Integrating Clinical Decision Support Into Workflow
Final Report

Integrating Clinical Decision Support into Workflow

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Preface

This project was funded as an Accelerating Change and Transformation in Organizations and Networks (ACTION) task order contract. ACTION is a 5-year implementation model of field-based research that fosters public–private collaboration in rapid-cycle, applied studies. ACTION promotes innovation in health care delivery by accelerating the development, implementation, diffusion, and uptake of demand-driven and evidence-based products, tools, strategies, and findings. ACTION also develops and diffuses scientific evidence about what does and does not work to improve health care delivery systems. It provides an impressive cadre of delivery-affiliated researchers and sites with a means of testing the application and uptake of research knowledge. With a goal of turning research into practice, ACTION links many of the Nation's largest health care systems with its top health services researchers. For more information about this initiative, go to http://www.ahrq.gov/research/action.htm.

This project was one of seven task order contracts awarded under the Improving Quality through Health IT: Testing the Feasibility and Assessing the Impact of Using Existing Health IT Infrastructure for Better Care Delivery request for task order (RFTO). The goal of this RFTO was to fund projects that used implemented health IT system functionality to improve care delivery. Of particular interest were projects that demonstrated how health IT can be used to improve decision support, automate quality measurement, improve high-risk transitions across care settings, reduce error or harm, and support system and workflow design, new care models, team-based care, or patient-centered care.
Structured Abstract

Purpose: The aims were to (1) identify barriers and facilitators related to integration of clinical decision support (CDS) into workflow and (2) develop and test CDS design alternatives.

Scope: To better understand CDS integration, we studied its use in practice, focusing on CDS for colorectal cancer (CRC) screening and followup. Phase 1 involved outpatient clinics of four different systems—120 clinic staff and providers and 118 patients were observed. In Phase 2, prototyped design enhancements to the Veterans Administration’s CRC screening reminder were compared against its current reminder in a simulation experiment. Twelve providers participated.

Methods: Phase 1 was a qualitative project, using key informant interviews, direct observation, opportunistic interviews, and focus groups. All data were analyzed using a coding template, based on the sociotechnical systems theory, which was modified as coding proceeded and themes emerged. Phase 2 consisted of rapid prototyping of CDS design alternatives based on Phase 1 findings and a simulation experiment to test these design changes in a within-subject comparison.

Results: Very different CDS types existed across sites, yet there are common barriers: (1) lack of coordination of “outside” results and between primary and specialty care; (2) suboptimal data organization and presentation; (3) needed provider and patient education; (4) needed interface flexibility; (5) needed technological enhancements; (6) unclear role assignments; (7) organizational issues; and (8) disconnect with quality reporting. Design enhancements positively impacted usability and workflow integration but not workload.

Conclusions: Effective CDS design and integration requires: (1) organizational and workflow integration; (2) integrating outside results; (3) improving data organization and presentation in a flexible interface; and (4) providing just-in time education, cognitive support, and quality reporting.

Key Words: information technology, workflow, clinical work, decision support, electronic health records, quality improvement, delivery systems
Purpose

We had two major objectives for this project: (1) to identify barriers and facilitators to workflow integration of clinical decision support (CDS) for colorectal cancer screening and 2) to prototype and test CDS design alternatives for improved integration into workflow through a controlled simulation study.
Scope

Computerized clinical decision support (CDS), as an integral part of an electronic health record (EHR), can improve clinician decisionmaking, support evidence-based practice, and ultimately improve quality of care.\textsuperscript{1-3} Integration of CDS into clinical workflow is consistently identified as one of the key factors influencing uptake and sustainability.\textsuperscript{4,5}

Notably, the Institute of Medicine recently called for a paradigm shift in providing cognitive support for clinical decisions, including: providing an integrative view of patient data; integrating decision support into clinical practice; providing clinicians evidence-based decision support and feedback; supporting data-driven process improvement; and linking clinical care and research.\textsuperscript{6} Additionally, new investments by the Office of the National Coordinator for Health Information Technology (Health IT) in the SHARP Program promise to foster more rapid nationwide, \textit{meaningful use} of EHRs in four areas: health care application and network design, patient centered cognitive support, security and health IT, and secondary use of EHR data. These critical investments emphasize the importance of identifying effective strategies for design of and integrating CDS into clinical work.

We chose to focus our study on the use of CDS for colorectal cancer (CRC) screening and followup, because of the disease prevalence, evidence-based recommendations, and the population health impact of increasing CRC detection.\textsuperscript{7,8} CRC ranks third among causes of cancer deaths, and is the third most common cancer among both men and women in the United States.

Notably, CRC has a significant economic impact on health care systems, patients, families, and society. The total costs attributed to CRC in the United States is approximately $8.4 billion, with 80 percent of these due to inpatient medical care costs, making CRC among the costliest cancers to treat.\textsuperscript{9} Stage at diagnosis is the primary predictor of survival.

Less than half (40 percent) of colorectal cancers are found at an early stage, in large part due to low rates of screening. There is strong evidence that CRC screening can reduce cancer-specific mortality.\textsuperscript{9} With strong evidence for screening effectiveness and low screening rates, the CRC screening process is an ideal opportunity for redesigning clinical practices and considering the integration of CDS into outpatient clinical workflow.

A seminal systematic review of CDS effectiveness by Chaudhry et al. identified four benchmark informatics institutions, the Regenstrief Institute (RI), Partners HealthCare System (PHS), Veterans Administration (VA), and Intermountain Healthcare, as most often cited in the medical literature demonstrating the efficacy of CDS in improving quality and efficiency.\textsuperscript{10} Because of the considerable experience in designing, implementing, and studying CDS in these institutions, they provided an optimal health care setting in which to study the design and integration of CDS into clinical work.

To understand how to better design and integrate CDS into clinical work, we observed its use in clinical practice at several different clinical settings (Phase 1). Phase 1 was conducted in outpatient clinics affiliated with four medical centers. In total, 120 clinic staff and providers and 118 patients were observed.

Based on findings from this extensive field study, we prototyped and tested a redesigned clinical reminder in a controlled laboratory simulation experiment (Phase 2). In Phase 2, prototyped design enhancements to the Veterans Health Administration’s (VHA’s) colorectal cancer (CRC) screening clinical reminder was compared against the VHA’s current CRC
reminder in a simulation experiment. Twelve experienced primary care providers (PCPs) from five outpatient clinics at the Veterans Affairs Medical Center (VAMC) study site participated.
Methods

The study was approved by the Indiana University Institutional Review Board, the Indianapolis VA Medical Center Research Committee, and IRBs at each individual study site.

Expert Panel Methods Review

Prior to beginning data collection, we organized and hosted an in-person expert panel to further refine our proposed methods, in order to potentially increase the impact of the project. A total of eight experts participated in the full day structured consensus meeting. Attendees included experts in primary care, colorectal cancer screening, clinical decision support, medical informatics research, and human computer interaction.

The topics for the breakout sessions included the following: identifying important considerations in how CDS impacts providers and patients; developing CDS design alternatives; system redesign and implementation; and approaches to refine the proposed methods.

Attendees were asked to rank potential key informant interview questions and opportunistic questions in order of importance for including in the study. These rankings were tabulated and results provided back to inform discussion. Additionally, attendees participated in breakout discussions, each facilitated by project personnel. In total, each attendee participated in two breakout sessions (four total sessions).

Project personnel facilitated the discussions, took notes and tabulated results from polls prioritizing potential project components in a structured consensus process. Suggestions and critical questions were considered as data collection methods were finalized. Participants completed a written Feedback Form on which they indicated specific recommendations for each phase of the study. As the result of the discussion and feedback from the expert panel, we conducted focus groups at two of the four sites, extended the observation period to 2 days, and asked clinics to identify patients that were due for a CRC screening (to focus observations).

Phase 1

Phase 1 was a multimethod qualitative study that used ethnographic observation, opportunistic interviews, key informant interviews, and focus groups to collect data.

Site Selection

Based on feasibility, we selected three of the aforementioned four benchmark health systems for the present study: VA, RI, and PHS.10 Two VAMC sites were selected based on having a strong medical informatics presence, strong clinical performance, and being geographically distributed nationally (south and east). Notably, one of the VA sites had developed an original CDS suite through an extensive interdisciplinary design process to provide additional cognitive support, risk stratification, and scheduling followup specialty diagnostic appointments. At each of the four sites, qualitative data was collected in multiple outpatient clinics. For both RI and PHS, outpatient clinics were located in multiple settings, so observations occurred at multiple community outpatient clinics.

Table 1 describes the clinic settings and the number of participants and patients observed at each site. The participants were physicians (35 percent), health technicians or medical assistants.
(23 percent), nurses (20 percent), nurse practitioners or physician assistants (10 percent), desk clerks (9 percent), and administrators (3 percent).

Table 2. Type of participating organization, number of key informant interviews, number of providers and clinic staff observed, and number of patients observed by site

<table>
<thead>
<tr>
<th>Organization</th>
<th>Type of setting</th>
<th>No. Key informant interviews</th>
<th>No. providers and clinic staff observed</th>
<th>No. patients observed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td>Two primary care clinics, one psychiatric outpatient clinic in VA Medical Center Tertiary care facility</td>
<td>3</td>
<td>Health technician, Medical assistant: 3, Front desk clerk: 2, Nurse (RN, LPN): 1, Nurse Practitioner, Physician Assistant: 2, Physician: 1, Other: 0, Total: 19</td>
<td>34</td>
</tr>
<tr>
<td>Site 2</td>
<td>Community based primary care clinic using Regenstrief Institute EMR</td>
<td>3</td>
<td>Health technician, Medical assistant: 3, Front desk clerk: 2, Nurse (RN, LPN): 1, Nurse Practitioner, Physician Assistant: 2, Physician: 1, Other: 0, Total: 19</td>
<td>30</td>
</tr>
<tr>
<td>Site 3</td>
<td>Three primary care clinics in VA Medical Center Tertiary care facility, one affiliated CBOC</td>
<td>2</td>
<td>Health technician, Medical assistant: 3, Front desk clerk: 2, Nurse (RN, LPN): 1, Nurse Practitioner, Physician Assistant: 2, Physician: 1, Other: 0, Total: 19</td>
<td>22</td>
</tr>
<tr>
<td>Site 4</td>
<td>Two community based primary care clinics, and one primary care clinic in large teaching hospital</td>
<td>3</td>
<td>Health technician, Medical assistant: 3, Front desk clerk: 2, Nurse (RN, LPN): 1, Nurse Practitioner, Physician Assistant: 2, Physician: 1, Other: 0, Total: 19</td>
<td>32</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>11</td>
<td>120</td>
<td>118</td>
</tr>
</tbody>
</table>

Field Study Methods

Investigators conducted rapid ethnographic observation11 (with opportunistic interviews) of CDS use and key informant interviews to identify putative best practices and barriers to effective use of CRC CDS. This data collection focused on the various modalities of CRC screening: fecal occult blood test (FOBT), flexible sigmoidoscopy, and colonoscopy. Additionally, focus groups with providers were conducted at the two VAMC sites.

Direct Observation

Investigators used direct observation to record the range of ways in which providers interact and use CDS tools in real time. During observations, two to four observers experienced in ethnographic observation separately shadowed nurses and providers as they interacted with CDS tools during an actual work shift. Observations were recorded via handwritten notes on a structured observation form during participant interaction with the CDS, capturing discrete activities and verbalizations. Data was also gathered on the context and process surrounding CDS use.

Observers conducted opportunistic interviews of providers on their use of CDS in the outpatient clinics to better understand the observational data.12,13 These interviews were conducted during breaks in patient care, so as not to disrupt the natural workflow of the
providers. This discussion included why providers took certain actions, as well as opinions and feedback about barriers to the use of CRC CDS. This opportunistic feedback was recorded in the field notes. This feedback supplemented and informed the understanding of corresponding observations.

**Key Informant Interviews and Focus Groups**

The key informant interviews covered mechanisms and best practices used to facilitate CDS implementation and integration into workflow. Although the same core questions were asked during each interview, the semi-structured nature allowed for flexibility and gave the interviewee an opportunity to elaborate upon, or cover important topics that would not have otherwise surfaced.

Sample questions included the following: At what point do you interact with clinical reminders for outpatients? What is your ideal workflow in the outpatient clinic? What difficulties have you experienced fitting use of clinical reminders into your optimal workflow? Key informants were identified by local contacts as clinical champions for CDS and/or CRC screening. In addition, focus groups were conducted at the two VHA sites. Providers who participated in the observations were also invited to participate in the focus groups.

**Data Collection**

Before each site visit, a local contact person was identified who served as the liaison during the visit. This person introduced the observers and scheduled the observations in outpatient clinics. For each site, investigators conducted observations during 2 full days in at least 2 different outpatient clinics. Providers included in the observations completed an informed consent. Participants were not given financial incentives for their participation. The handwritten observations were typed after each site visit, and a coding scheme applied to permit tracking of observer, site, clinic, day, and time.

Key informants at each site were identified from the outpatient clinics. The key informant interviews were conducted either in-person during the site visit or afterward by phone. At the two VHA sites, focus groups of five to six providers were facilitated by one of the observers to explore in-depth barriers to using CDS for CRC screening and followup.

**Data Analysis**

All data collected during observation, key informant and opportunistic interviews, and focus groups were analyzed using a coding template. The research team developed this coding template based on the sociotechnical systems theory. The coding template included a category for each component of the sociotechnical system: social subsystem, technical subsystem, and environmental subsystem. For each of these categories, subcategory labels were identified (see Figure 1).
The coding team consisted of five members of the research team, four of whom collected ethnographic data from the site.

The coding template (or codebook) was modified as coding proceeded, themes emerged from the data, and findings were integrated across sites into meaningful patterns (i.e., barriers to CRC screening and followup). Segments were coded according to the coding scheme using MAXQDA—a qualitative data analysis software package. All data was independently coded by two researchers. Following coding of the documents independently, the coders reviewed, discussed, and reached consensus on coding before moving to the next portion of data. A document represented all observations recorded by any single observer on any given day.

A total of 23 documents (each representing an observer-day) were coded with 42 codes. Researchers created a unique, orthogonal, definition for each code. Once the analysis team had completed coding, data was merged into MAXQDA and coded segments were extracted by code.

After coding was complete, the coding team came together for a 2-day analysis meeting consisting of a round table discussion, document review, and categorization of barriers and facilitators. In the round table discussion, team members individually recorded salient problems and barriers after completing the in-depth analysis of ethnographic observations.

The team compared these problems and barriers in the round table discussion. The convergence in identified problems and barriers was recorded. The team then completed a document review where they reviewed all the coded segments organized according to the coding tree, as well as meeting notes collected over the course of weekly analysis meetings. The team recorded any additional barriers and facilitators that surfaced.

**Phase 2**

In Phase 2, we prototyped a redesign of the Veterans Health Administration computerized clinical reminder for CRC screening, based on selected key findings from Phase 1. Computerized clinical reminders are the most frequently used form of CDS in the VHA’s EHR, known as the Computerized Patient Record System (CPRS).
**Prototypes**

The redesigned prototype was constructed using Adobe® Fireworks® as a low-fidelity mock-up and converted to an executable PDF. In other words, screen captures of the current design were used as a visual base and then graphically rendered in redesigned formats. Links and buttons were made interactive to mimic the actual function of how the CRs would work if fully programmed. To enable us to compare the redesign with the way the current system functions, we also “prototyped” the current system in the same fashion so that both designs were at the same simulation fidelity level.

The redesigned prototype (design B) differed from the current design (design A) in the following two ways: (1) a timeline visual was created to display a complete, integrated history of a patient’s colorectal cancer screening tests and results, including FOBTs, sigmoidoscopies, and colonoscopies and (2) a resource was added to assist the primary care provider (PCP) in providing patient education.

Figure 2 shows an example of the timeline visual for a fictitious patient with no abnormal screening results.

**Figure 2.** Timeline visual that integrates previous colorectal cancer screening results

![Timeline visual](image)

If a patient did have an abnormal result displayed on the timeline visual, a provider could click on the relevant test on the timeline to see specific information about that result (Figure 3). The patient education resource was added to the redesigned prototype through a link to a one-page synopsis of CRC screening facts, so that the provider could review it with the patient at the time of offering the screening. These design changes were implemented to address barriers to effective CRC screening identified during our multisite field study in Phase 1.

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Figure 3. Specific information for an abnormal result is displayed when the user clicks on the result from the timeline

Apparatus

The IRB-approved experiment was set-up in the Human-Computer Interaction (HCI) & Simulation Laboratory at the Indianapolis VA Medical Center. The Lab provides an environment to capture performance and usability data and assess user interaction with clinical information systems. Morae® usability testing software was used to capture the direct screen image of the participant’s screen in conjunction with a Web camera to record the participant’s face.

The experimenter was able to view the participant’s screen via the Morae® recording in real time from a different workstation, separated by a divider to reduce potential experimenter bias. Prototypes of the current and redesigned CRC computerized clinical reminder were displayed on the participant’s computer.

Procedure and Scenarios

A brief demonstration of the current (design A) and redesigned (design B) prototypes was provided to orient each participant. The demonstration, including both prototypes, lasted no longer than 5 minutes. Then, for the experimental protocol, each participant was introduced to designs A and B, in a counter-balanced fashion (i.e., participant 1 used design A first, participant 2 used design B first, etc.). Each participant was given brief, written instructions to resolve the CRC clinical reminder for two patient scenarios for each design (four total scenarios), with relevant patient information necessary to complete the reminder.

We developed two scenarios: (1) a simple and (2) a complex patient scenario with the assistance of a practicing VA physician and coauthor (DH). Differences between the paired patient scenarios across designs A and B were “surface-level” only (e.g., name, social security number) to reduce variability with user performance not related to the design of the CRC screening clinical reminder.

In addition to designs A and B being presented to participants in a counter-balanced fashion, the presentation order of the simple and complex scenarios was also counterbalanced within designs A and B (i.e., participants 1 and 2 received the simple scenario first for both designs, participants 3 and 4 received the complex scenario first for both design, etc.). An overview of the simple and complex scenarios included the following:

- Simple: Patient is a 60-year-old male veteran who first came to the VA about 12 months ago. He is interested in discussing colonoscopy. Prior to seeking care at the VA, he completed FOBT cards for his family physician. He thinks they were negative, but he can’t remember
when he had them done. In addition, he believes he had a flexible sigmoidoscopy when he turned 50. He was not sedated for the procedure.

- **Complex**: Patient is a 60-year-old male veteran who first came to the VA about 1 year ago. He wonders whether he is due for another colonoscopy. He had a colonoscopy 4 years ago. The previous colonoscopy wasn’t cancer, but showed multiple polyps that the GI doctors said needed to be followed up.

The prototypes included the fictitious patients’ active problem list, medications, clinical reminders, current vitals, two previous progress notes, and previous test results (including CRC screening results). Since design A did not have the new timeline visual, previous CRC screening results were available as test results, which are currently displayed in the Labs or Reports section of CPRS.

Participants completed both patient scenarios for one design (A or B) before completing the two scenarios for the other design. The computerized version of the NASA Task Load Index (TLX)\(^{16,17}\) was administered to the participants after each patient scenario, a total of 4 times per participant. We used unweighted TLX scores as the TLX dimensional weighting procedure has been found to be of limited benefit.\(^{17-19}\)

Usability (CSUQ)\(^{20}\) and workflow integration surveys (paper-based) were administered after the participant had finished both patient scenarios for a given design, a total of two times per participant. We appended the standard CSUQ usability survey with three questions specific to CRC screening. The workflow integration survey was developed by our team based on findings from Phase 1.

The workflow integration survey consists of 12 items and assesses a CDS tool in terms of navigation, functionality, usability, and workload. Participants respond using a 5-point Likert scale (1 = strongly disagree, 5 = strongly agree). After the experimental conditions, we conducted an open-ended debrief interview to gather additional feedback on the redesigned interface. Total experiment time for each participant was scheduled for a maximum of 45 minutes.

### Statistical Methods

The experimental design was a within-subject A (current design) vs. B (redesign) comparison (the single factor was Design Type). To test the hypothesis that participants would perceive design B to be easier to use than with A, we grouped similar usability questions together and used the nonparametric Wilcoxon Signed Ranks Test to compare the 7-point Likert-type scale (1 = strongly disagree, 7 = strongly agree) responses across A and B; responses to a Likert-type item are normally treated as ordinal data in which case a non-parametric test is appropriate. Responses to the NASA TLX scale (0-100) are considered interval data.

Therefore, to test the hypothesis that participants would have a lower perceived workload using design B than with A, we conducted paired t-tests for each TLX item (mental demand, physical demand, temporal demand, performance, effort, and frustration level) as well as the composite TLX score across designs A and B.

Finally, to test the hypothesis that design B would receive higher ratings for workflow integration compared to design A, we first grouped the 12 questions from our workflow integration survey to four subscales (navigation, functionality, ease of use, and workload). Then,
as with the usability survey, we treated the data from the workflow integration survey as ordinal data and used the non-parametric Wilcoxon Signed Ranks Test to compare the 5-point Likert-type scale (1 = strongly disagree, 5 = strongly agree) responses across A and B for the four subscales. All of the statistical tests were two-tailed with a 0.05 level of significance.

Qualitative analysis: Qualitative data included the Morae® video recordings of the participant sessions, an open-ended portion of the CSUQ usability survey where participants were asked to list the three most positive and negative aspects of the CRC screening clinical reminder, and the open-ended debrief interview notes. The video recordings were reviewed and all participant comments and performance-related interactions with the new design features (timeline visual and patient education resource) were compiled. Each comment or interaction with a new design feature was coded as positive, neutral, or negative.

The same broad coding was applied to the open-ended usability survey comments and debrief notes. Then, we integrated the findings using all of these qualitative data for common occurrences across the 12 participants (e.g., X of 12 participants expressed favorable comments for the timeline visual format of the CRC screening results).
Results

Phase 1

Themes and CDS type:

The resulting 29 barriers and facilitators were grouped into nine themes that relate to integrating CDS into workflow. Themes included the following: (1) coordination of outside results, (2) coordination between primary and specialty care, (3) data organization and presentation, (4) just-in-time provider and patient education, (5) interface flexibility, (6) technological enhancements, (7) role assignments, (8) organizational issues, (9) and connecting decision support to quality reporting.

Coordination of outside results refers to issues both in obtaining and tracking CRC screening results from clinics in other health care systems. While this type of coordination goes smoothly in some cases, it is most often a barrier. Providers noted that patient memory is often unreliable for providing details about past screenings and results. Provider access and the transfer of results from tests and procedures conducted at outside clinics are often limited. Coordination between primary and specialty care is key to accurate and timely followup of abnormal test results. While some organizations have tools and procedures in place to facilitate this type of coordination, we found several examples of barriers to coordination in our data. A lack of coordination between primary and specialty care hinders primary care providers' abilities to resolve CRC clinical reminders. Specifically, when procedures are not scheduled, or screening results are not communicated to the primary care clinic, then the primary care provider cannot resolve CRC clinical reminders.

Data organization and presentation refers to the ease or difficulty with which a provider determines whether a colonoscopy has been ordered or scheduled. This information is needed to track where the patient is in the CRC screening process. Additionally, this theme includes issues in how information is presented on the computer screen so that the information sought is easy or difficult to locate. Just-in-time provider and patient education includes provider's understanding of best practices for CRC screening. Patient educational needs include the availability of patient instructions for how FOBT cards are returned and educational materials about colonoscopy for patients. Interface flexibility refers to the rigidity/flexibility of the computer interface and navigation features that influence how easily the provider is able to perform necessary tasks. Technological enhancements include changes to the functionality of the computer software and ability to override inapplicable or inaccurate CRC screening clinical reminders. Role assignments refer to the level of clarity among clinic providers about who conducts CRC screening within primary care. Organizational issues include how the exam room is configured (position of computer relative to patient and provider), time needed for providers to satisfy clinical reminders, and computer accessibility. Connecting decision support to quality reporting refers to both positive and negative consequences of using CDS tools to support performance measurement.

A comparison of these themes with the type of CDS typically used at the site supported the validity of the coding. For example, the site with a relatively simple electronic reminder also had the most coded comments regarding interface flexibility. We suspect that this may be due to
extensive use of text and dialogue boxes in the reminder design. However, the most positive or negative comments regarding technological enhancements, especially functionality, came from the site using an electronic dashboard for health maintenance, likely due to the greater variety of functions incorporated in a single dashboard. The most comments regarding coordination came from the site that had a sophisticated, interdependent suite of decision tools that supported scheduling consultation and followup.

Phase 2

During the simulation study, data was not collected for two participants for the redesigned prototype (B) because it took longer than expected for them to complete the scenarios with design A; we were only IRB-approved to run 45-minute sessions. Both of these participants received design A to begin the experiment based on the counter-balancing of presentation order across participants. Furthermore, we did not include the CSUQ data from the first participant because she misinterpreted the survey instructions to answer the questions based on the entire EHR rather than the specifically the CRC screening clinical reminder. Therefore, the results reported in Table 2 are based on 9 paired comparisons rather than 12. We clarified the CSUQ instructions after the first participant to avoid similar confusion with subsequent participants. All other data was included for the first participant; therefore, the results in Table 3 for the workflow integration survey are based on 10 paired comparisons. Finally, an experimenter error for one participant resulted in the administration of only the Simple scenarios for designs A and B. Therefore, results reported in Tables 2 and 3 include scores for one participant based only on using the designs with the Simple scenario and not the Complex scenario.

Table 3. Results for the three items specific to CRC screening that were appended to the CSUQ usability survey

<table>
<thead>
<tr>
<th>Item</th>
<th>Mean, current, A</th>
<th>Mean, redesign, B</th>
<th>Standard deviation, current, A</th>
<th>Standard deviation, redesign, B</th>
<th>p-value (two-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>It is easy to find information about the patient's colorectal cancer screening history in this system.</td>
<td>3.3</td>
<td>5.2</td>
<td>1.3</td>
<td>0.9</td>
<td>0.015</td>
</tr>
<tr>
<td>It is easy to find the patient's current status with regard to colorectal cancer screening in this system.</td>
<td>3.0</td>
<td>5.3</td>
<td>1.5</td>
<td>0.8</td>
<td>0.017</td>
</tr>
<tr>
<td>The system provides helpful patient education materials for CRC screening.</td>
<td>2.8</td>
<td>5.6</td>
<td>1.7</td>
<td>0.8</td>
<td>0.011</td>
</tr>
</tbody>
</table>
Table 4. Results for workflow integration survey; the 12 survey items were grouped along four subscales (navigation, functionality, ease of use, and workload)

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Mean, current, A</th>
<th>Mean, redesign, B</th>
<th>Standard deviation, current, A</th>
<th>Standard deviation, redesign, B</th>
<th>p-value (two-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Navigation</td>
<td>2.5</td>
<td>3.8</td>
<td>0.9</td>
<td>0.6</td>
<td>0.011</td>
</tr>
<tr>
<td>Functionality</td>
<td>3.1</td>
<td>4.0</td>
<td>0.7</td>
<td>0.6</td>
<td>0.008</td>
</tr>
<tr>
<td>Ease of use</td>
<td>3.2</td>
<td>3.6</td>
<td>1.0</td>
<td>0.9</td>
<td>0.049</td>
</tr>
<tr>
<td>Workload</td>
<td>2.3</td>
<td>2.9</td>
<td>0.8</td>
<td>0.6</td>
<td>0.028</td>
</tr>
</tbody>
</table>

Dependent Measures

Analysis revealed no significant differences in ratings for the original items in the CSUQ usability survey between designs A and B. However, PCPs rated the redesigned CRC screening reminder significantly higher (better) for the three appended statements in the CSUQ by the Wilcoxon Signed Ranks Test (Table 2).

There were no significant differences between designs A and B for the total composite workload score or any of the individual six items for the NASA TLX. Finally, for the workflow integration survey, design B was rated significantly higher (better) than design A for each of the four survey subscales (Table 3). Additionally, the workflow integration survey revealed good internal reliability (for CPRS, $\alpha = 0.93$; for enhanced CPRS, $\alpha = 0.80$).

Qualitative Trends

For the CRC screening timeline, six providers said they liked the visual format. Conversely, one provider noted that they would prefer a text format over the graphical timeline of results. An additional provider said the visual timeline should have been detailed even further, with the types of screening (colonoscopy, flexsigmoidoscopy, and FOBT) on different lines for the timeline instead of them all being reported on a single horizontal line, “...because in my mind I have to separate those things out because they mean different things to me in terms of what needs to be done next.” The remaining four providers did not have direct feedback on the timeline visual.

Five providers questioned the accuracy or reliability of the data in the timeline visual. That is, they questioned the ability of the timeline to reliably display the patient’s screening history, especially results from outside of the VHA. Conversely, 1 participant said the timeline would be more reliable than patient memory (e.g., asking the patient the timing and results of their last colonoscopy). For the patient scenarios that indicated an abnormal colonoscopy result, 6 providers verbally expressed that the actual pathology report for the abnormal polyps was not available in the timeline. A single provider from the 12 participants determined that the pathology report was available from the timeline by clicking on the green box (see Figure 3).

Two providers commented on how the decision support (timeline) needed to provide additional support. For example, one provider noted, “If we have an existing recommendation by a GI doctor, it should tell me what to do in the [CRC screening clinical] reminder.” Finally, two providers gave feedback that the timeline visual should be adjacent to the CRC screening clinical reminder instead of having to click another button within the reminder dialog box to see the timeline.

There were fewer comments regarding the patient education feature in the redesigned prototype that included the one-page informative article about CRC screening. The only recurrent finding, coded across five participants, was a preference for having a preprinted patient
education form instead of having to click on a link to the form to print it during the patient encounter. For example, one participant noted that there were only two printers in her clinic and one works only half the time. Although not a recurrent finding across participants, one provider commented that she liked the patient education form but would prefer that it not be linked to the clinical reminder for CRC screening since she only resolves the reminders after the patient encounter. Another provider questioned the quality of the patient education form, specifically the figure in the form illustrating a colonoscopy, if it were printed in black and white instead of color.

Discussion

Our study demonstrates the importance of identifying effective strategies in the design, implementation, and integration of CDS into clinical workflow. While working in several different health systems with experienced informaticists, legacy EHRs, and advanced CDS, we found considerable consistency in the barriers identified.

Barriers and challenges to effective CDS design and use are common across the social, technical, and environmental subsystems. Our findings build upon and extend the findings of others using a variety of different methods.21-25

Phase 2 results supported the improved design of the redesigned prototype in multiple dimensions, and never demonstrated reduced performance. Design enhancements to the VHA's existing CRC screening clinical reminder positively impacted PCPs' workflow integration and usability ratings in terms of finding the patient’s relevant data, as well as in providing helpful patient education materials. However, the redesigned prototype showed no difference in terms of perceived workload as measured by the NASA TLX. Also, the improvements demonstrated by the usability survey were related only to the three questions specific to CRC screening design enhancements. Of these three, only the question about patient education reflected a functionality that was available in the redesigned prototype, but not in the existing reminder. Both the redesigned and current CRC clinical screening reminder may inform the patient’s cancer screening history and status.

The more general usability statements about simplicity, efficiency, learnability, error recovery, overall satisfaction, etc., did not produce significantly improved ratings for the redesigned prototype over the current design. These findings suggest that, while participants were supportive of the design changes to include the timeline visual and patient education materials, there is still room to improve the overall usability of the CRC screening clinical reminder and how it is integrated within the EHR.

The workflow integration survey received significantly higher (better) ratings for the redesigned prototype than the current design for each of the four survey subscales (navigation, functionality, ease of use, and workload). Interestingly, the NASA TLX did not show significant differences for workload. This suggests that the workflow integration survey may have been more sensitive to detect differences in workload than the NASA TLX. Alternatively, “workload” may have represented a different construct in the two instruments. The NASA TLX has several items that measure specific dimensions of workload (mental demand, physical demand, temporal demand, performance, effort, and frustration). In contrast, questions from the workload integration survey that comprised the workload subscale may measure a more global construct of “work”.

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Analysis of the Phase 2 qualitative data revealed broad support for both the (1) timeline visual and (2) patient education design features. In addition, participants offered feedback about potential enhancements that may further increase acceptance and usability of these features. For example, while six of the PCP’s directly expressed a positive experience with the timeline visual, five PCPs were skeptical about the reliability and accuracy of the results in the timeline. This finding represents a lack of trust in the quality or authenticity of the underlying data; potential, related solutions may be to (1) increase the quality of the underlying data and (2) transparently provide information regarding the data’s source.

In the case of patient education resources, PCPs generally found the resource to be helpful, but five PCPs expressed a preference for the patient education form to be available in their clinics as a pre-printed form rather than having to access and print it from the CDS as needed. One obvious issue with our redesigned prototype was the inability of all but one PCP to recognize that the specific results of abnormal tests (i.e., colonoscopy pathology reports) were available from the timeline by clicking on a green box. Provider awareness could be increased by making the box resemble a button and to provide surface descriptors (i.e., pathology) about what data resides in the next layer of information.

These results underscore the importance of iteration in design. Ideally, more than one laboratory simulation should be conducted prior to implementation. The next logical step in the design process should be to further improve the redesigned prototype, based on the results of this study, and then to repeat the experiment to determine if further improvements to usability and perceived workload are demonstrated. In our future work, we intend to pursue these tasks: building on our current design, conducting further laboratory testing of design changes, and ultimately testing in a live clinic environment.

**Limitations**

There are several potential limitations of this study. Since these results were obtained at institutions experienced with CDS, some may question the generalizability to institutions less experienced with CDS. Nevertheless, the integration of CDS into workflow is still a major concern at these benchmark institutions with a substantial amount of experience applying and studying CDS. Lessons from these institutions, which have often developed effective approaches to CDS design, testing and implementation over many years can inform others who plan to design and implement EHRs and CDS. Our findings may avoid the same types of implementation errors being made twice.

**Conclusions**

This study demonstrates that effective design and integration of new technologies requires mindful, iterative attention. Designing and testing prototypes based on these features may help inform development of the next generation of cognitive support tools for decision making. New CDS prototypes are needed that (1) improve data organization and presentation, and are adaptable as information needs change over time, (2) integrate outside results, and (3) provide just in time education and cognitive support. Prototypes will allow the exploration and refinement of technological solutions to better support CRC screening and followup. Furthermore, we anticipate these prototypes will be relevant to other types of screening such as breast and cervical cancer.
Presentations


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