Date: July 1, 2010

From: GLIDES

To: Health Information Technology Standards Panel (HITSP)

Re: Recommendations regarding Clinical Decision Support-related Standards

Background

On March 1, 2008, the Agency for Healthcare Research and Quality (AHRQ) funded two projects to develop Clinical Decision Support (CDS) Demonstration Projects: The Guidelines Into Decision Support (GLIDES) project headed by Richard Shiffman, MD and the Clinical Decision Support Consortium headed by Blackford Middleton, MD. One of the deliverables from these contracts is a set of recommendations to the Health Information Technology Standards Panel (HITSP) regarding the projects' findings on clinical decision support and knowledge management related standards activities. These two projects have formed somewhat different conclusions regarding what is both practical and possible with the translation, distribution and integration of CDS knowledge into EHRs. CDSC have provided recommendations to HITSP under separate cover. This document provides the GLIDES recommendations.

Electronic health records (EHRs), when used effectively, can improve the safety and quality of medical care. This improvement can be strengthened when EHRs are paired effectively with CDS systems to influence physician behavior. CDS includes a variety of techniques designed to facilitate and guide doctors' decision-making toward evidence-based practice. Common examples of CDS include computerized checks for drug interactions, electronic reminders for screening tests like mammograms and Pap smears, and condition- or situation-specific order sets.

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. Wider adoption of decision support has been held back by two key challenges:

1. Difficulty in translating medical knowledge and guidelines into a form that can be delivered, both accurately and electronically, through EHRs.

2. Difficulty distributing and integrating this electronic medical knowledge and guideline information into the clinical workflows and EHR systems in place at clinical sites across the US.

After reviewing current HITSP recommendations that specifically relate to clinical decision support, we are encouraged with the direction in which they are heading, while noting that they are currently insufficient in identifying both the syntactic and semantic standards necessary to exchange machine-readable patient data between systems.   The GLIDES project work has positioned us to provide what we believe to be useful insight to addressing this insufficiency. During our project work we have taken the following approach:

• Selected recent, evidence-based guideline recommendations for prevention of pediatric overweight and obesity, chronic management of asthma, post-discharge care for premature infants, and adult back pain.

• Applied models, techniques, and tools developed at the Yale Center for Medical Informatics to systematically transform the knowledge contained in these guidelines into a structured logic specification, a prerequisite to building computable models for this knowledge.

- Delivered the guideline knowledge via electronic decision support interventions at ambulatory sites at Yale New Haven Hospital's Pediatric Primary Care Center and Pediatric Specialty Clinics in Connecticut and at Nemours Foundation primary care and specialty clinics in Florida and the Delaware Valley. In Option Year 1, we have also designed and commenced implementation of CDS applications at Geisinger and CHOP.

- Begun to evaluate the effectiveness of the decision support tools in improving the quality of health care at the chosen sites.

- In addition, in Option Year 1, GLIDES "swam upstream" to work with guideline developers, through providing tools and guidance to improve the clarity and implementability of guidelines produced by these organizations. GLIDES worked with AAP and AO-HNS to demonstrate, pilot and implement tools and process improvements for guideline development.

Based on this experience, we can now offer the following insight and guidance to HITSP.

GLIDES Knowledge Transformation Process

The GLIDES project team used the approach depicted in Figure 1 to transform guideline knowledge into clinical decision support. This approach is intended to be systematic —generating defined artifacts—and replicable across guidelines and across implementation efforts.

The approach begins with defining clinical objectives for quality improvement. This process is critical because decision support must be seen as integral to quality improvement and not simply an information technology initiative. Selection of quality objectives leads directly to identification of relevant guideline recommendations. The guideline should be appraised with measures of quality (e.g., AGREE or COGS) and implementability factors (e.g., GLIA) at this time.
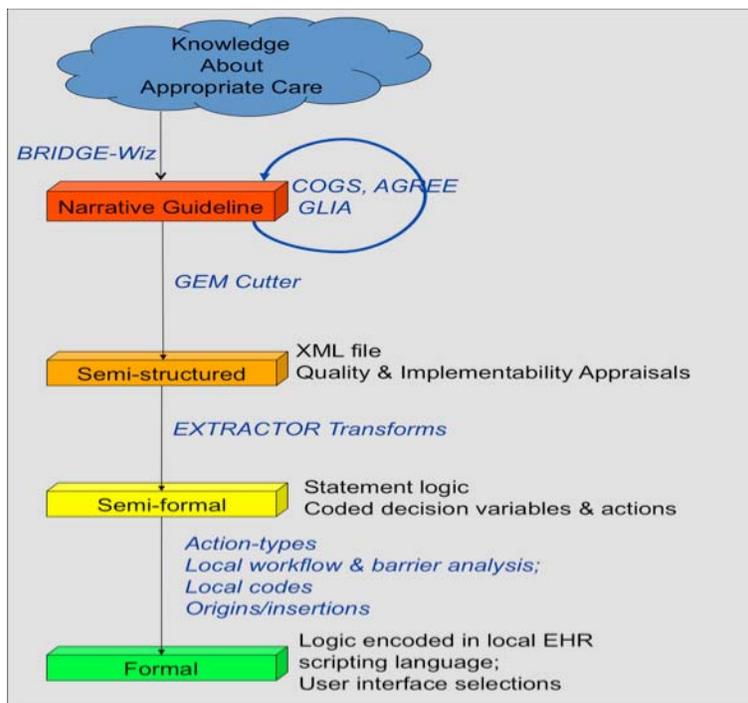
The GLIDES project has made use of the Guideline Elements Model (GEM) and related tools to begin the transformation of the selected recommendations. GEM was conceived and built in XML—and is positioned to take advantage of

emerging XML-related technologies. In 2002, ASTM International first approved the GEM Document Type Definition as a *standard representation* for guidelines using XML. In December 2006, a revised guideline document model in XML Schema format was successfully balloted and became ASTM Standard E2210-06.

GEM facilitates translation of guideline information and knowledge into a format that can be processed by computers while remaining readable by humans. The Guideline Elements Model employs a multi-level hierarchy to store the heterogeneous kinds of information contained in clinical practice guidelines. This information includes identification of the guideline's developer, description of the development process, definition of the guideline's purpose, its intended audience and target patient population, as well as a detailed model of the recommendations themselves. The hierarchy contains more than 100 semantic tags by which guideline information can be classified (marked up) and modeled at varying levels of abstraction.

The guideline's natural language narrative text (Level 1) is marked up using the GEM Cutter editor to populate the GEM XML schema (Level 2, Semi-structured layer in Figure 1). At this point, inconsistencies and lack of clear logic in the original narrative text can be clarified and resolved. Using a series of Web services [not sure we mean web services??], the recommendations are transformed into statement logic (in the natural language of the guideline developers). Additional reports permit the logic components to be viewed divorced from context to better appraise problems of decidability and executability in the natural language statements. Decision variables and actions are next translated into standard controlled vocabularies and the action types prescribed by the recommendation are specified

The resulting semi-formal Level 3 information is used by the GLIDES teams as input to functional and technical specifications for the development of the CDS.

Recommendation 1: Support GEM as a standard for guideline document representation.

A foundation for successful CDS design and delivery is a widely adopted standard for knowledge representation. GEM should provide that standard. Our approach, using GEM schema and tools, proved sufficient for producing Level 3 semi-formal knowledge, in effect producing a structured logic specification for each of the selected recommendations, and enabling the design and development of CDS systems for two specific EHR systems (Centricity and EPIC) in variety of clinical locations. The challenges involved in this process are linked primarily to the resolution of inconsistencies, omissions/commissions, vagueness and other problems inherent in the original narrative guidelines. In OY1 GLIDES completed a systematic GEM literature review, and identified 56 publications that reflected experience in using GEM. Analysis was performed, focusing on how GEM was used, or why GEM was rejected. Reflecting this input, we assembled concepts and requirements for new GEM release, which includes backward compatibility, multiple sources of expressed needs for new elements/attributes (BRIDGE-Wiz, eRec, NGC, etc), GEM Cutter improvements (repeated markup of same text is more clearly indicated, Drag-and-drop conditionals and imperatives to preserve original order), and new XSL Transforms for ECRI's expanded workup. While there are additional opportunities to refine the GEM-related process, data schema and tools, we recommend that HITSP:

> Encourage GEM adoption across the guideline implementation community, rather than consider new ways to reinvent and resolve the knowledge translation problems that GEM has already addressed.

Recommendation 2: Continue to support and promulgate the various controlled clinical vocabularies that are required to fully characterize the patient's condition.

Specifically, we believe that if controlled vocabularies were in routine use to encode the patient's medication list[1] (RxNorm or NDF-RT for classes), allergies (SNOMED-CT for reactions and severity), clinical problems and diagnoses (SNOMED), clinical laboratory results[2] (LOINC + SNOMED CT), radiologic images (DICOM), etc., that much more robust clinical decision support, that is sharable across implementations, would be possible.

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[1] HITSP Medication Management Interoperability Specification. August 27, 2008, v1.1
[2] HITSP Lab Result Terminology Component. August 27, 2008 v2.2

Distributing and integrating medical knowledge and guideline information into clinical workflows

Once CDS implementers have adopted standards and tools to accurately translate guideline knowledge into semi-formal information, the next challenge is how to distribute this information and integrate it into the multiplicity of clinical practice sites, workflows and computer systems in place across the US today. This challenge would be significantly easier to address were there not such a wide variety of clinical practices, workflows and computer systems in place today. GLIDES was tasked with exploring how the translation of clinical knowledge into CDS can be routinized in practice, and taken to scale.

A guiding philosophy of the GLIDES collaboration is that integration of decision support with the activities of the end-users of that support (clinicians) is essential. Robert Elson has stated that just as in real estate, the key success factor is location, location, location, in clinical decision support we believe the key success factor is workflow, workflow, workflow. In addition, the technical capabilities, and limitations, of each implementation-specific EHR system will constrain the ways in which the clinical decision support can be integrated into the workflow and delivered to clinicians.

In short, there will be balance between what clinical decision support design decisions can be made centrally (perhaps by the guideline developers themselves, or by standards bodies overseeing their implementation) and locally, during each implementation effort within the practice setting. GLIDES is currently examining this balance in the light of recent implementation experience

As part of this examination, GLIDES has added to work performed by Osheroff, Pifer, Teich, et al. (p.79), who have proposed use of an intervention specification form to document those aspects of the decision support that can be described centrally, i.e., in a generic manner that does not require knowledge of local workflows. For each clinical objective to be addressed by the decision support application, the intervention specification form should include: the desired action; the desired outcome; the clinical background; the target population (including inclusion and exclusion criteria); potential performance measures (process and outcomes) that may be put in place to assess success of the intervention.

Recommendation 3: HITSP should be aware that CDS requirements and implementation challenges vary significantly between primary care and specialty practices.

We determined that subspecialist-specific factors should not be underestimated when designing guidelines-based, computerized decision support systems for the subspecialty setting. We used a mixed methods approach to investigate use of a guidelines-based, computerized CDS system for asthma care by pediatric pulmonologists. The pediatric pulmonologists triggered the CDS by entering structured data for 89% of asthma care visits but only did so as part of documentation activities after the completion of clinic sessions. Low real-time utilization was related to a variety of clinical, social, technical, and workflow-related factors. These factors indicated barriers to computer use during the course of general medical care but also pointed to unique aspects of computerized CDS in a subspecialty setting. Knowledge about the use of computerized CDS in subspecialty settings is sparse. Lo *et al* found that subspecialists working in cardiology, dermatology, endocrinology, and pain management clinics could adopt an electronic health record without increasing overall patient visit time. Unertl *et al* found that providers in specialized clinics for diabetes, multiple sclerosis, and cystic fibrosis avoided computerized documentation during clinical encounters. Computerized CDS must be used during clinical encounters if it is to have an optimal effect on the care process.

At Yale, the pediatric pulmonologists identified many of the same factors reported to impede use of computerized CDS in primary care settings. Ease of use, adaptability to local workflow, and opinions about the underlying guidelines all impact the level of use. Use of the electronic health record in general depends heavily on the availability of non-electronic artifacts. Pediatric pulmonologists used a paper-based interval form to record interval history during patient encounters rather than using the EHR. By not accessing the EHR, integrated CDS advice remained unavailable until after a clinic session when information was transcribed into the EHR templates.

The pediatric pulmonologists also identified factors unique to the subspecialty setting. These included the necessity to compose well-written letters back to referring primary care providers, the influence of their own subject matter expertise on their opinions about practice guidelines, and the importance of meeting patient expectations for "face time" with subspecialists. While the computer supported various aspects of general medical care (e.g., printing prescriptions and creating asthma action plans) the computerized CDS did not adequately address what the pediatric pulmonologists believed to be the most important aspects of subspecialty care.

If subspecialist care encompasses unique characteristics, then unique opportunities may exist for computerized CDS to influence care in subspecialist settings. Incorporation of subspecialist-only pathways into CDS algorithms may be one way to accommodate subject matter expertise. Facilitating the composition of consultant letters to referring physicians may also prove amenable to computerized CDS systems. If the pediatric pulmonologists were able to complete their documentation during patient visits, including consultant letters facilitated by the computerized CDS, then they would have encountered the CDS as they were making patient care decisions and not afterwards. Designers of computerized CDS tools will need to address unique aspects of subspecialty environments if they hope to influence the level of guidelines-based care in these settings.

Recommendation 4: HITSP should be aware that successful implementation of CDS systems must overcome a wide variety of local challenges.

Successful implementation requires that systems delivering CDS must support best practices for CDS design and deployment. Implementers must retain considerable flexibility in tailoring CDS interventions to local conditions. HITSP should be aware of the practical need for balance between centrally-prescribed design decisions for clinical decision support, and locally-determined design decisions, given the multiplicity of clinical practices, workflows and systems.

For example, it is important to consider that processes, methods and tools intended to aid implementation of CDS must all operate within the context of other infrastructure in place for designing and implementing IT-enabled capabilities at any implementation organization. Therefore, these CDS-specific processes, methods and tools must be flexible so that they can be adapted into the current environment. We note that all GLIDES implementers took a slightly different approach to bridging the structured knowledge specification outputs from GEM to their own processes and tools for designing changes to EHR systems. For example, both Geisinger and Nemours adopted crosswalk tables to bridge GEM output to pseudo-code, while CHOP deployed a formal rules engine. These differences in bridging techniques reflect differences in the guidelines being implemented, in the systems development practices in place at each organization, and in the technical infrastructure being used for the EHR. We believe that different implementation organizations can learn much from the various bridging techniques but that it is not necessary, or desirable, to enforce a standard bridging strategy.

GLIDES views decision support as occurring in a wide variety of formats—not simply as alerts and reminders. More robust CDS requires a variety of modalities to solve different problems. These include displays of relevant information arranged so as to facilitate appropriate care, calculators of various forms that manipulate text and numbers to simplify and improve the accuracy of computation, order sets, documentation templates that prompt the user to collect appropriate information, algorithms, and info-buttons that provide context-sensitive information when requested.

GLIDES identified a number of broad design recommendations that can contribute to "best practices" for CDS implementation:

Category	Recommendation
Room layout	Layout must allow patients and their caregivers to sit next to the physician at the computer. Putting a larger computer monitor on an adjustable swivel arm would also facilitate showing the patient / parent data on the screen. Having a large monitor viewable from the exam table would facilitate data integration by the physicians during physical examinations. Having a keyboard accessible at the exam table with which to enter data during a physical exam would further facilitate real time documentation and use of CDS.
Form navigation	Form maps must always be viewable and consistently arranged.
Conversion of structured notes into letters	More readable letters should be automatically generated by the EHR
Need for shadow charts / forms available in the EHR	All forms should be scanned or entered into the EHR.
Changes to the note after finalizing	CDS design should include a message that should at least ask "do you want to update the letter" when changes to the chart are made after "finalizing" the letter. Alternatively, the EHR could either automatically update the letter or ask if the user wanted the letter update and do so. Note - it is conceivable that there are instances that new information is intentionally not passed on to other physicians.
Clinical workflow is unpredictable and is emergent	This cannot be changed. But, health IT can be better designed to support this reality. The principle to follow is to make more data visible more of the time during the visit. Having only a key-hole view into a large store of data is the wrong design for unpredictable and emergent workflows.
Patient communication is not supportive of real time documentation	Consider training physicians to proactively manage dialogue with patients to support real time documentation.
Hardware – Monitors	Use a minimum 19-inch and preferably larger monitors, hung from swivels. Consider two per room for easy viewing from the exam table.
Number of allowable character in EHR text fields	There should be infinite space in all text boxes for documentation.
Contrast ratios for text on background	Maximize the contrast ratios between text and background. Black text on a white background is preferred.
Use of font and text highlight color	Color should only be used as a secondary code, meaning color should not be the primary indicator of meaning. Size, shape, depth, and location are better primary codes. If colored font or highlights are used, they should always have a standard meaning. If color is only used to manage attention, use the same color in all cases to call attention and make sure the contrast ratios allow for good readability. The use of

Category	Recommendation
	green should only be used to indicate "good" or "go" and the use of red should only be used to mean "bad" or "stop." Even then, neither green nor red color should be the primary indicator of meaning. If red means "stop" use a red stop sign or red highlight for "warning" or "danger". If green means that something is good, use a ☺ and highlight it in green. That way people do not need to rely on the color. That also supports color blind users.
Insufficient text box height	Size text boxes so that more text can be viewed at any one time. Reduce the need to scroll.
Use of ALL CAPS	Never use ALL CAPS. Mixed caps are always preferred. TALLman lettering for medications is currently recommended by ISMP, FDA, and the Joint Commission.
Date for data entered into the EHR	The source and date of data entry should be clear.