

Findings and Lessons From

# AHRQ's Clinical Decision Support Demonstration Projects



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# Executive Summary

With the rapid growth in the publication of medical research and the development of evidence-based clinical practice guidelines, clinicians face a challenge in maintaining current knowledge of prevention and chronic disease management evidence and clinical recommendations. Even in familiar situations, busy clinicians must track and integrate a large amount of relevant information on the history, symptoms, clinical studies, and therapeutic options for each patient they see. Clinical decision support (CDS) systems can bring together relevant information about evidence-based practices with important information about each patient's history, values, and preferences to guide and support clinical decisionmaking at the point of care. The use of CDS to help achieve quality and safety improvements is explicit or implicit in many of the Federal meaningful use objectives for electronic health record (EHR) systems established under Title XIII of the American Recovery and Reinvestment Act of 2009, also known as the Health Information Technology for Economic and Clinical Health (HITECH) Act. This focus is reinforced in provisions of the 2010 Patient Protection and Affordable Care Act (ACA).

In August 2007, the Agency for Healthcare Research and Quality (AHRQ) announced a request for proposals focusing on “the development, implementation and evaluation of demonstration projects that advance understanding of how best to incorporate clinical decision support into the delivery of health care ... with the overall goal of exploring how the translation of clinical knowledge into CDS can be routinized in practice and taken to scale in order to improve the quality of health care delivery in the U.S.” The two CDS demonstration project awardees, Brigham and Women's Hospital, which developed the Clinical Decision Support Consortium (CDSC), and the Yale School of Medicine, which developed the GuideLines Into DEcision Support (GLIDES) project, were tasked with developing, implementing, and evaluating projects to demonstrate the best methods and approaches for incorporating CDS into clinical workflows. This report is not intended to be an evaluation of the projects. Rather, it serves as a summary of the knowledge gained from the initiative as a whole.

The CDS demonstration projects took related approaches toward creating processes and tools for translating clinical knowledge and narrative guidelines into formats that can be used by multiple EHR systems, and for implementing CDS across a range of care settings. Both projects studied and evaluated the full range of CDS development and implementation steps, but with somewhat different areas of emphasis. The GLIDES project focused especially on developing tools to expedite the translation of clinical practice guidelines into structured text. The CDSC project focused especially on CDS implementation, emphasizing a centralized Web service approach to CDS delivery on a large scale.

While both projects endorsed a four-level knowledge creation framework, CDSC focused primarily on levels three and four, seeking to create knowledge artifacts and implement decision support with Web services, whereas the GLIDES project focused more on levels two and three, seeking to expedite the extraction of content from clinical practice guidelines and make it more readily available to CDS systems.

*David Lobach, M.D., Ph.D.  
Member, Technical Expert Panel*

Both projects demonstrated the ability to translate evidence-based knowledge into useful, actionable guidance for clinical care through CDS. Further, the projects demonstrated the value of working with professional associations and guideline developers to provide tools and guidance for improving CDS development and clinical quality reporting. The projects also illustrated the value of aligning clinical quality measurement with CDS implementations; the action steps suggested by CDS systems provide opportunities for evidence-based performance measurement, and the systems can capture some of the data needed for quality measurement. As they moved to the implementation phase of the research, each project was able to evaluate how the CDS tools performed in real-world clinical settings.

Getting CDS “wrong” will not be the equivalent of not providing any CDS. Rather, there is a real risk of inefficiency and patient harm.

*Matthew B. Weinger, M.D., M.S.  
Member, Technical Expert Panel*

The GLIDES team worked with five implementation partners to design, build, test, deploy, and evaluate nine CDS applications in multiple clinical locations. Overall, the GLIDES team concluded that the CDS system performed reasonably reliably compared with clinicians for assessment of asthma control, but was less reliable for treatment. Specifically, in the Yale clinic the CDS-generated assessments of asthma control and severity, as well as treatment recommendations, were compared with clinician assessments. Clinicians agreed with the CDS in over 70 percent of the control assessments, 37 percent of the severity assessments, and 29 percent of the step treatment recommendations. In another implementation by the GLIDES team at 20 general pediatric practices, the Respiratory Syncytial Virus (RSV) Care Assistant was deployed and used to help manage the delivery of RSV vaccine during the first 2 months of the RSV season. At the end of the study period, 85 percent of eligible infants had received at least one dose compared with 77 percent the year before, and 65 percent received four or more doses compared with 54 percent during the prior year. These results indicate the feasibility of this approach to improving RSV prevention.

The CDSC project team tested the concordance of the preventive care recommendations generated by two different CDS approaches. The team executed the same set of preventive care guidelines using cloud-based CDS and in a local CDS system. The local system relied on proprietary CDS rules crafted by local experts. EHR data for the same set of patients seen in primary care were sent to the central CDSC server and to the local CDS system. The two systems generated a similar number of clinical reminders, but agreement between the two CDS systems varied across recommendations. Agreement was almost perfect for 7 out of 11 of the preventive care reminders, but was as low as one-third for the others. Subtle differences in rule logic, terminology mapping, and coding practices can cause such discordance. In the absence of a gold standard for CDS recommendations, it is not possible to say that one approach was more correct than the other.

The projects demonstrated that although centrally developed CDS is feasible, customization of CDS is still required on a site-by-site basis, which can be very labor intensive. This is due to the need to customize CDS applications to local EHR systems, and to follow local data coding conventions and practices. Furthermore, both projects faced major difficulties when the guidelines were updated. These implementation challenges point to the need for additional work on developing standards for EHR design, terminology, and data coding.



### Major CDSC and GLIDES Accomplishments

The demonstration projects refined approaches for bringing knowledge into clinical decision support in these ways:

- Refining a four-level knowledge transformation process for translating unstructured clinical guidelines and knowledge into machine-executable algorithms.
- Providing a framework upon which to develop standardized EHR data specifications to support decision support implementation, tailored to meaningful use criteria.
- Demonstrating and evaluating guideline implementation for quality improvement at a variety of sites.
- Implementing decision support through Web services using a shared portal that included a library of verified content.
- Collaborating with guideline developers and implementers on the creation and promotion of tools to facilitate CDS.
- Exploring the legal issues related to using and sharing clinical decision support content and technologies across organizations.

In addition to differences in EHR technologies and local IT infrastructure across implementation sites, both projects encountered challenges associated with local variations in clinical workflow. It is essential to understand early in the implementation process when in the course of clinical care the data elements needed by the CDS tool are entered into the EHR system, and when it is appropriate for the decision support to appear. Similar considerations will also dictate to whom the decision support should be addressed. Some changes in workflow may be needed to facilitate CDS implementation, but determining how much workflow change is necessary, feasible, and valuable requires discussion with local implementation partners. Also, CDS acceptance and use may differ substantially, depending upon the types of clinicians for whom the CDS is intended (e.g., specialists versus primary care clinicians).

The projects also identified legal issues related to intellectual property, liability, and other concerns that merit further discussion and policy development. The CDSC project structure in particular brought to the forefront the intellectual property and liability issues inherent in multiorganizational collaborations for CDS. These issues include

legal concerns regarding liability, intellectual property, and the use of CDS in defending against litigation; knowledge management issues, such as promoting the collection, grading or rating, maintaining, organizing, and making use of new knowledge in a way that can easily be translated into CDS; and issues regarding what CDS content can be shared for the public good in the most economical manner.

This initiative yielded important knowledge about translating narrative guidelines and other clinical knowledge into formats that can be used by EHRs, and about implementing CDS in clinical settings. It also leaves a range of important research questions still to be answered in the areas of guideline translation, local CDS implementation, clinician and patient factors that affect success, and policy and sustainability issues. In the current health care reform climate, there is an imperative for the use

In any multisite collaboration that involves automated data sharing, collaborators should not underestimate the potential legal hurdles and should consider addressing the legal issues simultaneously with the development of the system.

*Eta S. Berner, Ed.D.  
Member, Technical Expert Panel*

of CDS to assist health care providers and practitioners to improve care and service delivery. Without CDS, it will be increasingly difficult to be successful in the new world that expects clinicians to manage and assess large amounts of detailed patient information and stay current with the exponential growth of new evidence about treatment and diagnostics. CDS can also help clinicians deliver care in the context of ever-increasing resource constraints that require the elimination of waste from actions such as preventable errors, complications, and inefficiencies in care delivery. The AHRQ initiative anticipated these challenges and has helped to advance efforts to address them.

# Introduction

## Background

With the rapid growth in the publication of medical research and the development of evidence-based clinical practice guidelines, clinicians face a challenge in maintaining current knowledge of prevention and chronic disease management evidence and clinical recommendations, and applying that knowledge at the optimal time. Even in familiar situations, busy clinicians must track and integrate a large amount of relevant information on the history, symptoms, clinical studies, and therapeutic options for each patient that they see. This results in complex and continuous cognitive demands that create the circumstances where even experienced, skilled clinicians can make erroneous or suboptimal decisions. Health information technology (IT) can bring together relevant information about evidence-based practices with important information about each patient's history, medical situation, values, and preferences to guide and support clinical decisionmaking.

One approach that may be used to provide evidence-based information to clinicians at the point of care is the development of electronic clinical decision support (CDS) systems. CDS refers to the provision of clinical knowledge and patient-specific information to help clinicians and patients make decisions that enhance patient care (Osheroﬀ, Pifer, Teich, et al., 2005). In most cases, CDS systems match patient-specific information (e.g., current medication regimen, a recent laboratory result) to an evidence-based clinical knowledge set (e.g., known drug interactions, clinical contraindications), and then generate customized assessments or recommendations that can be communicated to clinicians in a variety of ways (e.g., via alerts or recommendations, order sets, documentation templates, reminders, and retrospective feedback, including comparisons of performance to benchmarks and lists of patients who need services).

### CDS in the Clinical Workflow – An Illustration

A "Smart Form" within the EHR provides real-time CDS to physicians about guideline-based care recommendations, and supports patient engagement and education. Key elements of the system are described below:

- **Point-of-care access:** The physician accesses the Smart Form from the EHR's notes section during the patient visit. The form contains a patient-specific health history and medication list. During the physical examination, the physician documents all relevant observations and information by clicking preexisting boxes, choosing statements from drop-down menus, and/or entering free text.
- **Automatic recommendations on care needs:** The system automatically generates recommended tests and treatments for the physician's consideration based on the available information and established clinical guidelines.
- **Identifying and addressing care and documentation gaps:** The form identifies any cases in which recommended care has not been provided (e.g., a comprehensive foot examination in the past 12 months for a diabetes patient) and prompts the physician to address the deficiencies. The physician can also easily fill in key pieces of missing information (e.g., blood pressure, weight, or smoking status) that have been flagged by the system.
- **Patient review:** The forms include a section that summarizes the patient's health status, care that has been given, and remaining care needs. The patient and physician review this information together to decide on future care needs and options.
- **Patient education and materials:** Physicians check off needed educational materials and click one button to print all information needed by the patient, including laboratory order forms, new prescriptions, and educational materials.

The structured data necessary for effective CDS can also be used for clinical quality measurement and feedback, creating an integral linkage between these processes in the design and use of clinical data systems.

When effectively implemented, CDS systems can provide information and context to support patient-centered, evidence-based clinical decisions. This vision goes beyond a simplistic “red-flag” approach to actions that appear to be incorrect, as clinicians will likely react negatively to CDS systems perceived as serving an oversight function. Rather, the systems should be positioned as support to help clinicians remember to do what they would like to do anyway, making it easier for them to make the right decisions. A recent systematic review of the effect of CDS systems found that both commercially and locally developed systems are effective at improving health care process measures related to prevention, ordering, and prescribing across diverse settings (Bright, Wong, Dhurjati, et al., 2012, Lobach, Sanders, Bright, et al., 2012). Other studies have shown that CDS has the potential to improve quality and reduce costs by increasing adherence to evidence-based practices (Berner, 2009).

Despite the great promise of CDS, its implementation faces several challenges, including—

- Converting evidence-based clinical guidelines and other clinical knowledge into machine-readable form reliably and efficiently.
- Incorporating electronic guidelines into a range of EHR systems.
- Applying these electronic modules at multiple clinical practices.
- Integrating CDS into clinical workflows in multiple care settings so that relevant information is presented to the right user at the right time, including patients and non-clinical staff.
- Accommodating variability in practice size and integration into larger health systems.
- Ensuring flexibility to accommodate changes in the evidence base and variations in patient and clinician preferences.

## Policy Context

### CDS and the Meaningful Use of Electronic Health Records

Under Title XIII of the American Recovery and Reinvestment Act of 2009, the Health Information Technology for Economic and Clinical Health (HITECH) Act was passed with the intent of improving health care delivery and patient care through the adoption and use of health IT (Pub.L. 111–5). One of the main provisions in the HITECH act is to ensure that the clinical workforce not only implements EHR systems, but also uses them in a meaningful way so that providers can significantly improve care (Blumenthal and Tavenner, 2010). The legislation ties Federal incentive payments to eligible providers specifically to the accomplishment of health care process and outcome objectives.

Attention to national policy decisions for supporting and incenting CDS deployment and maintenance is necessary.

*Margaret VanAmringe, M.H.S.  
Member, Technical Expert Panel*

On July 13, 2010, the Department of Health and Human Services (HHS) finalized the meaningful use criteria as part of the Medicare and Medicaid EHR Incentive Programs.<sup>1</sup> The aim behind these criteria is to encourage the use of EHRs in an effective manner by all providers in order to ensure high quality, safe, and effective health care delivery (and to ensure that the EHR technology itself facilitates such use). Such use of EHR technology is intended to facilitate the sharing of information among providers for coordinated care as well as to engage patients and families. Consequently, the intended benefits of successful implementation of the meaningful use criteria are more complete and accurate data collection, better access to information, and increased patient and family empowerment. In order to receive an EHR incentive payment (and avoid a penalty), providers have to meet thresholds for several objectives. The objectives vary by the type of eligible provider, including eligible professionals, eligible hospitals, and critical access hospitals. Over time, the meaningful use criteria, objectives, and measures will evolve from a focus on data capture and sharing, to increased emphasis on advancing clinical processes, toward the ultimate aim of improving outcomes.

The use of CDS to help achieve quality and safety improvements is explicit or implicit in many of the meaningful use objectives. Most directly, one of the Stage 1 objectives is for providers to “implement one clinical decision support rule relevant to specialty or high clinical priority along with the ability to track compliance with that rule.” Other meaningful use objectives recognize the importance of CDS in providing guideline-based recommendations and patient-specific information to providers, thereby reducing errors in treatment and medication decisions, and making health care safer. In addition, CDS implementation and CQM are directly related since the two processes can draw on common clinical data generated during the process of care. CDS is an important strategy for improving performance on CQMs, and thus integral to success on the quality improvement meaningful use objectives described below. CDS-related objectives for Stage 1 meaningful use include the following:

- Capturing clinical data in a standard, coded manner.
- Utilizing computerized provider order entry.
- Implementing drug-drug, drug-allergy, and drug-formulary checks.
- Setting patient reminders per patient preference.
- Performing medication, problem, and medication allergy reconciliation at transitions of care.

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<sup>1</sup> <http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/ehrincentiveprograms/>, accessed April 18, 2014.

As of May 30, 2013, of the 237,267 eligible professionals receiving incentives for meeting Stage 1 meaningful use requirements, all had implemented one CDS rule.<sup>2</sup> Further, all of the 3,722 eligible hospitals had implemented one CDS rule relevant to specialty or high clinical priority along with the ability to track compliance with that rule.<sup>3</sup>

Stage 2 meaningful use expands the emphasis on CDS implementation by requiring the use of CDS to measure and improve performance on high-priority health conditions. Providers are required to report on specific clinical quality measures (CQMs) and other measures selected by the HHS Secretary. In 2014, eligible professionals must report on 9 out of 64 total CQMs, while eligible hospitals and critical access hospitals must report on 16 out of 29 total CQMs. To achieve this objective, a provider must do the following:

1. Implement five CDS interventions related to four or more CQMs, if applicable, at a relevant point in patient care for the entire EHR reporting period.
2. Enable the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

Some of the goals of the meaningful use Stage 2 rules are to increase health information exchange between providers and to promote patient engagement by giving patients secure online access to their health information.

## CDS in the Affordable Care Act

The 2009 HITECH Act and the 2010 Affordable Care Act (ACA) (Pub.L. 111–148) were designed as part of a national strategy to improve the quality of care for individuals and the health of populations, while reducing the overall costs of health care (Hummel, 2013). This is exemplified in section 3011 of the ACA, which emphasizes the role of quality improvement and measurement in the strategic plan for health IT. Further, throughout the ACA, health IT is intended to serve as tool to achieve various health and quality goals. For example, in section 2717 of the ACA, the HHS Secretary is called upon to report on the implementation of activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence-based medicine, and health IT.

This impressive work has formed the foundation of new HL7 standards that we are confident will help providers bridge the gap between the care our patients are receiving and the [better] care that they should be receiving.

*Jacob Reider, M.D.*  
*Member, Technical Expert Panel*

The ACA also specifically discusses the use and implementation of CDS. In section 3201, the ACA discusses how programs eligible for Medicaid Advantage payment must utilize “health information technology programs, including clinical decision support and other tools to facilitate

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<sup>2</sup> Data abstracted from CMS’s Medicare Electronic Health Record Incentive Program Eligible Professionals Public Use file [http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EP\\_PUF\\_DataDictionaryCodebook.pdf](http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EP_PUF_DataDictionaryCodebook.pdf).

<sup>3</sup> Data abstracted from CMS’s Medicare Electronic Health Record Incentive Program Eligible Hospitals Public Use file [http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EH\\_PUF\\_Codebook\\_June.pdf](http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EH_PUF_Codebook_June.pdf).

data collection and ensure patient-centered, appropriate care.” Furthermore, section 937 of the ACA states that AHRQ will assist users of CDS in order to promote its adoption.

## The AHRQ CDS Demonstration Projects

In 2007, HHS established a department-wide steering committee to provide guidance and seek direction on the new frontier for enhancing the use of knowledge in clinical practice through technology. At that time, few EHR systems had CDS tools (info buttons and drug-drug interaction checking were typically the most extensively used tools), and there were no incentives for their use other than institutional programs, yet there was extensive interest among academic institutions and professional associations. The environment for this work has changed dramatically since that time in terms of both policy and the technology and its applications, and the spread and use of CDS systems in mainstream clinical practice has started to accelerate.

In August 2007, AHRQ announced a request for proposals focusing on “the development, implementation and evaluation of demonstration projects that advance understanding of how best to incorporate CDS into the delivery of health care ... with the overall goal of exploring how the translation of clinical knowledge into CDS can be routinized in practice and taken to scale in order to improve the quality of health care delivery in the U.S.” Although this announcement was prior to the passage of the HITECH Act, the definition of the objectives for meaningful use of EHRs, and the passage of the ACA, AHRQ’s health IT research agenda recognized the important role that CDS would play in improving the quality, efficiency, and safety of health care. The CDS demonstration projects would provide a foundation for implementation research and policy development in this area.

This effort began in 2007, when there were few EHR systems that had CDS tools, no incentives for their use other than institutional programs, yet extensive academic interest. The landscape for this work on both the technology and application front has changed dramatically.

Gregory Downing, D.O., Ph.D.  
Member, Technical Expert Panel

Both projects revealed just how complicated the translation from guidelines to executable CDS in the workflow actually is. The larger national implications of this work are profound in that the challenges of implementation are the same challenges many are discovering with meaningful use.

*Doug Rosendale, D.O.*  
*Member, Technical Expert Panel*

The CDS demonstration contract awardees were tasked with developing, implementing, and evaluating projects to demonstrate the best methods and approaches for incorporating CDS into clinical workflows. This goal was supported by objectives such as facilitating the integration of CDS into widely used health IT products, demonstrating cross-platform utility, and establishing best practices for CDS implementation across the health IT vendor community. The projects were designed 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 health care. In 2008, two CDS

demonstration projects were initiated: the Clinical Decision Support Consortium (CDSC) at Brigham and Women’s Hospital and the GuideLines Into DEcision Support (GLIDES) project at the Yale School of Medicine.

Each project was funded initially for \$2.5 million for a 2-year period, with an option for AHRQ to continue funding the projects for up to an additional 3 years. All of the additional option years were funded for both of the projects, resulting in a total of 5 years of demonstration project work ending in mid-2013. The major challenges addressed by the demonstration projects were as follows:

- How to create processes and tools for translating narrative guidelines into formats that can be used by multiple EHR systems.
- How to create processes and tools for implementing CDS in a range of settings, including settings with limited technical capacity and experience with health IT.
- Evaluating the processes and outcomes of the projects, including impacts on health.

AHRQ defined specific milestones for addressing these challenges, including the following:

- Incorporating CDS into certified EHR systems.
- Demonstrating that CDS can operate across multiple computer systems;
- Establishing lessons learned for CDS implementation relevant to the health IT vendor community.
- Assessing potential benefits and drawbacks of CDS, including effects on patient satisfaction and on measures of quality and efficiency.
- Evaluating methods of creating, storing, and replicating CDS elements across multiple clinical sites and ambulatory practices.

AHRQ recognized the importance of engaging stakeholders in the research and implementation process. Thus, these demonstration projects were supported by a Technical Expert Panel that reviewed findings, provided input and feedback for recommendations and reports, and offered guidance on how to disseminate the findings from this initiative most effectively. The panel members represented academia, medicine, quality measurement organizations, vendors, and Federal agencies, and have diverse experience in clinical guideline development, quality measurement, and clinical system development and implementation.

## **Purpose of This Report**

This report highlights key findings and lessons from the experiences of the two demonstration projects awarded in 2008 under AHRQ's CDS initiative. This program was designed to investigate approaches for designing and implementing CDS in a range of health care settings, and for evaluating its effects on patient experience, clinical efficiency, and quality of care. More details on the initiative can be found on the AHRQ Web site.<sup>4</sup> This report summarizes how the projects addressed these goals, and identifies practical insights and lessons

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<sup>4</sup> See <http://healthit.ahrq.gov/cdsinitiative>, referenced January 31, 2014.



from their work that can inform research priorities and provide guidance to others implementing CDS systems. The report describes the approach and findings of the CDSC and GLIDES projects, and discusses the projects in the context of the current state of CDS technology and policy. This report is not intended to be an evaluation of the projects. Rather, it serves as a summary of the knowledge gained from the initiative as a whole. Details on specific findings and lessons, and their implications for future research and practice, can be found later in this report.

Additional insights and perspectives on the CDSC and GLIDES projects can be found in AHRQ's CDS video series, available at <http://healthit.ahrq.gov/ahrq-funded-projects/clinical-decision-support-initiative>.

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## Methods

To prepare this report, Westat assembled a team to review CDSC and GLIDES project materials, identify key results and lessons learned, and synthesize the information into common themes and implications. Westat team members had subject matter expertise in CDS, clinical guidelines, health IT implementation and evaluation, and dissemination. Two team members had experience supporting the CDS demonstration projects' Technical Expert Panel in previous years. The team used the following approach to develop the report:

- **Identify relevant primary documents for review.** Team members reviewed publicly available and AHRQ-furnished CDS demonstration project materials, including annual reports on the projects, project status reports submitted by the grantees to AHRQ, publications and presentations, Technical Expert Panel meeting materials and notes, and other summary materials developed to support the synthesis.
- **Generate key discussion topics to guide the synthesis.** Discussion topics focused on the phases of the projects (i.e., guideline translation, implementation, evaluation) and the implications for policy and practice.
- **Assemble notes and observations about the demonstration projects.** Each member of the team reviewed the core documents and could review optional documents as needed. Reviewers used a standard template to document their notes by discussion topic.
- **Identify key findings and illustrative examples of common themes.** Team members engaged in a series of discussions to identify the key findings and themes across the projects. Technical Expert Panel members also were asked to provide written summaries of their impressions of the key lessons and implications to be drawn from each project. Key findings were iteratively refined over time, and when applicable, narrative examples of themes were identified.
- **Analyze key findings and themes in the broader context of the U.S. health care system.** After identifying the key findings, the synthesis team discussions shifted to focus on the implications of the findings. Team members drew on their own subject matter expertise, experiences with the demonstration projects, and synthesis notes. Summaries of the implications also were iteratively refined.
- **Draft and edit the report.** The draft report was reviewed and refined in consultation with AHRQ.

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# **AHRQ CDS Demonstration Project Descriptions**

The two CDS demonstration projects took related approaches toward creating processes and tools for translating narrative guidelines and other clinical knowledge into formats that can be used by multiple EHR systems, and for implementing CDS across a range of care settings. Both projects studied and evaluated the full range of CDS development and implementation steps, but with somewhat different areas of emphasis. However, the two initiatives differed somewhat in emphasis. Both projects were structured around a four-level framework for translating clinical knowledge into operational CDS, in which level one involves unstructured narrative text, level two represents semistructured text format, level three formally codes elements of the algorithm, and level four is a machine-executable code. Although both projects addressed all four stages of CDS implementation, the GLIDES project focused especially on levels two and three, seeking to expedite the translation of clinical practice guidelines into structured text. The CDSC project focused especially on levels three and four, emphasizing a centralized Web service approach to CDS delivery. The following sections provide additional details about each project's approaches and results.

## **GuideLines Into DEcision Support (GLIDES)**

The GLIDES project aimed to explore how the translation of clinical knowledge into CDS can be made part of routine practice and used to improve the overall quality of health care. It demonstrated how knowledge from clinical practice guidelines can be converted to computer-based CDS, and how to incorporate CDS into health care delivery at collaborating ambulatory care sites. The project sought to develop a routine, scalable process for developing CDS guidelines. The implementation approaches at the demonstration sites were designed to include site-specific technical support and customization to the local EHR system. Exhibit 1 summarizes key information about the GLIDES project.

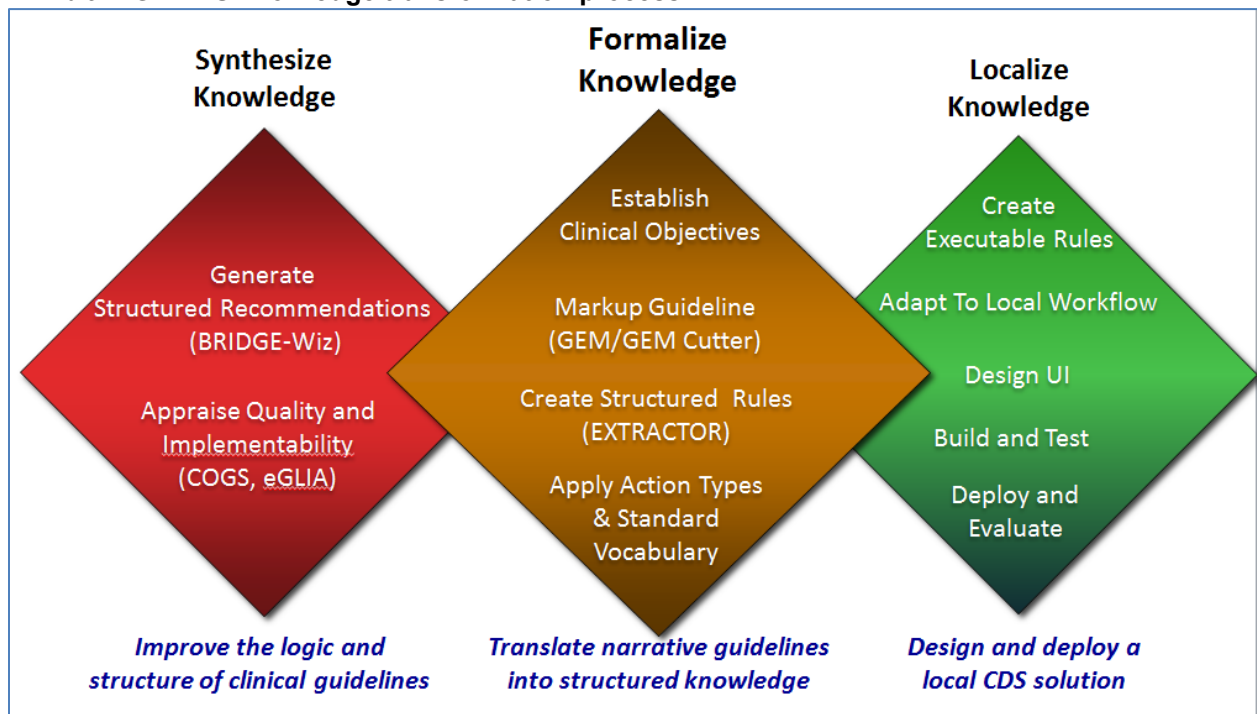
### Exhibit 1. GLIDES project summary

Lead organization	Yale School of Medicine
Project Team Organizations	<ul style="list-style-type: none"> <li>• Yale–New Haven Health (Project lead)</li> <li>• Nemours</li> <li>• Geisinger Health System</li> <li>• Children’s Hospital of Philadelphia</li> <li>• Alliance of Chicago</li> <li>• American Academy of Pediatrics (AAP)</li> <li>• American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)</li> <li>• American Urological Association (AUA)</li> <li>• American Society of Clinical Oncology (ASCO)</li> <li>• ECRI Institute</li> </ul>
Project Aims	<ul style="list-style-type: none"> <li>• Implement evidence-based guideline recommendations that address prevention of pediatric obesity and chronic management of asthma.</li> <li>• Apply the Guideline Elements Model (GEM) and associated tools that facilitate the development of executable code to systematically and replicably transform the knowledge contained in these guidelines into a computable format.</li> <li>• Deliver the knowledge via CDS to ambulatory sites that employ the Centricity EHR system at Yale and the EpicCare EHR system at Nemours.</li> <li>• Evaluate the fulfillment of these goals and the effectiveness of the CDS tools for improving the quality of health care.</li> </ul>
Tools Developed	The GEM Suite – a knowledge model and a collection of software tools that facilitate the development, dissemination, and implementation of clinical practice guidelines and other sources of evidence-based knowledge (Shiffman Michel, Rosenfeld, et al., 2012)
CDS Implementation Sites	<ul style="list-style-type: none"> <li>• Alliance of Chicago, Chicago, IL</li> <li>• Children’s Hospital of Philadelphia, Philadelphia, PA</li> <li>• Geisinger Health System, Danville, PA</li> <li>• Nemours, DE, PA, NJ, FL</li> <li>• Yale–New Haven Health System, New Haven, CT</li> </ul>
EHR Systems at Implementation Sites	EpicCare, GE Centricity
Target Populations	Patients with pediatric asthma, obesity, low back pain, retinopathy of prematurity, or RSV.

## Transforming Narrative Guidelines Into CDS

The GLIDES project used a multilevel process to transform narrative clinical guidelines into computable CDS (Exhibit 2). A centerpiece of the process is the Guideline Elements Model (GEM), a knowledge model for guidelines that incorporates a set of more than 100 tags to categorize guideline content. GEM provides an intermediate knowledge representation that permits natural language guidelines to be translated into a format that can be processed by computers. GEM uses XML to describe a comprehensive set of pertinent concepts, relationships between concepts, and attributes. The resulting guideline representation can be used for multiple purposes, including incorporation into CDS systems, electronic guideline distribution, and guideline querying.

**Exhibit 2. GLIDES knowledge transformation process**



The GEM Suite is a set of software tools that was developed to support best practices in knowledge transformation. The suite facilitates the translation of narrative guidelines into more formal CDS rules. It provides a bridge between the processes of knowledge discovery, synthesis, and CDS implementation to consistently translate narrative guidelines into structured knowledge that can be implemented across care delivery settings. For example, the GEM Cutter editor was designed to facilitate markup of guideline text and to facilitate its translation into XML. It was intended for use by an array of guidelines users, including developers, disseminators, implementers, quality appraisers, and end users.

Another tool, the BRIDGE-Wiz application (Building Recommendations In a Developer's Guideline Editor), uses a wizard approach to address the following questions: (1) under what circumstances? (2) who? (3) ought (with what level of obligation)? (4) to do what? (5) to whom? and (6) how and why? The BRIDGE-Wiz controls natural language usage to create and populate

a template for recommendation statements in a structured manner. This promotes clarity of recommendations by limiting verb choices (e.g., limiting the use of “consider,” which isn’t implementable by a computer), building active voice recommendations, and limiting Boolean connectors to facilitate the development of clear, transparent, and implementable guideline recommendations (Shiffman, Michel, Rosenfeld, et al., 2012).

The Guideline Implementability Appraisal (GLIA) is a Web-based tool that identifies indicators of the ease and accuracy of the translation of guideline advice into systems that influence care. The most critical dimensions of implementability are decidability (precisely under what conditions, such as age, gender, clinical findings, laboratory results, to perform a recommended activity) and executability (a specification of exactly what to do under those circumstances). A recommendation that lacks decidability or executability will not be implementable until that issue is resolved. GLIA was developed to identify these and other obstacles to successful implementation that are intrinsic to the guideline itself (Shiffman, Dixon, Brandt, et al., 2005).

**Dissemination and use of the GEM suite of tools.** The GLIDES team pursued a range of partnerships to promote GEM and GEM Cutter among guideline development organizations as follows:

- Pilot-tested the electronic Guideline Implementability Appraisal (GLIA) tool with the American Academy of Otolaryngology–Head and Neck Surgery (AAO–HNS) on several guidelines.
- Pilot-tested Electronic Guideline Implementability Appraisal tool (eGLIA) with the American Urological Association (AUA) on guidelines for *Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults*.
- Used BRIDGE-Wiz with AUA *Clinical Practice Guidelines for Adult Urodynamics*.
- Updated and published AUA *Guidelines Department Staff Training Manual–2013* to provide AUA staff with an in-depth understanding of the guidelines development process.
- Used BRIDGE-Wiz on several American Academy of Pediatrics (AAP) clinical practice guidelines, including *Fever in Infants Under 3 Months*, *Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome*, *Newly Diagnosed Type 2 Diabetes Mellitus (T2DM) in Children and Adolescents*, *Diagnosis and Management of Acute Otitis Media*, and *Diagnosis and Management of Acute Bacterial Sinusitis*.
- Revised AAP guideline development procedures in light of tools and Institute of Medicine report on *Standards for Developing Trustworthy Clinical Practice Guidelines*.
- Used BRIDGE-Wiz to help draft recommendations for *Systemic Therapy in Men with Metastatic Castration-Resistant Prostate Cancer (CRPC)*, an American Society of Clinical Oncology (ASCO) and Cancer Care Ontario clinical practice guideline.



- Worked with Children’s Mercy Medical Center, Kansas City, to pilot a version of BRIDGE-Wiz with the GRADE rating system for several guideline topics, including Febrile Infant, Diabetic Ketoacidosis, Jaundice, and others.
- Met with the American Thoracic Society to explore the potential of the project’s guideline developer tools.
- Held several discussions with the American Physical Therapy Association on the potential to use BRIDGE-Wiz.
- Demonstrated BRIDGE-Wiz at a meeting of the American College of Emergency Physicians (ACEP).
- Demonstrated BRIDGE-Wiz in a presentation to the Columbia University School of Public Health.

The project team received valuable feedback from each organization and used the information to improve the tools. As of June 2013, the GLIDES team was demonstrating and promoting the tools to additional organizations, including Kaiser Permanente, Geisinger Health System, the Centers for Disease Control and Prevention, and the American Thoracic Society. In addition, the team had discussions with the AHRQ National Guideline Clearinghouse (NGC) about the potential to use GEM Cutter on that collection of guidelines, and to disseminate the “GEM-cut” guidelines on the NGC Web site.

## **Implementation**

The GLIDES team implemented and evaluated nine guidelines-based CDS tools with five implementation partners. Two of the tools (asthma and obesity) were implemented at multiple sites with different EHR systems. CDS tools for retinopathy of prematurity, RSV, and low back pain were each implemented in a single site. The researchers collaborated with each site to customize the CDS to the local environment. This implementation experience is summarized in Exhibit 3. The GLIDES team worked directly with clinical and IT staff at each site on integration of the CDS modules into local EHR systems. This approach recognized the need for local engagement and the extent of local variability in systems, staffing, and workflow. The approach involved a high level of collaboration to take into account factors such as the degree of EHR maturity, the mix of clinicians (e.g., primary care vs. specialists), and the unique characteristics of particular EHR products. The challenge was to tailor the implementation so that it functioned in the local systems environment, was accepted and used by clinicians, and maintained the integrity of the guideline structure and logic.

### Exhibit 3. GLIDES implementation experience

Organization	CDS	Guideline/Description	EHR System
Yale	Pediatric Asthma	NHLBI Asthma Guideline for primary and specialty care	GE Centricity
	Obesity	Obesity Counseling Guideline for primary care	GE Centricity
	Patient-Centered Data Collection	Direct capture of patient information via iPad to facilitate use of CDS applications in clinic	GE Centricity
Nemours	Pediatric Asthma	NHLBI Asthma Guideline for primary and specialty care	EPIC
	Obesity	Obesity Counseling Guideline for primary care	EPIC
Children's Hospital of Philadelphia	RSV/Palivizumab	AAP Respiratory Syncytial Virus (RSV) and Palivizumab Guideline	EPIC
	ROP	AAP Retinopathy of Prematurity (ROP) Guideline	EPIC
Geisinger	Low Back Pain With Audio-Recording Tool	ICSI Low Back Pain Guideline (GLIDES funded GEM design work and audio-recording pilot)	EPIC
Alliance of Chicago	Pediatric Asthma	NHLBI Asthma Guideline Converted Yale Asthma CDS for Alliance network	GE Centricity

## Findings

**Translating guideline knowledge into actionable recommendations.** The GLIDES team designed and demonstrated a process for knowledge formalization that balances a core of structured processes, methods, and tools with a flexible approach that can be adapted to reflect the “on the ground” realities of how clinical systems are designed, built, and implemented at clinical sites:

- GEM was used to evaluate and transform recommendation knowledge into CDS “knowledge specifications” for five guidelines at five organizations.
- The project team refined the methodology for using GEM, including determining clinical objectives, developing marking-up guidelines, creating structured rules, and applying action types and vocabularies. Best practices, examples, templates, and lessons learned were documented for each of these activities, and the results were made available online in the GEM Suite of tools.
- A third revision of the Guideline Elements Model (GEM III) was designed, built, and tested as part of project work in 2010 and 2011. This release incorporates more granular concepts of knowledge components and new elements and attributes of codes and code sets. It also features integration with BRIDGE-Wiz, whereby guidelines authored in BRIDGE-Wiz can be stored in the GEM XML structure, to assist with implementation. GEM III was submitted in January 2012 to ASTM International for recognition as an international standard for representation of guideline knowledge, and was adopted as a standard in February 2012. GEM III is available online through the GLIDES Toolkit.

**Implementing CDS in EHR Systems.** The GLIDES project’s CDS development and implementation experience informed a range of findings and lessons. These are summarized briefly here and discussed in further detail in the section on initiative-wide findings and lessons.

- Implementers must carefully select CDS “targets” based on clinical needs or recognized gaps in care.
- Transitioning from recommendations expressed in statement logic—with conditions and actions encoded in structured vocabularies—to functional decision support is a complex, multifaceted process.
- Decision support can be delivered via a wide variety of modalities—not simply as alerts and reminders.
- Buy-in and engagement of local clinicians and IT personnel is essential.
- User-centered/iterative design and development processes are essential with close attention to local factors (including clinical policies, terminology, workflow, and human-computer interfaces, etc.).

The GLIDES team worked with five implementation partners to design, build, test, deploy, and evaluate nine CDS applications in clinical locations across the nation. Implementers noted the critical importance of selecting CDS “targets” based on locally recognized clinical needs or gaps in care. Each implementer experienced an extensive CDS development and implementation process, noting especially the challenges associated with developing code specific to the version of the EHR system running at their institution. Implementers also developed tailored education approaches during deployment to increase clinician familiarity, acceptance, and use of these systems. Educational approaches included Webinars, frequently asked questions (FAQs) forms, and other written and electronic resources.

Several sites evaluated the implementation and impact of the CDS systems. Overall, the GLIDES team concluded that the CDS system performed reasonably reliably compared with clinicians for assessment of asthma control, but was less reliable for treatment. Specifically, in the Yale clinic, the CDS-generated assessments of asthma control and severity, as well as treatment recommendations, were compared with clinician assessments. Clinicians agreed with the CDS in over 70 percent of the control assessments, 37 percent of the severity assessments, and 29 percent of the step treatment recommendations. An independent external review classified the majority of the disagreements as CDS errors, while a smaller number resulted from pulmonologist deviation from the guidelines or ambiguous guidelines. Many CDS flaws, such as attributing all “cough” to asthma, were easily remediable. This implementation experience demonstrated that complex decision support for diagnosis and management of pediatric asthma is feasible in the outpatient clinic setting.

RSV is a common wintertime virus that may cause significant health problems for premature infants. A vaccine (Palivizumab) can help avoid these problems, but it is expensive and requires monthly administration during the 5-month-long RSV season. AAP guidelines identify infants who are good candidates for the vaccine, and CDS can help ensure that they receive all of the

recommended doses in a timely manner. At 20 general pediatric practices, the RSV Care Assistant was deployed and used to help manage care during the first 2 months of the post-intervention RSV season. At the end of the study period, 85 percent of eligible infants had received at least one dose compared with 77 percent the year before, and 65 percent received four or more doses compared with 54 percent during the prior year. These results indicate the feasibility of this approach to improving RSV prevention.

Other findings and lessons from these implementation experiences are described in the section below on initiative-wide findings and lessons.

## **Clinical Decision Support Consortium (CDSC)**

The CDSC project sought to assess, define, demonstrate, and evaluate best practices for knowledge management and CDS in health IT at scale, across multiple ambulatory care settings and EHR systems. The project team selected a service-oriented approach to providing CDS over the Web. Cloud-based CDS services were developed at Brigham and Women's Hospital, the lead project site, and made available to clinical and IT partner organizations across the United States, as well as both human and machine-readable tools and documentation that are available through a publicly accessible knowledge portal. The CDSC project's development and support operations are now in the process of transition to Vanderbilt University.

The CDSC project also contributed to the development of the Health eDecisions (HeD) standards for CDS, and provided important feedback about the Continuity of Care Document (CCD) standard. In addition to these technical contributions, the project developed collaboration models and legal agreements to support approaches for sharing CDS that respect patient privacy and that balance intellectual property and liability concerns among developers and consumers of CDS. Resolving these organizational issues is critical for the sustainability of this approach to the development and delivery of CDS. The project approached implementation with a combination of centralized processes and site-specific support. Exhibit 4 summarizes key information about the CDSC project.

#### Exhibit 4. CDSC project summary

Lead organization	Brigham and Women’s Hospital, Boston, MA
Project Team Organizations	<ul style="list-style-type: none"> <li>• Partners HealthCare (Project lead)</li> <li>• Regenstrief Institute</li> <li>• Veterans Health Administration</li> <li>• University of Texas School of Health Information Science</li> <li>• Oregon Health and Science University</li> <li>• Kaiser Permanente</li> <li>• NextGen</li> <li>• Siemens Medical Solutions</li> <li>• GE Healthcare</li> <li>• Geisinger Health System</li> <li>• University of Utah Health Sciences Center</li> <li>• WVP Health Authority</li> <li>• Wolters Kluwer Health</li> </ul>
Project Aims	<ul style="list-style-type: none"> <li>• Assess and define best practices for knowledge management and CDS in ambulatory care.</li> <li>• Define a novel, practical knowledge representation model that facilitates the translation of knowledge into CDS within EHRs.</li> <li>• Build a prototype national knowledge repository to support access and use of knowledge artifacts and collaborative knowledge engineering.</li> <li>• Build publicly available cloud-based Web services to provide remote CDS.</li> <li>• Build end-user CDS dashboards that depict user’s compliance with CDS and provide feedback to knowledge engineers on CDS efficacy.</li> <li>• Demonstrate the feasibility of a service-oriented, architecture-based approach through multisite, multivendor demonstration projects.</li> </ul>
Tools Developed	Knowledge Authoring Tool
Implementation Sites	<ul style="list-style-type: none"> <li>• Partners HealthCare, Boston, MA</li> <li>• Regenstrief Institute, Indianapolis, IN</li> <li>• WVP Health Authority, Salem, OR</li> <li>• University of Medicine and Dentistry of New Jersey</li> </ul>
EHR Systems at Implementation Sites	Longitudinal Medical Record, <sup>5</sup> NextGen, CareWeb, GE Centricity
Target Populations	Adults, coronary artery disease, diabetes, hypertension

## Transforming Narrative Guidelines Into CDS

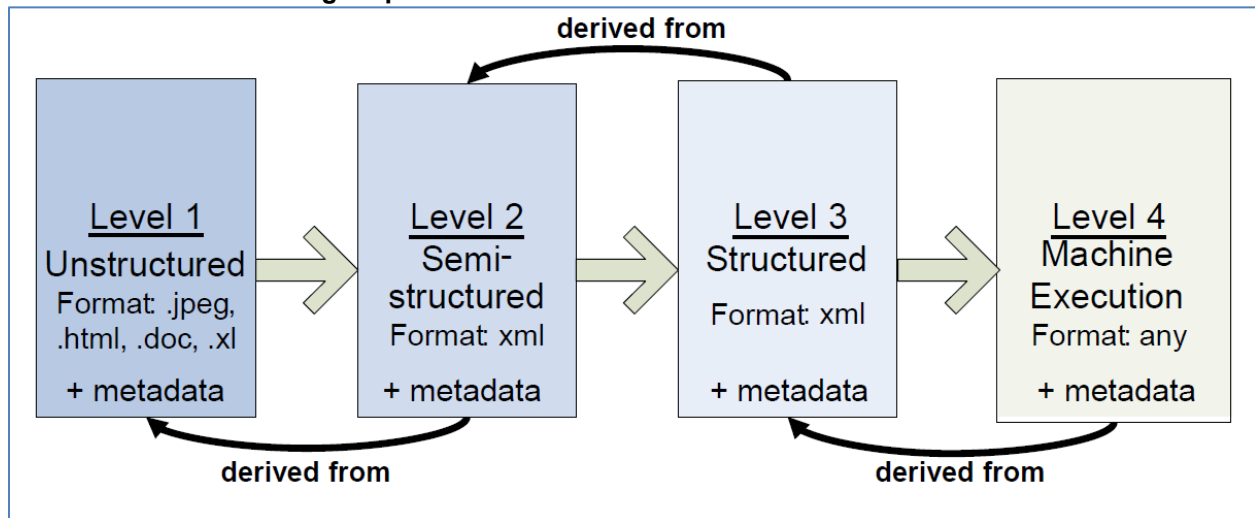
The CDSC project’s Knowledge Authoring Tool leverages a four-level knowledge representation model to routinely transform narrative guidelines and other clinical knowledge into CDS as shown in Exhibit 5 (Boxwalla, Rocha, Maviglia, et al., 2011). In the exhibit, each level is derived from the previous level as indicated by the arrows. This approach emphasizes modeling of unsequenced clinical decisions, rather than activities that are organized explicitly into flow sequences, in order to facilitate the use of knowledge management methodologies and tools. The project team developed, delivered, and maintained a suite of applications that enabled (1) online collaboration among CDSC members for clinical content development and project

<sup>5</sup> An EHR developed at Partners HealthCare.

administration, (2) centralized document management of clinical content, and (3) public dissemination of clinical content via a portal with worldwide, unrestricted access.

The project also developed a robust clinical content governance process and addressed issues related to provenance, standardization, localization, and versioning, as described below. This work provides an important foundation for developing a legal framework for sharing CDS content.

**Exhibit 5. CDSC knowledge representation levels**



**Dissemination and use of CDSC knowledge authoring and management tools.** Central to the project’s implementation strategy is the Knowledge Management Portal (<http://cdsportal.partners.org>), which supports a range of capabilities needed for adoption of CDS on a large scale, including CDS authoring tools, a searchable repository, and technical infrastructure for real-time, cloud-based CDS. The portal is organized to support its two primary purposes: allowing users to search for content (“knowledge assets”) within the portal and providing information about the portal and the project. The posting of content to the portal is restricted to CDSC members, but viewing of content is unrestricted, subject to the terms of use.

Currently, 18 academic or clinical organizations and 15 vendors are collaborating members of the consortium. Because of the collaborative and decentralized nature of the content development process, the project team developed an editorial policy document to guide the work. Submission of an entire level one through level four chain of documents is encouraged but not required; submission of an independent artifact at any level is allowed in order to promote sharing. As host of the Knowledge Management Portal, Partners HealthCare provided a default style sheet for rendering level two and level three content. CDSC members were encouraged to develop other style sheets customized for their own use or to support different user types. The submitters agree to be responsible for ensuring that all of the content they submit is reviewed and updated at least every 3 years, or else to indicate that an item is no longer being actively maintained. By uploading content, an institution grants a license to other members to use the content and make derivatives of the content, with reasonable indemnification clauses. CDSC members agree not to use another’s content or any derivative for monetary profit. The

consortium strongly encourages all derivative works to be widely disseminated, subject to the licensing agreement.

The CDSC level 3 format guided the HeD initiative, which sought to develop standards to enable the routine use of CDS. HeD's first goal (Use Case #1) was to develop standards or a schema for a structured health summary that can be consumed by CDS systems. Working backwards from the CDSC's (and GLIDES') level 3 formats, the HeD teams developed a novel schema known as the VMR. HeD was supported by the Office of the National Coordinator for Health Information Technology's Standards and Interoperability Framework. The HeD Use Case #1 schema passed ballot in January 2013 as an international draft standard for trial use in Health Level Seven International (HL7).

## Implementation

The consortium envisioned a centralized service approach to CDS implementation over the Web, with clinicians in participating organizations accessing real-time CDS at the point of care through a server-based portal. The CDS tools are designed to incorporate standardized data produced by the local EHR system, and return results through the EHR system with minimal on-site implementation support. This centralized approach to implementation, combined with the decentralized approach to content development described earlier, raised a host of intellectual property, liability, governance, and legal issues. To address these issues, the project leadership committees developed a legal framework for CDS operations. The framework built upon the licensing language at Creative Commons,<sup>6</sup> which served as a reference point for crafting language for the unique context of sharing and implementation of CDS artifacts. Language was drafted for both a publisher agreement and an end-user agreement. The publisher agreement covers attribution, publishing for free distribution, rights granted by the publisher to authorized end users, and warrants that the publisher owns the CDS materials. The end-user agreement covers content access and use, content ownership, and attribution (Hongsermeier, Maviglia, Tsurikova, et al., 2011).

In addition to the intellectual property issues, the CDSC team addressed the liability issues surrounding knowledge sharing and CDS. As in the case of authors and publishers of medical textbooks and clinical guidelines, CDSC members could make no warranty or guarantee of the accuracy of CDS content, and could take no responsibility for harm resulting from errors; the clinician remains the primary accountable party for all health care decisions. To formalize this, both the publisher and end-user agreements contain language stating that there are no warranties and ensuring mutual indemnification. It is expected that users will interpret CDS software advice for what it is—advice—and then exercise their own independent, professional judgment.

Building upon this implementation policy framework, the CDS services team aimed to demonstrate that a service-oriented, cloud-based approach, using nationally accepted standards, would enable consistent CDS to be provided across diverse clinical settings, regardless of each site's underlying technology or EHR vendor. The team conducted site visits with health care delivery organizations, clinical content vendors, EHR vendors, guideline development

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<sup>6</sup> See <http://creativecommons.org/about>, accessed December 13, 2013.

organizations, and government policymakers to gather input on implementation requirements and constraints. Enterprise Clinical Rules Services (ECRS), developed at Partners HealthCare, was the primary vehicle for executing decision support rules using standard terminologies and input and output formats, rendering them interpretable by clinical systems according to the workflow and needs of each system. This service does the following:

- Allows CDS rules to be shared and reused across locations.
- Enables multiple clients to share one logical/physical CDS service.
- Provides a consistent standard of care that applies the same rules everywhere.
- Allows consumers to focus on content by masking the underlying implementation details.
- Facilitates the use of standards in technology and terminology.

**Exhibit 6. CDSC implementation experience**

Organization	CDS	Guideline/Description	EHR System
Partners HealthCare	Diabetes Mellitus	American Diabetes Association (ADA) Diabetes Management Standards	Longitudinal Medical Record
	Coronary Artery Disease	American College of Cardiology Guideline for Anti-platelet Therapy & USPSTF Recommendation on Aspirin	Longitudinal Medical Record
	Hypertension	USPSTF Recommendation on Screening for High Blood Pressure	Longitudinal Medical Record
	Immunization	CDC-suggested schedules for immunizations* in all patient populations.	Longitudinal Medical Record
Regenstrief Institute	Diabetes Mellitus	American Diabetes Association (ADA) Diabetes Management Standards	CareWeb
	Coronary Artery Disease	American College of Cardiology Guideline for Anti-platelet Therapy & USPSTF Recommendation on Aspirin	CareWeb
	Hypertension	USPSTF Recommendation on Screening for High Blood Pressure	CareWeb
WVP Health Authority	Diabetes Mellitus	American Diabetes Association (ADA) Diabetes Management Standards	NextGen
	Coronary Artery Disease	American College of Cardiology Guideline for Anti-platelet Therapy & USPSTF Recommendation on Aspirin	NextGen
	Hypertension	USPSTF Recommendation on Screening for High Blood Pressure	NextGen



**Exhibit 6. CDSC implementation experience (continued)**

Organization	CDS	Guideline/Description	EHR System
University of Medicine and Dentistry of New Jersey	Diabetes Mellitus**	American Diabetes Association (ADA) Diabetes Management Standards	GE Centricity
	Coronary Artery Disease**	American College of Cardiology Guideline for Anti-platelet Therapy & USPSTF Recommendation on Aspirin	GE Centricity
	Hypertension**	USPSTF Recommendation on Screening for High Blood Pressure	GE Centricity

\* Includes immunization schedules for Diphtheria, Hepatitis A, Hepatitis B, Haemophilus Influenza type B, Human Papillomavirus, Influenza, Mean Corpuscular Volume, Measles, Mumps, Pneumococcal conjugate, Pertussis, Polio, Rotavirus, Rubella, Tetanus, and Varicella

\*\* Testing completed; however, the CDS was not “live” at the end of the demonstration project contract.

Over the 5 years of this study, the team has shown that the ECRS Web service is a reasonable model for providing CDS across multiple EHR systems (Paterno, Goldberg, Simonaitis, et al., 2012; Dixon, Simonaitis, Goldberg, et al., 2013). During the study, the consortium implemented the CDS service in the Longitudinal Medical Record system at Partners HealthCare, the CareWeb system at Regenstrief Institute, and the NextGen system at WVP Health Authority. Implementation of the service is in progress in the GE Centricity system at the University of Medicine and Dentistry of New Jersey (UMDNJ). The specifics of the implementation vary to accommodate local workflows and systems as summarized in Exhibit 6. At Partners, reminders are presented when a clinician opens a patient’s record, and updated when clinical data within the patient record changes. For example, signing a new problem of diabetes mellitus into the patient’s record would lead to the applicable reminders being generated and the screen display updated. In contrast, at Regenstrief, when a patient registers at the front desk, an electronic message is sent that triggers the assembly of a CCD document containing a limited data set that is transmitted via secure mechanisms to the ECRS decision support engine operated by Partners. The ECRS processes the record, evaluates selected CDS rules, and sends back applicable reminders to Regenstrief for storage in a data repository. Asynchronously (10 to 30 minutes later), the clinician treating the patient logs into the EHR order entry system and selects that patient’s record, where preventive care reminders are displayed.

The team oversaw continued enhancements and expansions over the course of the demonstration, including the development of a variety of technical resource documents such as EHR capability assessments. The CDSC team also developed and implemented two types of dashboards to provide feedback on actual clinical decisionmaking, compared with CDS recommendations. The provider dashboard focused on clinicians and clinics, and the developer dashboard focused on overall performance of implementation participants. The dashboards contain clinical performance measures, and allow providers to monitor their own performance relative to guidelines and to compare their performance with other providers. The dashboards allowed CDS developers to see a more granular assessment of the performance of the CDS interventions. This feedback can be an important part of both clinical process improvement and the development of more useful and relevant CDS content and presentation approaches.

During the final year of the project, the team developed and integrated new immunization content. In addition, the Regenstrief demonstration was significantly expanded, with new

providers participating. This site also moved the content from a general “clinical messages” section to a specific decision support section, significantly expanding the prominence of the content. The demonstration in the NextGen system at WVP Health Authority also went live during the last year of the project, and the demonstration in UMDNJ’s GE Centricity system went through the testing phase.

## Findings

**Translating guideline knowledge into actionable recommendations.** The development of CDS content is ongoing. Utilization of the Knowledge Management Portal steadily increased throughout the program. To date, a total of 111 CDS artifacts—including 19 at level 1, 3 at level 2, 33 at level 3, and 56 at level 4—have been published by team members and uploaded to the portal for open-access viewing and retrieving. These artifacts cover a range of clinical areas, including the following:

- Cholesterol screening: Recommends ordering a cholesterol panel for males at least 35 years of age and females at least 45 years of age who do not have both total cholesterol and high-density lipoprotein (HDL) cholesterol results within the past 5 years.
- Echocardiography for heart failure: Recommends ordering an echocardiogram for patients with a diagnosis of heart failure who have no previous echocardiogram recorded.
- Chlamydia screening for women: Recommends testing for chlamydia for females age 25 years of age and younger who are sexually active as determined by contraceptive use.
- Angiotensin-converting enzyme inhibitor (ACEI)/angiotensin receptor blocker (ARB) therapy in heart failure: Recommends ACEI therapy or ARB therapy (if contraindications to ACEI present) for patients with a diagnosis of heart failure who are not currently taking these medications.
- Antiplatelet therapy in ischemic vascular disease: Recommends antiplatelet therapy for patients with a diagnosis of ischemic vascular disease who are not currently taking these medications.
- Adult weight screening: Recommends taking height and weight measurements for body mass index (BMI) screening for adult patients who have not had BMI assessed in the past 6 months.

**Implementing CDS in EHR Systems.** Both the early CDSC development work and the subsequent implementation experience informed a range of findings and lessons specific to the cloud-based approach to CDS services. These are summarized briefly here and discussed in further detail in the section on initiative-wide findings and lessons.

- Privacy and security requirements are paramount to end users, and are particularly salient for the service-based CDS approach.

- Infrastructure at both the client and service ends must be sufficient to handle large and small volumes of data with acceptable performance.
- Network stability and support must be maintained at a very high level, as there is low tolerance for downtime.
- Legal agreements protecting both clients and services are necessary and are not presently standardized.
- Rigorous testing must be undertaken, as implementation is not a turnkey operation.
- The details of content and terminology must be understood by all parties. The mapping of local terminologies into national standard vocabularies requires careful attention.
- The ECRS as a service, and even the rules themselves, are but one piece of a large puzzle. At the client end, decisions need to be made about how and when to obtain data needed for the service, and how to present the results to the provider or patient.

To test the concordance of the preventive care recommendations generated by two different CDS approaches, the team executed the same set of preventive care guidelines in the cloud-based CDSC system and in a local CDS system. The local system relied on proprietary CDS rules crafted by local experts. EHR data for the same set of patients seen in primary care were sent to the central CDSC server and to the local CDS system. The two systems generated a similar number of clinical reminders, but agreement between the two CDS systems varied across recommendations. Agreement was almost perfect for 7 out of 11 of the preventive care reminders, but was as low as one-third for the others. Subtle differences in rule logic, terminology mapping, and coding practices can cause such discordance. The analysis uncovered other differences in how the systems used diagnoses and medical history to arrive at alerts, recommendations, and exclusions. In the absence of a gold standard for CDS recommendations, it is not possible to say that one approach was more correct than the other. Nonetheless, the study illustrates both the potential and the complexity of centralized cloud-based CDS services.

Other findings and lessons from these implementation experiences are described in the section below on initiative-wide findings and lessons.

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# Initiative-Wide Findings and Lessons

## Transforming Narrative Guidelines and Clinical Knowledge Into CDS

**It is feasible to reliably translate many guidelines into CDS, although not all guidelines provide the needed information in a clear, unambiguous manner.**

Both projects demonstrated the ability to translate evidence-based knowledge into useful, actionable direction for clinical care through CDS. For example, the GLIDES project tools such as GEM, GEM Cutter, GLIA, and BRIDGE-Wiz are extremely valuable for implementing knowledge in clinical practice. The GLIDES project can inform the language and recommendations chosen by future guideline developers, and thus foster the creation of practice guidelines that can be more easily incorporated into CDS systems. An important issue that the CDSC revealed is how to keep CDS content current in a manner that can benefit all end users, and accomplish this in an economical way. No single organization can afford to continuously update its knowledge base for CDS so as to ensure that the content stays consistent with the proliferation of clinically relevant information. The model of sharing state-of-the-art CDS content among many end users can achieve efficiencies and reduce the lag time between the creation of evidence-based information and its use in the field.

The projects also illustrated the value of aligning clinical quality measurement with CDS implementations. The action steps suggested by CDS systems can naturally provide opportunities for evidence-based performance measurement, and the systems can capture some of the data needed for quality measurement. The integration of CDS and performance measurement is an important area for future research.

One limitation of the demonstration projects is that neither one directly addressed the complexities of CDS for patients with multiple conditions that potentially could lead to conflicting clinical recommendations (e.g., a patient with diabetes, heart failure, and renal insufficiency). This is another area for further study into how evidence-based guidelines can be translated into useful and safe decision support.

### **Guideline developers can be important partners and stakeholders in CDS development.**

The GLIDES project in particular demonstrated the value of working with professional associations and guideline developers to provide tools and guidance for improving guideline development and reporting. The research team and the guideline development partners designed, implemented, and piloted processes and tools intended to make guidelines clearer and more implementable. This included application of BRIDGE-Wiz to help formalize the process of writing implementable recommendations using a controlled natural language, and incorporating decidability and executability checks and other productivity features. All four of the GLIDES project's guideline development partners (AAP, AAO-HNSF, AUA, ASCO) employed BRIDGE-Wiz in the development of their guidelines and found it to be very valuable to the recommendation formulation process. Benefits included making the process more systematic and

replicable, thereby minimizing variation in guideline development. In addition, the GEM Cutter software—used to markup guidelines for translation into XML—has been downloaded more than 563 times since 2000. Although many investigators have found GEM to be valuable, others criticized its failure to clarify guideline semantics, difficulties in markup, and the fact that GEM files usually are not executable (Hajizadeh, Kashyap, Michel, et al., 2010).

This work demonstrates that guideline developers can produce guidelines that are more amenable for CDS implementation, and that this is facilitated when CDS implementation considerations are addressed from the start of the guideline development process.

**Further research is needed to determine how formal the CDS coding should be prior to implementation.**

#### **Knowledge Representation Nomenclature**

The project teams came to a consensus on a standard nomenclature for describing various levels of knowledge representation, beginning with raw knowledge (e.g., a guideline text) and ending with CDS implementation. Initially, GLIDES used the terms “narrative guideline,” “semi-structured,” “semi-formal,” and “formal” to describe four levels. CDSC used “levels 1, 2, 3, and 4” to describe fairly similar concepts. Since the teams generally concurred about the process flow, but differed in what they called the various points along the way, Technical Expert Panel members urged the teams to see if they might be able to forge common names and terminology. This was accomplished as indicated in Exhibits 2 and 5, and can help ensure the lasting value of this work for the field.

*Technical Expert Panel discussion, June 2011.*

Both projects converged on a common set of general process steps for transforming clinical knowledge to CDS systems. Their experience demonstrated that as the information moved from level 1 through level 4 of the formalization process, the focus of knowledge transformation and implementation activity shifted from the work that could be completed by a centralized team to work that must be completed in collaboration with the implementation site. However, questions remain about how to most effectively standardize and formalize level 3 knowledge while also remaining flexible enough to be effectively implemented in a variety of clinical locations.

## **CDS Implementation**

**Centrally developed CDS is feasible, but customization of CDS is still required on a site-by-site basis.**

Both projects reported significant project effort with development and implementation of CDS, noting especially the challenges associated with developing code specific to the version of the EHR system running at an institution. Most of the “work” performed by everyday clinicians and patients is highly individualized. Thus, a deep understanding of the local, highly personal context is required to get CDS “right.” Moreover, getting CDS “wrong” will not be the equivalent of not providing any CDS. Rather, there is a real risk of inefficiency (e.g., interruption and distraction, leading the clinician to forget what she was thinking about before the CDS) and patient harm (e.g., acceptance of CDS that is inappropriate given the specific patient’s clinical situation). GLIDES refined a methodology for knowledge localization activities: creating

executable rules, adapting to local workflow, designing the user interface, building and testing the CDS, and deploying and evaluating the CDS in clinical settings.

Another challenge related to the inconsistency of EHR data across implementation sites. For example, data may be either missing, in different locations in the database, coded differently, and/or in different formats. Implementers had to analyze the structure and content of their data systems, and in some case perform extensive mapping or recoding of variables, as part of the implementation process. The teams mitigate risk by performing extensive data testing early in the system development process and releasing limited “beta” versions to small groups of clinicians to pilot the tools in real-world clinical environments.

Both projects faced difficulties incorporating changes in the clinical evidence base. GLIDES researchers found this challenging because not only was it necessary to redo the electronic representation of the guideline, but the changes had to be incorporated into the EHR system and the update had to be implemented at all sites. The CDSC team also would have to redo its representation if the guidelines changed, but because individual sites were accessing the central infrastructure and receiving the same electronic representation of the guideline, there is generally no need to update each individual site when changes in knowledge occur.

Neither project was able to thoroughly test the implementation of CDS in small- and medium-sized practices not affiliated with large health systems. CDS implementation in such settings would undoubtedly encounter challenges not experienced during implementation in larger and more research-focused settings.

### The 5 A's of CDS Implementation

**Awareness.** Too many people remain unfamiliar with CDS, or equate CDS only with intrusive, difficult-to-use alerts and reminders. Visibility must be raised about how CDS can help clinicians and organizations meet the many short- and long-term external challenges and demands they face, including reducing adverse events, readmissions, and resource use. Over time, clinicians may become more aware of the potential benefits of CDS as they receive training on information-seeking strategies and behaviors in medical school. In the near term, however, there is a need for national organizations (e.g., Department of Defense, Department of Veterans Affairs, Office of the National Coordinator for Health IT, Centers for Medicare & Medicaid Services) to raise the visibility of CDS on a broad scale.

**Acceptance.** Confusion still exists as to whether information generated by CDS systems is credible. Few people understand how the content that underlies CDS has been created, whether that content resolves conflicts in the literature over how to treat patients, and/or whether it applies to patients with multiple problems.

**Adoption.** Many people mistakenly believe that CDS systems are inevitably quite expensive, and they fear being responsible for significant upfront and maintenance costs. In addition, few monetary and/or other incentives exist to promote adoption and use of CDS.

**Assimilation.** CDS systems must integrate into existing workflows if they are to be used on a regular basis.

**Actionable.** As noted earlier, CDS must provide clinicians with information that is helpful to the specific patient and/or population being treated. The system should give clinicians a clear recommendation on what action to take and make it as easy as possible to execute that step.

*Technical Expert Panel discussion, August 2012.*

### **Additional work is needed on developing standards for EHR design, terminology, and coding.**

From both projects, it was clear that a lack of standards for terminology and a lack of interoperability between systems hindered CDS implementation. For example, the CDSC team made a decision to use the CCD as the basis for standardizing the service development effort. However, they found that there were often many different ways to interpret the CCD specifications, and the developers incorporating the CDS module into a local EHR system might make different decisions than the developers who built the module in the first place (Dixon, Simonaitis, Goldberg, et al., 2013; Paterno, Goldberg, Simonaitis, et al., 2012; and Ash, Sittig, Wright, et al., 2011). This difficulty was amplified once the project started to receive CCDs from outside the home organization and discovered even more variability. At one of the CDSC implementation sites, the problem list was already Systemized Nomenclature of Medicine (SNOMED)-coded, the labs were already mapped to Logical Observation Identifiers Names and Codes (LOINC), and there was a direct mapping from the drug terminology to RxNorm. However, many other standard terms were needed, ranging from service performance status to drug route and gender. The CDSC team completed a manual table-based mapping, which was a labor-intensive process. Even when using similar standards and terms, there are differences in the use of the terms across sites, and perfect matches to local terms may not be available. Thus, it is key for implementers to start exchanging sample files and comparing notes early in the process when changes are simpler, in order to better align the internal coding with standards and to minimize the amount of mapping that is necessary.

The qualitative observations by the CDSC team working at different sites uncovered an even more basic issue with terminology. Many of the end users did not consider the alerts, reminders, order sets, etc., as “clinical decision support.” They did not even realize they were using CDS. This indicates that the term CDS can be confusing to clinicians, especially because they may not even think that their decisions need any support. If another term that is more resonant with clinicians cannot be found, those who implement or study CDS may need to provide education on what CDS is and how the term applies to particular EHR tools.

### **It is important to understand implications of workflow and clinician mix.**

In addition to differences in IT systems across implementation sites, both projects encountered challenges associated with local variations in clinical workflow. It is essential to understand early in the implementation process when in the course of clinical care the data elements needed by the CDS tool are entered into the EHR system, and when in the course of clinical care is it appropriate for the decision support to appear. Similar considerations will also dictate to whom the decision support should be addressed. Some changes in workflow may be needed to facilitate CDS implementation, but determining how much workflow change is necessary, feasible, and valuable is as much an art as a science. The decision requires a balancing of factors, such as how much change an organization can accommodate, whether clinical leadership is committed to significant change, and whether the change can be well-designed and effectively implemented.



The implementation approach also may need adjustment based on the types of clinicians for whom the CDS is intended. For example, in implementing CDS tools for both specialists and primary care physicians, the GLIDES team identified design considerations that are more appropriate for each of these communities. One consideration is that in primary care, patients often present with multiple problems. Therefore, a CDS tool for primary care is more likely to be accepted and used if it accounts for multiple conditions rather than one specific condition. In general, primary care physicians were more open to a more prescriptive CDS approach. In contrast, specialists may believe either that they do not need CDS guidance, or that they know when it is appropriate to deviate from guideline-based CDS recommendations. The GLIDES project found that specialists did most of their interaction with the EHR system outside of their interaction with the patient, so they did not get the CDS information and support at the point of care. At one of the GLIDES implementation sites, pediatric pulmonologists deviated from guidelines in 9 percent of return visits and 18 percent of new visits. These deviations were not necessarily inappropriate, but they point to an inherent limitation of guideline-based CDS, because even a well-designed guideline will not cover all clinical situations and nuances. In general, the GLIDES team's CDS implementations for specialists (pulmonologists) at both Yale and Nemours were less successful than for primary care physicians, in the sense that usage levels were lower than expected.

**Intellectual property, liability, and knowledge management issues are an emerging area for policy discussion and development.**

The CDSC project structure in particular brought to the forefront the intellectual property and liability issues inherent in multiorganizational collaborations for CDS. Creative Commons, a nonprofit organization that enables the sharing and use of creativity and knowledge through free legal tools such as templates for copyright licenses, provided a useful starting point for addressing the legal and intellectual property issues. These licenses allow content developers to give others the right to share, use, and build upon that work, with appropriate attribution and restrictions, and protect the people who use that work from infringing on copyright. In that spirit, the CDSC team developed participant agreements that acknowledged authorship of guidelines and other materials, yet required authors to grant a license to other CDSC members to freely make derivatives of that content, citing the original source. The shared artifacts and derivatives must be shared freely within the consortium and may not be sold, and all parties mutually indemnify each other in the event of liability claims.

**CDS Financial Sustainability**

**Making CDS More Affordable, Especially for Small Organizations.** Many vendors sell content related to CDS and/or CDS systems that bring content and EHRs together. Yet potential users of CDS remain reluctant to pay for content, as they believe they already have it in-house. In other cases, the cost of buying CDS remains too high for some customers, particularly smaller organizations. Few vendors, in fact, focus on the needs of smaller sites. One key issue, therefore, relates to how to lower costs and hence allow smaller organizations to afford CDS. Public-private collaborations may be helpful.

**Paying for Updates.** Commercial EHR vendors spend significant amounts of money on updates, but this may not include CDS content. CDS users often do not have the financial resources to update their systems. The National Guideline Clearinghouse (NGC) may be helpful to CDS users, as it tracks which developers update their guidelines and when they do so. Updates, however, can create problems with version control, creating a need to highlight what has changed. The updating problem affects both electronic health record (EHR) vendors and users that implement and test updates when they occur. A similar problem exists with respect to regulatory alerts, such as a drug or device recall or the issuance of a black-box warning. The failure to keep up with such alerts can have huge implications for patient safety.

*Technical Expert Panel discussion, August 2011.*

Knowledge management issues, such as supporting the collection, grading/rating, maintaining, organizing, and making use of clinical knowledge, are a second administrative and logistical focus area that took on increasing importance for both projects as their collection of guidelines and CDS materials grew. The CDSC team developed style sheets and editorial guidelines to standardize the development and review cycles for its materials. The GLIDES team developed a suite of tools to make it easier for guideline developers to anticipate the standardization and logic necessary to translate guidelines into CDS. The researchers then worked with a variety of guideline developers to incorporate these elements into the guidelines from the start.

Although both the CDSC and GLIDES projects made progress in addressing these issues, clearly they will continue to be an area for future discussions among stakeholders as CDS content grows.

### **Competing priorities of key stakeholders limit industry-wide adoption and sustainability.**

Both projects found that their CDS implementation efforts had to compete for the time and attention of local partners and EHR vendors. Some of this had to do with the normal demands of running a clinical facility or business, and the absence of tangible rewards and resources for participating in the study. The academic motivators for conducting publishable research were not as strong for the partners as they were for the lead CDSC and GLIDES project organizations. The issue of competing priorities increased when the partners began to focus on meaningful use implementation. In the long run, involvement in CDS research may help an organization to achieve its meaningful use objectives, but in the short run many of the same individuals need to focus their work on a different set of activities. At some EHR vendors, staff were focused on updating systems to support the new meaningful use and certification requirements, and sometimes had to temporarily move software developers from CDS integration and research activities to meaningful use work, impacting study timelines. In addition, the marketplace pressures on EHR vendors to differentiate their products from their competitors, and the need to demonstrate adequate return on investment, had to be balanced against the value of adapting their products to incorporate the emerging CDS tools.

#### **Role of EHR Software Vendors**

**Data Standardization.** Effective CDS cannot occur if needed data elements are not in the system; however, many EHRs do not currently capture all of the information required for effective performance measurement and CDS. This indicates the need for standardized value sets that contain data elements and response choices of proven value for the delivery of clinical care.

**Data Capture.** Even if EHRs can store the needed information, clinicians must document the data appropriately during time-pressed visits. Consequently, vendors need to make the data capture process easy and valuable for physicians, without requiring them to make undesired changes to their workflow.

**System Updates.** A particular challenge is the need to keep systems current as clinical evidence and guidelines evolve. At present, this updating tends to be quite time- and labor-intensive. As personalized medicine evolves, CDS and the underlying rules and guidelines will become more complex, making it even harder for vendors to keep systems current.

**Market Factors.** CDS can be a product differentiator for EHR vendors, but not all vendors invest heavily in developing CDS content and tools, as this has not traditionally been a core vendor role, the return on investment is unclear, and liability concerns related to CDS persist. This market situation illuminates the need for CDS developers and EHR vendors to collaborate on project teams so that CDS can be better integrated into EHR products.

*Technical Expert Panel discussion, December 2011.*

**The business model for CDS development and implementation is not well-understood.**

These projects did not directly address cost and sustainability issues, but understanding the cost implications of CDS development and implementation is important for determining policy regarding the appropriate architecture for CDS. Not only may the CDSC and GLIDES approaches have different costs, but the costs may accrue to different entities. The majority of the CDSC project costs were involved with building the centralized infrastructure, but once this is developed, the provider sites would ideally require fewer resources to modify their EHR system and set up the Web services to access the CDS. For the GLIDES model, the EHR vendor and/or local technical teams incur the costs of incorporating CDS into their system and updating it as needed. Although these costs may ultimately be passed on to the customer, it is not clear to what extent EHR customers are willing to pay more for an EHR system that includes enhanced CDS capabilities. For both CDS models, the costs of building the initial architecture, costs for the clinical site to implement it, costs of updating the content, and other costs need to be better studied and matched with appropriate business models that balance costs and benefits to create value for participants at all levels. The projects have begun to explore how fee-based models might be designed.

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## Implications, Future Directions, and Research Needs

The CDS demonstration projects created valuable knowledge and made significant progress toward the aims of (1) creating processes and tools for translating narrative guidelines and clinical knowledge into formats that can be used by multiple EHR systems; (2) creating processes and tools for implementing CDS across a range of settings, including settings with limited technical capacity and experience with health IT; and (3) evaluating the processes and outcomes of the projects, including impacts on health. The findings from the projects have the potential to influence future directions of health care reform, such as ongoing programs of the Office of the National Coordinator for Health Information Technology (ONC), as well as programs associated with the HITECH Act and the ACA.

The work of the CDS demonstration projects has greatly informed the HeD initiative under the ONC Standards and Interoperability Framework<sup>7</sup> (Chaney, Shiffman, Middleton, et al., 2013). The goal of HeD is to identify, define, and harmonize standards to facilitate the implementation of shareable and scalable CDS. HeD has produced formal guidance for two use cases: (1) standards for structured medical knowledge in an executable format for CDS (“CDS Artifact Sharing”); and (2) standards for how a system can interact with a CDS service provider (“CDS Guidance Service”). Use case #1 harmonized the level 3 knowledge representations developed through the CDSC and GLIDES projects, along with the work of others, to create a standard input to CDS services known as the HL7 VMR.<sup>8</sup> Use case #2 built on the work of the CDSC centralized service model, and a CDSC partner, ECRS, successfully participated as a sample implementer of the HeD CDS service.

The evidence-based CDS developed using the techniques of the demonstration projects also can help provide the knowledge infrastructure for programs that utilize quality measurement. CDS and quality measurement rely on the same or similar data elements, but use them at separate times in the workflow. For example, for preventive screenings, CDS may be triggered prospectively based on the date of the most recent screening in the medical record, and the quality measure will be generated retrospectively based on the screening date. As more data elements are formally coded for evidence-based CDS in an EHR system, more information will be available for abstraction as quality measures. Many current and future health care initiatives will rely on quality measures to assess whether an organization is meeting standards of care. For example, accountable care organizations (ACOs) will be required to report on quality measures related to care coordination, patient safety, preventive care, and at-risk populations in order to qualify for certain reimbursements. CDS and quality measurement are also key elements of the meaningful use incentive program. Although the use of CDS is a core measure for all stages, meaningful use Stage 3 is expected to have a strong focus on using EHRs and CDS for quality improvement. Moreover, ONC is encouraging agencies and programs requesting the development of new EHR-based quality measures to support the development of CDS in the HeD format (Chaney, Shiffman, Middleton, et al., 2013).

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<sup>7</sup> <http://wiki.siframework.org/Health+eDecisions+Use+Case>, accessed January 14, 2014.

<sup>8</sup> <http://www.hl7.org/about/>, accessed March 18, 2014.

A national CDS infrastructure is an essential part of delivering high-quality, patient-centered care. The ACA authorizes the establishment of a patient-centered outcomes research (PCOR) trust fund, which will fund ongoing research activities at AHRQ, NIH, and the Patient-Centered Outcomes Research Institute. The long-term goal of PCOR is to provide evidence-based information that incorporates a wide range of patient-specific factors, including but not limited to comorbidities, gender, race, and family history, in order to improve health outcomes and patient satisfaction with care. To achieve this goal, providers and patients will need automated tools, such as CDS, to help process and deliver patient-centered information in real time on a national scale. Patient-facing CDS tools also can be incorporated into shared decisionmaking interventions, and can be used to guide care outside the clinical setting.

A central question illuminated by these projects is the role of EHR software vendors in this national framework and set of standards for CDS development and implementation. Currently, the vendors are often not directly involved in CDS development, and they do not necessarily have the incentives or resources to incorporate CDS into their systems in a standardized fashion. Greater clarity on the role of vendors in facilitating the incorporation and maintenance of CDS in their products is needed for the spread of these tools.

## **Outstanding Research Questions**

Important research questions still need to be answered for many of the steps of delivering CDS to clinicians at the point of care:

### **Guideline Translation**

1. How should a CDS designer deal with conflicting evidence or guidelines?
2. How should CDS systems address patients with multiple conditions, whereby multiple CDS rules will be triggered? Often, the recommendations are based on highly controlled single-condition studies that may have limited generalizability, and some recommendations are likely to be conflicting.
3. Many of the CDS rules rely on patient-specific data, some of which may be uncertain or unknown. What is the best way to portray CDS uncertainty to the clinician?

### **Local CDS Implementation**

4. What local factors affect the nature and quality of patient data available to a CDS system? How can the CDS system designer (or implementer) efficiently and effectively obtain that information at each installed site?
5. What local factors influence CDS usability, use, safety, and effectiveness? How can the CDS system designer (or implementer) efficiently and effectively obtain that information at each installed site?

## **Clinician and Patient Factors**

6. How do clinicians react to CDS in real time, and how can correct decisions be optimized in the moment? If reactions to CDS differ between inexperienced (e.g., residents) and experienced clinicians, how can the CDS system account for that?
7. What other clinician factors (e.g., sleep deprivation, mood) affect the response to CDS? Will clinicians develop “guideline fatigue” (similar to “alarm fatigue” among critical care nurses)?
8. How often does CDS need to be correct or useful in order for clinicians to accept and use it? No CDS system can give perfect guidance all the time, but it is critical to understand clinician tolerance for CDS inaccuracies and how it varies by clinician characteristics such as age or specialty, mode of CDS, organizational context, the clinical decision under consideration, and the interactions of these factors.
9. How does CDS affect real-time behavior of clinicians and patients? What is the evidence that following a clinical guideline actually improves a specific patient’s quality of life, and how does this vary by patient characteristics or diseases?
10. How can CDS systems be linked with personal health records and other patient-focused technologies to engage, support, and motivate patients to improve prevention and self-management of health conditions?
11. Can we build local learning into CDS by seeking clinician and patient feedback (e.g., “How useful was this recommendation?”)?

## **Policy and Sustainability Issues**

12. Is there a viable and sustainable business model for creation and delivery of CDS?
13. Under what circumstances does the inclusion of CDS make an EHR system a medical device, and what are the regulatory implications?
14. If CDS is provided by an outside entity, and a patient is harmed as a result, is the outside entity legally liable? The convention of transferring liability to clinicians on the premise that they can and should exercise medical judgment may be less applicable and acceptable to clinicians using CDS systems.
15. What is the appropriate role of EHR vendors in the development, implementation, and maintenance of CDS tools?

## **Evaluation**

16. How can the accuracy of decision support be assessed, and what level of correctness will be acceptable? If CDS needs to be 99.999 percent correct to avoid patient harm, is that feasible?
17. How does the specific mechanism for delivering CDS (i.e., user interface elements) affect CDS usability, use, safety, and effectiveness?
18. To what extent are there unintended consequences of CDS that may affect patient safety or the quality of care?



## Conclusion

Many opportunities to expand the use of CDS are associated with evolving national priorities that place a premium on value-based purchasing of health care services by the Federal government, adoption of EHR systems and exchange of patient information, reduction of preventable harmful events, and giving consumers and purchasers more performance information to drive the market through choices based on quality and service performance. The many Federal programs that are focusing on these national priorities include Medicare value-based purchasing, the meaningful use incentive program, the congressionally mandated penalty program for certain hospital-acquired conditions, and the Partnership for Patients. Health care organizations are being asked to meet performance thresholds or otherwise meet specific metrics in order to earn incentive payments or avoid payment penalties. In addition, Congress is considering a historic change to Medicare reimbursement so that clinicians would receive incentives based on resource use, EHR implementation, and quality improvement metrics.

All of these programs and priorities create an imperative for the use of CDS to help health care providers to measure and improve the quality of care. Without CDS, it will be difficult for clinicians to manage and assess large amounts of detailed patient information, stay current with the rapid growth of new evidence about diagnosis and treatment, and deliver care in the context of resource constraints that require the elimination of preventable errors, complications, and inefficiencies in care delivery. These challenging expectations underscore the need to pursue the development of CDS systems in order to ensure ongoing progress toward national goals. The AHRQ initiative anticipated these challenges and has helped to advance efforts to address them through the major accomplishments of the demonstration projects. These projects refined approaches for bringing knowledge into clinical decision support in several ways, including:

- Refining a four-level knowledge transformation process for translating unstructured clinical guidelines and clinical knowledge into machine-executable algorithms.
- Providing a framework upon which to develop standardized EHR data specifications to support decision support implementation, tailored to meaningful use criteria.
- Demonstrating and evaluating guideline implementation for quality improvement at a variety of sites.
- Implementing decision support through Web services using a shared portal that included a library of verified content.
- Collaborating with guideline developers and implementers on the creation and promotion of tools to facilitate CDS.
- Exploring the legal issues related to using and sharing clinical decision support content and technologies across organizations.

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## Appendix: Technical Expert Panel Membership

This appendix lists the members who served on the CDS Technical Expert Panel (TEP), with affiliations from the time period in which the Panel was active, along with their time served on the TEP and the TEP meeting dates. These meetings provided substantive input and guidance to the demonstration project teams and AHRQ on how to maximize the impact of the demonstration projects. The presentations for the TEP meetings are located at <http://healthit.ahrq.gov/ahrq-funded-projects/clinical-decision-support-initiative/cds-technical-expert-panel>.

TEP Member Name and Affiliation	Dates Served on TEP
Michael Barr, M.D., M.B.A., F.A.C.P. American College of Physicians	February 2010 – September 2012
Eta Berner, Ed.D. University of Alabama at Birmingham	May 2008 – September 2012
Helen Burstin, M.D., M.P.H. National Quality Forum	May 2008 – September 2009
Clayton Curtis, M.D., Ph.D. Veterans Health Administration	September 2009 – September 2012
Dave Davis, M.D. University of Toronto	May 2008 – September 2009
James T. Dove, M.D. Southern Illinois University School of Medicine	May 2008 – September 2010
Gregory Downing, D.O., Ph.D. Department of Health and Human Services	May 2008 – September 2012
Charles Friedman, Ph.D. Office of the National Coordinator for Health IT	May 2008 – September 2011
Norman Kahn Jr., M.D. Council of Medical Specialty Societies	May 2008 – September 2009
David Lobach, M.D., Ph.D.* Duke University Medical Center / Religent Health	September 2009 – September 2012
Clement McDonald, M.D. National Institutes of Health	May 2008 – September 2009
Virginia A. Moyer, M.D., M.P.H. Baylor College of Medicine	May 2008 – September 2012
Eduardo Ortiz, M.D., M.P.H. National Institutes of Health	May 2008 – September 2012
Douglas Owens, M.D., M.Sc. Veterans Administration Palo Alto Health Care System	May 2008 – September 2009
Rachel Nelson, M.H.A. Office of the National Coordinator for Health IT	September 2010 – September 2012
Greg Pawlson, M.D., M.P.H. National Committee for Quality Assurance	May 2008 – September 2009
Jacob Reider, M.D.** EHR Association/Office of the National Coordinator for Health IT	September 2009 – September 2012
Doug Rosendale, D.O. Veterans Health Administration	May 2008 – September 2012
Charles Safran, M.D., M.S. Harvard Medical School	May 2008 – September 2009
Michael Stearns, M.D., C.P.C. EHR Association	September 2011 – September 2012

TEP Member Name and Affiliation	Dates Served on TEP
Margaret VanAmringe, M.H.S. The Joint Commission	September 2009 – September 2012
Michael S. Weiner, D.O., M.S.M., M.S.I.S.T. Department of Defense	September 2009 – September 2010
Matthew Weinger, M.D. Vanderbilt University	September 2009 – September 2012

\* Dr. Lobach's affiliation changed from Duke University to Religent Health in January 2012.

\*\*Dr. Reider's affiliation changed from EHR Association to Office of the National Coordinator for Health IT in September 2011.