An Overview of Clinical Decision Support in Personalized Health Care: Interfaces with Electronic Health Information

Outline:

Background
Features of CDS Resources
Summary and Future Directions
Examples of CDS Tools
Glossary

BACKGROUND

This paper was developed by the Personalized Health Care (PHC) Initiative team at the Department of Health and Human Services to be used as a resource for the PHC workgroup's activities in the area of Clinical Decision Support.

As the frontiers of medical science and technology push forward with new and promising developments, the overall benefit of these new discoveries is dependent on their effective use in health care. With the accelerating pace of scientific discovery and development of new medical products, the time to integrate evidence for best practices in health care management has increased in parallel. In looking to the future and considering individualized approaches to managing health, a major challenge continues to be in the effective evaluation of options for evidenced based-decisions. Although not unique to the realm of personalized health care practices, the increased complexity presented through the applications of genetic-based tests, coupled with predictive risk assessments provided by family and medical history information, exemplifies the need for services, tools, and technologies to assist in patient-provider interactions.

From a clinician's viewpoint, an increasing amount of medical information must be gathered, interpreted, processed, and applied to maintain the most up-to-date best practice guidelines. For example, the clinician is expected to update and maintain a working knowledge of thousands of potential adverse drug-drug interactions and know where to seek information about them. Additionally, pharmacogenomics[1] is taking an increasingly important role in avoiding adverse events, determining the appropriate drug dose, and treatment selection. Clinical Decision Support (CDS) resources have the potential to aid the clinician by integrating patient data, providing options for care, and improving work flow. Consumer benefits from these tools may translate into more informed interactions with clinicians and predictable outcomes in health care strategies.

Rapid advances are occurring in the understanding of the interactions of genes and environmental factors that contribute mechanistically with disease and disease predisposition. However, most formal medical and allied health education typically provides minimal training in applications of this new information, leaving many clinicians unable to understand or interpret

[1] Pharmacogenomics is the understanding of how an individual's genetic variation account for differences in drug responses

genetic tests and information. The ability to easily acquire this knowledge is not possible under the current constrains and demands of clinical practice. Often clinicians require additional information from other sources, including the laboratory performing the tests, knowledge repositories, or genetic specialists, who can help interpret the result. Currently, this process is inefficient, and the burden for better information will increase, particularly among primary care practices.

CDS is conceptualized as providing clinicians, staff, patients, and other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care. It encompasses a variety of tools and interventions such as computerized alerts and reminders, clinical guidelines, order sets, patient data reports and dashboards, documentation templates, diagnostic support, and clinical workflow tools.[2] Designed as an electronic tool, many have envisioned CDS resources augmenting the applications of Electronic Health Records (EHRs). Although not widely deployed in health care at the moment, CDS tools may support a variety of processes to improve health care quality by enabling more informed decisions. CDS resources may also increase clinicians'' effectiveness by augmenting their ability to use a greater array of information to improve the quality of care, avoid adverse events, provide actionable guidelines, and help integrate newly discovered information into clinical practice.

FEATURES OF CDS RESOURCES

While methodologies for accomplishing these tasks vary among CDS tools, every CDS tool requires three components :

1. Data Collection
Selection of relevant data and the retrieval and integration of this data
2. Rule Algorithms
Processing of information and applications of guidelines
3. Messaging and Alerting
Presentation of processed, actionable information to the provider

1. Data Collection

The data collection supported by CDS tools can occur in two forms: passive and active. Passive collection involves manual input by the clinician of necessary values and information in order to obtain a result or output. Passive collection modules tend to be "stand alone" software applications that are not incorporated in an EHR system, however, passive collection modules can exist embedded within EHRs. CDS tools with passive collection, although helpful, may not be ideal as they require manual input of information, therefore interrupting the natural workflow. Active collection is a more recent, innovative approach for integrating CDS tools into the clinicians' workflow. CDS tools with active collection leverage existing personal and medical information stored in a system's EHR. These tools can actively analyze and track new data to provide a real-time analysis of the patient's health status. When an algorithm discovers a

[2] Osheroff, J., Teich, J., Middleton, B., Steen, E., Wright, A. and Detmer, D. *A Roadmap for National Action on Clinical Decision Support*, Office of the National Coordinator, Health and Human Services, June 13, 2006. http://www.jamia.org/cgi/content/full/14/2/141

messageable intervention or risk for the patient, either dependent or independent of a clinician's action, a message can alert the clinician. Active CDS systems are of greater utility to the clinician because they retrieve the necessary information and require minimal manual input, saving time and decreasing disruption through a more seamless integration into the natural workflow.

2. Rule Algorithms

CDS rule algorithms integrate the collected data, processes it, and then produces decision options based on the set of rules governing the algorithm. There are several types of algorithms for CDS tools:

A. Basic logic tools

These tools are based on simple rules that serve as a backup to clinicians and can, for example, provide automated reminders, cautions for potential adverse events via the EHR, or present reminders for overdue medical tests.

B. Complex logic tools

Examples of complex tools such as decision tree algorithms or computerized information resources that are abbreviated documents to guide decisions, interconnect basic logic rules that guide clinicians through a particular diagnostic pathway to evidence-based decision about health interventions. Widespread use of these logic CDS tools could minimize adverse drug events, augment use of preventive/preemptive treatment, therefore increasing quality, and efficiency of the healthcare system. For example, drug dosing can be determined based on multiple patient attributes such as age, gender, weight, and kidney function

C. Analytical tools

More sophisticated than logic tools, *analytical tools* help clinicians compute and compare information that extends beyond basic logic. These tools automate calculations involving multiple variables that the clinician would have had to perform manually prior to making a decision.. Calculation of disease risk and susceptibility to complex genetic disorders based on gene variants and family health history can be rapidly assessed using an analytical tool that otherwise would take extensive time and training to compute accurately. Analytical tools may also include individual patient preferences or conditions that may influence the parameters provided as options for action. For example, an individual patient may have ambulatory limitations that would preclude physical exercise options that may otherwise be recommended by logic or analytical tools in considering management of cardiovascular disorders, obesity, or diabetic conditions.

CDS rule algorithms should be based on current best practice guidelines. The entity responsible for determining and translating the best practice guidelines into actionable rules varies between tools. Some CDS vendors develop the rules themselves by convening their own panel of experts, and then integrate these guidelines into their software. Other CDS tools provide the framework for CDS capabilities but allow healthcare organizations, hospitals, and/or individual clinicians to independently design and implement their own CDS rules and alerts. In either case, rules are determined by a group of specialist in the particular field the CDS tool is designed to assist. Specific rules and care guidelines can therefore vary between organizations or vendors depending on the governing body that decided upon as the best practice guideline. National

standardization of best practice guidelines for CDS rule development has not occurred although it has been proposed in number of papers[3]. Vendor developed algorithms allow rules to be developed with uniform guidelines and are widely disseminated to many organizations for use and evaluation. Alternatively, some clinicians and institutions prefer to develop their own rules and guidelines so they can be better tailored to the user's preferences and practice needs. However, this can result in duplication of work that has previously been completed elsewhere. Ideally, CDS rules and guidelines would be interoperable between organizations to share rules development and evaluation responsibilities, improving the efficiency of the rule development process. This would still allow clinicians to select how they evaluate tools and select the rules they choose to deploy. CDS vendors could then compete on workflow and usability issues while keeping the rule development out of business and marketing.

3. Messaging and Alerting

Messaging and alerting is the third and very important aspect of CDS tools. As EHRs become more widely adopted, streamlining the deployment of CDS tools within the EHR will greatly enhance their utility. Additionally, appropriate levels of alerting must be attained for the CDS to be effective. This can be done by avoiding 'pop-up' alerts that interfere with workflow and being conservative on the alerts that are given. Even the most accurate, developed, highly EHR interoperable CDS tool can be disregarded by the clinician if it is viewed as an annoyance and hindrance.

SUMMARY AND FUTURE DIRECTIONS

CDS tools may represent a partial solution to the information overload and quality issues discussed above. In the purview of the use of EHRs to augment patient-centric care, particularly with the addition of family history and genetic laboratory test information, CDS resources have the potential to address the many complexities of medical decision-making. At this point in time, there is a lack of understanding about the feasibility of CDS use for improving the work flow of clinical practice. There is also a substantial need for an evaluation of the impact that these tools and the decisions that they support have on health outcomes.

More broadly, the integration of CDS resources along with EHRs to facilitate health information exchange is of interest to the health information technology community. The Roadmap for National Action on Clinical Decision Support was developed and presented to the Secretary of the Department of Health and Human Services and the American Health Information Community (AHIC) during the AHIC meeting on June 13, 2006. The roadmap recommends a series of activities to progress CDS development, implementation, and use throughout the U.S. healthcare sector. The immediate goal of these activities is "to ensure that optimal, usable and effective clinical decision support is widely available to providers, patients, and individuals where and when they need it to make health care decisions." The ultimate goal of these activities is "to improve the quality of health care services and to improve health in the United States." The CDS Roadmap lays out several key recommendations and a critical path for the development of CDS on a national level.

[3] Ibid.

EXAMPLES OF CDS TOOLS TO SUPPORT PHC PRACTICES

Inclusion of specific IT products does not constitute an official endorsement, but are used to serve simply as examples to demonstrate common principles and uses.

An analysis of several CDS tools was conducted through interactions with their developers and vendors to learn about their product and determine how they addressed the key aspects of CDS; data collection, rule algorithms, and messaging/alerts. This includes only a small sampling of CDS tools to represent the broad spectrum of types and characteristics of CDS tools. The examples will move in complexity from the most basic, passive, EHR-independent, logic based tools to the more complex, active, EHR-dependent, analytical tools. The purpose is to present the variation in tools development and intended use and to give a broad understanding of the development motivations.

Bilitool

Bilitool©[4] is an example of a passive web-based CDS tool that requires manual entry of laboratory data and other patient information by the clinician or consumer. The algorithm is based on best-practice guidelines of the American Academy of Pediatrics to assess risk of complications and aid in management of a single physiologic condition in newborns, hyperbilirubinemia (i.e., jaundice). The tool is independent of patient data repositories and EHRs. The logic-based rule uses age and levels of bilirubin as variables. The tool produces a result with risk stratification and provides recommended follow-up based on that risk. It provides useful information to the clinician at the point of care where the testing is often done, but can be inconvenient to clinicians who must alter their natural workflow, access the tool on the web, and manually re-enter information that may already be present in the patient's record or EHR.

The Breast Cancer and Melanoma Risk Assessment Tools

The Breast Cancer Risk Assessment Tool and the Melanoma Risk Assessment Tool are analytical CDS tools provided by the National Cancer Institute to assist clinicians and consumers in estimating over specific periods of time. The tools use personal medical history (presence of hyperplasia in previous biopsies or presence of certain size moles on back), family history (relatives with breast cancer), personal attributes (race and age), and lifestyle attributes (age of first born child or exposure to sun) which all are known to contribute to the risk of developing breast or melanoma cancer in some fashion. The model is passive and completely independent of an EHR, and uses both the patient's self-reported history and information from the clinician as its variables. The analytical rules are based on data from examined attributes contributing to the variable risks of these cancers. These tools provide the clinician with a risk calculation that would have taken an extensive period of time to, information as to why certain attributes were assessed, links to websites, characteristic pictures, and other information that the physician can use to make an accurate medical decision and provide answers to the patient.

WarfarinDosing

Another useful analytical CDS tool, WarfarinDosing©[5], uses a computational algorithm to help clinicians determine a proper therapeutic anti-coagulant dose. This CDS tool integrates

[4] www.bilitool.org
[5] www.warfarindosing.org

pharmacogenomic test information with other patient information to aid in deriving the correct dose of warfarin, an anti-coagulant medication, that is commonly associated with bleeding complications. The tool obtains general information, including sex, age, weight, height, smoking habits and liver disease; genetic information such as CYP2C9 and VKORC1-1639/3673 genotypes; and medical information such as laboratory tests for coagulation function. The algorithm produces an estimated therapeutic dose result as well as suggestions for specific observation for certain high risk scenarios. The tool is passive and independent from the EHR and must rely on data input by the provider. The dose estimations are based on data from over 1,000 patients; however, the tool continues to in an additional research and development stage.

TheraDoc

TheraDoc©[6] is a stand-alone CDS platform-based tool that can be actively connected to the clinician's EHR to provide automated access to historical and current patient information. It is able to provide active surveillance that recognizes changes in patient conditions, adverse events, and threats to patients' safety. TheraDoc applications include: Infection Control Assistant, Antibiotic Assistant, Clinical Alerts Assistant, and Adverse Drug Event Assistant. TheraDoc is developed independently from the EHRs but the software platform is able to interface with EHR systems utilizing health information technology standards such as HL7, LOINC, and SNOMED. This interoperability allows TheraDoc applications to accumulate data from the EHR, apply logic-based algorithm rules, and present messages within the workflow of the physician. Algorithms used by the TheraDoc software are developed and maintained by specialty advisory boards that are responsible for knowledge review to assure information and rules are current and accurate.

SafeMed

Similar to TheraDoc, SafeMed is an active CDS tool that is able to obtain necessary medical information from clinicians' EHR or any other medical information system. However, unlike TheraDoc, its software is XML web based and platform independent. The software consists of three performance improving components: SafeMed Imaging, SafeMed Pharma, and SafeMed Quality. SafeMed Imaging assists clinicians in identifying the most appropriate imaging test based on the level of effectiveness, cost, and side effects relative to the patient. SafeMed Pharma automatically and continuously checks current and prescribed medications for possible adverse drug reactions, efficiency, and cost-effectiveness comparison. SafeMed Quality is an active data accumulation process that checks for shortcomings in medical care as well as potentially harmful therapies. The logic-based rules are derived from best practice guidelines and are maintained and updated by SafeMed. Messaging and alerting is highly integrated into the providers EHR system.

PointOne Clinical Systems

PointOne Clinical Systems is an active platform-based system that uses genetic and family history information found in EHRs, medical claims, lab tests, health assessments and a web-based family history questionnaire. This CDS system serves to assist clinicians in identifying patients at high risk for certain diseases, and apply appropriate screening and risk reduction strategies. The system includes data capture tools, risk stratification algorithms, integrated reporting, care guidelines, and educational material for clinicians and patients. A patient-specific report from evidence-based guidelines is generated for the clinician, which includes an annotated

[6] http://www.theradoc.com/

family pedigree and patient risk stratification based on logic, analytical, and integrated algorithms. Currently the product is able to utilize information provided in the EHR but exists as a stand-alone software application which is not integrated into workflow of the EHR.

Intermountain Healthcare
Intermountain Healthcare (IHC) is a non-profit healthcare management organization that has been working on Health IT and CDS capabilities since the 1970s. IHC is currently developing a system with GE Healthcare that unifies EHR and CDS tools into one product. Cerner, an independent developer of healthcare information technology solutions, has developed a very similar product in which CDS capabilities are built into the EHR. Both of these products are similar as CDS capabilities are integrated in the EHR system, rather than developing a separate CDS tool that is able to access information in the EHR. These initiatives differ in their rule development. Intermountain has a process by which a group of physicians within a particular field develop rules for CDS interventions used by the entire IHC organization. Cerner, however, provides the capabilities and structure for the client clinician, hospital, or organization to develop their own alerts and warnings according to their own dictates and needs.

GLOSSARY

Adapted from the Roadmap for CDS
Available at http://www.amia.org/inside/initiatives/cds/cdsroadmap.pdf

Clinical Decision Support (CDS): Providing clinicians, patients or individuals with knowledge and person-specific or population information, intelligently filtered or presented at appropriate times, to foster better health processes, better individual patient care, and better population health. CDS interventions include alerts, reminders, and order sets, as well as other techniques for knowledge delivery including reference information and education (delivered with or without context sensitivity), health/clinical protocol and workflow orchestration support, display of context-relevant data, topic-oriented documentation forms, and others. Much of our discussion of clinical decision support here centers on its use within electronic health records and other computer-facilitated processes; however, the concept also applies to non-computerized knowledge delivery, such as paper mailings and brochures.

Clinical Knowledge: A generally applicable fact (or set of facts), best practice, guideline, logical rule, piece of reference information (such as a text article), or other element of information that is important to know for optimal data interpretation and decision-making regarding individual and population health and health care delivery. In a CDS system, a CDS **intervention** (see below) may use knowledge in at least two ways: as a logical rule to determine whether to deliver information, and as the information to be delivered itself. Example of clinical knowledge: “A mammogram should be ordered for any woman over 40 who has never had one.” A characteristic of clinical knowledge is that it can be open to controversy and often evolves over time.

Clinical knowledge producers: Synonymous in this document with knowledge producers. Refers to entities that create and/or disseminate clinical knowledge. Examples include health

care specialty societies, commercial clinical knowledge and CDS intervention vendors, health care organizations that share their clinical knowledge and CDS interventions with others, etc.

Clinical Information Systems: applications and hardware that manage patient care-related data. Application examples include Computerized Provider Order Entry (CPOE), Electronic Health Records (EHR), Personal Health Records (PHR), and departmental systems such as those that manage pharmacy, radiology and nursing information.

CDS implementers: health care delivery or other organizations that deploy CDS to end-users.

CDS Intervention: The delivery of one or more specific pieces of clinical knowledge or intelligently filtered data to an individual at a specific time and place to address a clinical objective. CDS interventions include the CDS content (i.e. clinical knowledge) and the logistics (such as software applications and workflow processes) by which it is delivered. Example of an intervention (using the example from the clinical knowledge definition): when a patient's electronic record is opened by a physician or nurse and positioned at an appropriate workflow