

Implementing Clinical Decision Support (CDS) Systems: The Experiences of AHRQ's Demonstration Projects – Second Annual Report

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Introduction

Clinical decision support (CDS) is “any system designed to improve clinical decisionmaking related to diagnostic or therapeutic processes of care.”¹ CDS systems are often computer-based, which allows the user to take advantage of the capacity of computer systems to process information from the patient record and to deliver appropriate recommendations to providers at the point of care.

In 2008, the Agency for Healthcare Research and Quality (AHRQ) funded two demonstration projects in support of the design, development, implementation, and evaluation of guidelines-based CDS. The demonstration projects were awarded to Brigham and Women’s Hospital (Clinical Decision Support Consortium [CDSC] project) and Yale University School of Medicine (GuideLines Into Decision Support [GLIDES] project). 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 three years. An additional one year (Option Year 1) was funded. This report summarizes the work undertaken in that Option Year 1. Both projects have multiple goals, including (1) incorporating novel CDS tools into multiple electronic medical record (EMR) systems, (2) sharing lessons learned during implementation with the vendor community, and (3) evaluating the processes and outcomes of the projects. The demonstration projects utilize a technical expert panel (TEP) that helps identify methods to maximize the impact of the projects at the implementation sites and in future settings.

Westat provides monitoring and dissemination support for the AHRQ CDS demonstration projects and supports the TEP. Westat’s role is to convene project representatives and the TEP, and through these meetings glean information about the factors that help or hinder the successful implementation of guidelines-based CDS in primary- and specialty-care practices.

This report summarizes the accomplishments, challenges, and lessons learned during the third year (March 2010 to June 2011) of the AHRQ CDS demonstration projects. The report describes the goals identified at the beginning of the year, the process and tasks undertaken to meet those goals, the progress on achieving those goals, and the lessons learned from these experiences. Westat developed this report by reviewing existing resources, reports, and plans from each CDS demonstration project, as well as documents generated from activities undertaken as part of the support project conducted by Westat. The report concludes with common themes across both projects that have implications for their future development and the larger CDS community.

Overview of the AHRQ Clinical Decision Support (CDS) Demonstration Projects

Background

CDS can support the delivery of high-quality healthcare by providing intelligently filtered, patient-specific knowledge at the point of care. CDS “encompasses a variety of tools and interventions such as computerized alerts and reminders, clinical guidelines, order sets, patient data reports, and dashboards, documentation templates, diagnostic support, and clinical workflow tools.”² CDS applications range from “electronically available clinical data (e.g., information from a clinical laboratory system or information from a disease registry), electronic full-text journal and textbook access, evidence-based clinical guidelines, and systems that provide patient and situation-specific advice (e.g., EKG interpretation and drug-drug interaction checking).”³

Recognizing the potential for CDS to help ensure the safety and quality of health care, and the need to develop consensus about the use of CDS to promote safe and effective care, the AHRQ Health IT Portfolio has focused on several CDS initiatives including the following: Details on each of these items can be found at http://healthit.ahrq.gov/portal/server.pt/community/ahrqfunded_projects/654/clinical_decision_support_initiative/13665:

- CDS eRecommendations project is focused on establishing a formalized process for translating narrative recommendations to clear-coded format that can be converted to machine executable format;
- Series of white papers on CDS. The two papers published in this series can be found;
- Step-by-step guide for implementing CDS can be found at Podcast series on CDS;
- Town hall meetings for community outreach; and
- Published report on challenges and barriers to implementing CDS.

In support of enhancing the utility of CDS and its adoption in the broader provider community, AHRQ awarded funds for development, implementation, and evaluation of CDS through two CDS demonstration projects.

AHRQ’s CDS Demonstration Projects

The CDS projects funded by AHRQ include two CDS demonstration projects: Yale School of Medicine is leading the GLIDES project, and Brigham and Women’s Hospital leads the CDSC project. The objective of the CDS demonstration projects is to develop, implement, and evaluate guidelines-based CDS and then share lessons learned with AHRQ and the health IT community. Each project was initially funded for \$2.5 million for a 2-year period, with an option for AHRQ to continue funding the projects in yearly increments for an additional three years. In

2010, the first option year was executed to continue implementation and evaluation efforts in both projects.

AHRQ recognizes the importance of establishing this research in the context of the provider community and engaging stakeholders in the research and implementation process. Thus, these demonstration projects are supported by a TEP that reviews findings, provides input and feedback for recommendations and reports, and offers guidance on how findings from this initiative can be most effectively disseminated. The panel members represent 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.

The overarching goals of these two demonstration projects are to develop, implement, and evaluate best practices in using CDS. Specifically, these two projects have been charged by AHRQ to:

- Incorporate CDS into certified electronic medical records (EMRs).
- Demonstrate that CDS can operate across multiple computer systems.
- Establish lessons learned for CDS implementation relevant to the health IT vendor community.
- Assess potential benefits and drawbacks of CDS, including effects on patient satisfaction and on measures of efficiency, cost, and risk.
- Evaluate methods of creating, storing, and replicating CDS elements across multiple clinical sites and ambulatory practices.

GuideLines Into Decision Support (GLIDES)

In February 2008, AHRQ awarded a 2-year, \$2.5 million contract to the Yale School of Medicine to finance the GLIDES project. This project aims to explore how the translation of clinical knowledge into CDS can be made part of routine practice and expanded to improve the overall quality of health care. It demonstrates how knowledge from clinical practice guidelines can be converted to computer-based CDS.

During the first two years, GLIDES transformed narrative clinical guidelines into computer-mediated CDS for asthma and pediatric obesity and initiated implementation in specialist and primary care settings.⁴ For details on the approach, tasks, and the progress during those two years, please refer to the report “Implementing Clinical Decision Support (CDS) Systems: The Experiences of AHRQ’s Demonstration Projects—Annual Report” at http://healthit.ahrq.gov/portal/server.pt/document/949198/cds_eoy_report_final_pdf?qid=77803932&rank=1.

The third year of the project focused on continuing the implementation efforts in additional sites, with changes and enhancements based on lessons learned in the first two years.⁵

Project Team for Option Year One

The primary contract is with the Yale University School of Medicine, with collaborators from Yale New Haven Health and Nemours. In the third year, GLIDES expanded its pool of collaborators to include the American Academy of Pediatrics (AAP), the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS), Geisinger Health System, and Children's Hospital of Philadelphia (CHOP). The project team includes representation from primary and specialty care medicine, nursing, informatics, information systems, clinical administration, epidemiology, and quality management. Richard Shiffman, MD, MCIS continued serving as project director.

Project Goals for Option Year One

The primary goals of this demonstration project for the third year were as follows:⁵

Implementation

- Using systematic and replicable processes:
 - Continue to design, develop, implement, and demonstrate guideline-based CDS;
 - Focus on new guidelines and implementation partnerships; and
 - Enhance and improve the CDS already produced at Yale and Nemours in the first two years of the project.

Guideline Development

- Work closely with guideline developers to provide tools and guidance to improve guideline development and reporting processes; and
- Update the Guideline Elements Model (GEM) and increase GEM adoption nationally and internationally.

Evaluation

- Evaluate the process and outcomes for existing and new implementations using a mix of qualitative and quantitative methods.

Dissemination

- Disseminate the knowledge and experience gained in the process of implementing at a variety of sites.
- Utilize various modalities (publications, presentations, best practices documents, etc.) in disseminating the findings and lessons learned from implementation experiences.

Project Design and Methods

The project design involves the development of CDS tools based on clinical guidelines. With the GEM as the centerpiece, the four cornerstones of the GLIDES strategy consist of:

- **Knowledge Generation** represents the gathering of existing guidelines and summarizing the information they contain.
- **Knowledge Transformation** represents the 4-step process of gathering the appropriate guidelines, extracting relevant narrative guidelines, translating them to semi-structured knowledge, and transforming that to structured knowledge that can be implemented consistently, e.g., in computer-mediated CDS. This process consists of using GEM Cutter (an editor) to markup embedded knowledge within guidelines, and converting it to an eXtensible Markup Language (XML) file. The XML file consists of narrative recommendations converted to If-Then rules. Concepts within these rules are converted to relevant controlled vocabularies for system development. Action types within those recommendations and rules help design the implementation.
- **Implementation** includes the design and operationalization of systems such as CDS with the purpose of influencing clinician behavior.
- **Project Management** consists of setting goals, gathering and finalizing requirements, involving stakeholders, establishing a governance structure, developing an effective work plan, and conducting evaluation.

Tasks and Accomplishments for Option Year One

- **CDS Implementation:** The four-prong strategy of the GLIDES team has led to development of structured processes, methods, and tools for implementing CDS at multiple sites. These methods and tools were adapted and used to construct complex CDS applications at two new sites in the third year of the project, while implementation efforts continued at the two sites that were initiated in the previous year.⁶ The four GLIDES implementation sites were:
 - Yale – New Haven Health System – previous year site
 - Nemours – previous year site
 - Children’s Hospital of Philadelphia (CHOP) – new site
 - Geisinger Health System – new site
- **Yale – New Haven Health System** was at a different stage of implementation because it had started in the previous year and was focusing this year on addressing one major challenge related to the use of the Electronic Health Record (EHR). The EHR was not being used during clinic operations, so the asthma CDS ended up being used after the fact as a data-entry/post-decision validation tool.

The solution adopted to resolve this was to automate paper-based patient information gathering using iPad technology to capture patient information directly from the patients. This required a redesign of the existing workflow at the point where patients enter information that gets transferred to the Centricity EHR system. Development of the iPad data capture application, loading of data from iPad to Centricity, and CDS screens infrastructure was completed this year. End-to-end transmission of iPad data into Centricity EHR was tested and achieved. Pilot testing of full use of iPad for patient data gathering will be undertaken in the next project year.

- **Nemours** had completed pilot development during previous years of the project. At Nemours, the GEM-based knowledge transformation process was integrated with the existing processes and conventions for system development. This year, Nemours completed the implementation and initial evaluation of CDS applications for asthma and obesity, and closed out the project.
- **Children’s Hospital of Philadelphia (CHOP)** implementation process consisted of identification of three guidelines for CDS system design: retinopathy of prematurity (ROP), respiratory syncytial virus (RSV) and Synagis, and hearing screening. GEM was effectively used for guidelines on ROP and RSV/Synagis and translated into implementation logic. On the other hand, guidelines on hearing screening required much more work from CHOP physicians in order to support implementation logic. Following the translation of narrative guidelines into structured logic, CHOP worked with end-users to design, develop, and test the CDS intervention. Workflow analysis was performed and a user interface was mocked up for design and development. The unique needs of the CHOP physicians required the design and development of the CDS system to go beyond alerts and notifications, and to include support for overseeing the entire process of managing patients from insurance approval to scheduling appointments and administering dosing. In the process of designing this system, a new centralized rules engine was created in the hospital’s EpicCare Electronic Medical Record (EMR) system. This centralized rules engine can be reused across multiple CDS applications.
- **Geisinger** identified the clinical guidelines on adult low back pain developed by the Institute for Clinical Systems Improvement for its implementation demonstration. The CDS developers used GEM Cutter to resolve guideline challenges in the process of creating the XML file; transformed guidelines into decision variables, actions, and directives to create guideline logic; and integrated GEM output with the design conventions required to implement the logic into Geisinger’s EpicCare EMR system. Development was completed this year and implementation will be undertaken in the next year of the project.
- **Improve Guideline Development Process:** In the third project year, the GLIDES team worked with two guideline developer organizations, the AAP and the AAO-HNS, with the goal of providing them tools and guidance to help make guidelines developed by these organizations clearer and easier to implement. In the process of doing so, GLIDES

demonstrated, piloted, and implemented two main tools and process improvements for guidelines development:

- **BridgeWiz (Building Recommendations in a Developer's Guideline Editor)** is a software assistant that is used by guideline authors with the purpose of improving clarity, transparency, and implementability. It leads guideline developers through a series of questions that help populate a model of guideline recommendations. BridgeWiz was successfully piloted by both AAP and AAO-HNS. GLIDES collected and used feedback from the pilot experience to enhance the tools.
- **The GuideLine Implementability Appraisal (GLIA)** is an instrument designed to conduct a thorough evaluation of guideline recommendations in order to make them easier to implement. This evaluation consists of reviewing several features of the guidelines as a whole, as well as nine dimensions of implementability. It also identifies obstacles to successful implementation. Feedback from the users was used to make revisions and publish the version 2.0 of the GLIA instrument.
- **Enhance and Expand the Adoption of GEM:** In the third year of the project, the GLIDES team conducted various activities for review, enhancement, expanded use, and feedback on GEM and GEM Cutter. Literature review input was used to develop concepts, requirements, and enhancements for the new GEM III release such as:
 - Backward compatibility;
 - Multiple sources for new elements/attributes;
 - GEM Cutter improvements (repeated markup of same text is more clearly indicated, Drag-and-drop conditionals and imperatives to preserve original order); and
 - Integration with BridgeWiz.

Adoption efforts consisted of collecting feedback from 11 guideline developers about GEM; the results emphasized the importance of developing guidelines in a way that they can be implemented in CDS. Other guideline developers were educated about GEM and the importance of crafting guidelines that can be used in CDS development. One consistent feedback from all these efforts was that all implementers would benefit from the ability to obtain GEM-processed guideline content via the AHRQ National Guideline Clearinghouse. This will be considered as an area of focus in subsequent years of the project.

- **Evaluation and Dissemination Activities:** Limited evaluation activities were undertaken during this year. Nemours completed evaluation activities for obesity and asthma CDS applications toward the end of the project year. Evaluation of the GLIDES CDS to support assessment and management of pediatric asthma in a subspecialty clinic setting indicated that although clinicians generally agreed with the CDS for asthma control assessments, agreement was limited for severity assessment and therapeutic step selection. Reasons for low use of CDS by pediatric pulmonologists were related to a combination of factors associated with general medical care and subspecialty care.

As part of the dissemination effort, nine publications focusing on different aspects of the work on the project were generated by the GLIDES team. Four were published in professional journals, while others were in review or revision stages. Numerous (approximately 13) presentations at meetings and conferences provided another method of disseminating information about the project work and outcomes.

Challenges Encountered

- With reference to knowledge generation, engaging different stakeholder groups with their unique perspective was challenging. GLIDES team had to adopt and adapt various strategies to engage these groups in understanding and applying new opportunities for tools and processes to make guidelines clearer.
- Implementation at each site revealed issues and challenges unique to the needs, requirements, and workflow processes of the local site. Adaptations to implementation strategy and technology had to be made to accommodate existing workflow and to meet the unique needs of the users.
 - Each implementation partner adopts a unique approach in bridging the GEM output to operational CDS. While this approach provides flexibility for users, capturing the different practices for developing guidelines or establishing best practices becomes challenging.
 - There is continued preference for waterfall methodology among IT professionals at some implementation sites. This makes it challenging to replicate the successful approach of prototyping CDS applications with iterative refinements.
 - At Yale, implementing new technology in a pilot mode within the corporate IT infrastructure was challenging.
 - At CHOP, differences in opinions among local experts on how to interpret certain guidelines had to be resolved. Also, controlling vocabulary and translation of concepts from guideline language to EpicCare EMR compatible language was challenging.
- Although some guidelines easily fit into the knowledge transformation approach of the GLIDES team, other guidelines (e.g., hearing screening guidelines) could not be easily converted for use in CDS systems. Involved clinical and technical teams had to find workarounds and creative solutions in working with those guidelines.
- Accommodating implementation metadata in the new version of GEM III remains a challenge.

Lessons Learned

The four implementation efforts undertaken by the GLIDES team have provided opportunities for examining a standard implementation process across a variety of settings.

These experiences offer a rich set of lessons learned that can be used for future efforts and enhancements. Below is a summary of these lessons learned across all implementation efforts.

- Transitioning from recommendations to functional CDS is a complex, multifaceted process. Current approach consists of an evolving set of considerations with some relevant toolsets.
- CDS implementation processes, methods, and tools must be flexible enough to integrate with existing infrastructure for IT design and implementation.
- Factors that determine the specific techniques to be adopted for this integration include:
 - The specific guidelines and their characteristics and complexity;
 - Systems development practices within the implementing organizations; and
 - Technical infrastructure of the EHR.
- Workflow change requires careful consideration of various factors, including an organization's ability to accommodate change, commitment of the leadership, and effective design and implementation of change. Local workflow and barriers analyses also helps determine when, how, and for whom CDS should appear.
- Categorizing activities for specific guideline recommendations can be helpful in communicating the benefits of those actions.
- Commercial EHR systems must make provisions for end-users to locally program more complex data capture and logic.
- Implementation planning can be made more effective by:
 - Involving end users in the development of tools and systems they will use;
 - Accommodating or reengineering the existing workflow;
 - Defining evaluation plans and requirements from the very beginning;
 - Understanding that no standard technique for integration can be enforced within an organization;
 - Including incentives, feedback loops, guideline champions, and performance measures as part of adoption efforts;
 - Integrating it with maintenance of certification or meeting meaningful use requirement efforts; and
 - Using it as an opportunity for broader quality improvement efforts.

- CDS should be provided in a wide variety of formats that include relevant information, calculators, order sets, documentation templates, algorithms, and info-buttons.

Plans for the Next Year

The next year will primarily focus on continuing the various implementation, enhancement, and evaluation activities initiated in the previous years of the projects.

- Implementation at CHOP will continue with an emphasis on final releases for Retinopathy of Prematurity (ROP) and Synagis, including use case and usability testing. CHOP team will also prepare and publish an implementation guide along with a technical appendix.
- Pilot demonstration of the CDS system will be initiated by Geisinger. The Geisinger team also plans to expand coded guidelines to translate into rules for real time application of management recommendations based on patient reported data on back pain.
- Pilot testing of iPad technology for patient data gathering will be undertaken at Yale.
- Potential for providing GEM-processed guidelines to interested parties via the National Guideline Clearinghouse will be explored.
- GLIDES team will make efforts to formalize the GLIDES methodology toolkit for implementation based on experiences on this project.
- Evaluation of implementation efforts will continue.

Clinical Decision Support Consortium (CDSC)

In March 2008, AHRQ awarded a second 2-year, \$2.5 million contract to the Brigham and Women's Hospital to fund the CDSC project. The overarching goal for the CDSC project is to assess, define, demonstrate, and evaluate best practices for knowledge management and CDS across various ambulatory care settings and technology platforms at scale.⁷ At the end of the 2-year contract, a third year (Option Year 1) was funded by AHRQ to support the continuation of implementation and demonstration efforts of the CDSC team.

Project Team for Option Year One

The CDSC team remained the same as the first two years of the project, providing stability and consistency. The team involves researchers from nine different organizations including: Partners HealthCare System's Clinical Informatics Research and Development (CIRD), the Regenstrief Institute (RI), Veterans Health Administration, University of Texas School of Health Information Science, Oregon Health Sciences University, Kaiser Permanente, NextGen, Siemens Medical Solutions, and GE Healthcare. All organizations involved in the CDSC project are intimately involved in creating and providing CDS tools and services in electronic medical records used in both academic settings as well as community-based physician office practices.

The primary contract holder for this project is Brigham and Women's Hospital, and the team is led by project director Blackford Middleton, MD, MPH, MSc, FACP, FACMI, FHIMSS.

Project Plans and Goals for Option Year One

The primary focus for the third year was to continue the efforts initiated in the foundation years to develop, implement, and evaluate CDS demonstration projects.⁸

Implementation

- Identify best practices for CDS features, functions, and knowledge management, and make recommendations to vendors and certification authorities.
- Facilitate the translation and specification of clinical knowledge into human- and machine-readable artifacts, and share knowledge via a portal or Web interface.
- Demonstrate CDSC services in two organizations with the aim of illustrating that a service-oriented architecture (SOA) approach to CDS is feasible and beneficial, thereby making guideline content interoperable, reliable, and reusable.
 - Continue with the implementation of CDS services and tools in the Long Term Medical Record (LMR) within four designated Partners HealthCare Service (PHS) practices for at least a 6-month demonstration and evaluation. Implementation was initiated in the previous year at the following four sites:
 - Massachusetts General Hospital Back Bay primary care group.
 - Brigham Primary Physicians at Faulkner.
 - Brigham and Women's Primary Care Associates of Brookline.
 - Brigham and Women's Hospital Foxboro.
 - Implementation at an additional member site (RI) will consist of (a) integrating the newly developed, publicly available Web service (Enterprise Clinical Rules Service [ECRS]) with the CareWeb EMR of the RI, and (b) piloting the demonstration at two Wishard Outpatient clinics of RI to coincide with the go-live of the CareWeb user interface at those sites.
 - The CDS dashboard created in the previous year informs the end user regarding compliance with CDS recommendations produced in the demonstration projects. CDSC planned to continue to support and enhance the dashboard. An additional goal for the third year was to develop a dashboard development guide with the purpose of defining a standard approach to developing a CDS dashboard.

Evaluation

- Evaluation plans for the third year of the project focused on specific elements of the infrastructure for the implementation and demonstration efforts. Some of the key evaluation activities planned for the third year included the following:
 - Assessment of the current state of vendor-based CDS and the readiness of vendors to participate in service-oriented CDS.
 - Evaluation of supporting infrastructure, including eRoom collaboration environment, CDSC knowledge portal, and dashboard usage evaluations.
 - Evaluation of CDSC services and demonstrations.

Dissemination

- The knowledge and experience gained in the process of implementing these CDS demonstration projects will be disseminated widely, in the form of products for general consumption and customized versions that target specific interests and specialties.
 - The findings will be disseminated through academic publications and presentations, as well as the appropriate reports for AHRQ.
 - CDSC team also planned to generate CDS best practices recommendations for specific groups such as clinicians, guideline developers, quality assurance specialists, and health IT policymakers.

Project Design and Methods

The CDSC project design consisted of a 5-prong strategy in which knowledge translation, specification, and management efforts provided the foundation and ongoing infrastructure for implementation and evaluation. For knowledge translation and specification, the CDSC developed a four-layer knowledge representation stack building from unstructured format (Level 1) to semi-structured format (Level 2) to structured format (Level 3) to machine executable format (Level 4). Information from the knowledge lifecycle assessment is used to define best practices for translating narrative clinical guidelines into an array of reader-friendly educational materials and public Web services.

The CDSC's technical development work and implementation strategy were envisioned to occur in a centralized way, with organizations accessing and downloading CDS tools through a server-based portal. The CDS tools are designed to process standardized data produced by the local EMR, with minimal on-site support. The core strategy for each service demonstration is to integrate the publicly available Web service, ECRS, with the existing EMR at the demonstration site. An evaluation will be conducted to document lessons learned from each implementation site.

Accomplishments for Option Year One

Work conducted in the first two years laid the foundation for the work done in the third year. Efforts in the third year focused on continuing the ongoing implementation that was in its initial stages at the end of the second year, utilizing the lessons learned to refine efforts in the new year, and initiating or continuing the evaluation efforts.⁹

Implementation

Knowledge translation, specification, and management activities:

- The CDSC semi-structured specifications (Level 2) were harmonized with the GEM.
- Level 2 and level 3 (semi-structured and structured) knowledge specifications were further refined based on user experiences, changes needed for modality specific content, and for GEM mapping. Modeling of two additional CDS modalities, order sets, and referential content for use with InfoButtons were completed.
- Several enhancements were made to the guideline editing and authoring tool including improved infrastructure and internal code optimization for robustness, portability, efficiency, and maintainability; more efficient and flexible schema support infrastructure and mechanisms; progress in clean up and improvement of style sheet templates; refined user-friendly startup & document loading, etc.
- CDSC developed dashboards separately for providers and developers; users were trained in fully utilizing all capabilities of the dashboards. Additionally, a Dashboard Developer's Guide was created to standardize the process of creating dashboards across all CDSC member sites.

Integration and demonstration activities:

- Initial steps for integrating ECRS with a second member site, RI's EHR CareWeb, were completed. These included establishing and testing connectivity between RI, PHS, and the ECRS, and setting up third-party signed digital certificates for production and quality assurance for data to be sent to PHS from RI.
- Service demonstration at RI could not be initiated due to several unanticipated challenges and barriers (see below).
- Phase I of the service demonstration at the four designated practices of the PHS listed earlier was completed this year. The CDS service rules developed in the base year for diabetes, coronary artery disease, and hypertension were used throughout the duration of the demonstration.

Evaluation

Numerous assessment and evaluation activities were undertaken with a focus on user satisfaction, system performance, and effectiveness of services provided. Some of the key evaluation activities are summarized below.

- The current state of vendor-based CDS and the readiness of vendors to participate in service-oriented CDS were assessed by visiting three content vendors representing commercial producers of order sets, medication content, and referential content. The overarching themes from this assessment were: (a) end users (health care organizations and individuals), EHR vendors, and content vendors all need to cooperate to reach their shared goal of better health care and (b) content vendors consider themselves simply a source of evidence-based information; this information is used by EHR vendors for display in EHR systems. The responsibility of appropriately utilizing this information within an EHR remains with the care provider who must use his/her judgment while utilizing this information.
- Evaluation of CDSC services and demonstrations is in progress. Site visits with PHS and RI assessed how well the CDSC services worked in the field. The CDSC team evaluated CDSC service performance and accuracy as well as acceptance of service delivered by clinicians and clinical performance. Overall, the findings indicate that services performed well and that acceptance of service-delivered reminders was as good as, or better than, performance of conventional reminders.⁹ The synthesis of findings from these site visits is in progress.

Dissemination

- Twelve papers on various topics related to the work of CDSC are in different stages in the publication process, including some that have been accepted for publication by various journals. Several posters and session presentations were made at various meetings and conferences during the year.
- Best practices recommendations were prepared and submitted to AHRQ for specific groups, including health IT policy groups, quality measure developers, and clinical professional organizations.

Challenges Encountered

Project Organization

- Collaboration efforts of the CDSC with the Advancing Clinical Decision Support (ACDS) project funded by the Office of the National Coordinator (ONC) were complicated by limited project-specific access to eRooms.

- The developer for the editing and authoring tool left Partners HealthCare Service (PHS) to pursue other opportunities; delays were experienced in finding the replacement developer.
- Resources allocated for the dashboard development guide when planning for the third year of the project proved to be inadequate and posed some management challenges.

Technical

The technical challenges encountered by the CDSC team across all task categories include the following.

- Technical issues related to peculiar characteristics of the Web browser (Mozilla Firefox was too cumbersome), search engine (Yahoo! was slow and complicated), and collaboration tools (eRoom has a steep learning curve) posed some challenges in the speed and efficiency of the work to be completed.
- New processes such as the purchase and installation of a third-party signed digital certificate for the RI quality assurance platform were delayed due to other competing priorities.
- RI was unable to establish message encryption using Security Assertion Markup Language; as a result, only connection encryption was established, which is not an ideal security approach.

Governance and Legal Issues

- Issues ranging from identifying the appropriate entity to sign the documents to clarifying the identity of CDSC as a research entity v/s a vendor to clarifying differences in two sets of intellectual property affected the process and timeline for resolving legal issues to the extent that implementation had to be pushed to next year.
- Differences in Institutional Review Board (IRB) standards created challenges requiring negotiation and compromises. PHS' IRB requires research-related data storage for seven years and RI wanted to store it only for 72 hours. Following discussions and negotiations, RI's IRB allowed data storage for a maximum of three years.
- Letters of understanding had to be developed to identify the roles and responsibilities of anyone interested in being involved or collaborating with the CDSC team, which was not anticipated at planning stage. Considerable time and efforts were spent in developing an agreement for involvement in the project in any form at any level.

- Reconciling the political and legal differences between content governance committee members of the CDSC and their unique local governance policies was challenging and time consuming.
- Content sharing on the CDSC portal remains challenging due to lack of clarity on liability, responsibility, and ownership issues.

Implementation

- The CDSC services at RI were being integrated with a new EHR called CareWeb. The deployment of CareWeb at the RI's Wishard Health Services was delayed by several months. The current infrastructure still cannot display CDSC reminders.
- Reports of slowness from the PHS clinics participating in the LMR demonstration caused them to halt the use of the services on two occasions for short periods of time.

Lessons Learned

- There is a disconnect between expectations and the reality of a CDS' ability to provide clear, definite, and accurate guidance to clinicians. CDS vendors push the liability risk back to the health care providers, who are expected to use their professional judgment. This needs to be taken into consideration in planning any CDS implementation effort.
- Inter-organizational collaboration, implementation, and service agreements must consider the following:
 - Each organization has its own staff, policies, and perspectives. Lawyers, administrators, and IRB will need to be educated and involved in discussions and negotiations on issues such as length of time for data storage, to issues around liability and ownership, to standards of security and encryption for data exchange.
 - All stakeholders within an organization should be involved from the beginning of the process. Completing a readiness assessment prior to initiating the integration efforts will be very helpful to both the service provider and the consumer sites.
 - Sufficient time and resources should be allocated to managing these inter-organizational issues at the planning stage of the project.
 - Sites are reluctant to share content due to liability concerns. Liability concerns are heightened in organizations that lack clarity about who is liable—the individual or the organization.
 - Each system has a unique workflow. CDS developers should avoid over-specifying interface components or insertion points.
 - Defining evaluation plans and criteria from the beginning helps in appropriately designing the system and making workflow re-design decisions.

- Health care settings and their various departments are often managing multiple projects. In the current environment of compliance with meaningful use requirements, many of them are experiencing transitions to new systems. This creates competing priorities that lead to unexpected delays in pilot projects such as the CDS implementation. Communication across different groups, planning, and managing interdependencies helps mitigate this risk.
- Evaluation and feedback should be sought from all stakeholders (programmers, analysts, clinicians) across all levels of involvement (mild, moderate, and heavy). Information from all locations and all formats should be accepted to collect comprehensive feedback.

Plans for the Next Year

Knowledge translation, specification, management, and supporting infrastructure tasks:

- Create specifications for additional modalities, which would include context-relevant patient data and documentation templates.
- Improve and enhance the developer's guide and the implementation packet for consumer sites external to the PHS.
- Enhance the knowledge portal based on high-priority content areas as determined by content governance committee.
- Continue to support and enhance the CDSC dashboard and distribute the dashboard development guide.

Implementation and evaluation tasks:

- Initiate the service demonstration at RI, since all legal agreements have been signed.
- Continue the CDSC service demonstration at PHS.
- Evaluation activities will continue from where they were at the end of the third year. For evaluations where data collection was completed, analyses will be conducted. For evaluations where the data collection was still in progress, efforts will be undertaken to complete the data collection and conduct analyses during the fourth year of the project.

Common Themes Across the Two Demonstration Projects

Knowledge Transformation as Foundation: Both projects require efforts to convert evidence-based guidelines and information into technology-mediated and -executed information that can be presented for CDS. Both projects have four steps or layers in conducting this conversion of raw data to information that can be used to design and implement CDS systems. The technical expert panel recommended that both projects standardize the nomenclature that would represent this process instead of using different terms that seem to represent the same

steps. A mapping of the models and approaches adopted by the two projects would help identify common factors, unique factors, and factors that may be missing in both models for an optimal CDS development effort. A toolkit consolidating the most significant aspects of knowledge transformation and implementation of CDS systems would prove beneficial for future efforts.

Uniqueness of Implementation Sites: Both projects generated lessons learned that highlighted the importance of recognizing the uniqueness of individual sites in planning and implementing CDS services. For CDSC, underestimating the time and efforts required to reach service legal agreements severely impacted the implementation. For GLIDES, plans and strategies had to be adapted to accommodate individual sites' unique requirements. These lessons will be useful to anyone undertaking CDS implementation efforts to better plan for dealing with each site's policies, perspectives, stakeholders, and technical and workflow requirements.

Public Sharing of Knowledge and Products: Both projects have developed models for transforming narrative, raw guidelines into technology-mediated CDS systems. In developing the models, applying them to different sets of guidelines, and testing them at multiple sites, several valuable products have been developed. In addition to the planned dissemination efforts undertaken by each project, TEP recommended providing more open access to the knowledge and products developed by these projects. Considering that content sharing even within the closed group of the CDSC project has been challenging, this task may require creative thinking and persistence for the larger CDS community to benefit from the knowledge and products developed by these two teams.

CDS and Quality Measures: Many similarities exist in the processes of developing CDS and developing quality measures. The tools and approaches to standardize CDS development process and eliminate ambiguities would benefit quality measure developers, as their efforts also focus on standardizing measure development and eliminating ambiguities. Both project leaders have participated in committees and groups that focus on quality measures development and standardization.

Liability and Ownership: The transformation of guidelines into technology mediated CDS systems to be used by clinicians brings into play multiple players (guideline developers, EHR vendors, clinicians) with ultimate implications for healthcare of patients. Liability and ownership issues related to the content and any impact the CDS systems may have on the patients are complex and challenging issues that need to be addressed by those involved in the development and use of CDS. Two key issues related to liability and ownership faced by CDS development and implementation teams are (1) who owns the guidelines that form the basis for CDS system development and (2) who is liable when something goes wrong due to the use of the CDS provided guidelines. Each involved party tends to pass along the responsibility for the use and impact of CDS on to another. Too many ambiguities exist with legal experts arguing whether CDS is a service or product, which drives the legal standards for liability and implications for ownership and entity that is liable. The TEP members have noted that these ambiguities and fear of being held liable creates resistance in the adoption of CDS systems.

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Acronym Reference List

AAO-HNS	American Academy of Otolaryngology-Head and Neck Surgery
AAP	American Academy of Pediatrics
ACDS	Advancing Clinical Decision Support
AHRQ	Agency for Healthcare Research and Quality
BridgeWiz	Building Recommendations in a Developer's Guideline Editor
CDS	Clinical Decision Support
CDSC	Clinical Decision Support Consortium
CHOP	Children's Hospital of Philadelphia
ECRS	Enterprise Clinical Rules Service
EHR	Electronic Health Record
EMR	Electronic Medical Record
GEM	Guideline Elements Model
GLIA	GuideLine Implementability Appraisal
GLIDES	GuideLines Into Decision Support
IRB	Institutional Review Board
LMR	Long Term Medical Record
ONC	Office of the National Coordinator for Health Information Technology
PHS	Partners HealthCare Service
RI	Regenstrief Institute
ROP	Retinopathy of Prematurity
RSV	Respiratory Syncytial Virus
SOA	Service-Oriented Architecture
TEP	Technical Expert Panel
XML	eXtensible Markup Language