

Lessons Learned from Implementing Service-Oriented Clinical Decision Support at Four Sites: A Qualitative Study

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ABSTRACT

Objective: To identify challenges, lessons learned and best practices for service-oriented clinical decision support, based on the results of the Clinical Decision Support Consortium, a multi-site study which developed, implemented and evaluated clinical decision support services in a diverse range of electronic health records.

Methods: Ethnographic investigation using the rapid assessment process, a procedure for agile qualitative data collection and analysis, including clinical observation, system demonstrations and analysis and 91 interviews.

Results: We identified challenges and lessons learned in eight dimensions: (1) hardware and software computing infrastructure, (2) clinical content, (3) human-computer interface, (4) people, (5) workflow and communication, (6) internal organizational policies, procedures, environment and culture, (7) external rules, regulations, and pressures and (8) system measurement and monitoring. Key challenges included performance issues (particularly related to data retrieval), differences in terminologies used across sites, workflow variability and the need for a legal framework.

Discussion: Based on the challenges and lessons learned, we identified eight best practices for developers and implementers of service-oriented clinical decision support: (1) optimize performance, or make asynchronous calls, (2) be liberal in what you accept (particularly for terminology), (3) foster clinical transparency, (4) develop a legal framework, (5) support a flexible front-end, (6) dedicate human resources, (7) support peer-to-peer communication, (8) improve standards.

Conclusion: The Clinical Decision Support Consortium successfully developed a clinical decision support service and implemented it in four different electronic health records and four diverse clinical sites; however, the process was arduous. The lessons identified by the Consortium may be useful for other developers and implementers of clinical decision support services.

BACKGROUND AND SIGNIFICANCE

Rationale for Clinical Decision Support

In 1976, McDonald et al. identified the fact that available clinical knowledge grew at a rate far faster than the capacity of healthcare providers to absorb it.(1) Since then, the rate of growth of the medical literature has increased remarkably. (2) As McDonald identified, computers, and especially, real-time clinical decision support (CDS) systems, which provide appropriate, timely, patient-specific reminders and information are essential to cope with the growth in medical knowledge. When implemented effectively, CDS has been shown to improve quality (3-7), and can be particularly effective for increasing appropriate use of evidence-based preventive services.(4, 6, 8) The federal “meaningful use” program for electronic health record (EHR) adoption in the United States also offers incentives for use of CDS.(9) Stage 1 of meaningful use required providers to adopt at least one clinical decision support rule, and stage 2 requires that they implement at least five clinical decision support interventions that promote their institutional quality goals.(10)

Challenges to Adoption of Clinical Decision Support

Despite these benefits and incentives, health systems face many barriers to achieving successful implementation of CDS. First, no complete and comprehensive library of shareable, actionable medical knowledge exists.(3, 11, 12) Second, institutions that have developed their own libraries have had considerable difficulty in managing this content and keeping it up-to-date.(11-13) It has also been difficult to resolve ambiguities in clinical guidelines, and to account for clinical realities such as co-morbidity.(11) Third, a patient’s data may be housed at several sites with no complete record of all data

available at any one institution. There are also limited mechanisms for sharing this patient data between sites(12), which makes it difficult to make complete and accurate inferences. Fourth, the evidence-base for the true effectiveness of CDS outside of a limited number of academic universities is limited.(11, 12) Finally, there are significant limitations in retrieving data to make inferences: implementing decision support in existing EHR platforms is challenging.(11, 12, 14)

In order to surmount these challenges, better guidelines (15, 16) and an improved understanding of EHR workflow and usability are needed.(17) However, another key advance needed to enable wider use of effective CDS is the ability to share actionable CDS content across sites.(11-14)

Past efforts have focused on sharing CDS among institutions with the same EHR vendor using internet-based libraries(18), which limits the scalability of CDS, or moving decision support artifacts from an institution with one EHR to another with a different EHR as structured logic representations.(19-21) Though numerous standards have been developed to facilitate guideline-sharing, the benefits have been counterbalanced by time-intensive efforts to resolve local terminology issues (e.g., Arden’s “curly braces problem”)(22), and a lack of consensus about which of the many standards to use.(11, 12)

Overview of the CDS Consortium

The Clinical Decision Support Consortium (CDSC) was convened by investigators from Brigham and Women’s Hospital, Harvard Medical School, and Partners HealthCare Information Systems, in conjunction with the Regenstrief Institute, Kaiser Permanente’s Center for Health Research, the Veterans Health Administration, Masspro, GE Healthcare, Siemens Medical Solutions, NextGen, Rutgers Biomedical and

Health Sciences in New Brunswick, NJ, the University of Texas Health Science Center at Houston, and the WVP Health Authority in Salem, Oregon to work toward practical solutions to sharing CDS across diverse clinical settings.(23) The CDSC was funded by the federal Agency for Healthcare Research and Quality. The goal of the CDSC was “to assess, define, demonstrate, and evaluate best practices for knowledge management and clinical decision support in healthcare information technology at scale – across multiple ambulatory care settings and EHR technology platforms”.

CDS Consortium Approach

CDSC considered several approaches to CDS content sharing, including adoption of a particular knowledge formalism, development of custom logic at each site and a service-oriented approach to CDS.(12) The CDSC elected to pursue a service-oriented approach to sharing CDS in order to promote scalability across diverse platforms.

Service-oriented CDS is an approach for securely connecting an EHR to central CDS services over the internet (13, 24-26). In contrast to guideline logic-sharing, service-oriented CDS allows the guideline logic to remain stationary while an external site packages and sends standardized, structured patient data to the service, the service computes the guideline-based, decision-support logic, and returns a recommendation to the client system. Service-oriented CDS systems are hardware and software-agnostic and rely on loose-coupling of services via standard data interchange formats.

In 2008, the CDSC began development of a service-oriented clinical decision support system, along with content for three disease areas: diabetes, coronary artery disease (specifically anti-platelet therapy) and screening for hypertension.(23)

The architecture of the service is shown in Figure 1. The service takes advantage of the Continuity of Care Document (CCD) (27) standard, along with the implementation guidance provided in the Health Information Technology Standards Panel C32 construct.(28) The C32 CCD is a standard, XML document which contains key patient data, including medications, laboratory results, vital signs, problems, procedures, allergies and patient demographics. Although each of the four CDSC sites has a different EHR, all are able to generate a CCD. At appropriate points in (or before) the actual visit workflow (discussed further in the results section under dimensions 3 and 5), each site's EHR generates a CCD which is passed via an encrypted connection over the internet to the CDSC's decision support service, termed the Enterprise Clinical Rules Service (ECRS). The ECRS, which is implemented with IBM's ILOG rule engine runs a series of rules (29) on the patient data embedded in the CCD, and returns coded recommendations (called inferences) as an XML document in the three content areas. The EHR receives these results and presents them in real time. Further details of the service and implementation are presented in other publications (26, 30) as well as in the results of this paper.

After development, the service was implemented at all four clinical sites and used during routine clinical encounters (though not necessarily in all clinics at each site).

Prior Findings of the CDS Consortium

As part of the Consortium's work, we previously explored a number of issues related to clinical decision support.(31) To support this study, we adapted a methodology for ethnographic assessment of CDS in the field called the Rapid Assessment Process, or RAP, which we described in detail in a previous manuscript (32). Using this

methodology, we explored the unique challenges of using CDS in a community setting (33) and the tasks and roles required of personnel involved in CDS development and implementation.(34) This prior work, however, was completed before the CDS service was implemented, so it reflects the experience of the study sites with traditional, locally developed, maintained, and executed CDS. This paper is the first qualitative assessment in which we investigate the socio-technical issues involved with the design, development, implementation, and use of service-oriented CDS.

In addition to several qualitative studies, we have also previously published four papers that describe the technical experience of implementing service-oriented CDS. The first describes the architecture of the ECRS in detail (26) while the second details the system performance of the service at two sites (30). The third paper describes the implementation of the service at one of the clinical study sites (RI) (35) and the fourth evaluates the accuracy and comparability of the service-oriented CDS logic and recommendations to that provided by each sites traditionally-generated CDS (36).

Although these prior studies provided insight into the socio-technical challenges and best practices for implementing traditional CDS as well as the technical dimensions of service-oriented CDS, we have not previously studied the unique issues and challenges posed by implementing the latter; thus, we conducted a follow-up study at the four sites (shown in Table 1) where the CDSC implemented the service-oriented CDS.

As shown in Table 1, the four sites differ in important ways. The goal of the follow-up study described herein was to assess the unique socio-technical challenges and issues related to service-oriented CDS. Although the demonstrations were ultimately successful, with all four sites eventually providing service-oriented clinical decision

support for real patients in routine clinical settings, the time and effort required to complete the service integration with the local EHRs and the local workflows was greater than expected. We used a qualitative approach to assess the reasons for these challenges, and to identify best practices for future implementers of service-oriented CDS.

METHODS

We used the previously-described RAP process, which was led by the Provider Order Entry Team (POET) from Oregon Health & Science University (OHSU) under contract to the CDS Consortium.

The details of the site visits conducted are given in Table 2. At each of the clinical sites, we conducted one baseline visit before go-live. The baseline visit focused on the site's experience with traditional CDS, and included interviews of clinical and quality leaders, informatics and IT staff and front-line clinicians. In addition, we observed front-line clinicians using the EHR at each site during the baseline visits, and asked questions about their experience with CDS. All baseline visits were in person.

Next, we conducted “after” site visits at each site, which were focused more specifically on the sites' experience implementing and using the CDS services. The visits were conducted shortly after they went live (with the exception of Regenstrief, where the after site visit was conducted as the site was about to go live) and included detailed interviews with IT and informatics staff about the experience of implementing the CDS services and demonstrations of the CDS implementations at the sites. Two of the “after visits” were conducted in person and two were conducted virtually. We did not perform clinician observations during the “after visits”. We also conducted virtual visits with the

EHR vendors that served the two clinical sites in our study with commercial EHRs (the other two sites had self-developed systems).

In sum, we conducted a total of 91 interviews – 43 “before” interviews, which assessed the baseline state of CDS at each clinical site and 48 “after” interviews which focused on the experience of implementing service-oriented CDS. Most interviews were one hour long. All interviews were transcribed and recorded. Approval was received from the Partners, Indiana University, RWJMS and OHSU institutional review boards (IRBs) – WVP relied on the OHSU IRB for review of the study.

After each of the site visits and telephone interviews, POET conducted team debriefings and analyzed the transcripts and other data to identify challenges to adopting service-oriented CDS at the two sites. The in-depth analysis followed standard qualitative processes outlined elsewhere.(32)

RESULTS

During analysis of all the data collected (see Table 3 for examples of the types of quotes identified), our team identified eight broad challenges to adopting service-oriented CDS, which contributed to development of an eight dimensional sociotechnical model (38) which we used as a framework for data analysis and for presentation of our results here. During many of our visits, we also saw prior lessons about traditional CDS that continued to hold true with service-oriented CDS (for example, the importance of placing CDS at the right point in the workflow, and making it actionable). However, we focused our analysis on the unique challenges of service-oriented CDS, and these challenges and lessons are presented here.

Dimension 1: Hardware and Software Computing Infrastructure

The demonstration sites encountered two different issues related to hardware and software computing infrastructure. The first was a performance issue: the CCD documents often took a long time to generate (an issue reported in more detail in a prior study (30)). Two factors drove the time requirements. First, CCD generation entailed calling a number of services to fetch patient data, and some of these services (which in turn relied on database queries) were slow. Though data-fetching services were called in parallel, CCD generation could only run as fast as the slowest of these calls. Second, services used to translate local, internal data codes (e.g. for medications, laboratory results and problems) to standard codes were also time-consuming. At Partners, where the services were implemented in real-time, and blocked loading of a patient's chart until they were completed, this added 2.3 seconds to the average chart-load time. However, for more complex patients, the load-time could be even longer. As such, Partners eventually set a five-second timeout for the CDS service. If the timeout expired, the rule logic was computed by an internal rule engine that was faster than the CDS service. This meant, however, that Partners had to maintain two copies of each rule: the main copy in the CDS service and the backup internal copy. Based on this experience, the other three sites decided to implement the service logic asynchronously, calling the service either during patient check-in, or the night before a visit based on the next day's schedule. This workaround was quite effective for the preventive services; however, certain types of CDS require real-time data, so the sites are also working towards improved CCD-generation speed.

A second challenge faced by the sites was the need to adapt the CCDs they generate. Although all sites generated C32-compliant CCDs that passed available

validators (39), each site's implementation of the standard proved quite different, and adaptation was needed at both the sending and receiving sites to ensure proper exchange of patient information. Regenstrief had the most experience with CCDs, and reported that they had encountered this issue each time they had attempted to exchange a CCD with a new partner in their health information exchange projects. Although the CCD is meant to be a standard there is much ambiguity in interpreting how to implement it.(27)

Dimension 2: Clinical Content

In addition to the structural issues in exchanging CCDs, the sites also experienced difficulties in achieving semantic interoperability. The demonstration sites used slightly different terminologies, and, just as crucially, selected different codes within the standard terminologies to represent similar concepts.

Each site had to ensure that its local coding systems were mapped to standard coding systems. For example, Partners already used LOINC for its laboratory results and SNOMED for clinical problems, but employed a proprietary terminology (mapped to First Databank) for medications. This terminology had to be mapped to RxNorm, but this mapping was complex because of variability and nuances in the level of granularity used in the two terminologies. Also, a host of other codes, including those for patient demographic data, had to be manually mapped. Similarly, Regenstrief had to map their internal code systems to the standard codes expected by the ECRS (and the C32 construct). WVP and RWJMS used ICD-9-CM codes for their problem list. Rather than mapping on the sending side, Partners extended the CDS service to accept ICD-9-CM codes in addition to SNOMED codes. The GE Centricity EMR used by RWJMS encodes

some procedure data (e.g. diabetic eye exams) as proprietary observation terms and these had to be translated to SNOMED codes in order to work with the ECRS.

Even after mapping to common, standard terminologies such as LOINC, the teams found they were using different subsets of the reference terminologies (more detail on this point is given by Dixon et al.(35)). Closing these gaps required further work for each site: the CDS service developers agreed to expand their valid input list, and the demonstration sites agreed to harmonize their mappings with the CDSC's preferred value sets in others.

Dimension 3: Human-Computer Interface

The four sites made different choices for their human-computer interface (HCI) designs, as shown in Figures 2-5. Partners (Figure 2) displayed the text of each alert on the main screen of each patient's chart, with actionable options to respond to each alert. Partners has many other CDS alerts, and the CDSC alerts (highlighted by a red rectangle) are intermingled with the "classic" alerts, providing a familiar user experience.

Regenstrief actually employed two different approaches. Initially, recommendations were delivered to a clinical "inbox" along with other messages – shown in Figure 3a. Later, Regenstrief moved the alerts to a "prevention/recommendations" section in the patient's chart to provide better integration with clinical workflow and an updated EHR platform (Figure 3b) (more detail on the system design is given in a prior study (40)). WVP provided a "CDS" button in NextGen that would appear when there were recommendations available for a particular patient. When clicked, the button would display all recommendations for that particular patient in a pop-up window. The Regenstrief and WVP implementations provided detailed recommendation text, but did

not support taking an action directly from the recommendation. RWJMS implemented the CDS service within a series of “encounter forms”, which are the main documentation and workflow tool in the GE Centricity system. The encounter forms allowed users to take suggested actions directly from the recommendation.

The HCI differences in local EHRs represent an important challenge for service-oriented CDS. Inferences from the CDS service must be sufficiently general that they can be implemented in a variety of different user interfaces and workflow contexts, without being so general that they lose meaning. The CDSC chose not to provide specific workflow or interface guidance for the implementing sites, so actual implementations differed significantly.

Dimension 4: People

One of the important lessons gleaned from the demonstrations of service-oriented CDS was the importance of peer-to-peer communication, particularly among clinical informatics staff and developers during the implementation of CDS services. In several cases, developers implementing the CDS services at the demonstration sites encountered challenges. At first, the implementing sites communicated these challenges to the CDS service developers at Partners through layers of analysts, support personnel and project managers, often causing significant delays and translation problems. Later, Partners created direct channels of communication between the developers responsible for creating the CDS service and the developers implementing the service. This significantly reduced “friction” in the communication process. Similarly, the sites had difficulty resolving terminology issues until terminologists, who were working on the mappings at each institution, had one-on-one discussions. Similarly, when the attorneys at each

institution consulted with one another to resolve legal issues, rather than communicating through their respective project managers, they were able to make significant progress. Ultimately, the peer-to-peer interactions provided a means for resolving technical, legal, and service-level issues in this multi-institutional collaboration.

Dimension 5: Workflow and Communication

Although the CDS content was the same at each demonstration site, the demonstration sites all made slightly different decisions on where to insert the call to the service into clinical workflow. Partners called the service synchronously at the time that a patient chart is opened, and the results are shown as a reminder at the top of the chart's summary screen. Regenstrief, by contrast, called the service in the background at the time that the patient registered for his or her appointment, and the result was then queued for the clinician as a clinical message. The asynchronous call allowed the service to utilize the entire time the patient was in the waiting room to present an alert so that CDS is not timed-out; however, it does not allow the service to present real-time decision support notifications in response to new clinical information recorded in the patient's EHR at this visit; such as, newly added medications or vital signs. WVP called the service the night before a patient visit, while RWJMS called the service at 7AM each day and generated recommendations for all patients on the schedule for that day. As described in dimension 3, designers of CDS services must take the range of workflow possibilities into account, and design inferences in a sufficiently generalizable way that they remain useful in a variety of implementation contexts.

Dimension 6: Internal Organizational Policies, Procedures, Environment and Culture

Tensions between operations and research teams posed obstacles to the implementation of service-oriented CDS. Both Partners and Regenstrief had distinct clinical and administrative operations and clinical informatics teams with complimentary yet distinct missions; these missions sometimes were in conflict. Primarily, the operations teams oversaw the development and day-to-day operation of the EHRs; the clinical informatics teams chaperoned the development and implementation of service-oriented CDS.

At Partners, there was tension between operations and research teams regarding the timeline to implement the service. There was disagreement on specifying the performance parameters of the service; such that, when the service was implemented to meet the timeline developed in the funding proposal, performance specifications had not yet been finalized. Thus, when the service experienced downtimes or slowed the EHR, the operations team would turn off the service. In many cases, it was later determined that the slowness was actually due to a bug elsewhere in the EHR platform and not in the service itself. Later, the research team deployed immunization rules that did not utilize a CCD in order to bypass the most inefficient component of the call and resolve concerns regarding the performance of the service.

Similarly, Regenstrief's clinical site, Wishard Hospital, made operational decisions regarding new products and platforms that were developed and implemented by research; such as, the rollout timeline of the new platform. This was difficult for the informatics team that developed these products because they did not have complete control over their implementation. Also, during the migration to the new clinical information system, Regenstrief experienced the competing resource-needs of the

operations and research departments, as there were fewer resources to put toward research and development due to the operational requirements of the migration.

WVP and RWJMS faced similar challenges with their vendors. Although both participating vendors (NextGen and GE) were highly committed to the project, they were also facing significant development schedule pressure owing to ONC-ATCB “meaningful use” certification requirements – a key business imperative. As a result, there were some delays in implementing the services until the required development resources could be freed to complete the integration.

Dimension 7: External Rules, Regulations, and Pressures

The collective experience of the clinical sites provided many useful insights regarding the legal complications involved in implementation of service-oriented CDS. In particular, due to the fact that Regenstrief was the first demonstration site, Partners’ and Regenstrief’s joint effort to overcome these legal issues provided the groundwork for the discussions and agreements that were to follow at the proceeding demonstration sites. More detail on the legal issues encountered is given in Hongersermeier et al. (41).

The most challenging hurdle was coming to agreement about whether and how long Partners would retain the patient data collected by Regenstrief. Service-oriented CDS required Regenstrief to transmit partially de-identified (specifically, a limited data set under 45 CFR 164.514) patient data in CCDs to Partners, so a data use agreement had to be negotiated. Regenstrief was hesitant about allowing Partners to store the CCD data due to concerns that Partners would conduct post-hoc analytical research on the data they received, or make other non-agreed-upon use of the data. Partners, alternatively, saw the need to maintain their own recordkeeping data bases of the CCD data in order to fine-

tune the service and identify the source of potential CDS errors. In the event of an erroneous decision support rule, Partners would then be able to determine if erroneous rules were due to errors in the data sent from Regenstrief or in the logic of the service itself.

The negotiated agreement ultimately allowed Partners to retain the patient data from the CCDs for three years in order to troubleshoot errors in the system. Partners also would retain service performance data for seven years in order to be compliant with their IRB. Further, the agreement addressed Regenstrief's concerns regarding Partners' use of CCD data to conduct research: under the contract, Partners "will only use the personal health information provided hereunder as necessary to operate, evaluate, troubleshoot, or improves the [CDSC Rules Service], pursuant to the IRB for that project [and] will maintain appropriate administrative, physical, technical and procedural safeguards to protect the confidentiality of electronic information... [including compliance with] ...HIPAA."(41)

Another issue that Regenstrief and Partners faced was writing the Services Sharing Agreement (SSA) to reflect the unique nature of the service. The first draft of the agreement was written as a software licensing agreement, and did not take into account the exchange of personal information or the fact that Regenstrief and Partners had a prior agreement regarding sharing clinical knowledge for CDS. For this reason, the initial SSA did not provide the appropriate safeguards for patient privacy and was not acceptable to Regenstrief's in-house legal team. As a result of consultations between attorneys from both institutions, the agreement was revised to account for existing agreements between

Partners and Regenstrief, and included safeguards for de-identification of patient data in accordance with HIPAA regulations.

Additionally, Partners and Regenstrief navigated disagreements regarding liability for the service's recommendations. Originally, both organizations sought indemnification from the other institution. However, in the end, the agreement they signed did not provide indemnification to either institution, stating that there would not be liability or warrantee for the service, and Regenstrief would display a disclaimer.(41) Additionally, both Partners and Regenstrief held the position that CDS was a tool, and that "a clinician is ultimately responsible for making the final decision on utilizing or not the provided decision support."(41)

Although significant work was required to develop the initial set of agreements used between Partners and Regenstrief, these same agreements were able to be used, with only minimal adaptation, for the WVP and RWJMS demonstrations.

Dimension 8: System Measurement and Monitoring

The demonstration sites implemented strategies for measurement and monitoring to ensure the reliability of the service. Partners developed instrumentation to monitor the services themselves, and all four demonstration sites developed real-time and retrospective tools to measure and monitor the impact of the service generation and consumption on their EHRs. In order to ensure the continued functioning of its EHR, even when the service failed, Partners also implemented a failover system.

Although this monitoring proved useful, the service did sustain several downtimes, not all of which were discovered by the monitoring systems. Over time,

additional measurement points were placed into the process in order to more quickly identify performance degradations and intervene in a timely fashion.

DISCUSSION

In this study, we described the successful implementation of a remotely-hosted CDS service in four diverse clinical environments. Our experiences are described in detail in the results section. Although some of the challenges encountered are common across all modes of CDS implementation, most are specific to the unique complexities of service-oriented CDS, particularly when the CDS system crossed organizational boundaries. In reflecting on these results, we have identified several recommended practices for future developers and implementers of CDS services:

- Optimize performance, or make asynchronous calls: The biggest challenge faced by the CDSC related to performance – primarily the time required to generate a CCD. When implemented synchronously, the user must wait for CCD generation and the CDS service call to complete before receiving the results of the inference (and, depending on implementation, the call may block the user from proceeding entirely). As such, asynchronous calls should be considered in situations where they work well (such as screening recommendations). However, many types of CDS are triggered by user actions (such as placing a medication order) (42), so they require synchronous calls. In these situations, it is important to maximize performance, which can be achieved through faster CCD generation supported by proper indexing and intelligent caching.

- Be liberal in what you accept: The CDSC encountered several situations where a clinical entity (exam, test, procedure or problem) was not properly identified by the CDS service. In most cases, this occurred because a code which was appropriate, but not expected, was sent. For example, Wishard used retinal photography to screen for diabetic retinopathy and sent the billing diagnosis for this procedure (the ICD-9 code V80.2, which is actually more general, corresponding to “screening for other eye conditions”) to the CDS service. However, the service was designed to look for the SNOMED code for ophthalmoscopic retinal examination, so it recommended retinal examination when it had already been performed. Most of these errors were caught during testing, but some occurred in production and required remediation. As such, we recommend that CDS service and content developers be liberal in the codes they accept – even those that they might not expect, and both developers and implementers should have frequent and detailed discussions about codes in use (and changes).
- Be transparent about clinical content: The preventive services recommended by the CDS services in this study were intentionally selected to be relatively uncontroversial; however, ensuring frequent discussion between content developers and content consumers is essential so that consumers understand and subscribe to the content that is developed.
- Develop a legal framework: The first demonstration at Regenstrief was delayed during the process of legal negotiation. We strongly recommend early discussions between attorneys at the CDS service developing and implementing sites to reduce

the risk of delay. However, the agreements developed generalized easily to the other sites, so it is possible that this is a one-time startup cost.

- Support a flexible front-end: All of the sites implemented the services at slightly different points in the workflow. Because the CDSC developed services that were clinically-oriented (i.e. the service made a structured recommendation to test a patient's HbA1c) rather than workflow-oriented (i.e. suggesting a pop-up), the implementing sites had significant flexibility to embed the content however they liked. We strongly recommend CDS service developers pursue a similar clinically-oriented approach to support flexibility.
- Dedicate technical and clinical resources for service implementation: A challenge at all four demonstration sites was securing the technical, clinical and informatics resources needed to complete the implementation. Where possible, dedicated resources should be identified and used, as other operational challenges may often interfere with CDS service implementation. Although dedicated resources are advantageous for all types of CDS implementation, they are particularly important for service-oriented implementation, since coordination across sites can be complex.
- Support peer-to-peer communication: As much as practical, communication between software developers, attorneys, terminologists, clinical informaticists and clinical content developers at the service-developing and service-implementing sites should be direct and peer-to-peer. Layers of complexity or filtering significantly increase friction and introduce errors in translation.
- Improve standards: An unexpected challenge for CDSC was the diversity of CCD implementations, even though all CCDs used passed validators. Additional work is

needed both to resolve ambiguities in the standards, and to increase the sophistication of validators.

CONCLUSION

The CDSC successfully developed a CDS service that was implemented and used in a live clinical environment at four diverse clinical sites. However, many challenges to the widespread adoption of CDS services were identified, and additional research and optimization is needed before such services are ready for widespread deployment.

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CONTRIBUTORSHIP STATEMENT

Drs. Wright, Sittig, Ash and Middleton were responsible for the conception and design of the study, as well as study supervision. All of the authors participated in acquisition, analysis or interpretation of the data. Dr. Wright and Ms. Erickson drafted the manuscript and the other authors provided critical revision of the manuscript for important intellectual content. Drs. Middleton and Wright obtained funding for the study.

COMPETING INTERESTS

The authors have no competing interests to declare.

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Table 1: Clinical Sites

Site	Location	Setting	EHR system	Start Year
Partners HealthCare	Boston, MA	Academic medical center	Self-developed	2010
Regenstrief Institute	Indianapolis, IN	Community practices	Self-developed	2011
WVP Health Authority	Salem, OR	Independent physician association	NextGen	2012
Rutgers Robert Wood Johnson Medical School	New Brunswick, NJ	Academic medical center	GE Centricity EMR	2014

Table 2: Site Visits

	Partners HealthCare	Regenstrief Institute	WVP Health Authority	Rutgers Robert Wood Johnson Medical School	EHR Vendor 1	EHR Vendor 2
Location	Boston, MA	Indianapolis IN	Salem OR	New Brunswick NJ		
Characteristics of setting	Academic and community outpatient	Academic and county clinics	Community outpatient	Academic outpatient	EHR Vendor	EHR Vendor
Type of System	Locally developed and commercial	Locally developed	Commercial	Commercial	NA	NA
Date of Visit	June, 2008 and December, 2010	September, 2008 and March, 2011	December, 2008 and May, 2013*	February, 2009 and September, 2012*	September, 2009*	May, 2011*
Hours observing	37	20	33	26	NA	NA
Individuals observed	17	16	27	17	NA	NA
Number of clinics observed	9	6	9	6	NA	NA
Number of interviews	13, 19	9, 5	9, 1	12, 1	10	12

* Site visit conducted virtually

Table 3: Representative Quotes

<i>8-Dimensional Model</i>	<i>Respondent Comments</i>
Hardware and software computing infrastructure	<ul style="list-style-type: none"> • If you take the existing decision support process that was implemented for CDS Consortium and was in production for LMR, the current chain of communication when LMR calls ECRS, ECRS calls CCD Factory, CCD Factory calls various data repositories, and then ECRS gets the data calls, iLog [the rule engine behind service-oriented CDS] answers the data [call] back, the most time-consuming part is getting the data from those repositories. That part can exceed the [time-out] threshold. (Lead Programmer) • Their [Regenstrief's] interpretation of the CCD standard was different from ours [Partner's]...They validated the CCD but it wasn't the same as ours...and there was some negotiation. (Program Manager)
Clinical content	<ul style="list-style-type: none"> • ...the underlying semantics might actually be the biggest challenge[s] of them all, and the most under-recognized challenges. Figuring out when one code maps one-to-one or when it maps one-to-many, anytime you try to translate from one vocabulary to another, there might be subtle losses of meaning or gaining of new meaning. (Team Member) • There were certain ACE inhibitors that could not be matched back to that class in NDF-RT. So we found out when Regenstrief sent us a patient CCD with this [particular] code, and we ran the rule, and they said, 'How come you gave us the recommendation that the patient should be on an ACE inhibitor? He's on an ACE inhibitor' ...and we've had to go back to RxNorm and to NDF-RT and say, 'Please add this in.' In the meantime, we have to put in Band-Aids, which a Band-Aid basically means, you put in an exception to the rule. (Medical Informatician)
Workflow and communication	<ul style="list-style-type: none"> • Partners LMR presents those recommendations in real-time, as the physician opens up the record. Regenstrief calls the service before the patient shows up, or maybe as the patient is registering, gets the recommendations, and populates a workflow application that is similar to email. (Medical Informatician)
Human-computer interface	<ul style="list-style-type: none"> • So the kinds of things like preventive care reminders where you can sort of calculate those prior, the performance isn't as important. But if you're doing on-the-fly sorts of reminders, you need to have pretty good performance, and some of that you can still sort of finesse in the background and start computing it before you actually need it. But for doing things like order entry...you need sub-second response times. (CDS Architect)
System measurement and monitoring	<ul style="list-style-type: none"> • We put in a ton of log monitoring of our own inside the ECRS, that alert us when we're getting these threshold-exceeded problems, or when a service doesn't respond. (Program Manager)
Internal organizational policies, procedures, and culture	<ul style="list-style-type: none"> • There were a couple of times at the beginning where the service performed kind of poorly, and [the research group] did our analyses and we figured it out, and put the checks in place. But the [LMR team], they basically became distrustful of the service, thereafter, any time anything went wrong with LMR, the first thing they blamed was the service. Since that time, since we've implemented these checks, I think we have not been the cause of any of their problems, but we are the scapegoat, and so that's been, I think, kind of a sore point. So sometimes in the LMR, the ECRS has been turned off, but there's nothing wrong with ECRS. There were other issues going on outside of ECRS. (Medical Informatician) • I just came out of a meeting before I came here, discussing those very tensions and it's an ongoing struggle. Obviously, we are first and foremost a research institute, right? But we have to do and manage the operations

<p>External rules, regulations, and pressures</p>	<p>and create and manage the infrastructure in order to do research. So, and sometimes those requirements are at odds with what the researchers want to do, and so that's a struggle we face every day. We're in a particularly awkward time right now, making the transition from [a prior CIS] to [a] new [CIS] and we have not yet completed that transition. Not wanting to invest a lot of time and resources in the [prior CIS] stuff, which limits some of the research that folks are able to do. So I mean, there is tension and we're at a juncture right now where there's probably even more tension than usual. (CDS Architect)</p> <ul style="list-style-type: none"> • The reason it gets much more complicated from the service model is because of the transfer of data. So then it gets to: What are you doing with the data? What can you use the data for? What can't you use the data for?...Based upon what we can do with the data that we're the custodian for, we can't give it to a third party and say, 'You also now have permission to grant access for research purposes.' We have to know exactly what's being done with that data, and it has to be, if it's research, it has to be limited to IRB-approved research. (Attorney) • Well, the initial draft of the agreement was written like I would expect a software agreement from Microsoft to be written – very one-sided, very 'everything-to-the-benefit-of-Partners' ...And it also got muddy because the initial draft didn't take into account the fact that we had an independent right, not to the software, but to all the decision support rules as they exist already through the consortium portal...And so we had to work through the fact that, we have these, some existing agreements, that already govern some of these things, and we can't have contracts that contradict each other. (Attorney) • It started out as an agreement that wasn't HIPAA compliant. I can't sign an agreement to give somebody PHI [personal health information] that disclaims security. Under HIPAA we can't do it. So that's been a big part of the challenge, is that the initial starting place appeared to me to be done by an outside attorney that Partners paid that specializes in software license agreements, and didn't understand anything about the project. And that started out as a big challenge. (Attorney) • There's also always the fact that a physician has to do what their training has taught them is best, no matter what a decision support tool might recommend, because the decision support tool will never have all of the information that the physician has. (Attorney)
<p>People</p>	<ul style="list-style-type: none"> • And then, I think the third thing that sort of made it complicated was the IRB aspect of this, and the fact that our counsel and IRB had sort of trouble understanding the requests from the other IRB. I think if I had to do it over again, I'd probably, early on, we would have just had our IRB attorney call [Partners'] IRB attorney, and have an IRB-attorney-to-IRB-attorney conversation, because our IRB attorney was talking to our counsel, who was talking to me [a project manager]...and you know how the game of 'Telephone' works, right? (Program Manager)

Figure Legend

Figure 1: Architecture of CDSC clinical decision support service

Figure 2: CDS Intervention in Partners LMR

Figure 3a: CDS Intervention in Regenstrief G3 system (original presentation, with alerts directed to inbox)

Figure 3b: CDS Intervention in Regenstrief G3 system (revised presentation, with alerts shown in "prevention / recommendations" section of patient chart)

Figure 4: CDS Intervention in WVP NextGen system

Figure 5: CDS Intervention in RWJMS GE system

Figure 1: Architecture of CDSC clinical decision support service

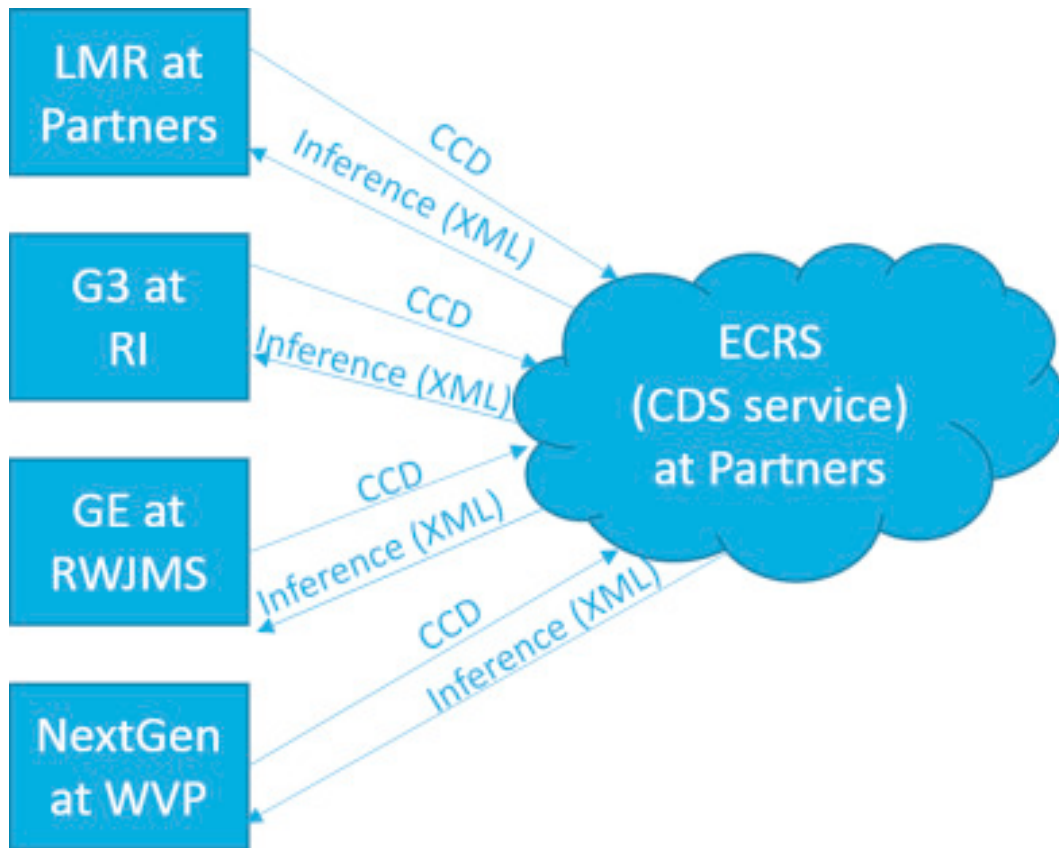


Figure 2: CDS Intervention in Partners LMR

LMR OC4A2 SUMMARY - Windows Internet Explorer

LMR OC4A2 SUMMARY

Bwhlmmrmapitest,Four

24252934 (BWH) 07/15/1939 (71 yrs.) F

Home Select Desktop Pt Chart: Summary Oncology Custom Reports Admin Sign Results ? Resource PopUp

Customize

Reminders

- No documented tobacco status. Click to enter status. Never used tobacco Execute
- Patient 65 yrs or older, due for Pneumovax.
- Patient 50 years old or greater, recommend influenza vaccination.
- Patient has CAD-equivalent on problem list and a beta blocker is not on the medication list. Recommend beta blocker.
- Patient has CHD-equivalent, overdue for lipid assessment (rec: q 1 year).
- Pt is overdue for colonoscopy (rec: q 10 years), FamHx indicates average risk for colorectal cancer. Referral requested Execute
- Diabetic patient is overdue for HgbA1c measurement (recommended every 6 months). Order HbA1c Execute
- Diabetic patient is due for ophthalmologic exam (recommended yearly). Appointment scheduled Execute
- Diabetic patient is due for foot exam (recommended yearly). Appointment scheduled Execute
- Diabetic Patient with renal disease, consider starting angiotensin-converting enzyme inhibitor (ACE-I). Order ACEI Execute
- Patient has CAD or equivalent, consider starting anti-platelet therapy, but potential contraindications exist. Order Aspirin Execute
- Patient is overdue for blood pressure assessment (recommended yearly). Done Elsewhere Execute

Flowsheets Add New

Medications Enter new med Add New

Procedures Enter new proced Add New

Physicians Enter new phys Add New

Notes Add New

Date	Subject	Provider
05/14/2010	Patient Note	Hanley, William A.
05/14/2010	Code Status/LST Note (MGH)	Hanley, William A.
05/14/2010	Code Status/LST Note (MGH)	Hanley, William A.
05/14/2010	Code Status/LST Note (BWH)	Hanley, William A.

Problems Enter new probl Add New

- Diabetes mellitus
- Renal insufficiency
- Coronary artery disease
- Peptic ulcer disease

Health Monitoring Enter new hm it Add New

HM Item	Date of Last	Result
---------	--------------	--------

Care Providers Add New

BMT Flowsheet

HM Form

Sticky Notes Add New

Allergies Add New

Allergen	Reaction
Milk Protein - Moderate	- Itching - Rash

Visits

Date	Provider	Clinic
------	----------	--------

Pharmacies Add New

Patient M/A List

Oncpro

To Do Add New

Immunization

Trusted sites 100%

Figure 3a: CDS Intervention in Regenstrief G3 system (original presentation, with alerts directed to inbox)

Welcome to G3! [Relay Health](#) [External Resources](#) [Leave Feedback](#) [Help](#)

No Patient Selected [Change](#)

[Inbox](#) **Dashboard** [Order Entry](#) [View Chart](#) [Medication Reconciliation](#) [Orderset Builder](#) [Relay Health](#) [ResNet](#) [Settings](#) [Adm](#)

Find Patient: [Advanced Patient Search](#)

Recently Accessed Patients

Last Name	First Name	MRN	DOB
TEST		17161134	06-Apr-1977
TRIAL		9993	25-Jun-1965
PRACTICE		999995	18-Apr-1945
TEST		999996	25-Feb-1992
TEST		12344	24-Apr-1974
TEST			

Inbox

Date Delivered	Patient	Subject
28-Dec-2010 15:03		Patient is overdue for blood pressure assessment (recommended yearly).
28-Dec-2010 15:03		Diabetic patient is overdue for HgbA1c measurement (recommended every 6 months).
28-Dec-2010 15:03		Diabetic patient is due for foot exam (recommended yearly).
28-Dec-2010 15:03		Diabetic patient is due for ophthalmologic exam (recommended yearly).

Figure 3b: CDS Intervention in Regenstrief G3 system (revised presentation, with alerts shown in "prevention / recommendations" section of patient chart)

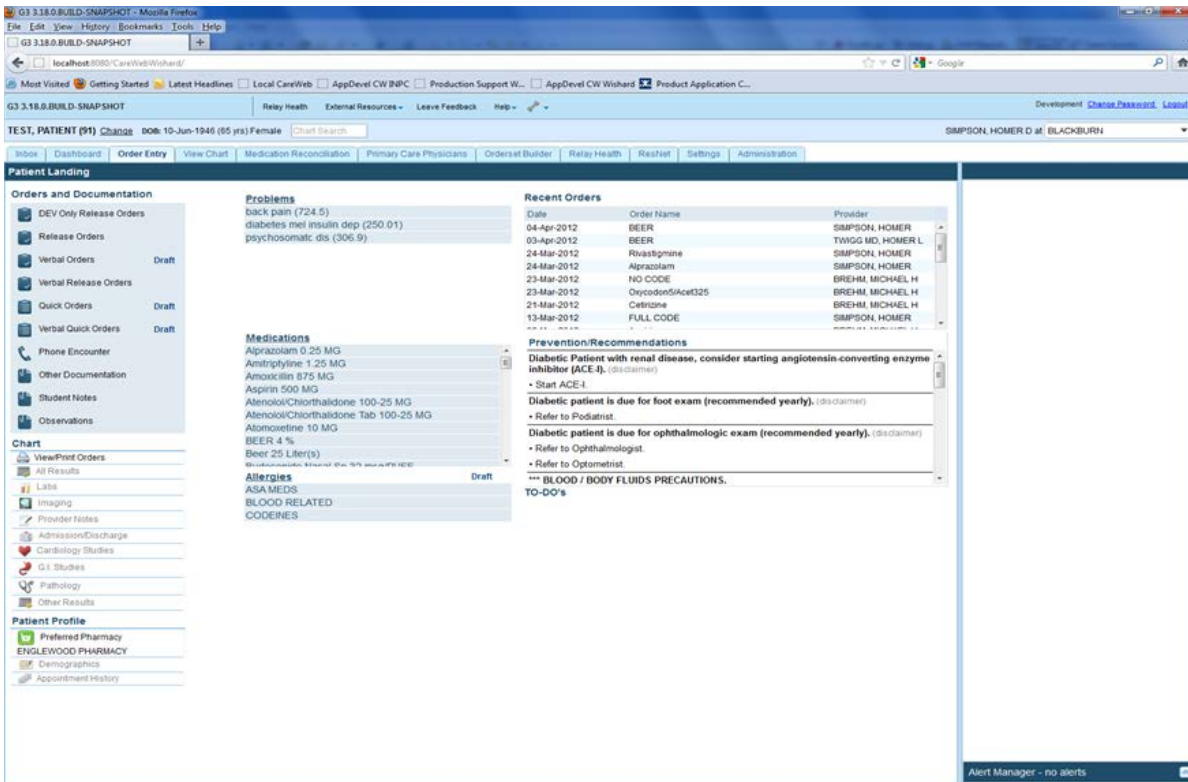


Figure 4: CDS Intervention in WVP NextGen system

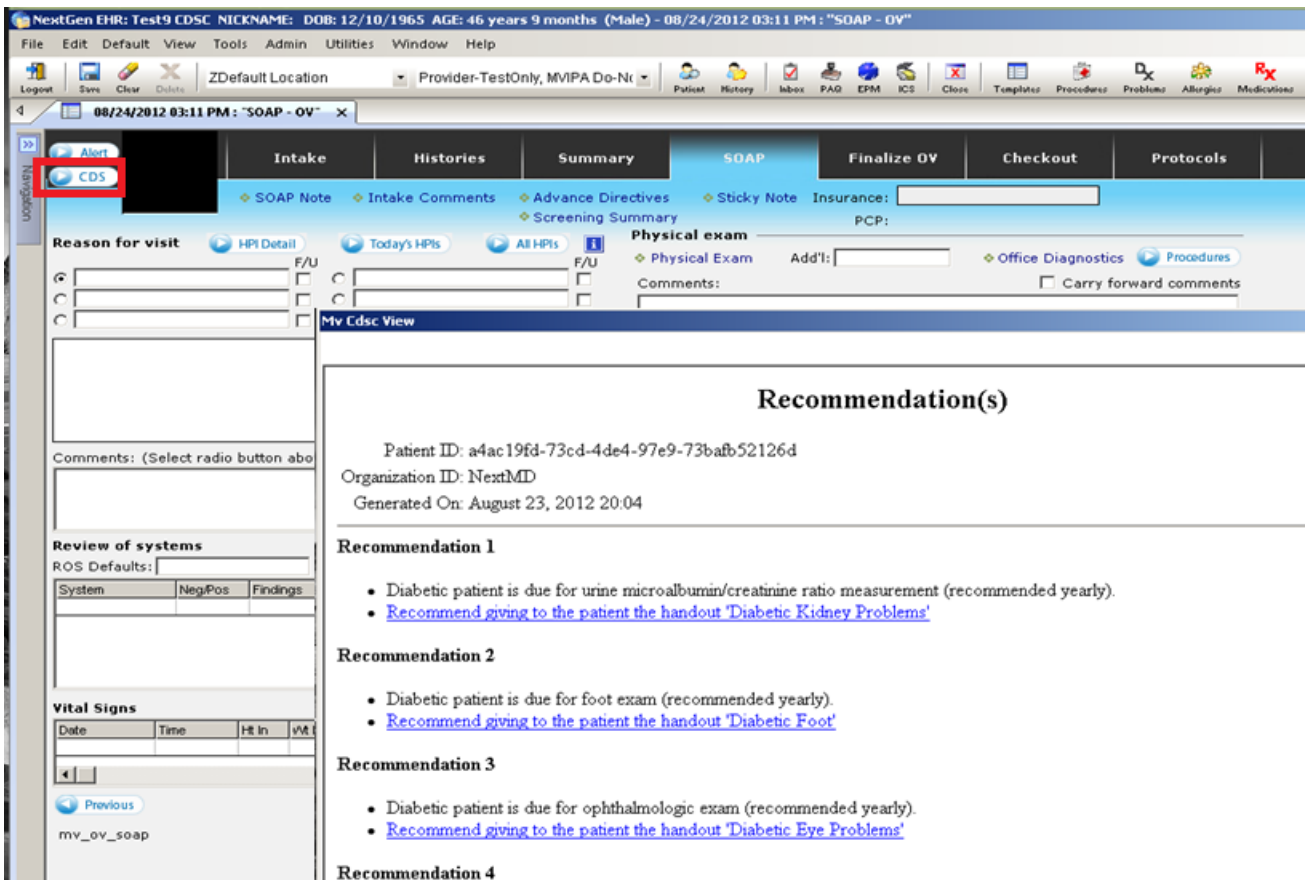











Figure 5: CDS Intervention in RWJMS GE system

Guardian: N/A Primary#: N/A Alt#: N/A Cell: N/A Insurance Company:

CDSC Advice: Case1 zzCDSC

CDSC Advice | Data Entry

Patient ID: Handle:  Version 1.02

Rule	Data	Message	Action
HgA1c			
01	HgbA1c not recorded 	Diabetic patient is overdue for HgbA1c measurement (recommended every 6 months). 	<input type="button" value="Order HgbA1c"/>
Diabetic Exams			
04	Eye Exam not recorded 	Diabetic patient is due for ophthalmologic exam (recommended yearly). 	<input type="button" value="Eye Exam"/>
05	Foot Exam not recorded 	Diabetic patient is due for foot exam (recommended yearly). 	<input type="button" value="Foot Exam"/>
Diabetic nephropathy screening/treatment			
Antiplatelet Rx			
Blood pressure screening			
11	Last BP not recorded 	Patient is overdue for blood pressure assessment (recommended yearly). 	<input type="button" value="Record new BP"/>