicians can easily follow a CDS intervention. 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 CDS intervention²⁵. For example, a rule that fired because a physician entered an order for a drug that 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 explanation²⁶.

Developers should utilize Continuity of Care Document (CCD) standard²⁷. While we realize that the HITSP process has already endorsed the CCD as a system interoperability standard for the exchange of clinical summary documents²⁸, 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 CDS 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, existing (as well as many new) clinical content development organizations will begin to make available actionable, real-time, CDS interventions on a widespread scale.

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 ²⁹ (RxNorm for medications and NDF-RT for medication classes), allergies [Systematized Nomenclature of Medicine - Clinical Terms (SNOMED-CT) for reactions and severity], clinical problems and diagnoses [Systematized Nomenclature of Medicine (SNOMED)], clinical laboratory results ³⁰ [Logical Observation Identifiers Names and Codes (LOINC) + SNOMED CT], etc., that much more robust clinical decision support, that is shareable across implementations would be possible.

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.

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.

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.

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 ³¹⁾ 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.

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.

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.

Support the HL7 InfoButton standard³² for at least: problems, medications, and laboratory tests.

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.

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 Health Level 7 (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 protocols³³.

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.

Clinical Knowledge Engineers-Local Sites

Consumers – clinicians, organizations

Healthcare organizations should adopt a high-quality, ONC-certified EHR system that enables meaningful use. In addition, local sites should implement both basic CDS (e.g., drug-drug interaction checking, drug-allergy warnings, etc.) and more advanced, specialty specific CDS (e.g., for pediatrics – weight-based dosing; for primary care – preventive health services reminders).

Evaluators - measurement, gov't,

Evaluators should base their recommendations as much as possible on the results of randomized trials of CDS at the patient, provider, and practice level to facilitate understanding of different aspects of these features, functions, and interventions. We believe this is necessary to allow organizations to test the effectiveness of the CDS interventions within their own environment, as well as to provide a firm scientific basis for dissemination of best practices.

Evaluators should continue to participate in refinement of the Health Quality Measure Format (HQMF) standards development process. The HQMF represents a health quality measure in a machine-readable electronic format. Through standardization of a measure's structure, associated metadata, definitions and logic, the HQMF provides quality measure consistency and unambiguous interpretation.

Evaluators should begin developing measure assessment software services. In much the same manner that we are experimenting with the creation of internet-based CDS services that take CCDs as input and return an evidence-based clinical recommendation, evaluators should begin to develop measure assessment software services. Such a service would take a series of CCDs from a clinician's EHR and return an estimate of that measure's value in the form of a report. A key assumption is that all the required information necessary to compute the measure would be available within the CCDs. In addition, it is critical that a clinician submit either a) a random sample of patient visits, or b) a consecutive series of patient visits over a pre-defined time frame (i.e., over the entire year) to allow for the accurate measurement of the rate of

compliance with the measure (i.e., accurate numerator and denominator for the calculation). A first use of such reports could be for the certification of meeting the U.S. Department of Health and Human Services' new "meaningful use" criteria. For example, we believe that a measure of compliance with a diabetic guideline stating that all diabetics should have their HbA1c levels checked every 6 months could be calculated using a service like this. These services could be developed by evaluators and hosted by regional health information exchanges.

Develop standards and infrastructure for submitting quality measurement results electronically. Clinical QMDs should begin developing the standards and infrastructure to allow individual clinicians and large healthcare organizations to submit their quality measurement results electronically. These results should then be rolled-up to create standard, nationwide quality measurements. These benchmarks should be available for review by any participating member (i.e., people or organizations who have submitted data).

3. 1 Clinical Quality Measure Developers

Collaborate with clinical guideline developers to eliminate ambiguous language from clinical guidelines. Clinical QMDs need to work hand-in-hand with both CDS developers and clinical guideline developers to significantly reduce and, if possible, to eliminate all ambiguous statements that are often contained in current clinical guidelines. For example, they must help clinical guideline developers to move away from statements such as, "achieve adequate glycemic control in diabetic patients" toward statements like, "for all patients billed for International Classification of Diseases – 9th Edition (ICD-9) codes 250.*, check that the value of their most recent HbA1c (in the last 12 months) is <= 9.0%".

Define methods of measuring the effect of CDS interventions on the behavior of clinicians. In order to improve the quality of healthcare delivered, many organizations have turned to advanced, state-of-the-art, point-of-care CDS interventions. Unfortunately, as currently implemented many of these interventions are not being used as anticipated [³⁴, ³⁵]. If the CDS community is going to improve their performance, they must have standard, reproducible methods of measuring the effect of these interventions on the behavior of clinicians. Therefore, clinical QMDs should focus a portion of their attention on defining measures such as the alert override rate or order set usage rate (i.e., how often are order sets used in patients for whom they are applicable).

Incorporate more clinical data from EHRs into measure specifications. As the percentage of clinicians and healthcare organizations using state-of-the-art EHRs continues to increase, clinical QMDs should begin incorporating more clinical data from EHRs into their measure specifications. This switch from relying on administrative data to clinical data must be carefully phased in so that clinicians who are slow to adopt EHRs are not further penalized by not being able to be included in any national quality measure benchmarks.

Provide feedback mechanism for clinicians and organizations regarding quality measures. Clinical QMDs should create an internet-based mechanism for individual clinicians and large healthcare organizations to provide their comments and feedback directly to the clinical QMDs

regarding newly developed quality measures. Such a mechanism could greatly increase the speed by which specific problems are identified and overall increase the turnover in the iterative refinement process for new measures.

Discussion

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.

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