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

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Acronym Reference List

AAO-HNS	American Academy of Otolaryngology-Head and Neck Surgery
AAP	American Academy of Pediatrics
ACEP	American College of Emergency Physicians
ACO	Accountable Care Organization
AHRQ	Agency for Healthcare Research and Quality
ASCO	American Society of Clinical Oncology
ASTM	American Society for Testing and Materials
ATS	American Thoracic Society
AUA	American Urological Association
BridgeWiz	Building Recommendations in a Developer's Guideline Editor
CCD	Continuity of Care Documents
CDS	Clinical Decision Support
CDSC	Clinical Decision Support Consortium
CHOP	Children's Hospital of Philadelphia
CIRD	Clinical Informatics Research and Development
CPT	Current Procedural Terminology
DEcIDE	Developing Evidence to Inform Decisions about Effectiveness
ECRI	Emergency Care Research Institute
ECRS	Enterprise Clinical Rules Service
EHR	Electronic Health Record
EKG	Electrocardiography
EMR	Electronic Medical Record
GE	General Electric
GEM	Guideline Elements Model
GLIA	GuideLine Implementability Appraisal
GLIDES	GuideLines Into Decision Support
HL7	Health Level 7
ICD-9	International Classification of Diseases, 9th Revision
IRB	Institutional Review Board
IT	Information Technology
LMR	Long Term Medical Record
NHLBI	National Heart, Lung, and Blood Institute
PCMH	Patient Centered Medical Home
PETS	Partners Enterprise Terminology Services
PHS	Partners HealthCare Service
RI	Regenstrief Institute
ROP	Retinopathy of Prematurity

RSV	Respiratory Syncytial Virus
SME	Subject Matter Expert
SNOMED	Systematized Nomenclature of Medicine
SOA	Service-Oriented Architecture
TEP	Technical Expert Panel
VMR	Virtual Medical Record

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Introduction

Clinical decision support (CDS) is defined as a "health information technology (health IT) functionality that builds upon the foundation of an electronic health record (EHR) to provide persons involved in care decisions with general and person-specific information, intelligently filtered and organized, at point of care, to enhance health and health care."[1] CDS systems are

are typically designed to integrate a medical knowledge base, patient data, and an inference engine to generate case-specific advice. CDS systems are 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.

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."[3] 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., Electrocardiography [EKG] interpretation and drug-drug interaction checking)."[4]

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 Agency for Healthcare Research and Quality (AHRQ) Health IT Portfolio has focused on several CDS initiatives. Details on these initiatives can be found at http://healthit.ahrq.gov/portal/server.pt/community/ahrqfunded_projects/654/clinical_decision_support_initiative/13665.

In 2008, 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 3 years. An additional 1 year (Option Year 1) was funded followed by funding for another year (Option Year 2). This report summarizes the work undertaken in that Option Year 2. 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 fourth year (March 2011 to June 2012) 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.

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 3 years. In 2011, the second option year was executed to continue implementation and evaluation efforts in both projects. Another option year has been approved for each project, and that work will be discussed in next year's report.

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

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 2 years, GLIDES transformed narrative clinical guidelines into computer-mediated CDS for asthma and pediatric obesity, and initiated implementation in specialist and primary care settings.[5] For details on the approach, tasks, and the progress during those 2 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 at additional sites, with changes and enhancements based on lessons learned in the first 2 years.[6] For details on the accomplishments and lessons learned during that third year, please refer to the report "Implementing Clinical Decision Support (CDS) Systems: The Experiences of AHRQ's Demonstration Projects— Second Annual Report" at http://healthit.ahrq.gov/portal/server.pt/gateway/PTARGS_0_11699_955507_0_0_18/Support_for_CDS_Option_Year_1_EOY_report_final.pdf.

The fourth year of the project focused on continuing the ongoing implementation efforts and adding new partners, and initiating evaluation of implementation efforts with existing partners.

Project Team for Option Year Two

The primary GLIDES contract is with the Yale University School of Medicine. The partners from previous years included Yale New Haven Health, Nemours, 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). Nemours completed and closed out the project in the third year. In the fourth year of the project, the GLIDES team expanded its pool of partners to include Alliance of Chicago, the American Urological Association (AUA), and the American Society of Clinical Oncology (ASCO). 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 Two

The primary goals of this demonstration project continued from the previous year with enhancements to the specific objectives under each goal.[5]

Implementation

- Using systematic and replicable processes, continue to design, develop, implement, and demonstrate guideline-based CDS with specific objectives to include—
  - Consolidate key conclusions and lessons learned for CDS development through collaborative interactions with the multiple implementation partners and engaging new advisors and experts.
  - Develop a set of tools and methods that is systematic, replicable, and documented based on successful practices and lessons learned from the multiple implementation demonstrations.

Guideline Development

- Work closely with guideline developers to provide tools and guidance to improve guideline development and reporting processes;
  - Expand the pool to include additional guideline developers, potentially including such developers as National Heart, Lung, and Blood Institute (NHLBI), the American Thoracic Society (ATS), AUA, ASCO, the American College of Emergency Physicians (ACEP), the American College of Chest Physicians (ACCP), and Developing Evidence to Inform Decisions about Effectiveness (DEcIDE).
  - Formalize the recommendations and then focus on dissemination to other guideline development organizations, with emphasis on promotion of software tools.
- 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 Formalization** is the process of translating narrative guidelines into structured knowledge that can be implemented consistently as automated CDS.

- **Knowledge Integration** covers the activities necessary to design and build a local CDS solution.

- **Knowledge Implementation** includes project organization, management, and evaluation activities necessary to implement the CDS in clinical settings.

Tasks and Accomplishments for Option Year Two

- **CDS Implementation.** The four-pronged 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 have been adapted and used to construct complex CDS applications at multiple sites. Three sites continued the implementation efforts from the previous year while a fourth new site was added as the new partner for the fourth year of the project. The four GLIDES implementation sites were as follows:

  – Yale – New Haven Health System – previous year site;

  – CHOP – previous year site;

  – Geisinger Health System – previous year site; and

  – Alliance of Chicago – new site.

- **Yale – New Haven Health System** implemented and evaluated Asthma CDS in the previous year and one of the major findings of that evaluation was that the pulmonologists avoided using the CDS in real time by making notes on a paper-based

clinical inventory. The GLIDES and Yale-New Haven team piloted the patient-centered data capture project using iPad tablets to address this problem. Under this program, patients entered on a tablet their interim history, which is necessary to trigger the CDS, and the information is only available to the provider within the EHR/CDS. The team continued to enhance, improve, and document this pilot project in the fourth year.

- **CHOP** implemented the Premature Infant Assistant, a CDS application for the management of premature infants. This CDS application was applied to two policy statements/guidelines from the American Academy of Pediatrics: (1) Retinopathy of Prematurity (ROP), and (2) Respiratory Syncytial Virus (RSV) and Palivizumab. GEM was used to transform the policy statements into 100+ rules applied to 30+ patient variables that were extracted from the EHR. CHOP involved more than 25 clinicians in conducting several user interface and workflow design and development sessions. Thus, the CDS application development process was extremely user-centered with active participation from the user group and extensive use-case development and validation.

  In addition, CHOP also compiled premature infant parent education materials and integrated them with the EHR. This integration of education materials with the EHR facilitated the automated production of education materials customized to the unique needs of each patient.

  This implementation process was well documented throughout, allowing the CHOP team to create an extensive implementation guide detailing the overall architecture and development process used. This implementation guide can be a useful resource to anyone who wants to replicate the process. This guideline will be available to the public from GLIDES at the end of next year, the last year of the project.

- **Geisinger Health System** used GEM in the previous year to codify the guidelines for primary care management of lower back pain and used those coded guidelines to design an electronic patient questionnaire. In the fourth year, GLIDES provided support to generate rules for real-time application of management recommendations based on the feedback received from the patients. This application is provided on the CDS Web display for the provider in an exam room. The Geisinger team is audio-recording the interactions between the doctor and patients where consenting patients are randomly assigned to the eLowBackPain intervention group or the usual care group. The audio recordings will be analyzed to assess the differences between patient interactions in the two groups.

- **Alliance of Chicago** was the new partner added in the fourth year to the GLIDES team to implement clinical decision support. The Alliance team decided to customize and re-use the Asthma CDS developed by the Yale team. Both Yale and Alliance use the same vendor-provided EHR (General Electric's [GE] Centricity). This year's efforts focused on the design and customized development, and carefully noted the barriers to and facilitators of transferring a working CDS from one site to another with the same vendor EHR.

- **Improve Guideline Development Process.** In the fourth project year, the GLIDES team worked with four national guideline development organizations: AAP, AAO-HNS, AUA, and ASCO 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 continued to use the two main tools used previously, i.e., BridgeWiz (Building Recommendations in a Developer's Guideline Editor) and the GuideLine Implementability Appraisal (GLIA). In the fourth year, the team continued to refine and enhance these tools by incorporating feedback from collaborators. These tools enhance the implementability of medical guidelines and policy statements independent of the infrastructure used by the guideline implementers.

- **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. In the fourth year, GEM III was submitted to the American Society for Testing and Materials (ASTM) for balloting as an international standard for representation of guideline knowledge. The team anticipates a successful balloting.[7]

  Recognizing the value of easily accessible GEM-processed guidelines, the GLIDES team worked closely with the team responsible for maintaining the National Guidelines Clearinghouse (NGC). Efforts in the fourth year focused on developing detailed specifications, design, project plans, and budget for "GEMification" of the NGC website.

- **Evaluation and Dissemination Activities.** Evaluation activities were undertaken at each of the implementation sites except the Alliance of Chicago, which was a new site this year. Initial evaluation at CHOP indicated that differential interpretation of the policy on Palivizumab administration would result in significant and costly differences in the eligible pool of patients. In addition, RSV care assistant was deployed to 20 general pediatric practices and was used to help manage the care of 343 patients in the first 2 months of the post intervention RSV season. Following this implementation, there was an increase in the number of eligible children (85 percent) who actually received at least one dose of Palivizumab compared to the previous RSV season (77 percent).

  The goal of the evaluation at Geisinger was to examine if the e-health back pain protocol resulted in better communication and decision making between patients and providers. Transcription and coding of the audio recordings of patients was completed this year. Results of the analyses will become available in the next year.

  At the Yale clinic where the iPad technology was implemented, all the pulmonologists expressed satisfaction with the system. Patients were able to use the system with minimal training and expressed satisfaction while the registrar staff were able to distribute the iPads without any trouble or additional burden.

  As part of the dissemination effort, nine publications focusing on different aspects of the work on the project were generated by the GLIDES team. Five were published in professional journals, while others were in review or revision stages. Numerous (approximately 21) presentations, posters, and webinars at local, national, and

international meetings and conferences provided another method of disseminating information about the project work and outcomes.

Challenges Encountered

- Implementation delays were a common problem across multiple sites, which had an impact on the overall timeline for subsequent tasks and plans. The reasons for delays varied slightly across sites. At CHOP, greater time and efforts in user testing and incorporating usability improvements caused delays. At Geisinger, requirements of the Institutional Review Board for a separate review and additional technical developments to customize to the individual site systems required additional time, effort, and resources with an impact on timeline and budget.

- Stakeholder involvement and buy-in remained challenging across multiple sites. This included not only the need to convince the stakeholders about the value of CDS but also negotiating the busy schedules of clinicians in engaging them in planning and decision making during the process of implementation.

- Issues with translating published guidelines into CDS was another challenge experienced during the implementation process this year. Additional efforts were required in forming an expert panel of clinicians to review, research, and make informed decisions to address ambiguity and gaps in guideline document translations.

- Inconsistency and poor data organization and quality within an EHR caused challenges for developing the CDS that depends on the EHR data for effective implementation. Additional analytics/reporting were required prior to development to test and validate the required data sources and queries.

- Funding source limitations to purchase hardware caused challenges in expanding the program beyond the pilot at the Yale-New Haven implementation site. This remains an unresolved issue.

- Issues unique to the new implementation site such as differences in technical specifications, workflow, clinical policy, and other factors made even a previously used CDS intervention challenging.

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. One of the sites implemented a previously developed and used CDS intervention, which provided a unique perspective and lessons learned during this year. 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.

- Involving high-level stakeholders and frontline clinical user groups from the very beginning stages of planning and decision making through development and testing remains a critical factor in the success of CDS implementation.

- The current approach and state of published guidelines make them impossible to use for CDS implementation without considerable effort in reviewing, revising, and making informed decisions to translate them into CDS rules. Until the guideline development approach changes, implementing entities will need to plan and prepare for this task.

- CDS rules, definition, and implementation depends on the data from the EHR. Until data standards are enforced across all EHRs, implementation teams will need to focus on reviewing, analyzing, and testing the data sources, quality, and consistency to ensure that they are compatible with the CDS rules.

- Each implementation site will have its unique needs, requirements, technical specifications, Institutional Review Board (IRB) rules, workflow issues, and user perspectives. These need to be taken into consideration while planning the timeline, budget, and tasks for each implementation even when a previously developed CDS is being re-used at a new site. In addition, the standard CDS should be flexible enough to accommodate the customization for each site while maintaining the core elements.

- For pilot demonstration projects, provisions need to be made from the very beginning for alternative funding sources for expansion and sustainability beyond pilot sites and time periods.

- Delays in the implementation timeline and resultant expending of resources beyond the budgeted amount is almost inevitable. Thus, keeping a reasonable margin in planned timelines and resources is important for accommodating these issues during implementation.

Plans for the Next Year

Next year will be the final year of the project. Thus, efforts will primarily focus on completing ongoing implementation, conducting evaluations, planning for sustainable products for the use of the larger community, and setting up alternative options for sites to continue expansion or maintain current CDS systems.

- GLIDES began the development of the repository, which will be a resource developed based on all the cumulative experiences of the GLIDES team and their collaborators. The repository will be a Web application to provide public access to knowledge, tools, and resources developed by GLIDES.

- Work on providing GEM-processed guidelines on the NGC website—the "GEMification" of the NGC website—will continue in the next year. The Emergency Care Research Institute (ECRI), the contractor responsible for maintaining the NGC website and a GLIDES collaborator, has provided draft specifications and designs, project plans, and budgets to the GLIDES team. These plans will be reviewed and finalized before submitting to AHRQ, which is also sponsoring the NGC.

- GLIDES will continue to develop the knowledge and transformation toolkit by enhancing GEM and related tools for the creation of implementable guidelines and the transformation of guideline knowledge into rules. GLIDES team will make efforts to formalize the GLIDES methodology toolkit for implementation based on experiences on this project. This toolkit will be updated and formalized for dissemination in this final year of the project.

- At CHOP, implementation will continue and evaluation will be completed. At Alliance of Chicago, development will be completed followed by implementation and rollout at multiple sites. At Yale, a document outlining the complexities involved in the use of patient-centered data collection device in an enterprise environment will be finalized and delivered. At Geisinger, analyses of the audio-recording of patient interaction with providers will be completed and evaluation findings will be disseminated.

- Evaluation of implementation efforts will be initiated at new sites and continue at old sites with the purpose of completing and disseminating the findings.

- Work with the various guideline development partners, old and new, will continue this year.

- New partnerships and collaborations identified and initiated in the previous year will be further developed in the next year.

Clinical Decision Support Consortium

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.[8] At the end of the 2-year contract, a third year (Option Year 1) was funded by AHRQ, followed by a fourth year (Option Year 2) to support the continuation of implementation and demonstration efforts of the CDSC team. This report provides the details of tasks undertaken during this option year 2.

Project Team for Option Year Two

While the core team of the CDSC remained the same as during the first 3 years of the project, providing stability and consistency, several new collaborators were added to the team. 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 (VHA), 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, M.D., M.P.H., M.Sc.

Project Plans and Goals for Option Year Two

The primary focus for the project's fourth year was to continue the efforts initiated in the foundation years to develop, implement, and evaluate CDS demonstration projects.[9] Overall, while the goals did not change for this year, the specific activities undertaken during this year built upon the experiences and activities initiated in the previous years.

Implementation

- Identify best practices for CDS features, functions, and knowledge management by making site visits, and based on the best practices identified make recommendations to vendors and certification authorities.

- Continue to facilitate the translation and specification of clinical knowledge into human- and machine-readable artifacts, and share knowledge via a portal or Web interface.

- Expand the previously created multilayered knowledge representation model by including modality-specific representations.

- Initiate demonstrations at sites with vendor-provided EHR Systems with the purpose of demonstrating cross-platform utility. One site uses a system from NextGen and another site uses an EHR provided by GE.

- Continue demonstrations that were initiated in the previous year at two sites 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 the Partners HealthCare Service (PHS) practices.
  - Continue implementation at Regenstrief Institute.
- The CDS dashboard created in the previous years informs the end user regarding compliance with CDS recommendations produced in the demonstration projects. In addition to continuing to support and enhance the dashboard, CDSC planned to conduct a feasibility analysis for the reimplementation of the CDS dashboards via an open source reporting tool.

Evaluation

- Evaluation plans for the fourth year of the project focused on continuing previously initiated evaluation activities and providing support to various evaluation teams.

Dissemination

- The team planned to widely disseminate the knowledge and experience gained in the process of implementing these CDS demonstration projects both within the consortium and with the larger community.
  - For the consortium members and collaborators, the team planned to disseminate its products through the knowledge management portal.
  - The team planned to disseminate its findings through academic publications and presentations, as well as the appropriate reports for AHRQ.

Project Design and Methods

The basic model of centralized CDS services provided to multiple clinical sites and vendors continued to be the fundamental approach for all work undertaken in the fourth year. Within this framework, this year's work consisted of solving problems, making enhancements, and exploring new options and approaches at all levels of knowledge translation, management, and implementation. Below is a review of the underlying project design and model as a context for the details on tasks for this year.

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 an unstructured format (Level 1) to a semi-structured format (Level 2) to a structured format (Level 3) to a 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 from the very beginning 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, Electronic Correspondence Referral System (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 Two

Work conducted in the first 2 years laid the foundation for the work done in the third year, and work initiated in the third year was continued in the fourth year. Efforts in the fourth year focused on continuing the ongoing implementation initiated in the previous year, utilizing the lessons learned to refine efforts in the new year, and initiating or continuing the evaluation efforts.[10]

Implementation

Knowledge translation, specification, and management activities:

- The team reviewed, updated, and maintained CDSC's content by scanning the literature and other sources to organize, prioritize, and frame issues for review first by subject matter experts (SMEs) and then with collaborative teams to finalize the proposed resolutions.

- Produced a model for representing modality-specific CDS knowledge artifacts such as order sets, info buttons, relevant data displays, and reminders/alerts. The CDS knowledge was represented in the form of actions, behaviors, presentations, and definitions.

- Refined the metadata structure to remove items that were not being used, better define existing elements, and define value sets for some elements.

- Several enhancements were made to the guideline editing and authoring tool. These enhancements included revising the templates to allow better use of space and increase efficiency; better integration of the tool with the knowledge representation schema making it easier to use and less prone to errors; and improving the overall programming efficiency.

- In order to support some new consumers who used International Classification of Diseases, 9th Revision (ICD-9) and/or Current Procedural Terminology (CPT), several ICD-9 and CPT subsets were built into the subset editor. The team created a refined

framework for building value sets for these new codes, published and released the actual value sets, and built and refined class rules for these codes.

- In order to identify the next set of rules to be programmed into CDS, a workgroup was formed to rank the top 50 most common diagnoses. This was done by gathering data on the top 200 most frequently billed ICD-9 diagnoses in the first 6 months of 2011, for inpatient and outpatient settings. Data were gathered from four of the CDSC collaborators. This work is still in progress.

Integration and demonstration activities:

- Demonstration of CDS services continued at PHS and improvements were noted in the creation of Continuity of Care Documents (CCD).

- Service demonstration at RI went live during this year after many legal challenges in the previous year delayed implementation.

- NextGen (an EHR vendor) worked on enabling their EHR to connect with the CDSC's CDS Web service using a CCD.

- The CDSC team began working with another new vendor (GE) late in the year to enable their EHR to connect with the CDS Web service using a CCD as input.

- Overall, the CDSC team continued to provide support for PHS ECRS at all demonstration sites in conjunction with the site teams and the service provider teams utilized by the ECRS.

Evaluation

- CDSC demonstration and service teams worked together to evaluate service performance and accuracy, acceptance of service delivered, 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 acceptance of conventional reminders.[9]

- The team performed an initial evaluation of ten open-source business intelligence suites in order to determine the feasibility of implementing the CDSC dashboards using a free open-source tool. Analyses of that evaluation is in progress and results will be available later this year.

Dissemination and Collaboration

- During this year, the CDSC continued to expand its membership in various categories. Eight new organizations joined the CDSC as collaborators and one organization joined as observer. The level of access and read/write capabilities vary among these different levels of memberships. Service sharing agreement with RI was amended to include all its sites as potential users of the CDS Web service.

- Internal dissemination: Considering that the team of collaborators within the CDSC has been growing, the collection, management, and dissemination of knowledge and resources internally among all collaborators became a significant task. The knowledge management portal developed in the previous years is the main platform for this kind of dissemination. All content developed under various task categories were made accessible to all collaborators by posting them on the portal.

- In terms of public dissemination, besides presentations at various meetings related to work conducted by CDSC, one paper was published in a professional journal, one presentation received a distinguished presentation award at a national conference, and one paper has been accepted for presentation at a conference later in the year.

Challenges Encountered

Project Organization

- While the knowledge management portal serves a critical function for providing easy access to all knowledge artifacts for all collaborators, the allocated resources required to meet the needs and demands of the community proved to be inadequate. Thus, many requests for reasonable enhancements to the portal had to be rejected.

Technical

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

- Expanding the use of originally developed structured recommendation schema in the knowledge stack to accommodate knowledge required for different CDS modalities proved to be very challenging.

- Enhancements to the knowledge authoring tool to accommodate transformation of rules from individual sites to the sharable format and to enable validation of knowledge artifacts automatically proved to be far more challenging than anticipated. The process was slowed down considerably due to frequent encounters with errors and bugs. The teams had to adapt and adopt different approaches including manual translation of rules.

Implementation

- Reconciliation of clinical practices, documentation, data coding, and terminology used at clinical practices with the ECRS rules to generate appropriate CDS was the biggest challenge faced at all implementation sites. This significantly affected the timeline and pace of implementation at all sites.

- There were delays in the rollout of RI's EHR, CareWeb, which impacted the CDS implementation.

- The third-party security certificate signed for exchanging data between RI and PHS ECRS expired within 6 months leading to additional work and delays.

- Not all sites were able to send data for the analyses to identify the high priority diagnoses for rules development. This resulted in adapting the evaluation plans to include a smaller number of institutions and smaller amount of data for analyses.

Lessons Learned

- The knowledge representation schema needs to be dynamic and continually evolving to accommodate changing needs and requirements.

- Diligently documenting and tracking current issues, new errors and bugs, and solutions that worked in the development of a knowledge management database is extremely important. This kind of tracking will save considerable time and effort if the process needs to be replicated for a new, similar site for implementation.

- As long as there are differences in individual vendor EHR systems, diagnosis and procedure coding (Systematized Nomenclature of Medicine [SNOMED], CPT, ICD-9), and terminology used at individual implementing sites, CDS implementation entities will need to expend considerable time and resources in mapping them and reconciling differences.

- The performance profile of implementation sites should be assessed extensively before finalizing the selection of clinics and planning implementation. Already poorly performing network systems will significantly impact the performance and acceptance of CDS systems.

- Many of the lessons learned were unique to the CDSC model of a centralized CDS service system:

  – With reference to centralized models such as the CDSC, it is important that the CDS systems are continuously monitored with complete and consistent feedback loops within all individual systems of the collaborative consortium. This continuous monitoring and feedback loop is essential for CDS development within the consortium and in the larger community.

  - A centralized Clinical Decision Support Systems (CDSS) like the ECRS has to have the ability to adapt to the heterogeneous data that come from multiple healthcare facilities.

  - While CCD standards are subject to interpretation, a CCD continues to be an important input for CDSS like ECRS to provide appropriate CDS. CCDs are only as complete and robust as the EHR systems that create them. The CDSS has to be robust in processing and responding to data in the form of a CCD in spite of the human and machine errors originating in the EHRs.

  - Integration of a centralized CDS Web service with a vendor/commercial EHR system is much more challenging than the integration with individual site owned/home-grown systems as there is far less flexibility with vendor systems.

- Open source is not the same as free open source. An active, thriving, and extremely responsive community is vital to a meaningful user experience with open source systems. Responses to the needs and requests of the users of open source software are influenced by the business interests of the company.

- Overall, involving stakeholders at all levels, collecting and responding to user feedback, and keeping the CDS design user-centered is important for CDS acceptance in practice settings.

Plans for the Next Year

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

- The CDSC team will explore the potential for adopting Health Level 7 (HL7) Virtual Medical Record (VMR) standard specifications.

- The team will continue to develop the knowledge authoring tool to make it more user-friendly and make it available publicly for early validation of new knowledge artifacts.

- Efforts will be coordinated between Partners Enterprise Terminology Services (PETS), Patient Factory, and ECRS to develop new classification rules for ICD-9 subsets.

- Work will continue in identifying the high priority diagnoses to be programmed into rules for CDS.

- Potential for an open source re-implementation of the knowledge management portal will be further explored.

Implementation, management, and evaluation tasks:

- CDSC demonstration efforts will continue at all four sites: PHS, RI, NextGen, and GE.
- As the ECRS becomes more complex and CDSC adds more consumers, the team will continue to expand CDS service and infrastructure monitoring capabilities.
- Efforts to keep the project, products, and work sustainable beyond the next year after AHRQ funding ends will continue during the fifth year of the project.
- Evaluation activities will continue from where they were at the end of the third year. For evaluations in which data collection were completed, analyses will be conducted. For evaluations in which the data collection were still in progress, efforts will be undertaken to complete the data collection and conduct analyses during the fifth year of the project.

Technical Expert Panel Meetings

During Option Year 2, three of the four planned TEP meetings were conducted by June 15, 2012, with the final meeting being scheduled for early August 2012. The underlying theme of the meetings throughout the year was "From Demonstrations to Standard Practice," with the purpose of discussing and facilitating the sustainability and durable results of the demonstration projects once their funding from AHRQ concludes. More details of each of the meetings are available at: http://healthit.ahrq.gov/portal/server.pt?open=512&objID=654&&PageID=14466&mode=2#presentations.

The schedule, specific themes, and some discussion highlights for each of the meetings were as follows:

1st Meeting, In-Person, on December 6, 2012
Meeting Theme: From Demonstrations to Standard Practice: Developing Sustainable Tools and Processes for CDS

Discussion Highlights:

Establishing Standards for CDS – There was emphasis on the need for accelerating the development of standards and interoperability to promote the sustainability of CDS. Vendors remain desperate for standards. Progress on interoperability is also needed, as the ability to share knowledge remains limited, even within organizations (let alone between them).

Centralizing CDS products – There was a call for greater attention to making existing GLIDES and CDSC products more usable by real-world implementers; usability studies may be helpful in improving them. Efforts should also be made to make the products easier to find. To facilitate interest, the various tools and resources should be clearly mapped to those factors driving increased interest in CDS, payment reform initiatives, including accountable care organizations (ACOs) and patient-centered medical homes (PCMHs).

Establishing a business case for CDS – As new payment models begin to reward quality and efficiency, providers may begin to see increased value in CDS systems that help to promote better care. Further, sustainability depends in part on having appropriately aligned incentives; those who benefit economically from HIT and CDS should pay for them.

Repositioning CDS – Many providers view CDS as a "computer telling them what to do." As a result, they react negatively to it. Yet these same providers want all the things that CDS actually does, including helping them determine when to refer patients, avoid duplicative testing and treatments, and customize orders to their patients' needs. Consequently, there may be a need to reposition CDS in providers' minds, which should improve the business case.

Importance of open-source knowledge – Attendees emphasized the relative importance of open-source knowledge versus open-source rules engines. Knowledge and knowledge representation should be considered the sustainable asset. Once knowledge is represented in the right way, different kinds of software and rules engines can be developed to allow for effective use of that knowledge. If the knowledge is not correct and up to date, however, CDS will have little or no value. One of the key challenges noted during the meeting, however, is the difficulty inherent in updating CDS as guidelines are continuously being updated.

2nd Meeting, Teleconference, March 7, 2012

Meeting Theme: From Demonstrations to Standard Practice: Who are CDS customers and what do they want?

Discussion Highlights:

Raising awareness and commercializing products – Products and services will not be adopted unless would-be users know about them and find them easy and valuable to use. In addition to representing a clearly better way to do something, the most successful products are easy to use. To achieve broad adoption, any complex processes that go on behind the scenes must remain invisible to the user.

Ability to customize – Would-be users may reject the idea of adopting something invented elsewhere. Consequently, there must be a way to customize the product and make it feel more like one's own. This manipulation and customization process must be easy, or the guideline will not be used.

A neutral party to facilitate access to tools – It would be useful to have a neutral party catalogue and facilitate access to knowledge artifacts and other CDS tools and services developed by the project teams. The end product must be customer-focused, making it easy to identify and access available products.

Public-Private Partnership – Specific parts of the infrastructure required to promote widespread use of CDS may not be sustainable in the private sector, and hence could require ongoing support from the public sector.

Leveraging Institute of Medicine (IOM) report – The IOM released a report in 2011 (http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx) that lays out recommendations to ensure that guidelines are both rigorous and trustworthy. The release of this report represents an ideal time to raise awareness of the many tools available to assist guideline developers and implementers.

3rd Meeting, In-Person, May 29, 2012

Meeting Theme: From Demonstration to Standard Practice (part 3) **–** CDS Products: Packaging and Marketing for the Customers

Discussion Highlights:

Need for translation from academic to commercial product – Some of the CDS tools developed by the demonstration projects should be translated from "academic" products into commercial products. Use of open-source technologies may not be the best way to make sure that translation occurs, as participating users will likely not fix the usability problems highlighted earlier. Rather, a separate entity may be needed to fund the translation to a commercial product that can be sold in the market. Products that are difficult and time-consuming will generally not sell unless some entity mandates that they be used. However, well-designed products that can help with guideline development and implementation will be well received.

Merits of open-source maintenance of knowledge – Attendees generally supported the idea of considering an open-source approach to the maintenance of some demonstration project tools. Some organizations may not have the ability to acquire new technology, but could commit resources and time to an open-source community. Many stakeholders will likely be interested in participating in open-source communities designed to maintain knowledge. Fewer may be interested in open-source software. Whenever this approach is used, the goal should be to find a community of like-minded individuals and organizations that takes "ownership" of the products.

Financial incentives for CDS – Today's payment systems still create misaligned incentives, with CDS-generated cost savings and/or quality enhancements generally not benefiting the purchaser economically. When such incentives are aligned, interest in CDS should accelerate. In the meantime, public support of CDS may be required for the next several years until the market can sustain itself.

Repackage and reposition product – Current users are not interested in CDS; rather, they are interested in what improves quality, reduces costs, and saves time and resources. The packaging and positioning of the product should focus on the outcome, not the process for getting there. Any repackaging effort should include careful consideration of the language used, with a focus on the value proposition being created for the user.

Importance of usability to system uptake – Presentation, language, terminology, and other features of the CDS system must fit into user expectations and workflows. Consequently, uptake of an exclusively cloud-based CDS system might be limited, since it would be difficult to customize the system to local preferences and requirements. From the physician's perspective,

usability also includes making sure that the appropriate person sees appropriate information. Alerts and reminders that require physician intervention should be brought to the attention of physicians, while those best handled by others (e.g., nurses, front-desk staff) should be routed to those individuals.

Need for common value sets – Vendors and other stakeholders are very interested in the development of validated, standard sets of codes (value sets) representing clinical concepts of interest that tie into both CDS and quality reporting systems. The National Library of Medicine or some other entity could potentially serve as the host of a repository of value sets, with stakeholders contributing to their development and maintenance, including critiquing and refining those already in use. Such a service would lower the barriers to suppliers of CDS services and to the development of sharable CDS systems.

From these meetings, there were three common themes that resonated throughout the year:

1. **Standardize CDS while encouraging customization –** The group expressed a need to develop standards for CDS that will allow various parties, including vendors, to exchange information in a consistent manner and hence increase the sustainability of CDS. However, even though CDS would be standardized, local organizations should still have the ability to customize CDS products to accommodate their unique local clinical processes and systems.

2. **Central resource/location for CDS information –** As the demonstration projects' contracts are coming to a close, it was recommended that details of the work conducted, outcomes, and products developed by the two projects be made accessible to the public in a user-friendly format. Further, there should be a central hub that provides necessary toolkits and information related to CDS products.

3. **Developing a business plan for CDS and marketing it –** The sustainability of CDS depends on making a strong business case for CDS. There needs to be more work outside the "academic framework" of CDS and a focus on aligning CDS with payment plans and financial incentives. Future work should involve developing an argument for the financial benefits of CDS and its positive impact on quality of care. Further, the group may need to address how to define, describe, and position CDS so that it is appealing to vendors, payers, and providers.

Common Themes Across the Two Demonstration Projects and the TEP Meetings

Knowledge Transformation Efforts. Both projects realize that the current state and approach for guideline development makes them impossible to implement for CDS without considerable labor-intensive review, revision, and informed decision making involving both the CDS service providers and the users of the CDS systems.

CDS and Standards. In the absence of universal standards for diagnosis and procedure coding, terminology used, and documentation practices at clinics combined with individualized design of EHR systems, CDS implementation teams will have to plan to expend considerable time, effort, and resources in reconciling all these differences at every site.

Open Source. Both projects, for different reasons, realized that use of open source platforms and software is not as easy as it may seem. Many complicated issues related to licensing, funding, support, and maintenance are involved with open source platforms and software.

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. Terminology mapping, customizing even a previously developed CDS for a specific site, reconciling local rules and practices with the rules in the CDS system, and individual policy issues were some of the tasks and issues unique to each site, which posed considerable challenges across both projects.

Documenting Details. Both projects recognized the importance of documenting in great detail the processes, issues, bugs, solutions, and decisions made in designing a CDS intervention for a specific site. Such documentation is helpful as new issues and needs arise for the same site over a period of time, as well as for a new site that is trying to implement a CDS guideline previously developed and used by another site.

EHRs as a Source of Data for CDS. The EHR being used by an implementation site is the primary source of a CCD, which in turn is the input that the CDSS relies on for generating CDS. Thus, quality and consistency of data from the originating EHR will greatly impact the quality, reliability, and usability of a CDS. This is an important factor to take into consideration in the design, implementation, and evaluation of a CDS intervention and a CDSS.

CDS Marketing and Packaging for Customers. There are some issues to be addressed with regard to identifying the customers for CDS and the appropriate packaging and marketing approach to reach out to these customers in the pursuit of widespread acceptance of CDS. Both projects struggled with these issues throughout the year and the TEP meetings focused on them as well. There was consensus that the groups that have to pay for CDS are often not the groups who benefit financially from CDS. Thus, the interests of various groups are not aligned, making it difficult to identify a definite customer to target the marketing and packaging approaches toward. Also, researchers from academic settings involved in these kinds of demonstration projects for CDS do not typically have the expertise in marketing and sales necessary to carry the work beyond the demonstration context, to implement CDS at scale.

Demonstration Projects and Sustainability. Publicly funded demonstration projects such as these two projects have a necessarily constrained purpose, scope, funding, and timeline with a definite endpoint. That endpoint is fast approaching for these two projects. Planning for sustainability of these efforts is critical, both in terms of keeping the academic work going after the original funding ends, and in terms of generating products that can outlive the funding stream, providing durable value to the larger community.

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