Challenges and Barriers to Clinical Decision Support (CDS) Design and Implementation Experienced in the Agency for Healthcare Research and Quality CDS Demonstrations

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Contents

I. INTRODUCTION

Overview of Clinical Decision Support

To improve the quality of medical care in the United States, efforts are being made to increase the practice of evidence-based medicine through the use of clinical decision support (CDS) systems. CDS provides clinicians, patients, or caregivers with clinical knowledge and patient-specific information to help them make decisions that enhance patient care.[1] The patient's information is matched to a clinical knowledge base, and patient-specific assessments or recommendations are then communicated effectively at appropriate times during patient care. Some CDS interventions include forms and templates for entering and documenting patient information, and alerts, reminders, and order sets for providing suggestions and other support. Although CDS interventions can be designed to be used by clinicians, patients, and informal caregivers, this report focuses on the use of CDS interventions by clinicians to improve their clinical decisionmaking process. In addition, while CDS interventions can be both paper and computer based, their application in the following projects is limited to electronic CDS because of its greater capability for decision support.[2]

The use of CDS systems offers many potential benefits. Importantly, CDS interventions can increase adherence to evidence-based medical knowledge and can reduce unnecessary variation in clinical practice. The process for development and implementation of CDS systems can establish a standard knowledge structure that aligns with written evidence-based guidelines published by medical specialty societies or Federal task forces, such as the U.S. Preventive Services Task Force (USPSTF). CDS systems can also assist with information management to support clinicians' decisionmaking abilities, reduce their mental workload, and improve clinical workflows.[3] When well designed and implemented, CDS systems have the potential to improve health care quality, and also to increase efficiency and reduce health care costs.[4]

Despite the promise of CDS systems, numerous barriers to their development and implementation exist. To date, the medical knowledge base is incomplete, in part because of insufficient clinical evidence. Moreover, methodologies are still being designed to convert the knowledge base into computable code, and interventions for conveying the knowledge to clinicians in a way they can easily use it in practice are in the early stages of development. Low clinician demand for CDS is another barrier to broader CDS system adoption. Clinicians' lack of motivation to use CDS appears to be related to usability issues with the CDS intervention (e.g., speed, ease of use), its lack of integration into the clinical workflow, concerns about autonomy, and the legal and ethical ramifications of adhering to or overriding recommendations made by the CDS system.[4] In addition, in many cases, acceptance and use of CDS systems are tied to the adoption of electronic medical records (EMRs), because EMRs can include CDS applications as part of computerized provider order entry (CPOE) and electronic prescribing (eRx) systems. This is evidenced by the results of the 2008 National Ambulatory Medical Care Survey, which show that only 38 percent of physicians used an EMR, and only 4 percent used an EMR with CDS system capabilities.[5]

Recent Federal and payer initiatives are providing support for EMR and CDS adoption. For example, the Agency for Healthcare Research and Quality (AHRQ) has funded CDS demonstrations. In addition, AHRQ and the U.S. Department of Health and Human Services Office of the National Coordinator for Health Information Technology (ONC) funded the development of a Roadmap for National Action on Clinical Decision Support and held workshops to support CDS system development and implementation. Most recently, the American Recovery and Reinvestment Act of 2009 (ARRA) created financial incentives through Medicare and Medicaid for providers to "meaningfully use qualified" electronic health records (EHRs). Under the Notice for Proposed Rulemaking (NPRM) for the EHR Incentive Program published by the Centers for Medicare & Medicaid Services (CMS), the criteria for meaningful use include the implementation of five CDS rules, including the ability to track compliance with those rules.[6]

The incorporation of evidence-based guidelines into an EMR by using CDS interventions that include quality measures may help align care delivery with payment incentives. Federal and private payers' current and proposed payment models offer incentives based on the quality of care provided.[7-10] CDS alerts, reminders, and standardized order sets can also help clinicians follow these guidelines and support the payment of clinicians based on their performance (e.g., pay-for-performance). In addition, CDS documentation can be used to evaluate care from a population-based perspective and to move from the measurement of care processes to the measurement of patient outcomes.

Overview of AHRQ's Clinical Decision Support Demonstration Projects

In 2008, AHRQ funded two demonstration projects in support of the design, development, and implementation of CDS systems. These projects aimed to:

- Incorporate CDS into EMRs that have been certified by the Certification Commission for Health IT (CCHIT).
- Demonstrate that CDS can operate on multiple information systems.
- Establish lessons learned for CDS implementation relevant to the health information technology (IT) vendor community.
- Assess potential benefits and drawbacks of CDS, including effects on patient satisfaction, measures of efficiency, cost, and risk.
- Evaluate methods of creating, storing, and replicating CDS across multiple clinical sites and ambulatory practices.

The projects were required to select two or more clinical practice guidelines in the public domain that had not yet been translated into a broadly available electronic CDS intervention.[11] The chosen clinical practice guidelines were to address either preventive services or management of multiple common chronic conditions. The contractors were then to implement the CDS intervention in at least one health IT product certified by CCHIT, applying American National

Standards Institute (ANSI) Health Information Technology Standards Panel (HITSP) standards when available and applicable. The CDS system being developed was to be demonstrated in ambulatory settings. In addition, the projects were required to evaluate methods for creating, storing, and replicating the CDS system across multiple clinical sites and EMR systems.

The two demonstration project contracts were awarded to Brigham and Women's Hospital (BWH) for its Clinical Decision Support Consortium (CDSC) project and Yale University School of Medicine for its GuideLines Into DEcision Support (GLIDES) project. Each project is funded 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.

Objectives of This Report

This report briefly describes the two AHRQ CDS demonstrations, as well as the challenges and barriers that the contractors encountered during the initial periods of their CDS demonstration project, how they addressed these obstacles, and the effectiveness of their strategies. The goal of this report is to share the experiences of the contractors throughout the planning, design, and implementation phases to aid others who are considering funding or undertaking similar efforts.

Methodology

The information for this report is based on the contractors' monthly status reports, project proposals, evaluation plans, and other documents submitted to AHRQ project officers. In addition, discussions were held with the contractors' staff onsite and by telephone from June to September 2009. A review of the general CDS literature was also performed in order to provide a context for the contractors' activities.

Terminology

The list below defines terms used throughout the report that may have multiple definitions. These definitions are used consistently throughout the document.

- "Guidelines" refers to written statements developed by medical specialty societies, disease-focused organizations, or expert panels to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.
- "Rules" refers to the abstraction of guidelines into programmable prediction statements (i.e., IF-and-THEN statements).
- "CDS Service" refers to a CDS functionality accessible over standard Internet protocols that is independent of the underlying EMR platform or programming language.
- "CDS intervention" refers to the variety of CDS applications (e.g., alerts, reminders, order sets) used to communicate knowledge to the clinician.
- "Knowledge management tool" refers to resources designed to assist with the extraction, evaluation, storage, and retrieval of guidelines, frameworks, pieces of code, and other

artifacts related to CDS system development (e.g., Documentum's Web Publisher, Content Management Services, the Guideline Elements Model (GEM) software tool GEMCutter, EXTRACTOR, Conference on Guideline Standardization (COGS) statement, Guideline Implementability Appraisal (GLIA)).

- SmartForm is an electronic form with electronic completion, dynamic sections, database calls, electronic submission, and other capabilities. It enables writing a multi-problem visit note while capturing coded information and providing sophisticated decision support in the form of tailored recommendations for care.
- Dashboard is a Web-based application available to clinicians that displays relevant and timely information to support clinical decisionmaking for patient care, quality reporting, and population management. Dashboards may support viewing of condition-specific information and/or functionality to take action (e.g., ordering of a lab test) from the application itself.

Organization of This Report

The remainder of this report is organized into three sections. The next section provides a description of each project and summary of the challenges and barriers faced by each of the contractors. This is followed by an analysis and discussion of their experiences. The last section offers overall conclusions and recommendations for future work to promote CDS design and implementation.

II. EXPERIENCES OF AHRQ'S CDS DEMONSTRATION PROJECTS

This section begins with a summary of the CDSC project and the experiences project staff has faced thus far. It is followed by a similar summary of the GLIDES project. Both summaries begin with an overview of the project and then present the challenges and barriers experienced, as well as the strategies enacted throughout the project planning, design, and implementation phases.

Clinical Decision Support Consortium

Overview of the CDSC Project

The CDSC project was awarded to Brigham and Women's Hospital and also includes Partners HealthCare System (Partners), an integrated health care system that includes primary care and specialty clinicians, community hospitals, two founding academic medical centers (including BWH), specialty facilities, and other health-related entities. For this project, BWH is collaborating with the Regenstrief Institute, the Veterans Health Administration (Roudebush Veterans Administration Medical Center), Kaiser Permanente, the University of Medicine and Dentistry of New Jersey (UMDNJ), MidValley Independent Physicians Association (MVIPA), and EMR vendors (i.e., Siemens Medical Solutions, GE Healthcare, and NextGen). Management

of and technical expertise for this project are provided by staff of the Partners HealthCare System's Clinical Informatics Research and Development (CIRD) group.

The CDSC project's goal is to assess, define, demonstrate, and evaluate best practices for knowledge management and CDS in health IT —across multiple ambulatory care settings and EHR technology platforms. The project is organized around six research objectives:

- Assessing the current state-of-the-knowledge management process and life cycle at a diverse set of clinical sites.
- Developing a four-layered model for knowledge translation and specification.
- Constructing a knowledge portal and repository.
- Building CDS knowledge content and Web services and conducting demonstrations of the services in real clinical systems.
- Evaluating the results of the research.
- Disseminating the results widely.

The CDSC project team is focusing on chronic disease management and prevention screening that are common in adult ambulatory care settings, with diabetes, coronary artery disease, and hypertension as the targeted conditions. The guidelines selected for the project are:

- American Diabetes Association's Diabetes Management Standards of Care.
- American College of Cardiology's guidelines on Antiplatelet Therapy Prescribed for Patients with Coronary Artery Disease.
- USPSTF recommendations on Aspirin for the Primary Prevention of Cardiovascular Events.
- USPSTF recommendations on Screening for High Blood Pressure.

In accordance with the CDSC project plan, the project team will translate these guidelines using a four-layer model, where the first layer is the narrative text of the guideline; the second layer is a semistructured representation; the third layer is a formally structured, unambiguous knowledge specification; and the fourth layer is computer executable. The project team will also create a Web-based service that will use the computer-executable version of the identified guidelines. These services will be available to all project collaborators. CDSC will build a knowledge portal and repository that will house all levels of these specifications. Other activities include building Dashboards to provide feedback on clinical performance and adherence to guidelines, evaluation of each project stage, and dissemination of project findings.

For the technical design and architecture of its CDS system, the CDSC project team is utilizing a service-oriented architecture (SOA) that uses the Health Level 7 (HL7) Continuity of Care Document (CCD) for the exchange of clinical information, and the ANSI HITSP-endorsed standards for data exchange and standard terminologies (e.g., SNOMED for problems, findings, and diagnoses; LOINC for laboratory observations; and RxNorm for medications) to achieve interoperability.

The CDSC project team intends to demonstrate cross-platform utility of its CDS system intervention within both homegrown and vendor-based EMRs. The CDSC project team first implemented the CDS Service module using Partners' Longitudinal Medical Record (LMR), Partners' homegrown EMR system, which is used by the majority of Partners' clinicians practicing in an ambulatory setting. After validation of the Partners model for CDS within its LMR, the approach would be attempted by the Regenstrief Institute (which has its own homegrown EMR), UMDNJ (GE Centricity EMR), and MVIPA (NextGen EMR). The goal is that collaborators will be able to send a set of pertinent clinical data via the CCD to the Web-based CDS Service, producing a result that can be relayed back to the originating system irrespective of platform or programming language and that can be displayed to the user in an appropriate format.

The technical implementer of this demonstration, the Partners CIRD group, has a long history of supporting health IT use among BWH's and other Partners' affiliated clinicians, including extensive experience with CDS systems. It has been a leader in the design of CDS interventions (e.g., Dashboards, SmartForms). Prior to this project, Partners CIRD began developing a knowledge management infrastructure, including governance processes, a knowledge repository, and tools to support the content management processes. Its infrastructure also supports clinical reminders for the conditions targeted for this project (i.e., diabetes, coronary artery disease, and hypertension). This project will build on and improve its CDS infrastructure, replace its clinical reminders with content developed for this project, and change the way reminders are delivered.

Challenges and Barriers Experienced by the CDSC Project Team

As of July 2009, the CDSC project team had completed the translation of the written guidelines and was near the end of its design phase. It was testing the technical implementation of the CDS Services and was preparing for trial implementation of the CDS intervention within Partners' LMR, which went live at the end of 2009.

Project Planning and Management

BWH's initial planning process began with the release of AHRQ's Request for Proposals in July 2007 and continued until its proposal submission to AHRQ 2 months later. With 2 months to design a project plan and proposal, BWH stretched to align collaborating organizations, conceptualize a strategy, devise an organizational chart, and develop a budget for 2 years of activities. Despite its considerable experience designing and implementing health IT projects of similar scope, the project's new and untried tasks proved challenging to incorporate into the project plan and budget.

As outlined in its original project plan, the CDSC project activities are organized into nine work areas, each with a corresponding work team that includes representatives of BWH and its collaborators. The project is managed by a principal investigator, research program manager, and financial officer. Research team leads provide direction and management for nine distinct research teams and meet biweekly as a project-wide research committee. A steering committee provides broad direction and oversight. This organizational structure was intentionally designed to facilitate the buy-in and sharing of the CDS intervention by the project's numerous

collaborators. Nevertheless, its size and complexity have posed difficulties, and the project has faced numerous planning and management issues, as detailed below.

The organizational structure is large and complicated. The CDSC project team's organizational chart includes a large steering committee consisting of 21 members, and nine teams with more than 10 members each. Collaborating organizations, such as Regenstrief and vendors, are represented in each of the nine work teams as well as the steering committee. CDSC project leadership coordinates the project by interlinking the teams (i.e., a few members from each team are assigned to other teams, and the steering committee includes members from each team); conducting regularly scheduled meetings; taking notes and distributing or posting meeting minutes; and promoting discussion and decisionmaking via the use of eRoom, a product of the EMC Corporation that provides a Web-based collaborative workspace to enable distributed teams to work together more efficiently.[12] Nevertheless, active engagement and forward progress can be difficult to achieve when staff are unable to attend multiple meetings. In addition, some project team members felt that a division of responsibilities among nine teams can lead to duplicate efforts and inconsistent decisionmaking.

It was hard to envision what would be required in terms of resource allocation (staffing and time) when writing the proposal. First, the complexity of what was being promised was not well understood. As BWH soon discovered, some tasks required significantly more staff hours than originally projected. For example, the development of the CCD and the CDS Service was more difficult and time consuming than initially anticipated. Partners' organizational complexity and multiple stakeholders also contributed to increasing the total time required for completion of certain tasks, as the signoff process was frequently required. The CDSC management team also found that existing staff skills did not always match the ones needed for project tasks. In such instances, staff needed to be trained in the new skill or new staff needed to be hired. Ultimately, the underestimation of hours and budget required staff to work overtime and/or be paid through other funds.

Managing the CDSC project within BWH and across collaborators is difficult. In addition to BWH, a number of Partners' entities are involved with the CDSC project, including Partners' HealthCare Information Systems and their affiliated physician organizations. However, project staff members from these entities have other project responsibilities and tasks as well, which are at times difficult to balance with their CDSC project work. Management across the CDSC collaborators is also challenging, as the collaborators represent a range of institutions (e.g., academic medical centers, community health systems, health maintenance organizations, health IT vendors) that are geographically located far from where most of the CDSC project staff are based. Furthermore, the project timeline requires that multiple products be developed simultaneously (e.g., Dashboards, CDS Service), which further complicates the management of this project.

Vendors are hesitant about their participation. Vendors express some hesitancy about the CDSC project. This may be due to discomfort with an academic institution taking charge of knowledge management or to a perception that they have little to gain from the development of open-source applications. Some of the participating vendors are unsure of the potential impact of the CDSC project. One vendor said that while BWH views the CDSC project as a national

solution, he views it as a pilot demonstration. Another stated that what the CDSC project team is designing may be very "BWH specific" and based on local practices and EMR configuration. Nevertheless, vendors are participating in CDSC project meetings, and project staff is working to gain vendors' view of the CDS landscape. In the near future, the views of vendors may become more supportive in response to the requirement to implement CDS rules under the proposed rule for meaningful use.

Design Approach

The CDSC team aimed to create a repository of knowledge for future use by Partners and its collaborators. Using knowledge management tools (Documentum's Web Publisher and Content Management Services), the CDSC staff translated the unstructured written clinical guidelines into human- and machine-readable forms. This knowledge is represented in four portal submission levels: Level 1: unstructured (format: JPEG, HTML, DOC, XLS); Level 2: semistructured (format: XML); Level 3: structured (format: XML); and Level 4: machine execution. Each level also includes metadata explaining the origin of the data (e.g., Level 3 was derived from a Level 2 document). After validating these specifications, artifacts are uploaded to the CDSC knowledge portal, thus forming the knowledge basis and repository for the CDSC project that will be made available to the project collaborators.

The knowledge management tools and portal are key but require well-designed procedures, staff time, and expertise. The CDSC portal is currently separate from Partners' portal, but it is using Partners' knowledge management tools and procedures for its development. Partners had been developing a knowledge management portal prior to this project and continues to systematize its approach by creating and revising policies and procedures. For example, at the start of this project, the CDSC staff analyzed the content of Partners' portal and found that it was difficult to determine who authored or created the rules or what the evidentiary basis was for a particular rule included in the portal. Thus, the CDSC project team has implemented very specific procedures for gaining agreement on the rules and for carefully documenting the sources of evidence and verifying versions of clinical content information. CDSC has also worked carefully with the Partners and with site legal teams to draft license and indemnification language for the content and portal.

Although the approach is consensus driven, obtaining consensus is difficult. As BWH has found, gaining clinicians' consensus for clinical rulemaking requires patience, perseverance, and established policies. While compromise or accommodation may help to achieve consensus, these approaches were thought to produce undesirable outcomes. As one project team member stated, "If you came up with a guideline everyone agreed with, it would be mushy." Thus, determining achievable levels of consensus is key.

To address ambiguities in the guidelines and to develop the more specific criteria necessary for creating computer-executable rules, the CDSC project team established a Content Governance Committee. This committee conducts literature reviews to gather evidence and uses the clinical expertise of BWH's clinicians to clarify ambiguities in published guidelines. The project team has discovered that the clinicians often disagree on the rules, and whenever this happens, the Content Governance Committee has stepped in to mediate. Through careful evaluation of the evidence base and by facilitating discussion, the Content Governance Committee has attempted

to reconcile the disagreements and has assisted with the development of an agreed-upon rule set. Nevertheless, other BWH clinicians have continued to voice their disagreement with the rules. To gain clinician buy-in, the CDSC project staff is educating BWH's clinician leadership and individual clinicians about the benefits of knowledge management. The steering committee has helped to coordinate these decisions.

It is unclear whether collaborators will accept the rules developed by the CDSC project team or customize them. Collaborators' representatives are involved in the project's knowledge translation and content governance process, and their organizations have granted them authority to accept the rules developed by the project team. Nevertheless, there is concern that collaborators' clinicians may insist on reevaluating these rules. Project staff suggest that collaborators' acceptance of CDSC's knowledge management will vary by type of institution: providers at large academic medical centers will be more likely to review the rules developed by the project team and choose either to adapt these rules or create new ones, while many physician practices and small to midsized community hospitals and health plans will most likely accept the rules as they are because they may be unable to devote the time and effort necessary to review these rules and adapt them or create their own. There is concern that other organizations that choose to develop their own rules will not be able to complete the Level 3 to Level 4 translation on their own. Thus, project staff intends to create easy-to-use editing tools to make the translation process more accessible to others. Because this may still be too complex for some organizations, BWH plans to offer assistance with coding.

Written guidelines do not allow for their direct translation to computable code. The project's principal hypothesis is that written guidelines can be unclear and often do not include the level of specificity necessary for translating them into computer-executable code. They also may not include evidence that has emerged from recently published studies. In addition, current clinical guidelines usually do not address how to treat patients with multiple chronic conditions. Although the project team has tried to anticipate common comorbidities, it is nevertheless challenging to write rules that are very specific, pertain to a relatively small subset of patients, and for which limited clinical evidence exists. Opinions from clinical experts are frequently sought to help clarify ambiguities in the guidelines, as well as provide the details and specifics that are necessary to create a rule. In these instances, the recommendations are often based on the experience of these experts, especially in cases where the evidentiary basis is limited.

The technical translation of guidelines into executable code requires a high level of clinical and programming knowledge and experience. To translate the guidelines into executable code for CDS functionalities, the BWH team utilized individuals with skills and expertise in clinical informatics, programming, and medicine. To implement the CDS methods under study in the contract, additional skills necessary for this project required staff to undergo supplementary training in specific software applications and programming languages. For example, the CDS Services team received training in the IBM iLog enterprise rules engine software and authoring tools. The knowledge translation process utilizes GELLO, a class-based, object-oriented query and expression language used for specifying decision criteria, abstracting or deriving summary values, and expressing logical statements. Using GELLO requires a significant amount of technical expertise, as the GELLO syntax is complex.

Adoption of standards, including terminologies and data exchange formats, is a slow process. Acceptance of HL7 standards, including the CCD, has been slow among vendors and organizations with homegrown EMR systems. Mapping proprietary (local) terminologies to the terminologies used in the CCD and related data exchange standards is difficult. This is further complicated by the fact that the standards often have a number of permissible variations that can contribute to inconsistent adoption and affect future interoperability. Despite BWH's extensive experience with health IT, it had no experience in building a CCD. To create a CCD, the CDSC team needed to coordinate the retrieval of patient data stored in multiple databases that are managed by individuals who are not associated with the project. The project team also realized that the LMR utilized a number of local, proprietary codes and free-text fields. Creating mapping tables from existing local codes to accepted HL7 standards and generating a usable CCD posed challenges. Standard terminologies sometimes did not include certain clinical practice variations, and the CDSC team had to propose modifications to the existing standards to meet these identified needs. Moreover, while the CCD provides a standardized format for sending information, the types of data and format required for CDS differ from the care-transfer needs for which the CCD was intended. However, it was felt that this format is the best standard currently available.

Suboptimal data entry into the EMR has implications for CDS interventions. An electronic CDS intervention that is designed to be implemented within an EMR depends on the quality of the patient data entered into the EMR. However, the data entered by clinicians are not always well defined and complete. Missing data and inaccurate information caused by clinicians' failures to update problem lists and medication lists can make it difficult for the CDS application to generate appropriate and effective interventions and applications. Also, EMR fields that allow free-text entry cannot always be effectively mapped and thus cannot enable CDS applications. These issues became apparent during the testing and demonstration stages, as CDSC staff struggled with how to deal with missing and free-text data and the level of data-fixing that should be done. They now believe that training users to correctly enter data is an important step to achieving better defined and more complete data.

GuideLines Into DEcision Support

Overview of the GLIDES Project

The GuideLines Into DEcision Support (GLIDES) project is a collaboration between Yale University School of Medicine, Yale New Haven Health System, and the Nemours Foundation.

The GLIDES project's goals are to:

- Implement evidence-based guideline recommendations that address both preventive practices and complex management of chronic disease.
- Apply models, techniques, and tools developed at the Yale Center for Medical Informatics to systematically transform the knowledge contained in these guidelines into a computable format.

- Deliver the guideline knowledge via electronic decision support interventions at ambulatory sites that employ CCHIT-certified, widely used electronic health record systems.
- Evaluate the fulfillment of knowledge transformation goals and the effectiveness of the decision support tools in improving the quality of health care at the chosen sites.
- Disseminate the findings of the demonstrations in a variety of formats, including direct recommendations to guideline developers and IT vendors.

The GLIDES project team is focusing on the ambulatory pediatric setting, with an aim to improve the management of asthma and to prevent obesity. The GLIDES asthma CDS intervention is being implemented in both pediatric pulmonology and primary care settings, while its obesity CDS intervention is being implemented in the pediatric primary care setting only. Two evidence-based guidelines were chosen for the initial knowledge base. These guidelines are:

- Expert Panel Report-3, Diagnosis and Management of Asthma, from the National Asthma Education and Prevention Program of the National Heart, Lung, and Blood Institute, National Institutes of Health.[13]
- Expert Committee recommendations on the Assessment, Prevention, and Treatment of Child and Adolescent Overweight and Obesity, convened by the American Medical Association (AMA), and HHS's Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC).[14]

To demonstrate cross-platform utility and establish a wide range of best practices for the inclusion of a single CDS intervention into multiple EMR products, the GLIDES project will implement its CDS intervention into two different EMR systems, both of which are certified by the CCHIT. Yale will incorporate its CDS intervention into its current EMR, a GE Centricity system, and Nemours will integrate its CDS intervention into its EPIC EpicCare system EMR. The ANSI HITSP standards will be used where available and applicable.

The CDS system is to be developed, conducted, and evaluated in a total of six clinical sites: Yale New Haven Hospital's Primary Care Center and Pediatric Specialty Clinic; Nemours' Delaware Valley primary care clinics; and Nemours' Florida Orlando, Jacksonville, and Pensacola specialty care clinics.

Yale and Nemours both have previous experience with CDS system development. Yale developed the Guideline Elements Model to aid in the organization of information contained in a guideline, as well as software tools (GEMCutter) to aid in the knowledge transformation process. Nemours developed SmartForms and other CDS interventions and provides incentives for clinician adherence to best practices and evidence-based care. Each of these organizations has a continuing commitment to CDS systems, with Yale funding the further development of GEM and Nemours organizing a CDS Workgroup that will develop governance structures for future CDS system implementations.

The project began with a 6-month preimplementation period for project planning and knowledge transformation. The following 18 months have been devoted to implementation, conducted in three phases:

- Phase I: Asthma CDS system implementation at Yale Specialty Clinic.
- Phase II: Obesity CDS system implementation at Yale Primary Care and Delaware Primary Care, and asthma CDS system at Nemours' Jacksonville, Orlando, and Pensacola facilities.
- Phase III: Asthma CDS system implementation at Yale Primary Care and Delaware Primary Care.

The preimplementation work was completed on schedule (June 2008), and the implementation phases have been proceeding as planned. Phase I went live in November 2008 and Phase II went live in June 2009. By February 2010, when this report was finalized, GLIDES was implementing the third and final phase of its CDS tools—Asthma for Primary Care Physicians at Nemours and Yale.

Challenges and Barriers Experienced by the GLIDES Project Team

This report summarizes the challenges and barriers of the first 18 months of the GLIDES project, from January 2008 to July 2009. During the project's 6-month preimplementation period, clinical knowledge was structured into a computable (XML) format and the CDS interventions were designed and built. In the implementation period, the structured knowledge was adjusted to operate within the sites' EMRs and workflow arrangements. The GLIDES project team's major challenge was to ensure an appropriate balance between these two phases.

Project Planning and Management

GLIDES' project planning and management are conducted by a small core team. The GLIDES Project Director is based at Yale and serves as the leader for the Yale CDS project, while Nemours also has a designated CDS lead. These key personnel devote considerable time and effort, but no one is full time on the project. In addition to key personnel, Yale and Nemours each has its own programming, implementation, and evaluation teams.

Under the direction of the Project Director and the Decision Support Council, four workgroups (Knowledge Transformation, Yale Implementation, Nemours Implementation, and Evaluation) were convened to plan and execute the project. The CDS intervention was to be demonstrated in ambulatory settings in six different pediatric practices to enable GLIDES' project staff to test the generalizability of its findings and products. Logistical challenges and barriers encountered during the implementation process were more difficult to overcome than those experienced during the preimplementation phase. Nonetheless, the design process is iterative, not sequential, requiring that guideline experts, clinicians, and IT staff work together to reassess and revise the CDS interventions.

The project plan emphasizes the implementation of the CDS intervention, rather than planning for the CDS system's design and development. The timeline for transforming the knowledge and designing the CDS interventions during the preimplementation period was 6

months. Eighteen months, however, were allotted for implementation. The GLIDES project team completed its preimplementation phase and began implementation on schedule. During the initial preimplementation period, GLIDES' project staff completed a baseline assessment of pediatric specialist and primary care physician attitudes about and usage of current asthma guidelines and examined the differences between primary care providers' and specialists' needs. Upon implementation, however, it became apparent that the specialists were not using the CDS applications as anticipated and that there were numerous workflow and other issues associated with the applications. The GLIDES' project team struggled to prioritize clinicians' concerns, design strategies to address them, and make any necessary changes and revisions. However, if more time had been devoted to identifying potential issues during the preimplementation period, the CDS interventions might have fit better within the workflow, required fewer modifications, and been better utilized by the clinicians.

The organizations' goals and other initiatives were not always aligned with the GLIDES project's prioritized conditions. While the GLIDES project focused on asthma and obesity, Nemours' management focused on other conditions. For example, prior to beginning the GLIDES project, Nemours' pediatric pulmonology group selected cystic fibrosis as the condition of emphasis for its quality improvement initiative. According to Nemours' project staff, if asthma had been the selected condition of emphasis, then pulmonologists might have been more interested in using the asthma CDS intervention. In contrast, obesity has long been a high-profile condition at Nemours, and GLIDES staff expects that this will drive clinicians' interest in and use of its obesity CDS application.

Financial incentives were too small to directly influence CDS use but may be symbolically important. Nemours staff considered using financial incentives to support the use of CDS applications. At the Delaware Valley clinics, Nemours currently compensates its clinicians for adherence to immunization and other preventive care guidelines, and its obesity CDS application could fit nicely into this framework. The financial incentives offered by Nemours, however, are relatively small, and it is unclear whether these minor incentives will influence the clinicians' behavior. Nevertheless, the Nemours project team felt that even small financial incentives helped convey the importance of these initiatives.

Design Approach

The GLIDES team began translating the knowledge in the clinical practice guidelines for asthma and pediatric obesity into computer-executable code. The team made extensive use of Yale's GEM,[15] a model for the representation of clinical practices in a programming language (XML), along with other related tools (GEMCutter, EXTRACTOR, COGS, GLIA), to transform the knowledge of the guidelines into a standardized format. As Yale and Nemours have different EMR vendors, workflow, and existing CDS applications (e.g., reminders, alerts, SmartForms), it was determined that Yale would provide the GEMCutter output to Nemours, and then both would create their own asthma and obesity CDS systems. They confer with and share their CDS systems with each other, but each has decisionmaking autonomy.

The GLIDES project's transformation of the guidelines was a four-step process—from narrative guideline, to semistructured, to semiformal, to formal. This process begins with the written

clinical guidelines and objectives, transforms this knowledge, incorporates clinical workflow design, and results in system design documentation (i.e., developer specs form, screen designs, code, and scripts) and rules that are computer executable. GLIDES staff found that the written guidelines themselves pose challenges for CDS development, as do the current workflow, vendor applications, and tools used for the knowledge transformation process. Nevertheless, addressing local intervention design challenges and building stakeholder consensus drove the design phase. The most challenging design phase activity was gaining agreement from each site's key clinical stakeholders as to how the CDS interventions should be integrated into existing workflows and how the CDS interventions should be presented.

Defining the prescriptiveness of the CDS interventions was difficult. The project team struggled to determine the expectations for clinicians' adherence to the CDS recommendations and the appropriate level of enforcement for each recommendation, particularly when the evidence base for the guidelines and rules was weak. As one team member said, expectations ranged from "clinicians should *consider* the recommendations" to "clinicians should *be required* to follow the recommendations." Although there were differing views on this within and among institutions and local sites, both Yale and Nemours acknowledge that they lack the ability to mandate—or even strongly influence—clinicians' use of CDS applications. They have found that a high level of autonomy is given to clinicians, which allows for resistance to CDS and other health IT efforts.

Finding the correct balance between implementing CDS interventions within the current workflow vs. reworking the current workflow for optimal CDS use was challenging. The GLIDES team assumed that the CDS interventions could be designed and integrated into existing clinical workflows without requiring the workflow to be substantially changed. Nonetheless, it was more difficult than expected to incorporate CDS interventions into the existing workflow, and early in the implementation period it became apparent that workflow inefficiencies were a barrier to implementation and use. This created a dilemma for the project team: on one hand, CDS interventions would be less effective if the workflow issues were not addressed; on the other hand, the timeframe and budget imposed constraints on addressing workflow issues. Also, in many instances, GLIDES project staff lacked the authority to alter the current workflow. The GLIDES staff has strived to maintain a "balanced approach," meaning that it made only those changes to the workflow that could be executed relatively easily and within budget.

Written guidelines were often ambiguous or incomplete. The Expert Panel Report-3 (EPR-3) asthma guidelines do not provide straightforward diagnosis and treatment recommendations, making it difficult to convert them to computer-executable code. The GLIDES team addressed this by engaging pulmonologists at each site to discuss and resolve areas of ambiguity. The pulmonologists sought an evidentiary basis to guide these decisions, but when this was not available, their recommendation was based on consensus following internal negotiations. The written obesity recommendations of the AMA, HRSA, and CDC are much less detailed and have a much weaker evidence base than the EPR-3 asthma guidelines. In instances where agreement was difficult or the guidelines were sparse (as with obesity prevention), the team moved to a less rigid design that provided more options for the clinician to choose from.

Focus on individual clinical conditions poses problems for the management of multiple conditions. The GLIDES staff found that clinical guidelines written for a single condition do not address the large proportion of patients with comorbidities. This intensifies the challenges for writing rules for CDS applications. It also reinforces clinicians' belief that CDS is not useful and that its clinical advice may be incorrect. The asthma guidelines, for example, assume that cough is attributable to asthma, even when this is not the case. (For example, a chronic cough may be due to gastroesophageal reflux disease rather than asthma.) In another example, allergists in the pulmonary division suggested that the written asthma guidelines underestimate the impact of allergies and are pressing for the addition of allergy-related questions to the asthma SmartForm. As GLIDES staff learned, the project team needed to consider issues with the development of rules for the CDS system, such as comorbidities, that were beyond the limited scope of the guidelines.

Vendor applications had limitations in user-customizability. The GLIDES project incorporated two vendor EMR products (GE Centricity and EPIC EpicCare) that employ hard-coded configurations to implement CDS interventions. The challenges Nemours faced with EpicCare included configuring the SmartForm so that clinicians would not need to search for it. Also, the functionality required multiple steps in order to generate clinical notes and letters through its SmartForms. Once the note or letter was generated, clinicians felt that it lacked the style of a document that was dictated and professionally transcribed. Yale has experienced similar limitations with Centricity's user interface design tools in being able to make the display of the SmartForm graphic more aesthetically pleasing. Also, Yale has been unable to obtain accurate time stamps of when the data were entered into its EMR (to assess whether the entries were made during or after the patient's visit). In addition, both sites had difficulty accessing usage data from their vendor systems for evaluation purposes. Technical flexibility was also lacking, as the versions of the vendor systems used at the GLIDES project sites did not use SNOMED, a vocabulary used by the GLIDES team for encoding rules centrally. Thus, the IT teams needed to map local, proprietary codes to SNOMED.

Further development is necessary for tools that assist with the transformation of a guideline to executable code. Technical teams at Yale and Nemours utilized reports created from GEMCutter to take the first step in converting a guideline to a rule. However, both teams found that additional translation was necessary from the GEMCutter outputs before it was possible to generate programmable code. Furthermore, GEMCutter had difficulty processing PDF documents and embedded graphics, which is partially related to changes in PDF standards. To complete the final step of the transformation process, a better understanding of the clinical implications and systems programming is needed.

CDS System Implementation

The project's implementation period focused on demonstrating and evaluating its methods for creating, storing, and replicating CDS elements across multiple clinical sites. Focusing on effective CDS design and delivery while also being dependent on wider workflow and system utilization factors continues to be a major challenge for the GLIDES project. Implementation challenges were exacerbated by concurrent implementations of the asthma and obesity CDS

interventions at Yale and Nemours, and the different needs of specialty and primary care clinicians at both institutions.

Adoption of CDS interventions has been lower than expected. The GLIDES team was disappointed to find that most pulmonologists are not using the CDS interventions during the patient visit. For example, although the pulmonologists were completing the SmartForms, most completed them after the visit was over. Also, the team discovered that the pulmonologists think that the CDS application is not very useful to them. According to one project team member, specialists believe they are providing optimal care and are experts in their specialty; thus, they do not value a review of their clinical decisions. In addition, many clinicians say that they find the CDS intervention to be an intrusion, as it takes them time and effort to complete or respond to the application. In some cases, GLIDES staff agreed that certain CDS interventions were nonintuitive and cumbersome—for example, finding the pathway to the asthma SmartForm within EpicCare. GLIDES staff overall believe this criticism regarding the usability and perception of the usefulness of the CDS interventions to be unwarranted, but they are aware that problems do exist.

The involvement of the clinicians during the preimplementation and design phases did not result in their acceptance of CDS. Yale conducted a formal needs assessment of the pediatric pulmonology department, and pulmonologists were active in the knowledge transformation and CDS intervention design process. However, this did not translate into their acceptance and use of the CDS intervention. In fact, there was a disconnect between what pulmonologists supported during the design phase and what they found useful once the CDS intervention was implemented. Although the preimplementation phase design process clearly focused on developing the intervention to support decisionmaking, after implementation it became evident that the pulmonologists are using the CDS intervention for other purposes. For example, they are using the CDS intervention to assist them in drafting letters to the referring primary care physicians. This is accomplished as the information entered into the SmartForm is converted to SmartText (preformatted text that quickly and efficiently populates free-text fields), and the clinician then modifies the letter. The pulmonologists are also using the CDS application to teach the guidelines to their clinical fellows and residents.

Implementation relies on resolving underlying issues related to EMR usage. Because the CDS intervention is embedded in the EMR system, its use is dependent on clinicians' use of the EMR. However, the GLIDES staff recognizes that the way that the EMR is used by clinicians is not optimal. At Yale, pediatric pulmonologists almost always use their computers only after the patient has left. They do so because they feel that the hardware is not up to date and is slow. When clinicians complained that their computers took a long time to "boot up," the organization sought to address this by having medical assistants turn on the computers before the clinicians arrived. While some EMR usage barriers were more easily addressed than others, many pertain to general workflow and system adoption challenges at Yale and Nemours. For example, clinicians continue to rely on paper forms; thus, the data entry forms and templates are replicating what is being done on paper, making it less likely that clinicians will use the electronic forms. As another example, Nemours provides its clinicians with three options for entering their documentation into the EMR: the dictation of notes and their insertion into the record within 24 hours; notes manually typed as free text; or documentation entered using

templates (e.g., SmartText). The first two options—the insertion of the notes after the patient has left and the inclusion of free text—result in information that cannot be used by the CDS application.

Workflow issues were evident during the implementation. In addition to EMR usage issues, workflow issues emerged as the CDS intervention was being implemented. Clinicians stated that they were being slowed down by manual data entry into the CDS applications. Some said that too many "clicks" were required to use them. Overlap with other EMR functions also created workflow problems. For example, Yale's asthma SmartForm data overlap with the primary complaint and problem list data. In addition, Yale originally programmed its asthma SmartForm so that asthma drugs are ordered using this form. However, the SmartForm does not link to the overall drug ordering screen, which makes the clinician more likely to skip the asthma SmartForm and place the order from the EMR's overall drug screen so that all medications are ordered together.

There are differences between primary and specialty care needs and uses for CDS interventions. The GLIDES team found unique differences in how primary and specialty care providers use the EMR and CDS interventions. For example, primary care physicians typically use the EMR in the exam room; specialists do not. In addition, their clinical needs differ, in part due to differences in provider training and in part due to differences in their patient populations. Specialists assert that their patients are those who do not respond to standard treatment, while primary care patients are more likely to do so. They believe that clinical guidelines might apply to primary care patients but are less applicable to specialty care patients. Also, primary care physicians prefer a prescriptive intervention format (one that offers recommendations), while specialists prefer a critiquing format (one that notifies the provider if an option selected differs from the guideline recommendations). Consequently, Yale's asthma CDS intervention, which had been designed for its pulmonary clinic, needed to be redesigned for primary care department use.

Training clinical residents and fellows to use the CDS applications is important, but attending physicians may not be the best role models or trainers. Attending physicians who completed their medical training without the presence of EMRs may be less comfortable using computers and CDS applications during a clinical encounter. Nevertheless, the attending physician often plays a major role in training clinical residents and fellows. For example, residents or fellows typically bring a paper chart to the attending physician for review and signature, rather than the attending physician conducting a review of the electronic record. This practice reinforces attitudes and workflow patterns that do not incorporate the use of health IT applications, including CDS.

Efforts to train clinicians as a group have had mixed results. Although the project team at both sites tried to schedule group training sessions, clinicians had such varied availability that many had to be trained individually. These one-on-one training sessions interfere with efforts to generate buy-in, as group training helps to establish an expectation that peers will be using the CDS intervention. Thus, the GLIDES team designed a diversity of training media—training manuals, streaming audio and video files, and in-person sessions—to try to meet the clinicians'

training needs. For in-person sessions, Nemours found that having clinician leaders lead the training generated buy-in.

Formative and qualitative evaluation efforts are necessary to identify what contributes to clinicians' acceptance and use of CDS interventions. The GLIDES team initially thought that clinicians' adherence to the guidelines would be the primary measure of the success of the CDS intervention. However, when it became apparent that the pulmonologists did not feel guidelines directly apply to the care they provide, GLIDES staff realized that evaluating "adherence" to guidelines may be a flawed metric. Also, in those instances in which there are valid reasons for providing treatment or services that do not adhere to the rules, measuring adherence to the rules may not be valid. Thus, the GLIDES team broadened its evaluation efforts to include qualitative evaluation activities (including open-ended interviews, observations, and artifact analysis), discrepancy analyses to examine differences between clinical decisions and CDS recommendations, and data collection on actual CDS usage.

III. ANALYSIS AND DISCUSSION

While having similar overarching requirements and goals, both projects are using distinct approaches to develop and implement CDS systems in ambulatory care settings. The CDSC staff focused on the technical aspects of building a CDS system, the knowledge management process, and the development of a Web-based CDS Service to share the CDS interventions with its collaborators. The GLIDES project focused on transforming the knowledge of the guidelines and on designing and implementing EMR-specific CDS interventions, first at Yale and then at Nemours.

During the course of the projects both teams have faced numerous challenges, and both the CDSC and GLIDES projects were able to overcome many of the challenges and barriers that arose. Their different interests, team structures (size and organization), objectives, processes, and expertise may also have contributed to the different challenges and barriers that they experienced. Nevertheless, many of the obstacles they encountered are similar and should be useful to others interested in designing and implementing CDS systems. These challenges and barriers, and how they were addressed, are described below.

The management of the design of clinical decision support interventions takes considerable time and effort. Both contractors experienced staffing issues, as hiring and retaining clinical and IT staff for a project lasting 2 years or longer was difficult. Also, although project staff, clinician, and collaborator meetings were considered important for project management, strategy development, coordination, and buy-in, gaining attendance at meetings was difficult because of busy schedules. Communication difficulties were exacerbated by staff being located at different geographical locations. To improve communication within the teams and across collaborators, CDSC staff distributed meeting minutes and summaries and utilized multimedia forums to share information promptly. When the GLIDES staff determined that clinicians' schedules could not accommodate a group meeting, it conducted one-on-one meetings. Project management was

further complicated because the labor hours estimated during the proposal writing stage were often insufficient.

Lack of alignment with an organization's overall goals and incentives can affect CDS projects. There were few organizational goals or financial incentives to promote clinicians' use of CDS interventions at the contractors' organizations. However, where they did exist, they seemed to be effective. Also, the organizations' prioritized conditions for disease management or preventive screening did not always match the conditions selected by the CDS projects (e.g., cystic fibrosis, not asthma, was Nemours' targeted pulmonary condition). GLIDES project staff believed that if the conditions selected for the CDS project also had been the organization's prioritized conditions, this would have fostered use of the CDS interventions.

Clinicians do not agree on how prescriptive the CDS application should be. As the contractors found, clinicians have diverse opinions on how prescriptive guidelines should be. Some believed that adhering to the guidelines should be mandatory; others believed that adherence should be optional. Clinicians may lack motivation to use CDS applications because they believe that they already know and follow guidelines, the guidelines do not apply to their patients, or the guidelines may be incomplete. To gain the support of clinicians, both contractors have tried to disseminate information to clinicians on the importance of CDS systems and to involve clinicians in the knowledge management process.

Local institutions and providers chose to "customize knowledge." The GLIDES project offered its knowledge base to Nemours, but Nemours chose to customize it locally. Similarly, the CDSC team is concerned that its collaborators will want to customize the knowledge rules the project team has developed. Many of the staff and providers involved in this project believe that the patients and workflows of their institutions differ from others, and that rules designed by others will not work for them. Nevertheless, customizing rules and keeping them up to date require significant time and resources that many institutions are not able to afford. To promote the use of its CDS interventions by others, BWH included its collaborators in a content governance committee decisionmaking process, although it is too early to know whether the providers at the collaborating organizations will accept these rules. In the future, as the evidence base for guidelines improves, providers may be more willing to accept a centralized or other knowledge base that is developed and maintained by others.

Written guidelines are ambiguous and unclear, making it difficult to translate them to computable code. Both the CDSC and GLIDES projects found that written guidelines must be interpreted and that additional rules need to be written to clarify the guidelines and provide the specificity needed by programmers. To translate the written guidelines to computable code, both contractors used the assistance of clinicians with extensive informatics experience and knowledge management tools to aid in the process. To ensure that future written guidelines are more appropriate for CDS, the contractors have begun working with guideline developers and organizations to include the level of detail necessary to create computer-executable code.

Terminology and data exchange standards are still maturing and lack constrained implementation specifications. As noted in both the CDSC and GLIDES projects, initial standards adoption (e.g., the mapping of diagnosis codes used locally at a particular health care

organization to SNOMED) can be challenging, as can regular maintenance to accommodate newer versions of standards. Technical documentation needs to be developed that clearly indicates the requirements for data exchange, including the standards and versions utilized. Presently, standards, such as Health Level 7 (HL7) for messaging, can be variably implemented. Implementation specifications that constrain the available choices can simplify interfacing, promote consistent application of standards, and reduce variations caused by differences in interpretation. The CDSC team recognizes that the development of technical documentation will be key in allowing collaborators to create a CCD that can be sent to the CDS Service they are developing.

Suboptimal EMR usage by clinicians diminishes the impact of CDS interventions. As both contractors found, many clinicians at their and their collaborators' organizations are entering data after the patient visit, which reduces the potential benefit of the CDS intervention since it is not triggered at the point of care. Many are also entering patient information as free text or are leaving some fields blank, rendering the information unusable for CDS and for later data extraction. The GLIDES team is attempting to improve EMR usage and has worked to resolve minor workflow barriers (e.g., length of time to boot up computer). Future projects might analyze factors that decrease EMR usage at the point of care and attempt to resolve these issues prior to the design of a CDS intervention.

There are no easy solutions to gaining clinicians' acceptance and use of CDS interventions. After going live with the CDS interventions, GLIDES found that many clinicians ignore or do not adhere to its recommendations. CDSC, through its interviews with providers and prior CDS work done by BWH and Partners, has experienced similar resistance. Workflow and design-related issues appear to be the primary barriers to acceptance and use, but clinicians' lack of buy-in as to the value of guidelines or CDS applications also plays a role. The contractors are using multiple approaches to address these issues, including a needs assessment of clinicians during the design phase, use of well-respected clinician leaders to educate clinicians about the value of CDS, redesign of the clinical workflow, improvements in the design of CDS interventions, and documentation of the evidence base. They are also training clinicians to use the CDS application, as clinicians may be more comfortable with the technology if they understand its basis and how to use it.

The impact of these approaches for improving clinician acceptance is constrained by a number of factors. First, the contractors' project directors often lack the authority to make major changes in workflow, buy computer hardware, offer incentives, or require clinicians to attend trainings. They are also compelled to adhere to the project's timeline, budget, and the agreed-upon work plan, even though many of the approaches for gaining clinicians' acceptance of CDS interventions require more time, effort, and expense than were budgeted for. In addition, the contractors felt tension between designing CDS interventions for their current practice vs. designing interventions to support redesigned care practices. It may also be the case that the quality and scope of today's clinical guidelines are not sufficiently accurate or comprehensive enough to encourage clinicians to adhere to the CDS systems' recommendations. This is particularly true for comorbid conditions, as clinical guidelines address only single conditions.

Challenges Common to CDS Systems

Similar governance and implementation challenges have been experienced by others designing and implementing health IT and CDS systems. As Goldstein et al. found, considerable effort and commitment are required to unite team members from disparate disciplines, organizations, and cultures so that they have a common understanding of the CDS system's overall objectives and can perform and hand off tasks appropriately.[16] Research also suggests that an organization's failure to align the information system with its strategies can result in lost opportunities, wasted resources, and unfavorable performance.[17] Numerous other studies have also documented the difficulties gaining physician acceptance and use of CDS interventions, as well as obstacles to integrating CDS interventions into the workflow.[18-20] So that they could avoid the challenges and barriers experienced by others, the CDS demonstration contractors incorporated past lessons learned into their project design. However, the obstacles they face may be compounded as they attempt to deliver the CDS systems in a variety of ambulatory settings, at multiple geographic sites, via various EMR systems, and for multiple clinical conditions and services.

From a technical perspective, the translation of written guidelines to computer-executable code can be difficult. Although the development of tools to simplify this process is ongoing, knowledge management in its present stage requires the utilization of specialized skills and expertise in medicine and informatics.[21,22] In addition, to use a CDS service model as suggested by the CDSC project, mapping of local, proprietary codes to accepted standards (e.g., SNOMED, LOINC) and formats (e.g., CCD) can be a challenging process. These difficulties with mapping are not unique to the CDSC and GLIDES projects, as they are also being encountered by vendors and organizations with homegrown systems that are attempting to achieve interoperability.[23,24] Resolving these difficulties will support CDS and other health IT information exchange efforts.

Multiple Factors Involved

Multiple factors are believed to affect the success or failure of CDS intervention implementation. Clearly, a successful CDS intervention is dependent on the completeness and accuracy of the evidence base used to support it and the technical design of the interventional modalities. However, CDS is not just about technical content or technical design; CDS interventions also involve workflow. It is clear from the empirical studies of CDS implementation and current recommendations for their design that integration with workflow is key to success. How to integrate the CDS interventions with clinicians' workflow, however, remains a challenge, in part because there are no current standards for clinical workflow. In addition to integration with the workflow, the success of CDS interventions is determined by the policies, norms, constraints, and tasks of the organization in which they are being used, which might be a group of partners; the policies, norms, practices, rules, and technology of an entire clinic; and the context of the broader health care industry.[3]

IV. CONCLUSIONS AND FUTURE WORK

As the GLIDES project has shown, and as the CDSC project is confident it will also demonstrate, CDS systems can be successfully developed and implemented, and the knowledge base can be shared across clinical sites and EMR systems. Both contractors have successfully concluded the preimplementation phase and have completed the design phase. The GLIDES project is now operating its CDS intervention at its multiple clinical sites and organizations, while the CDSC project is demonstrating its CDS intervention at its primary contractor sites and will soon be ready to share the knowledge and technical specifications with collaborators' sites.

Both contractors found that the knowledge management and technical design process require considerable time and funding, as well as high-level clinical and technical staff, that are in short supply. Also, the process necessary to design and implement CDS interventions is lengthy (approximately 1½ to 2 years for the GLIDES and CDSC projects) and expensive. By sharing the responsibility for the design of the CDS system or by using the contractors' CDS intervention as is, collaborators can implement the CDS intervention without paying the full design costs. The ability to share or use knowledge can make CDS implementation possible for other organizations.

Despite the advantages of sharing or using another's CDS system, there are also limitations. Providers often want to modify the CDS interventions or underlying rules, as they may believe they have a different workflow or other needs or expectations. Hard-coded CDS interventions in differing vendor and homegrown EMR systems also inhibit transference from one system to another. Utilizing a standard data exchange format and terminologies can promote sharing across EMR systems via a service-oriented approach. While the CDSC project suggests that this is technically feasible, the implementation phase will prove whether collaborating partners' patient information can be sent to CDSC and whether the decision support can be returned to clinicians accurately and efficiently. It could be a major barrier to national distribution of CDS if different sites do not accept rules in a centralized repository.

The technical aspects of CDS system design and implementation pose difficulties, but they may be less of a barrier than gaining clinicians' acceptance and adoption of CDS interventions. As the GLIDES project found during the implementation of its asthma CDS intervention in specialty clinics and as the CDSC project documented through discussions with collaborators, acceptance and adoption of CDS interventions among clinicians are low. The contractors are training clinicians, modifying the CDS system to address clinicians' suggestions and complaints, and implementing a host of other strategies to improve clinicians' acceptance and adoption.

Many of the contractors' strategies aimed to gain clinician acceptance of CDS interventions by fitting the interventions within the current workflow, thereby creating minimal disturbance in the existing system. However, the design of their CDS interventions for the current but not optimal workflow contributed to the challenges and barriers they experienced. To enable CDS interventions to *improve* clinical workflow, the use of user-centered design principles and techniques during the initial design phase is suggested. In particular, determining user needs rather than user desires is an important consideration. As Karsh states, a system that is

considered usable and useful at a particular point in time may not be viewed the same way after users gain experience with the system.[3] By incorporating these findings into the design of the CDS interventions, fewer changes should be required after implementation, as it is more expensive and difficult to make changes to the CDS intervention after it has been designed.

Although many of the challenges and barriers experienced during the design stage were overcome, additional ones may arise during the implementation phase. It is yet unknown whether clinicians will accept and use the CDS system as envisioned and whether it will fit within their workflow. The success of an interoperable CDS system that can be used by other institutions, as the CDSC project team proposed to develop, has not yet been demonstrated, and whether other institutions will choose to use it as originally designed is also unknown. Nevertheless, the findings from these projects are useful for the future development and implementation of CDS systems. It is hoped that the next phases of the contractors' projects will shed light on how this can be achieved.

Lessons Learned

The experience to date of these two contractors provides lessons that are particularly relevant to guideline developers, IT vendors, standards development organizations, health care provider organizations, and policymakers. The lessons particularly pertinent to each group are given below.

Guideline developers:

- Guidelines should be specific, unambiguous, and clear.
- Guideline development committees should include individuals with programming expertise and health informaticians.
- Updates of the guideline recommendations are needed. Guideline developers should consider issuing statements of update when new medical evidence is brought forth and providing regular review and updates of guidelines. For example, the USPSTF re-reviews each topic every 5 years.[25]

IT vendors:

- As most organizations utilize vendor systems with hard-coded functionality, vendors should consider ways to reduce the need for an organization to rebuild the CDS content when upgrading or implementing a new EMR system (e.g., adopting a module or service-oriented approach).
- Incentives for vendor participation in CDS initiatives should be aligned with efforts, such as defining meaningful use criteria, to encourage standards adoption.

Standards development organizations:

- Implementation specifications and guides should be produced that simplify existing standards and support consistent application of standards for messaging, interfacing, and mapping purposes.
- The development of standards and implementation specifications and guides should accommodate appropriate clinical practice variations.

- When developing newer versions of standards, ways to reduce interoperability problems and data-mapping issues should be considered.

Health care provider organizations:
- The goals of CDS development and implementation projects should align with organizational priorities to promote buy-in from both management and staff.
- The organizational working environment should foster meaningful EMR usage, including not only software and hardware needs but also the attitudinal changes needed to support adoption.
- Engaging a well-respected clinician "champion" to lead CDS education, training, and implementation efforts will promote clinician adoption.
- Institutions wishing to utilize a knowledge management process will need access to personnel with specialized knowledge in clinical informatics and experience in designing new tools or using existing tools to support CDS development.

Policymakers:
- The development of standards and clinical guidelines can promote the goals for interoperability as well as support the development of the knowledge base necessary for developing CDS systems.
- Incentives by funding bodies, including governmental entities, can promote EMR installation, implementation, and use of these systems. To achieve the promise of EMR to improve the quality of health care through interventions such as CDS systems, policymakers need to continually reexamine ways to promote adoption of quality practices, including performance-based payments, incentives, and providing clinicians and patients with comparative data.

Future Work To Support CDS

Although the contractors were able to overcome many of the challenges and barriers they faced, they were not able to overcome them all. Additional research and work are needed to address these outstanding obstacles, as they are important for the advancement of the design and implementation of CDS systems. These include:

- Development of a stronger evidence base for guidelines (single conditions, comorbidities, associated treatment options).
- Creation of more specific implementation guides and specifications to promote consistent application of standards.
- Comparison of the resources required by a provider organization to develop its own knowledge management system vs. use of a ready-made knowledge management portal.
- Long-term evaluation to determine whether clinicians' use of the EMR and CDS systems changes or stabilizes over time.
- Understanding of factors that enable EMR and CDS intervention acceptance and use by clinicians.
- Effectiveness of the various CDS interventions on clinician performance and clinical outcomes.

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