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Clinical Decision Support: Design Strategies and Quality Outcomes in Primary Care

A dissertation submitted in partial satisfaction of the requirements for the degree

Doctor of Philosophy in Health Policy and Management

by

Julian William Maxwell Brunner

2018

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ABSTRACT OF THE DISSERTATION

Clinical Decision Support: Design Strategies and Quality Outcomes in Primary Care

by

Julian William Maxwell Brunner

Doctor of Philosophy in Health Policy and Management

University of California, Los Angeles, 2018

Professor Emmeline Chuang, Chair

In medicine, computers are increasingly used not only to document patient care, but to support clinical decisions with relevant medical knowledge and patient information. This function is referred to as clinical decision support (CDS). Decades of scholarship have focused on evaluating CDS effectiveness, with promising but highly variable results. Having established that CDS can be useful, many have turned to more complex questions: what factors make CDS more effective and better-received by its users? How does CDS fit in with other strategies meant to ensure that clinical decisions are informed by current medical knowledge? When CDS works well, why and how does it do so? These are particularly important questions within the Department of Veterans Affairs (VA), which has a long history of using CDS, and has a massive scale that can enable CDS improvements to affect millions of patients. In this dissertation, I explore the use of CDS in VA primary care clinics. In study 1, I use VA-wide survey data to evaluate "user-centered design" strategies intended to make CDS easier to use and more

effective. In study 2, I link that survey data with administrative records on colorectal cancer screening to examine CDS as one of several strategies for implementing evidence-based practices. In study 3, I use data from semi-structured interviews with primary care providers at VA clinics around Los Angeles to understand how CDS works for a specific clinical decision (prostate cancer screening).

I find that “analysis of impact on performance improvement” is positively associated with perceived utility of CDS, but no association is evident for the other three user-centered design strategies examined. In assessing CDS efficacy alongside other strategies to support colorectal cancer screening, I find that neither CDS, nor any other implementation strategy examined, is associated with screening. In the qualitative study, I identify key factors in the effectiveness and acceptability of CDS for prostate cancer screening, including: workflow compatibility, the use of a trusted clinical guideline, and consultation with the intended users of CDS as part of its implementation.

Conclusion. Judicious implementation and governance of CDS are important determinants of its usefulness.

The dissertation of Julian Brunner is approved.

Elizabeth M. Yano

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2018

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LIST OF ACRONYMS

Acronym	Definition	Acronym	Definition
A-CDS	Advancing Clinical Decision Support	HITECH	Health Information Technology for Economic and Clinical Health
AUA	American Urological Association	ICC	Interclass Correlation Coefficient
CDS	Clinical Decision Support	IRM	Information Resources Management
CI	Confidence Interval	ISO	International Organization for Standardization
CPOS	Clinical Practice Organizational Survey	IT	Information Technology
CPRS	Computerized Patient Record System	OR	Odds Ratio
CRC	Colorectal Cancer	PCP	Primary Care Provider
EHR	Electronic Health Record	PSA	Prostate-Specific Antigen
EPRP	External Peer Review Program	QI	Quality Improvement
FOBT	Fecal Occult Blood Test	RAP	Rapid Assessment Process
GEE	Generalized Estimating Equation	RN	Registered Nurse
GUIDES	GUideline Implementation with Decision Support	SD	Standard Deviation
HHS	Health and Human Services	USPSTF	United States Preventive Services Task Force
HIMSS	Healthcare Information and Management Systems Society	VA	Veterans Affairs
HIT	Health Information Technology	VHA	Veterans Health Administration

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In study 1, author contributions were as follows: Julian Brunner conceived and designed the study, analyzed and interpreted the data, and wrote the manuscript. Emmeline Chuang assisted in study design and in the analysis and interpretation of the data, revised the manuscript for important intellectual content, and approved the final version. Caroline Goldzweig assisted in the analysis and interpretation of the data, revised the manuscript for important intellectual content, and approved the final version. Cindy Cain assisted in the analysis and interpretation of the data,

revised the manuscript for important intellectual content, and approved the final version.

Catherine Sugar assisted in the analysis and interpretation of the data, revised the manuscript for important intellectual content, and approved the final version. Elizabeth Yano acquired the data, assisted in study design, assisted in the analysis and interpretation of the data, revised the manuscript for important intellectual content, and approved the final version.

BIOGRAPHICAL SKETCH

Julian Brunner is a health services researcher at the Department of Veterans Affairs Center for the Study of Healthcare Innovation, Implementation, and Policy. He implements and evaluates organizational interventions, including clinical decision support tools, quality improvement programs, and national policies.

Previously, he worked for the Center for Medical Technology Policy, where he developed disease-specific guidance for conducting comparative effectiveness research, and was the director of research for the Green Park Collaborative International, where he convened health plan leaders from 8 countries to compare and align guidance for researchers. Before he began his research career, he worked for the NYC Department of Health Primary Care Information Project, where he helped primary care providers adopt prevention-oriented electronic health record systems.

He earned a Bachelor of Arts from Vassar College in 2007, and a Masters of Public Health from Johns Hopkins Bloomberg School of Public Health in 2011, where he served as a teaching assistant for graduate courses on public health informatics. As a PhD student at UCLA he was the recipient of the UCLA Clinical and Translational Science Institute Predoctoral Fellowship, the UCLA Graduate Division Dissertation Year Fellowship, and the Department of Health Policy and Management Community Partner Fellowship. Previously, he was also awarded the Lockheed Martin Information Technology Scholarship, the Health and Human Services' Office of the National Coordinator for Health IT Informatics Training Program Award, and the Johns Hopkins MPH Field Experience Award.

Publications include:

May F, Yano EM, Provenzale D, Brunner J, Yu C, Phan J, Bharath P, Aby E, Dinh D, Ehrlich DS, Storage TR. Barriers to Follow-Up Colonoscopies for Patients With Positive Results From Fecal Immunochemical Tests During Colorectal Cancer Screening. *Clinical Gastroenterology and Hepatology*. 2018 May 29.

Brunner J, Schweizer CA, Canelo IA, Leung LB, Strauss JL, Yano EM. Timely access to mental health care among women veterans. *Psychological services*. 2018 Apr.

Brunner J, Chuang E, Washington DL, Rose DE, Chanfreau-Coffinier C, Darling JE, Canelo IA, Yano EM. Patient-Rated Access to Needed Care: Patient-Centered Medical Home Principles Intertwined. *Women's Health Issues*. 2018 Mar 1;28(2):165-71.

Brunner J, Chuang E, Goldzweig C, Cain CL, Sugar C, Yano EM. User-centered design to improve clinical decision support in primary care. *International journal of medical informatics*. 2017 Aug 1;104:56-64.

Hamilton A, Brunner J, Cain C, Chuang E, Luger T, Canelo I, Rubenstein L, Yano E. Engaging multilevel stakeholders in an implementation trial of evidence-based quality improvement in VA women's health primary care. *Translational Behavioral Medicine*. 2017 Jun 5. 1-8

Chuang E, Brunner J, Mak S, Hamilton AB, Canelo I, Darling J, Rubenstein LV, Yano EM. Challenges with Implementing a Patient-Centered Medical Home Model for Women Veterans. *Women's Health Issues*. 2017 Jan 4.

Chuang E, Brunner J, Moody J, Ibarra L, Hoyt H, McKenzie TL, Binggeli-Vallarta A, Cervantes G, Finlayson TL and Ayala GX. Factors Affecting Implementation of the California Childhood Obesity Research Demonstration (CA-CORD) Project. *Preventing Chronic Disease*. 2016 Oct 20 13: E147.

Brunner JW, Sankare IC, Kahn KL. Interdisciplinary Priorities for Dissemination Implementation and Improvement Science: Frameworks, Mechanics, and Measures. *Clinical and Translational Science*. September 2015 Dec 1; 8(6): 820-823.

Itagaki M, Talenfeld A, Kwan S, Brunner J, Mortell K, Brunner M. Percutaneous Vertebroplasty and Kyphoplasty for Pathologic Vertebral Fractures in the Medicare Population: Safer and Less Expensive than Open Surgery. *Journal of Vascular and Interventional Radiology*. 2012 Nov 30; 23(11): 1423-1429.

Samantaray R, Njoku VO, Brunner JWM, Raghavan V, Kendall ML, Shih SC. Promoting Electronic Health Record Adoption Among Small Independent Primary Care Practices. *American Journal of Managed Care*, 2011 May; 17(5): 353-358

Dissertation Introduction

Clinical decision support (CDS) systems can serve several functions but are best known for their ability to identify and disseminate organizational priorities for preventive care, and make evidence-based practice more convenient to implement. However, there is substantial variability in the outcomes of CDS (1), and the literature is rife with reports of ineffective implementations, unintended consequences and even harms (2-5).

Prior research has attempted to explain variability in CDS outcomes and identify factors associated with successful CDS. A systematic review of studies evaluating the ability of CDS to improve clinical practice identified 12 different studies that emphasized the importance of engaging local users in CDS development (6). Many investigators have attempted to integrate a user-centered design approach to developing and implementing CDS – testing CDS before and after it is deployed, getting feedback on its usability and effectiveness – similar to the techniques that software developers have used for many years to make their products more reliable and easier to use (7). These strategies also fit into a tradition of quality improvement (QI) in health care, which emphasizes iterative testing, workflow analysis and redesign, and involvement of clinical stakeholders in the development and implementation of innovations (8).

Research on the application of these approaches to CDS, and on CDS in general has been hampered by some key limitations, discussed below. The most important and novel contributions of this dissertation to the CDS literature are: a) a national scope in evaluating user-centered design strategies, b) the inclusion of an array of contextual factors that operate alongside CDS to support evidence-based practice, and c) an emphasis on the understudied post-implementation phase of CDS use.

National-level data on user-centered design for CDS

User-centered design strategies for CDS have mostly been investigated at one or two facilities (9), but have not been explored across a large number of facilities, and, for this reason, have not typically taken other organizational factors into account such as IT resources and clinic policies, procedures, and culture (10). This dissertation examined user-centered design strategies using a national sample of VA primary care clinics, and accounts for multiple relevant organizational factors. To complement this quantitative analysis, the dissertation also includes qualitative interviews that apply a user-centered design approach to a clinical alert.

Organizational context of CDS

Numerous studies have linked CDS use with quality of care outcomes, but controls for other organizational factors related to the implementation of evidence-based practice are sparsely included in those studies, and interrelationships with those other factors (e.g. performance feedback, incentives, clinical champions, dedicated disease management) are underexplored. A 2014 systematic review (10) concluded that “the most important improvement that can be made in health IT evaluations is increased measurement, analysis, and reporting of the effects of contextual and implementation factors.” The VA is an excellent setting for this research because these contextual and implementation factors within VA clinics have been extensively characterized. This dissertation evaluated links between CDS and quality of care – in particular, the use of evidence-based preventive practices – while accounting for a rich array of contextual (organizational) factors.

Post-Implementation Setting

Studies of CDS have frequently focused on summative evaluations of the adoption of CDS systems (1, 11), and have given insufficient attention to the continuous process of updating those systems to keep pace with medical knowledge while mitigating unintended consequences (12). Now that a substantial number of health care organizations already have electronic health records systems with CDS functionality in place (13), the relative lack of research focusing on the “post implementation” phase is an increasingly important problem. The VA is a particularly suitable setting for exploring the ongoing improvement and updating of CDS because it has had an electronic health record with CDS in place since the 1990’s (14).

Research objectives

This dissertation included three distinct studies, and used both quantitative and qualitative methods to analyze the use of CDS at VA primary care clinics.

The first study used national surveys of leadership in 250 VA facilities to assess which user-centered design strategies work best to ensure that CDS supports its users and accomplishes its stated goals. Namely, it considered: pilot testing CDS, assessing provider satisfaction, assessing usability, and analyzing CDS impact on performance. The study examined the association between each of these strategies and the perceived utility of CDS as a tool to disseminate evidence-based practices. The hypothesis was that each of four strategies would be associated with higher CDS utility.

The second study used data from the surveys in the first study, linked with quality measures. These data were used to evaluate the relationship between CDS and quality of care, as exemplified by a measure of colorectal cancer screening. This study sought to help distinguish

CDS as a substitute or complement to other tools for supporting evidence-based practice, and included patient-level and site-level analyses. The hypothesis was that use of CDS would be associated with higher levels of recommended colorectal cancer screening.

The third study used qualitative interviews with providers to understand the clinical context for a specific instance of CDS: an electronic alert about prostate-specific antigen (PSA) screening.

This study represented an application of user-centered design principles to identify facilitators and barriers to evidence-based screening decisions.

Together, these three studies provide a nuanced view of the role that CDS plays in implementing evidence-based practices in primary care. The design and integration of these studies was guided by a theory-based conceptual model, described below.

Conceptual Framework

Study activities were informed by a conceptual model that built on user-centered design principles while still reflecting the clinical and organization context of CDS use: Sittig and Singh's sociotechnical model of safe and effective HIT use in complex adaptive healthcare systems (15). The sociotechnical model draws on principles of user-centered design, models of human-computer interaction, research in complex adaptive systems, and frameworks designed to explore unintended consequences of HIT (2) and determinants of patient safety (16, 17), and adds to these models additional detail about the user interface, clinical content, and technological infrastructure of the HIT being studied.

In contrast to models designed to study the dissemination and implementation of innovations, the sociotechnical model is particularly well suited to study the use of CDS after the overall CDS system has been implemented – i.e. the continuous process of turning clinical practice guidelines

into computerized tools that facilitate evidence-based practice, while minimizing potential negative impacts of this process on efficiency, communication, provider autonomy, and satisfaction. Moreover, the model lent itself to this dissertation because its development was informed by analyses of health IT interventions within the VA and it has been used in several analyses of CDS implementation and use (18-21).

The dimensions of the sociotechnical model are described in Table 1, and the operationalization of each is summarized in the methods sections below. The dimension “internal organizational features” has been modified from its original conceptualization as “internal organizational policies, procedures, and culture” to also include structural features of the organization.

Table 1. Sociotechnical Model

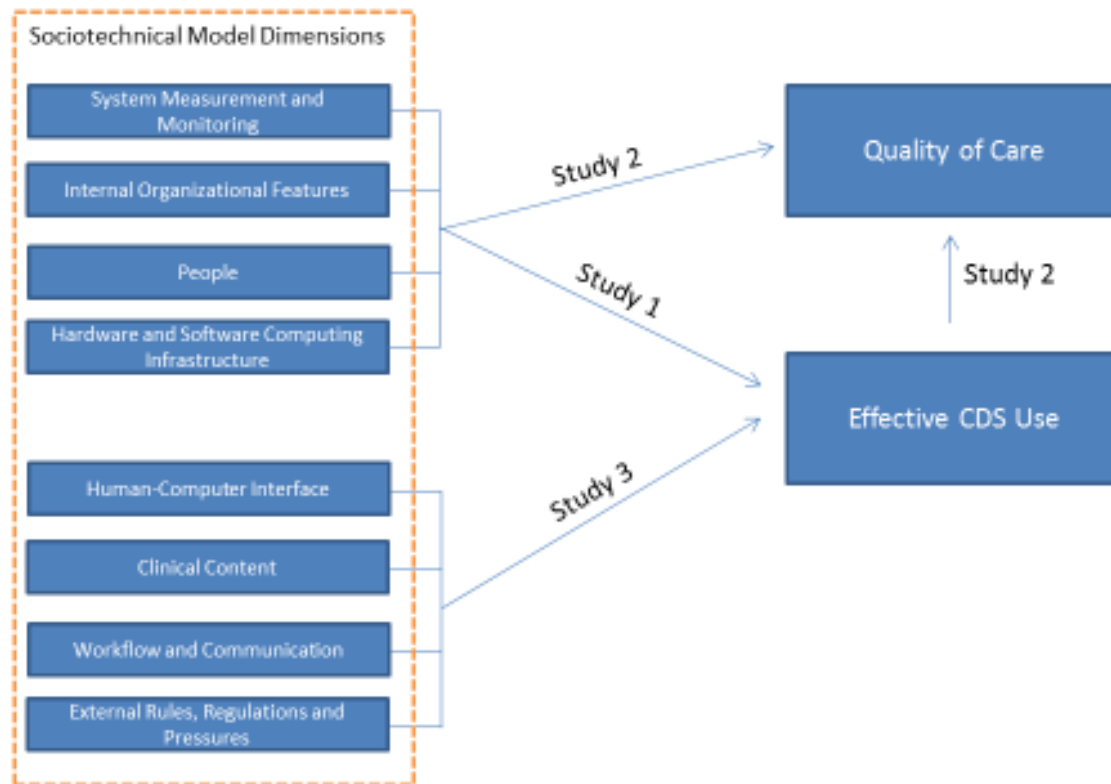
Sociotechnical Model Dimension	Definition*
System Measurement & Monitoring	This dimension includes: i) measuring the effect of the HIT intervention on healthcare delivery, ii) identifying unintended consequences, iii) measurements of system downtime/availability, and iv) actual use of the system (e.g. rates of overriding alerts).
Internal Organizational Features	This dimension includes both structural features of a clinic setting (e.g. its size, types of services offered) as well as its policies, procedures and culture.
People	This dimension includes the users of HIT systems as well as those who design, implement, and optimize those systems, and is in part a function of the knowledge, skills and training of these individuals.
Hardware and Software	This is a purely technical dimension referring to physical devices and the software that keeps those devices running.

Human-Computer Interface	This describes the visual presentation of information in a HIT system and the ways that users interact with the system.
Clinical Content	This might represent the controlled clinical vocabularies that HIT systems reference or the clinical guidelines or pathways that they help to operationalize.
Workflow and Communication	This dimension represents the actions that providers and staff take in caring for patients and collaborating to support that care. Effective HIT use typically requires a balance of the HIT intervention being tailored to accommodate the clinical workflow and the workflow being tailored to accommodate the intervention.
External Rules, Regulations and Pressures	This dimension refers to the laws, incentives, and regulatory requirements governing the use of HIT and the practice of medicine in general. These pressures may emphasize particular quality goals, or may dictate the ways that patient information can be used and shared.

*Definitions adapted from Sittig and Singh, 2010

Each of the three studies in this dissertation were informed by key dimensions from the sociotechnical model. As illustrated in Figure 1, the first and second studies emphasized effects of i) system measurement and monitoring, ii) internal organizational features, iii) people, and iv) hardware and software computing infrastructure, and examined their relationship with quality of care and CDS use. The third study focused on i) the human-computer interface, ii) clinical content, iii) workflow and communication, and iv) external rules, regulations and pressures.

Figure 1. Conceptual Model



Policy Significance

By examining CDS from multiple perspectives, the studies in this dissertation should help administrators understand the factors that foster successful CDS. In doing so, the findings may help health care systems balance the often-competing goals of providing needed services (e.g. appropriate preventive care) more consistently, reducing harmful and wasteful overutilization, and conserving providers' time and attention so that they can focus on patients instead of computers.

References

1. Bright TJ, Wong A, Dhurjati R, et al. Effect of clinical decision-support systems: A systematic review. *Ann Intern Med.* 2012;157:29-43. doi:10.7326/0003-4819-157-1-201207030-00450.

2. Harrison MI, Koppel R, Bar-Lev S. Unintended Consequences of Information Technologies in Health Care - An Interactive Sociotechnical Analysis. *J Am Med Informatics Assoc.* 2007;542-549. doi:10.1197/jamia.M2384.
3. Koppel R, Cohen A, Abaluck B, Localio a R, Kimmel SE, Strom BL. Role of Computerized Physician Order Entry Systems in Facilitating Medication Errors. *J Am Med Assoc.* 2013;293(10):1197-1203. doi:10.1001/jama.293.10.1197.
4. Saleem JJ, Militello LG, Arbuckle N, et al. Provider perceptions of colorectal cancer screening clinical decision support at three benchmark institutions. *AMIA Annu Symp Proc.* 2009;2009:558-562.
5. Campbell E, Sittig DF, Ash JS, Guappone KP, Dykstra RH. Types of Unintended Consequences Related to Computerized Provider Order Entry. *Jamia.* 2006;13(5):547-556. doi:10.1197/jamia.M2042.Introduction.
6. Kawamoto K, Houlihan C a, Balas EA, Lobach DF. Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success. *BMJ.* 2005;330(7494):765. doi:10.1136/bmj.38398.500764.8F.
7. Kling R. The Organizational Context of User-Centered Software Designs. *MIS Q.* 1977;1(December):41-52. doi:10.2307/249021.
8. Plsek PE. Quality improvement methods in clinical medicine. *Pediatrics.* 1999;103(1 Suppl E):203-214. doi:10.1542/peds.103.1.SE1.203.
9. Russ AL, Zillich AJ, Melton BL, et al. Applying human factors principles to alert design increases efficiency and reduces prescribing errors in a scenario-based simulation. *J Am Med Inform Assoc.* March 2014:1-10. doi:10.1136/amiajnl-2013-002045.
10. Jones SS, Rudin RS, Perry T, Shekelle PG. Health information technology: an updated systematic review with a focus on meaningful use. *Ann Intern Med.* 2014;160(1):48-54. doi:10.7326/M13-1531.
11. Lobach D, Sanders GD, Bright TJ, et al. Enabling health care decisionmaking through clinical decision support and knowledge management. *Evid Rep Technol Assess (Full Rep).* 2012;(203):1-784. doi:AHRQ Publication No. 12-E001-EF.
12. Sittig DF, Wright A, Osheroff JA, et al. Grand challenges in clinical decision support. *J Biomed Inf.* 2008;41(2):387-392. doi:10.1016/j.jbi.2007.09.003.
13. Jamoom E, Hing E. Progress with electronic health record adoption among emergency and outpatient departments: United States, 2006-2011. *Natl Cent Heal Stat.* 2015;187(187):2006-2011.
14. Brown SH, Lincoln MJ, Groen PJ, Kolodner RM. VistA--U.S. Department of Veterans Affairs national-scale HIS. *Int J Med Inform.* 2003;69(2-3):135-156.
15. Sittig DF, Singh H. A new sociotechnical model for studying health information

- technology in complex adaptive healthcare systems. *Qual Saf Health Care*. 2010;19 Suppl 3(1):i68-i74. doi:10.1136/qshc.2010.042085.
16. Vincent C, Taylor-adams S, Stanhope N, et al. Framework for Analysing Risk and Safety in Clinical Medicine Linked references are available on JSTOR for this article : Framework medicine for analysing risk and safety in clinical. 2015;316(7138):1154-1157.
 17. Carayon P, Schoofs Hundt a, Karsh B-T, et al. Work system design for patient safety: the SEIPS model. *Qual Saf Heal Care*. 2006;15(suppl_1):i50-i58. doi:10.1136/qshc.2005.015842.
 18. McCullough J Mac, Zimmerman FJ, Rodriguez HP, Bell DS, Torrens PR. Impact of clinical decision support on receipt of antibiotic prescriptions for acute bronchitis and upper respiratory tract infection. *J Am Med Informatics Assoc*. 2014;21(6):1091-1097. doi:10.1136/amiajnl-2014-002648.
 19. Wright A, Ash JS, Erickson JL, et al. A qualitative study of the activities performed by people involved in clinical decision support: recommended practices for success. *J Am Med Informatics Assoc*. 2014;21(3):464-472. doi:10.1136/amiajnl-2013-001771.
 20. Sittig D, Ash J. On the importance of using a multidimensional sociotechnical model to study health information technology. *Ann Fam Med*. 2011:390-392. doi:10.1370/afm.1291.T.
 21. Thirukumaran CP, Dolan JG, Webster PR, Panzer RJ, Friedman B. The Impact of Electronic Health Record Implementation and Use on Performance of the Surgical Care Improvement Project Measures. *Health Serv Res*. 2015;50(1):273-289. doi:10.1111/1475-6773.12191.

Study 1: User-Centered Design to Improve CDS at VA Primary Care Clinics

Introduction

Background

User-centered design draws on cognitive science, psychology, and computer science to make information systems more useful and easier to use (1). Though user-centered design has been applied to a range of clinical and operational processes, researchers have found it particularly relevant to clinical decision support (CDS), the tools that make evidence-based medical knowledge accessible and salient (2). There are good reasons for this: CDS can be highly effective, but there is substantial variability in the usability, efficacy, and even safety of CDS (3–6), and user-centered design offers a way to identify and respond to these potential deficiencies (7).

A growing body of literature on user-centered design has helped to disseminate and refine user-centered design practices and has uncovered important lessons about the application of user-centered design in a clinical context (8). This research often takes the form of papers that propose new approaches to user-centered design or that describe the application of these approaches in a clinical setting. However, user-centered design in these studies has often been directed or heavily influenced by informatics researchers. This involvement increases the possibility that results may differ in settings that do not benefit from the expertise and regular participation of experts in informatics whose work is frequently supported by a research grant. In addition, most studies on user-centered design of clinical decision support have necessarily been conducted within an individual clinical site or a small network of sites (9). There remains an opportunity to study user-centered design across many sites with different users, different structural characteristics, and different resources, policies, and challenges. These contextual

factors have been underexplored not only in studies of user-centered design but in studies of health IT in general, with one systematic review noting that “the most important improvement that can be made in health IT evaluations is increased measurement, analysis, and reporting of the effects of contextual and implementation factors.”(10)

In this study, we seek to fill these gaps in the literature by analyzing national survey data from a census of Veterans Healthcare Administration (VA) health care facilities with large primary care caseloads. The survey data provide information about user-centered design practices and the perceived utility of CDS.

We examine user-centered design practices through the lens of organizational behavior and implementation science, and this lens informs the type of outcome we evaluate and the types of contextual information we consider. We analyze reports of CDS utility from the primary care director at each clinic. In VA health systems, the primary care director is responsible for supporting population health and evidence-based decision-making across the clinic. These reports represent a unique perspective focused on organizational priorities. We also account for clinics' resources, implementation climate, and structural characteristics – factors that are routinely incorporated in organizational behavior studies, but are rarely represented in studies of user-centered design. We take advantage of the variability in clinical practice and organizational strategies within the VA (11) which provides study sites that are comparable in many respects (e.g. general structure, overall payment model, national leadership) but that differ in meaningful and well-documented ways (12). In addition, we present rarely-accessible information about user-centered design practices that are not necessarily led by informatics researchers.

With these data, we assess which of four user-centered design practices work best to ensure that CDS accomplishes its stated goals. Namely, we consider four practices that are recommended by multiple guidelines for user-centered design (13–15): 1) pilot testing CDS, 2) assessing provider satisfaction, 3) assessing usability, and 4) analyzing the impact of CDS on performance improvement. We examine the association between each of these practices and the perceived utility of CDS. Each of these practices were hypothesized to be associated with higher perceived utility of CDS.

User-Centered Design Practices

All four of the user-centered design practices we examined are intended to improve the formatting and framing of CDS, and optimize its fit within the clinical workflow. They are also designed to help determine which applications of CDS should be retained and which should be discarded. The goals and processes of each user-centered design practice are elaborated below:

Pilot testing is a foundational aspect of software design, human factors, ergonomics, quality improvement, and nearly all frameworks for managing change within a complex system (7,16–18). Published guidance on user-centered design of CDS recommends not only pilot testing but iterative testing (13,14); however the limited time and resources available to local clinical informatics teams may preclude highly iterative processes. In this analysis, we examined pilot testing, a practice that is arguably a bare minimum for user-centered design.

Provider satisfaction assessment is a modest step toward usability testing: it serves as a rough gauge of the acceptability of clinical decision support. In the parlance of quality improvement, provider satisfaction assessment functions as a “balancing measure,” (18) that helps to determine whether short-term gains in technical quality of care come at the expense of provider

and staff well-being. Reduced provider satisfaction is by no means the only potential unintended consequence of CDS but it is among the easiest to anticipate and can function as a proxy for other important organizational factors associated with care quality (19,20).

Formal usability assessment is the practice that is perhaps most emblematic of user-centered design. It often involves some combination of interviews, focus groups, questionnaires, and analysis of clinical artifacts in the name of evaluating the three dimensions of usability defined by the International Organization for Standardization (ISO): effectiveness, efficiency, and user satisfaction (2,21). These dimensions are evaluated as properties of the *interaction* between a user (e.g. a provider) and the product (CDS) and not as inherent properties of the CDS itself.

Analyzing the impact of CDS on performance improvement helps to keep CDS goal-oriented, and can provide evidence as to whether CDS efforts are helping clinics meet quality targets. It is particularly germane at the VA because of the VA's substantial infrastructure for measuring performance at multiple levels of the organization and targeting improvement efforts on the basis of those measures. For example, the VA's External Peer Review Program (EPRP) defines clinical quality measures at a national level but delegates most development of computerized clinical reminders and disease-specific templates to individual VA medical centers (22). The specific measures within EPRP have changed over time to reflect changing goals within the VA and new medical evidence, but have consistently included information about preventive care (e.g. the provision of important vaccinations and screenings), and other high-value practices in both inpatient and outpatient settings. This program is one of several performance improvement programs within the VA, with others focusing on, for example, patient experience of care (23), patient safety (24), and overutilization (25).

These four practices do not reflect the entirety of user-centered design, but are commonly-recommended, readily-implementable strategies for improving the utility of CDS. As illustrated in Table 2, each of the four user-centered design practices studied was explicitly recommended by the Healthcare Information and Management Systems Society (HIMSS) toolkit “Improving Outcomes with Clinical Decision Support: An Implementer’s Guide” (13) and by the United States Department of Health and Human Services (HHS)-funded technical report on “Advancing Clinical Decision Support” (14) – resources that are specifically targeted at user-centered design of CDS for the purpose of local improvement. The practices are also consistent with the Rapid Assessment Process (RAP), a methodological approach that is geared toward understanding how and why health IT systems succeed or fail while providing “actionable information” to organizations about their health IT systems. Two of the four practices are explicitly recommended within the RAP framework and all four are consistent with the RAP approach (15,26,27).

Table 2. User-Centered Design Practices for Clinical Decision Support

User-Centered Design Practice	Survey Item	Recommended By
	Which mechanisms are usually used to develop computerized clinical reminders and/or disease-specific templates?:	
Pilot testing	Test piloting reminders prior to full scale implementation	HIMSS; A-CDS; RAP
Provider satisfaction assessment	Post implementation assessment of provider satisfaction	HIMSS; A-CDS; RAP
Formal usability assessment	Formal evaluation of reminder usability (human factors or usability assessment)	HIMSS; A-CDS
Analysis of impact on performance improvement	Analysis of reminder impact on performance improvement	HIMSS; A-CDS

HIMSS = Improving Outcomes with Clinical Decision Support: An Implementer’s Guide; A-CDS = “Advancing Clinical Decision Support” Technical Report; RAP = Rapid Assessment Process

Methods

Setting and Sample

The VA is the largest integrated healthcare delivery system in the United States, with hospital and community-based clinics that span all 50 states. By the end of 1999, when electronic health record systems were sparsely adopted across the US, all VA facilities had implemented an EHR, on a common platform, with computerized provider order entry and integrated CDS (28). The VA's early adoption of health IT makes it a particularly informative setting for this research: in 2006, the VA was at the stage of CDS use that many other health care systems have yet to begin: the stage of continuously updating and improving the medical knowledge and user interface of a system that is already in place.

VA facilities are organized into VA medical centers, typically anchored at a hospital. Most VA medical centers are affiliated with multiple primary care clinics – usually one clinic based at a hospital and multiple clinics based in the community.

The survey data we use, the Clinical Practice Organizational Survey (CPOS) (29), was developed by VA investigators to study organizational influences on quality of care including but not limited to health information technology. The content of the survey is based on input from a steering committee comprised of representatives from several research and operational offices within the VA, as well the National Committee for Quality Assurance and the Kaiser Health Institute. The CPOS encompasses over 1,000 variables addressing processes and tools for the management of clinical operations, resource sufficiency, and barriers to quality improvement. The survey has an emphasis on primary care, but includes inpatient care as well. The team that developed the survey used pilot testing and cognitive interviewing to verify that VA clinical and managerial leaders interpreted items as intended (30).

To facilitate the study's emphasis on clinic-level factors, and to put the investigation into the broader context of research on strategies to support implementing evidence-based practice, we grouped measures according to domains from organizational behavior and implementation research (31). The use of these domains helps reflect the depth of available information about clinics' structural characteristics, implementation climate, and available resources.

Data for this study were drawn from two modules of the CPOS administered in 2006-2007: a chief of staff survey and a primary care director survey. The primary care director survey (the clinic-level survey) includes data from 250 clinics, which represents a 90% response rate. The VA medical center chief of staff survey includes data from 111 respondents, representing an 86% response rate (29). Each chief of staff reported on the use of user-centered design practices for his or her entire VA medical center, and these responses were attributed to all primary care clinics under their control, an average of two clinics for each chief of staff.

Data from the two survey modules were merged, which resulted in a sample of 193 clinics with data from both modules. Because our analyses require data from both modules, clinics with data from only one module were not included. None of the 193 clinics were missing observations of the outcome (perceived CDS utility), but 23 were missing at least one observation of a covariate, which resulted in a final analytic sample of 170 clinics. We examined characteristics of the omitted clinics, and confirmed that they did not systematically differ from clinics with complete data, with the exception of two variables: clinics excluded because of missing data were less likely to report that they conduct analyses of provider satisfaction after implementing CDS (35% vs 62%), and scored lower on a measure of CDS customization by roughly half a point on a 4-level Likert scale. We also ran a model excluding the 4 variables that most contribute to

missingness, which yielded a sample size of 185; the coefficient estimates in this model were similar to the estimates in the primary analysis. Our secondary analysis of data was approved by the Institutional Review Boards at the VA and the University of California, Los Angeles.

Measures

Perceived utility of CDS

Perceived utility of CDS was operationalized as a 3-item measure ($\alpha = .77$) reflecting the key intended benefits of CDS: improving the dissemination of new information (e.g. new medical evidence), reducing medical errors, and supporting the clinical decision-making process (32). This measure was drawn from the primary care director survey module, i.e. was collected directly at the clinic level. A table illustrating the full model specification is available in the appendix.

User-centered design practices

User-centered design practices are represented by four yes/no questions following the prompt: “Which mechanisms are usually used to develop computerized clinical reminders and/or disease-specific templates?”: 1) test piloting reminders prior to full scale implementation; 2) post implementation assessment of provider satisfaction; 3) formal evaluation of reminder usability (human factors or usability assessment); 4) analysis of reminder impact on performance improvement. The use of these practices is reported by the VA medical center chief of staff, and in most cases applies to multiple primary care clinics affiliated with each VA medical center. These indicators were selected because they embody the principles of user-centered design that pertain most directly to the use of CDS and could be ascertained from the Clinical Practice Organizational Survey.

Additional covariates were chosen on the basis of their theoretical or empirical associations with: a) the effective implementation and use of CDS, or b) clinic directors' perceptions about computer-based approaches to improve the quality of care. This includes clinics' structural characteristics, implementation climate, and available resources. Constructs with $\alpha > .7$ were represented in the model as a mean across items; otherwise, items were specified separately.

Structural Characteristics

We included three measures of the structural characteristics of each primary care clinic: its "type" (i.e. whether it is a hospital-based clinic or a community-based outpatient center), its size as measured by the number of unique patients (in 1,000s) seen at the primary care clinic in the year the survey was administered, and its academic affiliation status (i.e. whether the clinic has a primary care training program) (11,33).

Implementation Climate

Studies of the implementation of innovations in health care organizations have operationalized implementation climate in a number of ways; the construct is typically innovation-specific, in that items that describe it refer to the innovation itself (34). The measures of implementation climate we included describe the implementation of evidence-based practices, as opposed to the implementation of CDS itself. We chose this approach because the study is focused on the role of CDS in supporting evidence-based practice and performance improvement.

The analysis incorporated 7 different measures of implementation climate. We included a measure indicating whether primary care providers are required to observe explicit practice guidelines, and a measure indicating whether providers sometimes turn guideline prompts off. The latter was included because turning guideline prompts off may suggest that providers are

customizing the CDS system to reduce alert fatigue, or, alternatively, may suggest that there are fewer opportunities for CDS to play a role in clinical decisions (35). This variable was reported at the VA medical center level because it was unavailable at the clinic level. Two items representing competing demands were included: one represents difficulty making changes in the practice because providers and staff are busy seeing patients; the other describes the extent to which competing demands across initiatives are a barrier to improving performance. Items representing resistance to performance improvement were also included: resistance from primary care providers, from local managers, and from local support staff.

Available Resources

Three measures of available resources previously shown to affect implementation and perceived efficacy of health information technology were included (31, 36- 38): A measure of IT staff sufficiency included both technical staff (e.g. Information Resource Management) and the staff in charge of maintaining the clinical content of the electronic record system ($\alpha = .80$). A measure of the adequacy of health IT training was also included ($\alpha = .88$), along with a single-item measure of access to medical informatics expertise, specified at the VA medical center level.

Statistical Analysis

We examined descriptive statistics for the sample, as well as for excluded observations to determine whether missing observations were missing at random. We also examined correlations among independent variables to identify potential collinearity. Only two pairs of items had correlations greater than 0.5: clinic type (hospital-based vs community-based) was correlated with clinic size ($r = .589$), and resistance to performance improvement from support staff was

correlated with resistance to performance improvement from local managers ($r=.592$). No changes were made to the primary model on the basis of these correlations, but a sensitivity test examined a model excluding clinic size and resistance from local managers. Statistical analyses were conducted with Stata 13 (36).

Primary Analysis

A random intercept model was used to account for clustering of clinics within VA medical centers, while permitting examination of cluster-invariant factors (user-centered design practices reported at the medical center level). In initial analyses, a fully unconditional random intercept model had an ICC of 0.243. We also examined a model with random slopes and intercepts, but a likelihood ratio test did not support the addition of random slopes ($p = .981$). Because the outcome was the mean of three Likert items, with several non-integer values, we treated it as continuous. We also evaluated square root and natural log transformations of the outcome, and neither transformation improved the normality of the distribution. In addition, we examined results stratified by clinic type (hospital-based vs. community-based) to determine whether associations were similar across settings.

Sensitivity Analyses

We conducted several sensitivity analyses to evaluate the robustness of our findings: we examined each of the 3 outcome items in separate models to determine whether there were different associations with different aspects of perceived CDS utility. We also tested different modeling approaches to evaluate model fit statistics and to verify that results were consistent across model specifications: we tested a naïve regression model, a clustered regression model with robust standard errors, and a generalized estimating equation model. We excluded some

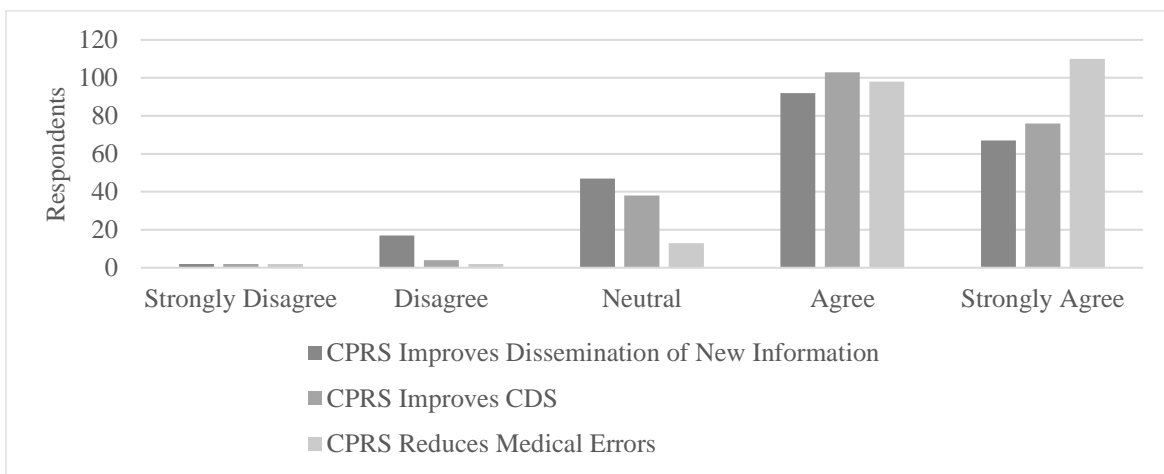
potentially relevant variables in our primary model in order to avoid overfitting, but as a sensitivity test we also evaluated a model with those covariates included – namely, measures of the extensiveness of CDS use at each clinic, a measure of clinic complexity developed by VA researchers (33), a measure of the primary care director’s authority over operational changes within the clinic, and a measure of the sufficiency of available computers. To further protect against overfitting, we examined the sequential inclusion of each domain of covariates, with and without the primary regressor.

Results

Descriptive Results

Perceived CDS utility was relatively high overall, with a mean of 4.17 (+/- .67) out of 5 on the composite measure. The distribution of the items that comprise perceived CDS utility are shown in Figure 2.

Figure 2. CDS Utility Rated by Primary Care Directors (n = 193)



CPRS = Computerized Patient Record System

Some user-centered design practices were much more common than others: analysis of reminder impact on performance improvement was reported at 79% of clinics, while formal usability assessment was reported at 36% (Table 3). There was substantial variability in clinics' structural characteristics, and measures of implementation climate and of available resources were fairly moderate, with average scores falling near the middle of the 5- and 4-level scales.

Table 3. Characteristics of VA Primary Care Clinics (n = 170)

<i>Clinic Characteristics</i>	<i>Mean (or %)</i>	<i>SD</i>
Perceived CDS utility	4.42	0.68
User-centered design practices		
Pilot testing CDS (%)	73.5	
Assessing provider satisfaction after implementation (%)	62.4	
Formal usability assessment (%)	35.9	
Analysis of CDS impact on performance improvement (%)	79.4	
Structural Characteristics		
Community-based clinic (vs. hospital-based) (%)	52.9	
Academic affiliate (%)	50.6	
Unique patients at the clinic (thousands)	28.0	19.4
Implementation Climate		
Required guideline use (%)	42.4	
Health IT use / customization (1-5)	2.88	1.09
Competing demands (1-5)	3.46	0.71
Hard to make changes because busy seeing patients (1-5)	3.67	1.04
PCP Resistance to Performance Improvement (1-4)	2.11	0.75
Local Manager Resistance to Performance Improvement (1-4)	1.74	0.76
Support Staff Resistance to Performance Improvement (1-4)	2.05	0.84
Available Resources		
IT staff sufficiency (1-5)	2.91	1.13
Access to medical informatics expertise (1-5)	3.44	1.06
Health IT training adequacy (1-5)	2.69	0.92

CDS = Clinical Decision Support; IT = Information Technology; PCP = Primary Care Provider

Regression model results

We hypothesized that each of the four user-centered design practices would be associated with perceived CDS utility. One of the four practices (analysis of CDS impact on performance improvement) had a significant association, $b = .47$ ($p < .001$), controlling for other variables in the model and adjusted for clustering (Table 4). A subgroup analysis showed that the association is present in hospital-based clinics, $b = .34$ ($p < .05$), but is stronger at community-based clinics, $b = .61$ ($p < .001$). There was no observed association for the other three user-centered design practices we examined.

None of the additional explanatory variables had a statistically significant association with the outcome. The statistical significance of the explanatory variables of interest (the user-centered design strategies) was consistent across all sensitivity analyses. In addition, the direction and approximate magnitude of the statistically significant association was similar across all analyses.

Table 4. Multilevel Model of Perceived Utility of CDS

<i>Domains</i>	<i>Explanatory Variables</i>	<i>Model Coefficient</i>
User-Centered Design Practices	Test piloting reminders	-0.19
	Assessments of provider satisfaction after implementation	-0.11
	Formal usability assessment	0.00
	Analysis of reminder impact on performance improvement	0.47***
Structural Characteristics	Community-based clinic (vs. hospital-based)	0.20
	Academic affiliate	0.12
	Unique patients at the clinic (1000s)	0.00
Implementation Climate	Required guideline use	0.16
	Providers sometimes turn guideline prompts off	-0.02
	Hard to make changes because busy seeing patients	-0.07

	Competing demands across too many initiatives	-0.05
	PCP resistance to performance improvement	0.05
	Local manager resistance to performance improvement	0.03
	Local support staff resistance to performance improvement	0.00
Available Resources	IT staff sufficiency	0.02
	Access to medical informatics expertise	-0.03
	Health IT training adequacy	0.05
	Constant	4.03

*p< .05 **p<.01 ***p<.001; PCP = Primary Care Provider; IT = Information Technology

Discussion

This study is one of the first to examine user-centered design practices for CDS across more than a handful of clinics. We identified widespread adoption of user-centered design practices with the exception of formal usability assessment, which was reported at only 36% of clinics. Our analyses also revealed high ratings of CDS utility, with the majority of respondents agreeing that CDS is useful, but also identified some variation in these ratings.

The results are highly supportive of the practice of analyzing the impact of CDS on performance improvement. To understand the implications of this finding, it is helpful to understand its context: performance measures are analyzed in multiple ways at multiple levels of the VA. Perhaps most relevant is that site leaders, including primary care directors, are accountable for quality measures, and these measures are monitored regularly by regional and national leadership. At many clinics, individual provider-level measures are also tracked and in some cases presented to providers (37). Given this robust and long-standing system of performance measurement, it is intuitive that a mechanism linking CDS to these measures would be helpful.

The results of this study also suggest that analyzing the impact of CDS on performance improvement, though related to user-centered design, is distinct from other user-centered design practices, and may have a different type of influence on the effectiveness of CDS. These other user-centered design practices (pilot testing CDS, assessing provider satisfaction, formal usability assessment), which have been shown to be important and meaningful in other studies (38,39), may be inseparable from the implementation climate and the organizational resources that enable them to take place. However, aspects of the study design (described in section 4.1) may bias results toward the null, so the absence of observed associations must be interpreted with caution.

Study Design and Setting

Our use of two separate surveys, with separate groups of participants, is an important asset to the study. A handicap for a great deal of survey-based research is that it frequently relies on a single person to report both the outcome and explanatory variables. This is a particular concern when the relevant survey items are at all subjective: perhaps administrators who think that their clinic's activities qualify as "user-centered design" are also more likely to have a charitable opinion of CDS - either because they have a more positive disposition, or because they themselves oversaw these user-centered design practices, and would like to believe that those practices have been effective. This study overcomes that common limitation by linking two surveys together, with one survey providing the explanatory variables of interest, and the other survey providing the outcome and covariates. This design adds to the credibility of the statistically significant findings, but also merits particular caution in the interpretation of the null findings, especially because of the "one to many" linking of the two surveys - i.e. a single VA medical center chief of staff reporting the user-centered design practices on behalf of multiple clinics.

The study also benefited from its inclusion of sites regardless of their funding for informatics research or involvement of informatics researchers in user-centered design, thereby better reflecting user-centered design “in the wild.” This does not mean that sites with informatics research funding were excluded (we do not have data that would permit such an analysis), but it means that the study was able to take a wider, more representative view of user-centered design practices.

The timing of the data collection is also meaningful for the interpretation of the results: data were collected after all sites had been using some version of CDS for at least 8 years (28), so this study contributes to the body of research on the ongoing improvement and maintenance of CDS, which is a much less studied period of time than the years immediately following the new implementation of a clinical decision support system. As the number of organizations using CDS grows, the assessment processes surrounding new CDS “rules” (i.e. new decision support) for existing CDS systems will become increasingly important. There are changes that have occurred within the VA since these surveys were fielded in 2006-07, but the timing actually improves the study’s relevance to clinics outside the VA with much shorter histories of CDS use.

The data were also collected before the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act that dramatically altered health IT in the private sector of the United States (40). In some ways, the “meaningful use” provisions of the HITECH act served to make the environment in the private sector more similar to the environment within the VA: well before the HITECH Act, the VA had fostered the adoption of CDS by a) developing CDS for some conditions at a national level, and rolling it out to VA facilities across the country, and b) holding VA medical centers and regional networks accountable for health

care quality indicators, and encouraging those medical centers to develop CDS related to those indicators. The HITECH Act provided the federal government with a less-direct mechanism for encouraging the effective use of CDS in the private sector: namely, adjustments to reimbursement from Medicare and Medicaid. But because most care within the VA is paid for by the VA itself, and not by Medicare or Medicaid, HITECH's influence on the VA was modest.

This study is among the many health informatics studies conducted at large healthcare systems with homegrown information systems. This category of research can provide insights into what is possible with sufficient flexibility and control of a system, and helps identify some of the negative implications of systems that do not permit health care organizations to make changes on the basis of their own investigations. The vendor-developed (3rd party) EHR systems and CDS systems in use at an increasing number of hospitals are often criticized for lacking this flexibility (41).

The VA's capacity for performance measurement is also a factor in the interpretation of this analysis. Outside the VA, most health systems have a much smaller infrastructure for performance measurement, and have likely placed relatively less emphasis on those activities in the past. This difference may be diminishing as payers increasingly shift to value-based payment systems (e.g., Medicare's Merit-based Incentive Payment System), thereby placing pressure on primary care practices to invest in such an infrastructure. Still, the nature of performance measurement remains different at the VA, which has measured and reported its performance to Congress for decades.

Study Outcome

There are inherent limitations in the use of a subjective measure of CDS utility, and utility from the perspective of primary care clinic directors may diverge from the utility perceived by other clinicians who use the system on a regular basis for patient care. However, supporting clinical decision-making, disseminating information about medical best practices, and reducing medical errors are among the central responsibilities of primary care directors at the VA, which makes them well-positioned to assess the usefulness of CDS in supporting these aims. Evaluations of health IT systems frequently use clinical or operational data from the systems being evaluated, e.g. clinical quality measures, orders placed, clicks recorded, etc. But qualitative research on health IT implementation supports the notion that a good way to assess whether a health IT system is functioning well is to ask a person who depends on that system (2).

The outcome measure was also bolstered by sensitivity analyses. These analyses, beyond illustrating that the findings were robust, show that the findings are consistent across each of the 3 aspects of perceived CDS utility: supporting clinical decisions, improving the dissemination of new information, and reducing medical errors.

Measures of User-Centered Design

Our findings are best understood in the context of a growing awareness of usability issues and the potential value of user-centered design for CDS: of 120 usability studies published in the last 25 years, 88% were published in the last 10 years (42). These studies occur at several phases of system development and deployment (requirements/development, prototyping, etc.), but the majority are implementation / post-implementation evaluations, and our analyses shed light on this important subset of user-centered design.

The survey data we use are highly informative but are not a comprehensive representation of user-centered design. The research team that developed the survey conducted cognitive interviews and pilot tests to ensure consistent interpretations of survey questions; however, as with all surveys, some variability in how respondents interpreted questions may have persisted and contributed to measurement error.

Conclusions

The first implication of these findings is that analyzing the impact of CDS on performance improvement appears to be important and useful, and should be done more consistently. The practice was significantly associated with the perceived utility of CDS across all model specifications adjusting for a wide range of other factors, and indeed it was the only practice to show an association with perceived utility of CDS in this study. This finding provides quantitative support to qualitative work conducted in diverse practice settings that similarly highlighted the value of linking CDS to quality goals and performance improvement (26). The association does not necessarily mean that VA medical centers that already analyze the impact of CDS on performance improvement should do so more often, or more extensively; we could not evaluate a “dose-response” relationship. However, the study did find that the association was particularly strong for community-based clinics, which further supports the value of this practice as a way to improve CDS at clinics that are less connected to VA medical center resources, and have fewer opportunities to be influenced by the culture of improvement that can be fostered at a large academic medical center.

The process of evaluating the impact of CDS on performance measures is not costless: it requires an investment of time and resources, and we were not able to evaluate these investments in this

study. Indeed, this is true for all four of the user-centered design practices we examined: we sought to evaluate their potential benefit, but a description of the costs of these practices was beyond the scope of the study. In addition, the over-application of performance measurement has the potential for unintended consequences, particularly at organizations that have already achieved high levels of performance (43), but this analysis helps identify an underappreciated way that performance measurement can be constructive.

Research on clinical decision support has often highlighted the impact of factors that are extremely difficult to change such as provider workload and time constraints (44). This study took structural characteristics and implementation climate into account, but explicitly examined individual practices that can be adopted fairly readily. Given the VA's infrastructure for performance measurement and improvement, drawing connections between these measures and CDS is a highly feasible step that facilities can take to improve CDS (45,46). These findings have the most direct relevance within the VA, which has a long history of performance improvement and of CDS, but clinics outside the VA increasingly face similar performance improvement imperatives, and are rapidly adopting CDS systems that mirror the ones the VA has used for years (47).

In many respects, CDS is emblematic of the many changes that accompany the transition from volume to value: it has the potential to transform the practice of medicine, but its effectiveness is highly dependent on the way it is implemented and maintained. Our analysis identifies high average levels of perceived CDS utility, but also points toward informative variability. In doing so, the study represents a step toward understanding the mutable factors that distinguish the clinics most successful in using CDS.

References

1. C.M. Johnson, T.R. Johnson, J. Zhang, A user-centered framework for redesigning health care interfaces., *J. Biomed. Inform.* 38 (2005) 75–87. doi:10.1016/j.jbi.2004.11.005.
2. P.-Y. Yen, S. Bakken, Review of health information technology usability study methodologies, *J. Am. Med. Informatics Assoc.* 19 (2012) 413–422. doi:10.1136/amiajnl-2010-000020.
3. T.J. Bright, A. Wong, R. Dhurjati, E. Bristow, L. Bastian, R.R. Coeytaux, G. Samsa, V. Hasselblad, J.W. Williams, M.D. Musty, L. Wing, A.S. Kendrick, G.D. Sanders, D. Lobach, Effect of clinical decision-support systems: A systematic review, *Ann. Intern. Med.* 157 (2012) 29–43. doi:10.7326/0003-4819-157-1-201207030-00450.
4. M.I. Harrison, R. Koppel, S. Bar-Lev, Unintended Consequences of Information Technologies in Health Care - An Interactive Sociothechnical Analysis, *J. Am. Med. Informatics Assoc.* (2007) 542–549. doi:10.1197/jamia.M2384.
5. R. Koppel, A. Cohen, B. Abaluck, a R. Localio, S.E. Kimmel, B.L. Strom, Role of Computerized Physician Order Entry Systems in Facilitating Medication Errors, *J. Am. Med. Assoc.* 293 (2013) 1197–1203. doi:10.1001/jama.293.10.1197.
6. E. Campbell, D.F. Sittig, J.S. Ash, K.P. Guappone, R.H. Dykstra, Types of Unintended Consequences Related to Computerized Provider Order Entry, *Jamia.* 13 (2006) 547–556. doi:10.1197/jamia.M2042.Introduction.
7. J. Horsky, G.D. Schiff, D. Johnston, L. Mercincavage, D. Bell, B. Middleton, Interface design principles for usable decision support: A targeted review of best practices for clinical prescribing interventions, *J. Biomed. Inform.* 45 (2012) 1202–1216. doi:10.1016/j.jbi.2012.09.002.
8. A.W. Kushniruk, V.L. Patel, Cognitive and usability engineering methods for the evaluation of clinical information systems, *J. Biomed. Inform.* 37 (2004) 56–76. doi:10.1016/j.jbi.2004.01.003.
9. V.L. Patel, T.G. Kannampallil, Cognitive informatics in biomedicine and healthcare, *J. Biomed. Inform.* 53 (2015) 3–14. doi:10.1016/j.jbi.2014.12.007.
10. S.S. Jones, R.S. Rudin, T. Perry, P.G. Shekelle, Health information technology: an updated systematic review with a focus on meaningful use., *Ann. Intern. Med.* 160 (2014) 48–54. doi:10.7326/M13-1531.
11. E.M. Yano, L.M. Soban, P.H. Parkerton, D. a. Etzioni, Primary care practice organization influences colorectal cancer screening performance, *Health Serv. Res.* 42 (2007) 1130–1149. doi:10.1111/j.1475-6773.2006.00643.x.
12. E.M. Yano, B.F. Simon, A.B. Lanto, L. V. Rubenstein, The evolution of changes in primary care delivery underlying the Veterans Health Administration’s quality transformation, *Am. J. Public Health.* 97 (2007) 2151–2159.

doi:10.2105/AJPH.2007.115709.

13. E.A. Pifer, J.M. Teich, D.F. Sittig, R.. Jenders, Improving outcomes with clinical decision support: an implementer's guide., 2nd ed., Himss, Chicago, 2011.
14. C. Byrne, D. Sherry, L. Mercincavage, D. Johnston, E. Pan, G. Schiff, Advancing Clinical Decision Support, 2011.
15. C. McMullen, J. Ash, D. Sittig, A. Bunce, K. Guappone, R. Dykstra, J. Carpenter, J. Richardson, A. Wright, Rapid Assessment of Clinical Information Systems in the Healthcare Setting: An Efficient Method for Time-Pressed Evaluation., *Methods Inf Med.* 50 (2011) 299–307. doi:10.3414/ME10-01-0042.Rapid.
16. K.M. Unertl, L.L. Novak, K.B. Johnson, N.M. Lorenzi, Traversing the many paths of workflow research: developing a conceptual framework of workflow terminology through a systematic literature review., *J. Am. Med. Inform. Assoc.* 17 (2008) 265–73. doi:10.1136/jamia.2010.004333.
17. D.F. Sittig, H. Singh, A new sociotechnical model for studying health information technology in complex adaptive healthcare systems., *Qual. Saf. Health Care.* 19 Suppl 3 (2010) i68–i74. doi:10.1136/qshc.2010.042085.
18. G. Langley, R.D. Moen, K.M. Nolan, T.W. Nolan, C.L. Norman, L.P. Provost, *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance*, John Wiley & Sons, 2009.
19. P.H. Mitchell, S.M. Shortell, Adverse outcomes and variations in organization of care delivery., *Med. Care.* 35 (1997) NS19-32.
20. S.M. Shortell, J.E. Zimmerman, D.M. Rousseau, R.R. Gillies, D.P. Wagner, E.A. Draper, W.A. Knaus, J. Duffy, The performance of intensive care units: does good management make a difference?, *Med. Care.* 32 (1994) 508–25.
21. ISO 9241-210, Ergonomics of human-system interaction -- Part 210: Human-centred design for interactive systems, (2010).
http://www.iso.org/iso/catalogue_detail.htm?csnumber=52075 (accessed October 22, 2015).
22. S.J. Hysong, C.R. Teal, M.J. Khan, P. Haidet, Improving quality of care through improved audit and feedback, *Implement. Sci.* 7 (2012) 45. doi:10.1186/1748-5908-7-45.
23. P.D. Cleary, M. Meterko, S.M. Wright, A.M. Zaslavsky, Are Comparisons of Patient Experiences Across Hospitals Fair? A Study in Veterans Health Administration Hospitals, *Med. Care.* 52 (2014) 619–625. doi:10.1097/MLR.000000000000144.
24. M.H. Shin, J.L. Sullivan, A.K. Rosen, J.L. Solomon, E.J. Dunn, S.L. Shimada, J. Hayes, P.E. Rivard, Examining the validity of AHRQ's patient safety indicators (PSIs): is variation in PSI composite score related to hospital organizational factors?, *Med. Care Res. Rev.* 71 (2014) 599–618. doi:10.1177/1077558714556894.

25. S.D. Saini, A.A. Powell, J.A. Dominitz, D.A. Fisher, J. Francis, L. Kinsinger, K.S. Pittman, P. Schoenfeld, S.E. Moser, S. Vijan, E.A. Kerr, Developing and Testing an Electronic Measure of Screening Colonoscopy Overuse in a Large Integrated Healthcare System, *J. Gen. Intern. Med.* 31 (2016) 53–60. doi:10.1007/s11606-015-3569-y.
26. A. Wright, J.S. Ash, J.L. Erickson, J. Wasserman, A. Bunce, A. Stanescu, D. St Hilaire, M. Panzenhagen, E. Gebhardt, C. McMullen, B. Middleton, D.F. Sittig, A qualitative study of the activities performed by people involved in clinical decision support: recommended practices for success, *J. Am. Med. Informatics Assoc.* 21 (2014) 464–472. doi:10.1136/amiajnl-2013-001771.
27. J.S. Ash, D.F. Sittig, K.P. Guappone, R.H. Dykstra, J. Richardson, A. Wright, J. Carpenter, C. McMullen, M. Shapiro, A. Bunce, B. Middleton, Recommended practices for computerized clinical decision support and knowledge management in community settings: a qualitative study., *BMC Med. Inform. Decis. Mak.* 12 (2012) 6. doi:10.1186/1472-6947-12-6.
28. D.C. Evans, W.P. Nichol, J.B. Perlin, Effect of the implementation of an enterprise-wide Electronic Health Record on productivity in the Veterans Health Administration., *Health Econ. Policy. Law.* 1 (2006) 163–9. doi:10.1017/S1744133105001210.
29. A.F. Chou, D.E. Rose, M. Farmer, I. Canelo, E.M. Yano, Organizational Factors Affecting the Likelihood of Cancer Screening Among VA Patients., *Med. Care.* 53 (2015) 1040–9. doi:10.1097/MLR.0000000000000449.
30. P.C. Beatty, G.B. Willis, Research synthesis: The practice of cognitive interviewing, *Public Opin. Q.* 71 (2007) 287–311. doi:10.1093/poq/nfm006.
31. L.J. Damschroder, D.C. Aron, R.E. Keith, S.R. Kirsh, J. a Alexander, J.C. Lowery, Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science., *Implement. Sci.* 4 (2009) 50. doi:10.1186/1748-5908-4-50.
32. K. Kawamoto, C. a Houlihan, E.A. Balas, D.F. Lobach, Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success., *BMJ.* 330 (2005) 765. doi:10.1136/bmj.38398.500764.8F.
33. B.T. Carney, P. West, J. Neily, P.D. Mills, J.P. Bagian, The Effect of Facility Complexity on Perceptions of Safety Climate in the Operating Room: Size Matters, *Am. J. Med. Qual.* 25 (2010) 457–461. doi:10.1177/1062860610368427.
34. B.J. Weiner, C.M. Belden, D.M. Bergmire, M. Johnston, The meaning and measurement of implementation climate., *Implement. Sci.* 6 (2011) 78. doi:10.1186/1748-5908-6-78.
35. E.S. Patterson, B.N. Doebbeling, C.H. Fung, L. Militello, S. Anders, S.M. Asch, Identifying barriers to the effective use of clinical reminders : Bootstrapping multiple methods, 38 (2005) 189–199. doi:10.1016/j.jbi.2004.11.015.
36. StataCorp, Stata Statistical Software: Release 13, 2013. (2013). doi:10.2307/2234838.

37. S.J. Hysong, R.G. Best, J. a Pugh, Audit and feedback and clinical practice guideline adherence: making feedback actionable., *Implement. Sci.* 1 (2006) 9. doi:10.1186/1748-5908-1-9.
38. A.L. Russ, A.J. Zillich, B.L. Melton, S. a Russell, S. Chen, J.R. Spina, M. Weiner, E.G. Johnson, J.K. Daggy, M.S. McManus, J.M. Hawsey, A.G. Puleo, B.N. Doebbeling, J.J. Saleem, Applying human factors principles to alert design increases efficiency and reduces prescribing errors in a scenario-based simulation., *J. Am. Med. Inform. Assoc.* (2014) 1–10. doi:10.1136/amiajnl-2013-002045.
39. B. Middleton, M. Bloomrosen, M.A. Dente, B. Hashmat, R. Koppel, J.M. Overhage, T.H. Payne, S.T. Rosenbloom, C. Weaver, J. Zhang, Enhancing patient safety and quality of care by improving the usability of electronic health record systems: recommendations from AMIA., *J. Am. Med. Inform. Assoc.* 20 (2013) e2-8. doi:10.1136/amiajnl-2012-001458.
40. D. Blumenthal, Launching HITECH., *N. Engl. J. Med.* 362 (2010) 382–5. doi:10.1056/NEJMp0912825.
41. R. Koppel, C.U. Lehmann, Implications of an emerging EHR monoculture for hospitals and healthcare systems., *J. Am. Med. Inform. Assoc.* 2 (2014) 1–5. doi:10.1136/amiajnl-2014-003023.
42. M.A. Ellsworth, M. Dziadzko, J.C. O’Horo, A.M. Farrell, J. Zhang, V. Herasevich, An appraisal of published usability evaluations of electronic health records via systematic review., *J. Am. Med. Inform. Assoc.* (2016) ocw046. doi:10.1093/jamia/ocw046.
43. A.A. Powell, K.M. White, M.R. Partin, K. Halek, J.B. Christianson, B. Neil, S.J. Hysong, E.J. Zarling, H.E. Bloomfield, Unintended consequences of implementing a national performance measurement system into local practice., *J. Gen. Intern. Med.* 27 (2012) 405–12. doi:10.1007/s11606-011-1906-3.
44. J.J. Saleem, E.S. Patterson, L. Militello, M.L. Render, G. Orshansky, S.M. Asch, Exploring barriers and facilitators to the use of computerized clinical reminders., *J. Am. Med. Inform. Assoc.* 12 (2005) 438–47. doi:10.1197/jamia.M1777.
45. S.J. Hysong, M.M. Khan, L.A. Petersen, Passive monitoring versus active assessment of clinical performance: impact on measured quality of care., *Med. Care.* 49 (2011) 883–90. doi:10.1097/MLR.0b013e318222a36c.
46. S.J. Hysong, R.G. Best, J. a Pugh, Clinical practice guideline implementation strategy patterns in Veterans Affairs primary care clinics., *Health Serv. Res.* 42 (2007) 84–103. doi:10.1111/j.1475-6773.2006.00610.x.
47. C.J. Hsiao, A.K. Jha, J. King, V. Patel, M.F. Furukawa, F. Mostashari, Office-based physicians are responding to incentives and assistance by adopting and using electronic health records, *Health Aff.* 32 (2013) 1470–1477. doi:10.1377/hlthaff.2013.0323.

Study 2: CDS for Colorectal Cancer Screening

Introduction

A wealth of evidence supports the efficacy of screening for colorectal cancer (CRC), but substantial variability exists in screening rates (1). The Veterans Health Administration (VA) has achieved relatively high rates of screening – aided by a range of programs focused on systems and providers (2). However, screening rates still vary across VA clinics (3).

Research on barriers and facilitators to CRC screening has examined patient-level factors as well as provider- and organization-level factors (4–6). A substantial body of research has characterized racial/ethnic disparities in screening and has sought to explain and mitigate those disparities, along with other demographic factors associated with screening (7,8). However the largest and most consistent predictor of screening is a provider’s recommendation (4,9–11), which has led researchers to consider organizational factors that encourage providers to facilitate appropriate screening (3,7,12).

Previous VA-based research has explored organizational factors associated with screening rates, and identified the importance of clinic leaders’ autonomy over the internal structure of care delivery, and “clinical support arrangements” for screening (e.g., computers, appropriate equipment, patient education space) (12). This research has been complemented by qualitative work seeking to identify more granular practice-based factors that might support CRC screening: in a series of interviews with providers, Rosenwasser et al (13) identified a “lack of effective reminder systems” as a prominent practice-related barrier to appropriate screening. Such “reminder systems” belong to the larger category of clinical decision support (CDS), which

includes electronic health record system-based reminders and disease-specific templates, and a host of other electronic tools to help support clinical decisions and to make medical knowledge more accessible and salient. However, the role of CDS in supporting CRC screening remains underexplored.

The objective of this analysis is to evaluate the relationship between CDS and CRC screening while accounting for other organizational characteristics. An important strength of earlier VA-based research on CRC screening is that it has operationalized and measured the organizational context within which screening decisions and CDS take place. Characterizing these contextual factors was highlighted by systematic review as “the most important improvement that can be made in health IT evaluations.” (14) An understanding of the role of CDS in the context of other tools to support screening will allow CDS to be to be deployed more strategically and effectively. Our hypothesis is that CDS will be associated with higher CRC screening rates.

Methods

Data for this aim are drawn from an organizational survey and from linked quality measures of 42,098 patients from the VA’s External Peer Review Program (EPRP). The conceptual constructs and corresponding measures we used are listed in Appendix A.

Data Source for Quality Measures:

EPRP captures measures related to primary and specialty care, extracted via chart review of a sample from each clinic in 2007-08. EPRP measures are defined by a group within the VA that prioritizes evidence-based practices from clinical practice guidelines and develops detailed VA-relevant definitions and exclusion criteria for each measure, as illustrated in Appendix B.

Survey Data:

This study uses data the primary care director module of the VA's Clinical Practice Organizational Survey (CPOS) (3) administered in 2006-2007. This survey module includes responses from 250 clinics, which represents a 90% response rate (3).

Measures

Primary outcome

This study's primary outcome measure is CRC screening. This measure is analyzed at the individual patient level (dichotomous) and at the clinic level (% of eligible patients screened).

The definition of the measure is described in detail in Appendix B, and follows the VA's External Peer Review Program (EPRP) that adapts measure specifications from clinical practice guidelines for use in the VA. The measure indicates which participants, out of those who are 51-80 years old at the time of a visit, have documentation of at least one of the following: Fecal occult blood test (FOBT) during the past year, flexible sigmoidoscopy during the past 5 years, colonoscopy during the past 10 years, or double contrast/air contrast barium enema during the past 5 years.

Primary regressors

Use of CDS is represented by two dichotomous variables indicating whether the clinic uses either a computerized reminder or a specialized template to promote that preventive practice, as reported by the primary care director. While "clinical decision support" can also refer to other tools such as dashboards with feedback on quality indicators, or information retrieval mechanisms embedded within an electronic health record system (15), this project focuses on reminders and templates because they can directly reflect organizational priorities for performance yet are distinct from population-level quality measurement and feedback, and their role in the clinical workflow gives rise to unique challenges and opportunities (16,17).

Covariates

Other factors to be considered for inclusion in models for this analysis were identified on the basis of studies identifying organizational predictors of CRC screening. The clinic-level and patient-level covariates listed below were each identified as significant predictors of colorectal cancer screening within the VA (12).

Other Tools to Support CRC Screening: we included covariates that are specific to CRC screening, including: performance profiling and feedback to providers, incentives, use of a designated local clinical champion, use of a delegated RN, and provider education.

Other clinic characteristics: we included measures of the size of the practice, the primary care director's authority over clinical protocols, and the sufficiency of clinical support arrangements.

Patient characteristics (for patient-level analyses): we incorporated measures of age, gender, income, and each patient's number of visits in the prior year. The operationalization of these variables is further described in an earlier VA study on predictors of colorectal cancer screening (12). While race/ethnicity is an important factor in CRC screening, this variable was not available for the majority of our sample. An analysis including patient race/ethnicity was conducted as a sensitivity test, with listwise deletion of observations that have no race/ethnicity information available, but the primary analysis does not include this variable.

The internal consistency of multi-item scales was evaluated, and scales with low Cronbach's alpha values were disaggregated. Also, the distribution of each of the covariates was examined and the variables were parameterized accordingly.

Statistical Analyses

We evaluated the relationship between CDS and CRC screening at two different levels of analysis. A *patient-level analysis* adjusted for patient-specific covariates that might be related to CRC screening (in addition to site-level covariates), with each individual patient's screening status as the outcome. A *site-level analysis* focused on the clinic characteristics that might be predictive of screening, with the outcome defined as the proportion of eligible patients screened.

Patient-Level Analysis:

We examined the distributions of the sample of eligible patients screened and not screened, and compared the groups using chi-square tests for categorical variables and t-tests for continuous variables.

To evaluate the association between CDS and CRC screening, we used a generalized estimating equation (GEE) model – an approach that has been used in previous studies using EPRP data (18). The model uses a logit link to reflect the binary outcomes and an exchangeable working correlation matrix to account for clustering at the clinic level. Such a model assumes the same correlation among all units within a cluster, and provides estimates of marginal effects. The relatively large number of clusters (250 clinics) also makes this an appropriate analytic approach.

The primary model includes all of the theoretically-derived covariates. We examined the patterns of missing data to identify potential threats to the validity. We also performed additional patient-level analyses to determine the robustness of our findings:

Subgroup Analyses: we examined results in community-based outpatient clinics and hospital-based primary care clinics separately, as well as analyses stratified by patient gender (19).

We also conducted an analysis that included race/ethnicity as a covariate; this analysis was only possible to conduct in the relatively small subgroup of participants for whom race/ethnicity is known.

Logistic regression with cluster-robust standard errors: An alternative model analyzed the data using traditional multivariate logistic regression techniques with robust standard errors that take into account clustering at the clinic level. This conservative approach provides another test to help evaluate the robustness of the results.

2-level and 3-level models: we also used a 2-level model with a random intercept specified at the clinic level, and a 3-level model with random intercepts at the clinic and VA medical center levels. These models provide an alternative way to account for the clustering of patients within clinics and within VA medical centers.

Clinic-Level Analysis:

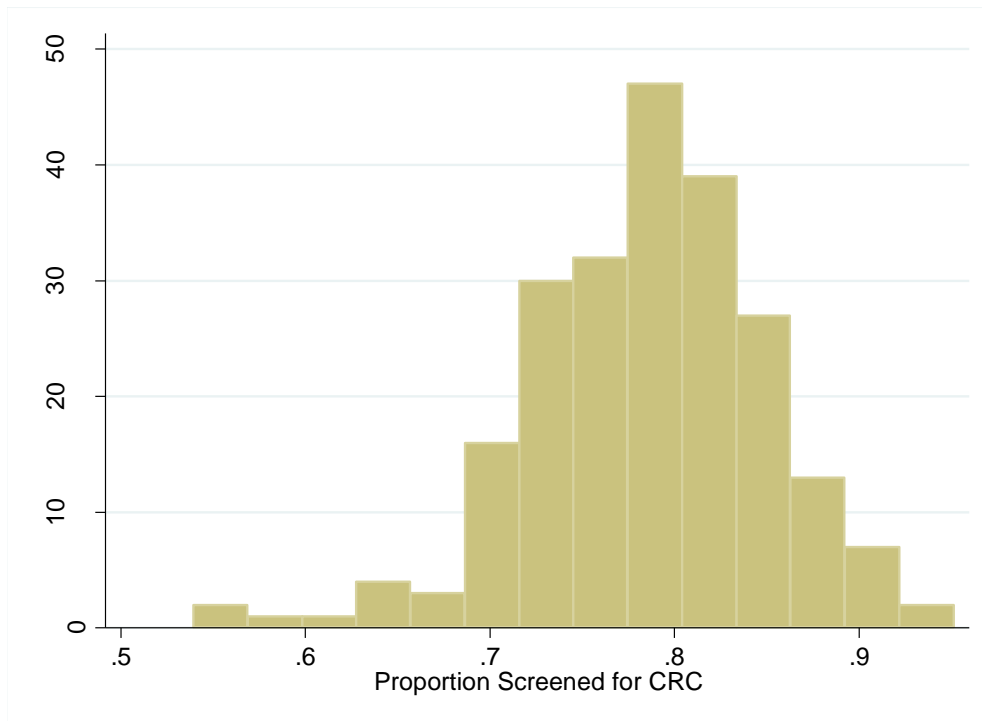
We also analyzed predictors of the proportion of eligible patients screened for CRC at each clinic using logistic regression. Though logistic regression techniques are commonly applied to dichotomous outcomes, they are also useful for analyzing continuous outcomes bounded by 0 and 1. We excluded patient-level variables from the primary clinic-level analysis, but, as a sensitivity test, we also analyzed a version of the model that included the mean levels of patient characteristics in the clinic.

Results

Descriptives

The overall proportion of patients screened was 78%. Clinic-level screening rates ranged from 54% to 95%, but the vast majority of clinics screened between 70% and 90% of eligible patients (Figure 3).

Figure 3. Clinic-Level Screening Rates



95% of patients were seen at clinics that use electronic reminders for CRC screening and 40% were seen at clinics that use an electronic template for colorectal cancer screening.

Table 5. Patient and Clinic Characteristics by CRC Screening Status

Variable	Not Screened (n = 9,137)	Screened (n= 32,961)	p-value
Primary Predictors			
Reminders	94.5%	95.1%	.01
Templates	40.2%	39.2%	.08
Other Tools to Support CRC Screening			
Profiling and feedback	60.2%	59.5%	.23
Incentives	23.8%	22.9%	.05
Clinical champion	27.4%	27.5%	.92
RN disease manager	7.3%	8.2%	.01
Provider education	40.7%	42.2%	.01
Other clinic-level covariates			
Clinic size (Unique patients, in 1,000s)	36.45 (SD:20.85)	35.62 (SD: 20.23)	<.001
Community-Based Outpatient Clinic	31.2%	31.9%	.20
Local authority over clinical protocols (1-4)	2.98 (SD: 0.70)	2.99 (SD: 0.69)	.49
Sufficiency of clinical support arrangements (1-5)	3.56 (SD:0.74)	3.58 (SD: 0.73)	.02
Patient-level covariates			
Age			<.001
	50-65 66.1%	51.5%	
	65-75 20.6%	28.1%	
	75+ 13.3%	20.4%	
Female	3.1%	2.8%	.09
Income			<.001
	<10k/year 30.3%	27.8%	
	\$10-19k/year 28.2%	25.6%	
	\$20-29k/year 20.2%	20.3%	

	\$30k+ / year	21.3%	26.3%	
Race / ethnicity				<.001
	White	69.7%	75.8%	
	Black	21.6%	17.6%	
	Other Race*	8.8%	6.7%	
Number of visits (In the past 12 months):				<.001
	<6	38.8%	33.7%	
	6-10	38.3%	41.0%	
	11+	22.9%	25.2%	

*Combines Hispanic White, Asian, and other race/ethnicity categories

CRC = Colorectal Cancer; RN = Registered Nurse

Unadjusted differences in the clinic characteristics of those screened and those not screened were modest: none of the variables differed by more than two percentage points (Table 5). Though the magnitude of the differences were small, several of them were statistically significant: the use of reminders, the presence of an RN disease manager for CRC, and the use of provider education on CRC were all more common at the clinics of patients who were screened; these clinics were also on average slightly larger in size.

Patients who received screening differed from unscreened patients in substantial ways. Screened patients tended on average to be older, higher-income, and more likely to be white. Patients who had visited more often were also more likely to have been screened.

Adjusted patient-level analyses

Patient-level analyses are shown in Table 6. None of the clinic-level predictors were associated with screening status at the individual level. As in the unadjusted associations, patient age,

number of visits, and income were each positively associated with screening. The associations with patient-level factors (and lack of observed associations with clinic-level factors) persisted across all alternative model specifications. The analysis of the subsample with available information about race/ethnicity also showed similar results, and suggested an adjusted association between race/ethnicity and screening, with “other race/ethnicity” patients and black patients each significantly less likely to be screened.

Some differences emerged from subgroup analyses. At VA medical center sites, there was a modest positive association between reminders and screening (OR = 1.3, p = .05), and at community-based outpatient clinics a trend toward a negative association (OR = 0.8, p = .09). The association between income and screening observed in the full sample was not evident among women veterans. Otherwise, the statistical significance and direction of associations in subgroup analyses were similar to the primary analysis.

Table 6. Adjusted Associations with CRC Screening (Patient-Level Analysis)

	OR	95% CI
Primary Predictors		
Reminders	1.04	(0.85,1.27)
Templates	0.96	(0.86,1.07)
Other tools to support CRC screening		
Profiling and feedback	0.98	(0.87,1.09)
Incentives	0.99	(0.88,1.12)
Clinical champion	0.97	(0.87,1.09)
RN disease manager	1.12	(0.94,1.34)
Provider education	1.07	(0.96,1.19)
Other clinic-level covariates		
Community-based outpatient clinic	1.00	(0.89,1.12)
Local authority over clinical protocols (1-4)	1.00	(0.93,1.06)
Sufficiency of clinical support arrangements (1-5)	1.02	(0.95,1.08)
Clinic size (Unique patients, in 1,000s)	1.00	(1.00,1.00)
Patient-level covariates		
Female	0.98	(0.86,1.13)
Age (Ref: 50-65)		
65-75	1.77***	(1.67,1.87)

75+	2.00***	(1.86,2.14)
Number of Visits (past 12 months) (Ref: <6)		
6-10	1.32***	(1.25,1.39)
11+	1.43***	(1.34,1.53)
Income (Ref: <10k/year)		
\$10-19k/year	0.99	(0.93,1.05)
\$20-29k/year	1.11**	(1.04,1.19)
\$30k+ / year	1.32***	(1.24,1.41)
Observations	42,098	

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$; CRC = Colorectal Cancer; RN = Registered Nurse

Adjusted clinic-level analyses

None of the clinic-level factors we examined were associated with clinics' screening rates – neither in the primary analysis, nor in the sensitivity analysis that included clinic means of patient variables in the model.

Table 7. Adjusted Associations with CRC Screening (Clinic-Level Analysis)

	OR	95% CI
Primary Predictors		
Reminders	0.98	(0.24,4.02)
Templates	0.98	(0.46,2.08)
Other tools to support CRC screening		
Profiling and feedback	0.96	(0.43,2.12)
Incentives	1.00	(0.41,2.42)
Clinical champion	1.00	(0.43,2.32)
RN disease manager	1.15	(0.33,3.99)
Provider education	1.05	(0.50,2.20)
Other clinic-level covariates		

Community-based outpatient clinic	1.02	(0.46,2.28)
Local authority over clinical protocols (1-4)	1.00	(0.63,1.58)
Sufficiency of clinical support arrangements (1-5)	1.04	(0.66,1.66)
Clinic size (Unique patients, in 1,000s)	1.00	(0.98,1.02)
Observations	222	

CRC = Colorectal Cancer; RN = Registered Nurse

Discussion

This analysis did not identify associations between clinical decision support and CRC screening. In fact, no clinic-level factors were associated with CRC screening, a result which diverges from previous studies (3). Patient-level associations were observed in the expected direction, with older patients and white patients more likely to be screened, as well as those who had visited the clinic more often and higher-income patients more likely to be screened.

The lack of an observed association with CDS, alongside the lack of observed associations with other tools intended to support CRC screening, may indicate that further provider-focused efforts for improving screening yield diminishing returns. The relatively high screening rates at the VA may be attributable to national-level factors affecting all of the clinics in this study: in January of 2007, a national VA directive mandated that eligible veterans at “average or high risk for CRC” must be offered CRC screening. Therefore, one interpretation of this study’s findings is that after the national VA mandate, most of the remaining variability in screening rates is attributable to differences in patient preferences rather than differences in clinics’ offering CRC screening. The fact that only patient-level factors were found to be associated with CRC screening is consistent with this interpretation. This would also help to explain the divergence between this study’s findings and previous studies that used 1998 VA data from before the mandate.

The national VA mandate for offering CRC screening may have crowded out the potential effects of other strategies intended to improve CRC screening. However, as demonstrated by the observed variability in clinics' screening rates of eligible patients, the presence of a mandate does not guarantee uniform performance. The roles of various strategies for putting mandates into practice remain worthy objects of study.

There were also some limitations to the available data: we did not have access to information about whether CRC screening was offered but refused. Several other studies have examined compared the provider's role with the patient's role in screening, which is why this study sought to focus on provider-facing factors. If data were available on whether CRC screening was offered, this information would provide a compelling alternative outcome. However, CRC mortality depends on screening, not on the mere offer of screening, and paying attention only to the "offer" would obscure the important and difficult work of educating and counseling patients about CRC screening, addressing potential fears about the screening procedures, identifying a modality acceptable to the patient, and facilitating the screening itself.

The way that care is organized and paid for in the VA helps to mitigate the potential confounding effects of insurance coverage and provider reimbursement for CRC screening (7,20); however the VA is also somewhat unique in its ability to mandate certain medical practices. This ability may limit the generalizability of findings that may be closely tied to the mandate.

The results of this study are consistent with research documenting "ceiling effects" that limit the influence of tools intended to support appropriate screening and other preventive practices (21). In a 2014 study, 80% of VA primary care providers identified the "volume of clinical reminders," as "moderately-to-extremely challenging" – the highest proportion among 48

different challenges identified by national VA primary care leaders (22). The present study suggests that provider-facing CDS may be most effective when targeted at clinical decisions that have not already been made highly salient to providers. This study helps to illustrate the principle that CDS should be carefully considered and continuously reevaluated in order to have the greatest impact.

References

1. CDC, Vital Signs: Colorectal Cancer Screening Test Use — United States, 2012, *MMWR. Morb. Mortal. Wkly. Rep.* 62 (2013) 881–887. doi:10.1001/jama.296.22.2671.
2. H.H. Chao, A.R. Schwartz, J. Hersh, L. Hunnibell, G.L. Jackson, D.T. Provenzale, J. Schlosser, L.M. Stapleton, L.L. Zullig, M.G. Rose, Improving colorectal cancer screening and care in the veterans affairs healthcare system, *Clin. Colorectal Cancer.* 8 (2009) 22–28. doi:http://dx.doi.org/10.3816/CCC.2009.n.004.
3. A.F. Chou, D.E. Rose, M. Farmer, I. Canelo, E.M. Yano, Organizational Factors Affecting the Likelihood of Cancer Screening Among VA Patients., *Med. Care.* 53 (2015) 1040–9. doi:10.1097/MLR.0000000000000449.
4. A.Z. Gimeno Garca, Factors influencing colorectal cancer screening participation, *Gastroenterol. Res. Pract.* 2012 (2012). doi:10.1155/2012/483417.
5. S. Gupta, A.T. Brenner, N. Ratanawongsa, J.M. Inadomi, Patient trust in physician influences colorectal cancer screening in low-income patients, *Am. J. Prev. Med.* 47 (2014) 417–423. doi:10.1016/j.amepre.2014.04.020.
6. S.L. Pruitt, T. Leonard, S. Zhang, M. Schootman, E.A. Halm, S. Gupta, Physicians, Clinics, and Neighborhoods: Multiple Levels of Influence on Colorectal Cancer Screening, *Cancer Epidemiol. Biomarkers Prev.* 23 (2014) 1346–1355. doi:10.1158/1055-9965.EPI-13-1130.
7. N.U. Ahmed, V. Pelletier, K. Winter, A.N. Albatineh, Factors explaining racial/ethnic disparities in rates of physician recommendation for colorectal cancer screening, *Am. J. Public Health.* 103 (2013) 91–99. doi:10.2105/AJPH.2012.301034.
8. A.K. Singal, Y.-L. Lin, Y.-F. Kuo, T. Riall, J.S. Goodwin, Primary care physicians and disparities in colorectal cancer screening in the elderly., *Health Serv. Res.* 48 (2013) 95–113. doi:10.1111/j.1475-6773.2012.01433.x.
9. A.O. Laiyemo, A.O. Adebogun, C.A. Doubeni, L. Ricks-Santi, S. McDonald-Pinkett,

- P.E. Young, B.D. Cash, C.N. Klabunde, Influence of provider discussion and specific recommendation on colorectal cancer screening uptake among U.S. adults, *Prev. Med. (Baltim)*. 67 (2014) 1–5. doi:10.1016/j.ypmed.2014.06.022.
10. D.A. Haggstrom, C.N. Klabunde, J.L. Smith, G. Yuan, Variation in primary care physicians' colorectal cancer screening recommendations by patient age and comorbidity, *J. Gen. Intern. Med.* 28 (2013) 18–24. doi:10.1007/s11606-012-2093-6.
 11. F.P. May, C. V Almario, N. Ponce, B.M.R. Spiegel, Racial Minorities Are More Likely Than Whites to Report Lack of Provider Recommendation for Colon Cancer Screening., *Am. J. Gastroenterol.* 110 (2015) 1–7. doi:10.1038/ajg.2015.138.
 12. E.M. Yano, L.M. Soban, P.H. Parkerton, D. a. Etzioni, Primary care practice organization influences colorectal cancer screening performance, *Health Serv. Res.* 42 (2007) 1130–1149. doi:10.1111/j.1475-6773.2006.00643.x.
 13. L. Rosenwasser, J. McCall-Hosenfeld, C. Weisman, M. Hillemeier, A. Perry, C. Chuang, Barriers to colorectal cancer screening among women in rural central Pennsylvania: Primary care physicians' perspective, *Rural Remote Heal.* 13 (2014) 2504–21.
 14. S.S. Jones, R.S. Rudin, T. Perry, P.G. Shekelle, Health information technology: an updated systematic review with a focus on meaningful use., *Ann. Intern. Med.* 160 (2014) 48–54. doi:10.7326/M13-1531.
 15. T.J. Bright, A. Wong, R. Dhurjati, E. Bristow, L. Bastian, R.R. Coeytaux, G. Samsa, V. Hasselblad, J.W. Williams, M.D. Musty, L. Wing, A.S. Kendrick, G.D. Sanders, D. Lobach, Effect of clinical decision-support systems: A systematic review, *Ann. Intern. Med.* 157 (2012) 29–43. doi:10.7326/0003-4819-157-1-201207030-00450.
 16. K. Kawamoto, C. a Houlihan, E.A. Balas, D.F. Lobach, Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success., *BMJ.* 330 (2005) 765. doi:10.1136/bmj.38398.500764.8F.
 17. B.-T. Karsh, *Clinical Practice Improvement and Redesign: How Change in Workflow Can Be Supported by Clinical Decision Support*, AHRQ Publication No. 09-0054-EF, Rockville, Maryland: Agency for Healthcare Research and Quality, 2009.
 18. B.G. Druss, R.A. Rosenheck, M.M. Desai, J.B. Perlin, Quality of preventive medical care for patients with mental disorders, *Med Care.* 40 (2002) 129–136. http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=11802085.
 19. S.M. Frayne, E.M. Yano, V.Q. Nguyen, W. Yu, L. Ananth, Y. Chiu, C.S. Phibbs, S.M. Frayne, M. Yano, Y. Chiu, C.S. Phibbs, Gender Disparities in Veterans Health Administration Care of Accounting for Veteran Status Importance, 46 (2015) 549–553.
 20. S. Gupta, D.A. Sussman, C.A. Doubeni, D.S. Anderson, L. Day, A.R. Deshpande, B. Joseph Elmunzer, A.O. Laiyemo, J. Mendez, M. Somsouk, J. Allison, T. Bhuket, Z. Geng, B.B. Green, S.H. Itzkowitz, M.E. Martinez, Challenges and possible solutions to

colorectal cancer screening for the underserved, *J. Natl. Cancer Inst.* 106 (2014). doi:10.1093/jnci/dju032.

21. A. a Powell, K.M. White, M.R. Partin, K. Halek, J.B. Christianson, B. Neil, S.J. Hysong, E.J. Zarling, H.E. Bloomfield, Unintended consequences of implementing a national performance measurement system into local practice., *J. Gen. Intern. Med.* 27 (2012) 405–12. doi:10.1007/s11606-011-1906-3.
22. M.M. Farmer, D.E. Rose, L. V Rubenstein, I. a Canelo, G. Schectman, R. Stark, E.M. Yano, Challenges facing primary care practices aiming to implement patient-centered medical homes., *J. Gen. Intern. Med.* 29 Suppl 2 (2014) 555–62. doi:10.1007/s11606-013-2691-y.

Study 3: Primary Care Provider Perspectives on Clinical Decision Support for Prostate Cancer Screening

Introduction

In study 3, rather than isolating CDS, we sought to understand its context in substantial depth by examining the use of a single alert in the Greater Los Angeles VA's healthcare system. We used qualitative methods to richly characterize the underlying clinical decision targeted by the alert, primary care providers' (PCPs') reasoning about that clinical decision, the organizational/workflow context in which the decision occurs, and the role that the alert plays in the decision. Because the alert operationalizes clinical practice guideline recommendations, we also sought to understand PCPs' perspectives on relevant guidelines. Finally, because the alert is but one example of CDS, and its reception and effectiveness may be influenced by the CDS ecosystem in which it resides, we also explored PCPs' perspectives on alerts and reminders beyond the one that was the focus of our study.

An alert to reduce unnecessary prostate cancer screening

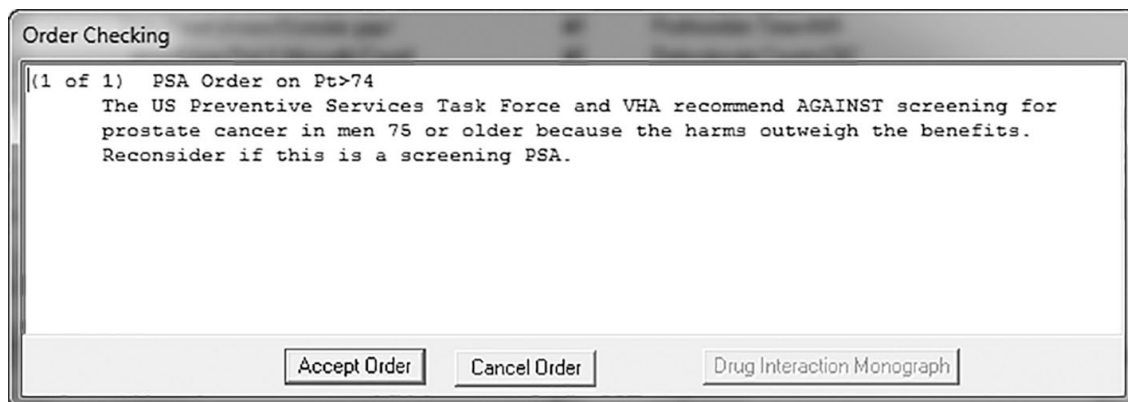
Screening for prostate cancer is controversial even for men in the age group (age 55-69) most likely to benefit. Some organizations recommend against it altogether, and others advise caution and shared decision-making (1-3). However, the modest and contested benefits of screening in this optimal age group are virtually absent among men 70 and older, while the potential harms of screening are substantial: false-positives and over-diagnosis – whereby men are correctly diagnosed with a disease that would never cause symptoms or death – frequently lead to invasive and harmful treatment (1).

African American men and men with a family history of prostate cancer are at elevated risk for prostate cancer (4, 5), which in theory means that patients between 50 and 69 who have those risk factors may benefit from screening more than average-risk patients would. Of particular relevance to the VA, Agent Orange exposure has been proposed as an additional risk factor (6), though the validity of this evidence has been called into question (7). However, even in high-risk groups, screening is not recommended for patients above 70, on the basis of evidence from randomized controlled trials that show little benefit and significant risks (1).

To date, most research on prostate cancer screening decisions has been quantitative, and has focused on provider characteristics associated with screening rates, or on tools to aid communication with patients (8, 9). Only two qualitative studies, both conducted in Australia, have explored providers' approaches to prostate cancer screening. One study distinguished between "proactive screeners," who offer screening routinely, and "reactive screeners," who offer screening only at patients' request (10). Another study was centered around providers' attitudes toward over-diagnosis, i.e. correctly diagnosing a disease that would never cause symptoms or death, and under-diagnosis, i.e. the threat of missing potentially fatal cancer (11). That study described four patterns ('heuristics') in providers' reasoning: 1) some are chiefly concerned about under-diagnosis, 2) some are chiefly concerned about over-diagnosis, 3) some make highly individualized decisions for every patient, and 4) some do not think about over- or under-diagnosis at all. However, these studies have not examined providers' reasoning about older men – a population for whom screening is much less controversial, and who represent a much clearer gap between evidence and practice.

In an effort to reduce unnecessary screening, a team of physicians in the Greater Los Angeles VA developed an electronic alert (Figure 4) that notifies doctors when ordering a potentially unnecessary prostate cancer screening test. A key feature of this alert is its sensitivity: it relies on an extensive list of exclusion criteria to minimize the number of times it appears unnecessarily, and it exempts patients between 70 and 74 in order to focus on the elderly population for whom there is maximum agreement across otherwise-conflicting guidelines. An evaluation in 2015 showed that the alert was associated with a reduction in unnecessary screening (12), but the alert's role in clinical decision-making has not been explored. In our study, we endeavored to build on the quantitative evaluation of the alert by interviewing primary care providers to better understand the alert's context, as well as how and why the alert works. In doing so, we sought to identify principles of CDS design, implementation and governance that may help explain the alert's effectiveness and positive reception, as well as its limitations.

Figure 4. Screenshot of Alert



Research on CDS

To study a given example of CDS in context is to study a great many things at once: it is the study of a medical decision, a study of communication between patient and provider, of

providers' relationship with and receptivity to medical evidence in an organizational context, of the implementation and governance of an intervention to change provider behavior, and of a computer system and its place in medicine. A vast array of theoretical traditions (e.g. socio-behavioral science, organizational behavior, implementation science) are applicable to each of these phenomena, but none capture them all. However, researchers have developed health IT-specific models that unite diverse theoretical perspectives with empirical evidence from CDS implementation and experiential insights from practitioners (13-16).

One widely-used model, the sociotechnical model for health IT (see Figure 1 of the dissertation introduction), identifies eight dimensions that merit consideration in both development and evaluation of CDS. A key feature of this model is that it conceptualizes health information technology as inseparable from its context, with the computer and its social/organizational environment collectively forming a "sociotechnical system." These systems have dynamic interdependencies and emergent properties that tend to limit the usefulness of static causal models. For this reason, the sociotechnical model does not make casual predictions. Instead, it identifies the dimensions of the sociotechnical system that interact to contribute to the success, failure, or limitations of health IT interventions.

This model is complemented by more specific and prescriptive frameworks for CDS, including a widely-cited 2003 list of "10 commandments" for effective CDS (13), a 2012 set of interface design principles for CDS (14), and a 2018 checklist ("GUIDES") that offers advice to CDS implementers (16). In contrast to the sociotechnical model, which simply identifies important dimensions, these prescriptive frameworks – or "process models" as defined by Nilsen (17) – make specific recommendations for ways to improve the development, implementation, and

governance of CDS. As explained in greater detail in the methods section, these prescriptive frameworks best represent the backdrop of evidence about CDS to which this study contributes, even though the study is not designed to test hypotheses about these models, one of which was published while this study was underway.

The current study builds on this literature in the following ways: first, this study offers evidence about an alert that aims to discourage an unhelpful practice rather than encourage a helpful one – i.e. *de-implementation* as opposed to implementation (18). Although CDS has been studied as a tool for de-implementation, it has been primarily used in the context of advanced diagnostic imaging(19, 20), leaving the role of CDS in de-implementation of other unproductive practices under-developed. Second, the majority of empirical evidence about CDS – about implementation, de-implementation, or other types of decisions – is derived from CDS that was designed to guide medication ordering or diagnostic imaging decisions, but research on CDS to guide decisions about *cancer screening* – a complex, preference-sensitive, and anxiety-provoking clinical topic – is also under-represented (16, 21, 22). Third, a growing evidence base supports the efficacy of CDS tools that involve “hard stops” – i.e. CDS that makes non-preferred choices highly inconvenient (e.g. requiring approval from an authority), but there is less evidence available about the efficacy of CDS tools that rely instead on “soft stops” like the one examined in this study (22). Particularly in light of the unintended consequences that have been linked to hard stops (23), we aim to add to the evidence base for soft stops – i.e. CDS that helps to make a clinical practice guideline recommendation accessible and salient while minimizing its “footprint” on the clinical workflow.

Methods

We developed an interview guide using the sociotechnical model for health IT (15), also drawing on principles for CDS (13, 14) and previous research on cancer screening in older adults (24). Of the 8 dimensions of the sociotechnical model (described in the dissertation introduction, p. 7.) we developed the interview guide to elicit the most information about the two dimensions that we expected to be especially important determinants of the alert's efficacy and acceptability: the *clinical content* and the *human-computer interface*. We also sought contextual information related to other dimensions of the model, e.g. internal organizational features, external pressures, and workflow and communication. After developing an initial version of the guide, we refined it iteratively based on pilot tests with providers and feedback from a panel of health services researchers. In the interviews, the guide was used to elicit information about 4 topics: 1) approaches to PSA screening for older vs. younger patients (include the workflow context for screening), 2) perspectives on the electronic alert for PSA screening, 3) perspectives on the VA's electronic alerts and reminders in general, and 4) perspectives on guidelines for PSA screening and education about new medical knowledge. The interview guide is shown in Table 8.

Table 8. Interview Guide

Topic	Questions and probes
Screening Context	<ul style="list-style-type: none">• Can you think back on the last few times you've ordered a PSA screening test?<ul style="list-style-type: none">○ Is the veteran always in the room with you? (i.e. is PSA screening ordered during the visit itself or is it sometimes done beforehand or afterwards?)• Are you always the one who places the order?• What is the main reason for the visit most of the time when you order PSA-based screening?
Screening Decision	<ul style="list-style-type: none">• What are some of the things you take into consideration when you're deciding whether to order PSA-based screening?<ul style="list-style-type: none">○ What about for older patients?• How do you talk to patients about the screening?

	<ul style="list-style-type: none"> ○ In what circumstances would you make a recommendation?
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Sample Screening Scenarios	<ul style="list-style-type: none"> ● You are evaluating a 76 year old African American man who has type two diabetes and glaucoma. Would you offer him PSA-based prostate cancer screening if he never brought it up? <ul style="list-style-type: none"> ○ [If no]: If he asks about it? ○ Why? ● You are seeing a 41 year old white man for an annual exam. His only medical problem is mildly high cholesterol. During your evaluation he indicates that his father died of prostate cancer at age 66. Would you offer him PSA-based screening for prostate cancer? <ul style="list-style-type: none"> ○ [If no]: Would you offer screening in the future? At what age? ○ Why?
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Alert	<ul style="list-style-type: none"> ● Have there been times when an alert has appeared in [the VA's electronic health record system] asking you to reconsider a PSA order that you're placing? <ul style="list-style-type: none"> ○ Do you find the alert to be helpful sometimes? <ul style="list-style-type: none"> ▪ What's helpful about it? ▪ Does it ever change your mind about an order? ○ Is there anything you do not like about the alert? ● What changes do you think would make the alert system more effective? [not limited to PSA screening]
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Guidelines	<ul style="list-style-type: none"> ● Which guidelines about PSA screening are you most familiar with, if any? ● Of the guidelines you are familiar with, which do you trust more? Why? ● What are some of the ways that you learn about new guidelines or best practices?
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Conclusion	<ul style="list-style-type: none"> ● Is there anything we did not touch on that you think is important?
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We also used clinical scenarios to identify revealed decisional factors in addition to the factors explicitly stated by providers. These scenarios were designed using recommendations for the use of clinical scenarios in research (25). In contrast to the scenarios often used in survey research, the scenarios in our study were not designed to provide a controlled test of a hypothesis about clinical decision-making. Instead, they served to make interview questions about clinical

decision-making less abstract, and to present a clinical decision-making context that is more familiar to providers, in order to revealing underlying perspectives.

Sample and Recruitment

We recruited primary care providers from VA primary care clinics across the greater Los Angeles area. This included physicians, physician's assistants, and nurse practitioners – all of whom might be responsible for ordering PSA screening. We focused on primary care providers because they have primary responsibility for overseeing patients' screening, while other specialties are more likely to use PSA tests for disease surveillance, or other uses outside the scope of this investigation.

In order to ensure that interviews were conducted with providers who are faced with decisions about PSA screening, we restricted the sample to primary care providers who had ordered at least 1 PSA test in a year-long period before recruitment.

Potential participants received an email introduction to the study and a request for their participation, along with information explaining the voluntary nature of participation. If participants did not respond to the email, we made up to a total of four contact attempts via email, phone, or instant message.

Of 121 eligible providers we contacted 51 to invite them to participate. We used purposeful sampling to ensure adequate variation in clinic type and PSA order volume. Of the 51 we invited to participate, we interviewed 25 (49%). Of the invited non-participants, 9 declined to be interviewed, and 16 did not respond. Per VA policy, no compensation was offered. Of the participating providers, 15 work at a VA medical center, and 10 work at a community-based outpatient center.

Interviews

Interviews were conducted by phone. The study was approved by the VA and University of California, Los Angeles (UCLA) Institutional Review Boards. Interviews were audio-recorded, professionally transcribed and spot-checked for accuracy.

Analysis

We conducted thematic analysis of the interview transcripts using a combination of deductive and inductive techniques (26); a coding manual based on the interview guide served as a starting point. We modified the manual to incorporate themes noted during interviews, then further adapted it to incorporate themes identified from the transcripts. The lead author (JB) coded each transcript, and a second reviewer (EC) coded a subset (1 in 5) and discussed and reconciled discrepancies in coding.

Results

Our results are organized to reflect the order in which the topics were discussed in interviews: first focusing on the PSA screening decision itself (for older vs. younger men), then discussing the alert intended to support that decision, then broadening the scope to consider alerts and reminders in general, and finally discussing guidelines and education. To promote ease of interpretation, we present provider reports at face value (e.g. “providers differed” instead of “providers reported differences”).

PSA screening decision

To reflect the different evidentiary landscapes about PSA screening for older vs. younger men, we discuss our findings separately according to patient age groups. Providers’ perspectives on screening older men are most relevant to understand the role of the electronic alert, because that is the population targeted by the alert. In contrast, their perspectives on screening younger men

better reveal their clinical reasoning because those decisions are more complex and the evidence less decisive. We observed modest diversity in providers' approaches to screening older men, and substantial diversity in approaches for younger men. None of the observed variation in perspectives coincided with differences in clinic type or PSA order volume. Within each of the two age categories, we present general perspectives, then examples from clinical scenarios.

PSA screening for older men

The vast majority of providers mostly avoid PSA screening for prostate cancer in patients older than 70 or 75. *"We're not going to do anything for the prostate cancer after a certain age. As we tell patients: the prostate cancer's not going to be what kills you"* [025]. Most providers viewed age 70 or 75 as a key turning point in their approach for PSA screening, with a roughly even split between age 70 and 75. Some focus on life expectancy (at any age) rather than age itself, *"I would tend to use 75 as a cutoff or a reasonable life expectancy of at least 10 years as a cutoff"* [043], but the majority focus on age directly. Some consider life expectancy indirectly: they primarily use an age cutoff, but make exceptions for veterans who are in exceptional health. Only one provider indicated routinely screening above age 75. That participant described ordering a screening PSA for patients every 2 years, without discussion, until age 80.

In older patients, the majority of providers do not discuss PSA screening, mostly to avoid over-testing, (*"I think generally if they're outside of the guidelines, I try not to bring it up because — everybody comes in wanting the 'cancer test,' whatever that might be. So just to avoid over-testing, if it's somebody that's older, I won't necessarily bring it up"* [002]). A few providers, however, discuss the screening with patients but discourage it. Nearly all providers screen older patients who demand or request it, but these requests are infrequent, (*"pretty rare, maybe less*

than 5% does that ever happen” [027]; “maybe a couple of times a year someone will absolutely insist that it gets ordered regardless of their age”[062]).

Clinical scenario: older patient

The first clinical scenario we presented to participants, in which we asked whether they would offer PSA screening to a 76-year old African American man with type II diabetes and glaucoma, helped clarify participants’ perspectives about screening older men. USPSTF guidelines do not recommend screening such a patient, and most participants indicated that they would not offer screening. Of those who would offer screening, most would leave the decision to the patient without making a strong recommendation for or against screening:

“I would discuss it with him but I wouldn't strongly recommend it. [I would tell him] ‘It's very controversial especially in your age group, but I want you to know it's available. If it's positive it can lead us to a whole group of evaluations that can have their own problems’” [029]

“I would just have that frank discussion that there's no real [age] cutoff that everybody agrees to” [045]

Most also expressed ambivalence about the appropriateness of screening for this patient, and noted the wider range of considerations that might influence the decision, including overall health, potential agent orange exposure, and the availability of previous PSA results:

“There’s such variation of these patients that we see. Sometimes you’ll see a 76-year-old guy with an A1c of 6, exercises every day, and for a guy like that, I would consider screening. If you have a guy that comes in and he’s had an A1c of 12 for five years and he’s in end-stage renal or something like that, then maybe I’m not.” [002]

“If he’s here and he’s a Veteran, he may have been exposed to agent orange. So someone like that I may consider if he’s never had one. It wouldn’t be such a bad idea because a lot of people who were exposed to agent orange, especially African-Americans, seem to have prostate cancer.” [027]

“If his PSA's were always low, then I would follow the guideline on that... ..[But if] his PSA's up to that point, at age 75, were borderline, it would make me discuss it more with him, to say that it's not indicated, that it hasn't been shown to decrease mortality and

there's risk for morbidity. We may have a longer discussion about it, [if] his PSA's were high over the years. But if it's been low, I probably would not pursue it.” [090]

A small number indicated that they would recommend or automatically order screening – in one case without specific justification, and in other cases because of potential risk factors:

“Yes, I would. It would just be part of the screening process. If it's a new patient then I would definitely order it. If it's a follow up patient I would look at the labs the last time it was performed, and if it was not then I would order it.” [097]

“I would [offer screening, because] being African American I think makes me a little more concerned about his risk.” [014]

“If he was a Vietnam Veteran, yes I would, [because of] potential exposure to agent orange, although I don't remember if prostate cancer is an agent orange condition.” [100]

PSA screening for younger men

The “initiation age” at which providers begin to recommend PSA screening varied from 40 to 59, with age 50 as the most common initiation age. A few providers tailor the initiation age based on patient risk factors. For patients in the optimal age range (as perceived by providers), most providers discuss the option to screen, along with the pro’s and con’s. But even in the subset of providers who have this discussion, there was considerable variation in the provider’s role in the decision. A few only make a recommendation regarding screening if pressed for one by the patient, a few *recommend* the screening but leave it open for discussion, and a few *discourage* the screening but leave it open for discussion. Some tailor their level of involvement in the decision based on the patient’s risk profile (e.g. race, family history):

“I go through the whole risk versus benefit thing upfront and I always tell them it’s their decision. And you know, there’s not a right or a wrong decision. So I kind of put it back on them unless they’re at higher-risk. Those are the only people that I say, yeah, I do recommend this. Or with males between the age of 40 and 60, especially if they’re

functioning really well, if they're worried I might say, 'You know, you might want to do this, just because you would be in the age group that would most benefit from treatment, but I don't strongly recommend it. You know, it's really your choice. We don't have an exact answer.'" [124]

Several providers order PSA for some or all "appropriately-aged" patients automatically, without discussion, treating it as one of the routine lab tests.

"I mean from the age of 50 to 80 it's just every two years for me." [097]

"Within the 40-60 [age] range... ..I just add it as part of their screening labs just like I would check their cholesterol and check them for diabetes." [025]

"Whenever their one year is up, I always make sure I order the whole lab screen including the PSA if they're a candidate." [027]

Some avoid bringing it up, and offer it only if a patient is at unusually high risk, or demands it, or if other, more pressing clinical priorities have been addressed.

"If the patient does not bring it up, I will bring it up when I think the patient might be at higher risk for prostate cancer." [120]

"I adhere to the recommendation from the USPSTF which advises that it not be done. Much like many other things that shouldn't be done, we shouldn't be randomly bringing them up just to tell patients that we're not going to do it" [043]

"If they have no risk factors and no symptoms, then the topic does not usually come up unless I'm done with everything else under the sun with them. That's very seldom. And there's always other things to do and bigger fish to fry in terms of screening, so much discussion and sort of cajoling that has to be done with things like colonoscopies and a bunch of the different vaccines that have come out, and actually counseling about risks and benefits of vaccines, counseling about risks and benefits of colonoscopy and that sort

of thing, it takes quite a bit of time. Counseling about diet, exercise, sleep, stress management.” [107]

Finally, some providers described instances in which patients, when offered a choice about screening, turn the decision back to the provider:

“Actually probably about 60% [of patients] say, ‘Hey, I’m not the doctor. You’re my doctor. Anything you say, anything you may know, I totally trust you.’ About 60% of the patient’s go like that.” [006]

Clinical scenario: younger man with family history

The second clinical scenario that we presented to participants provided additional insight about their perspectives toward screening younger men. In this scenario, we asked participants whether they would offer PSA screening to a 41-year-old white man whose father died of prostate cancer at age 66. Despite the elevated risk implied by this family history, USPSTF guidance would not recommend PSA screening for such a patient.

The majority of providers would offer screening to this patient. Of those who would *not* screen the patient at 41, most indicated that they would instead begin recommending screening at age 45 or 50. Responses illustrated the providers’ ambivalence about the decision, and other factors that might influence the decision, including evolving evidence, the patient’s willingness to undergo digital rectal examination, and the way that the test will be interpreted:

“I do go ahead and do a [digital rectal examination] as recommended and if they [decline] it, then I will order the PSA.” [073]

“By the time he turns 45, the guidelines may change... ..we’ll have another discussion based on what the new evidence shows.” [107]

“I would get a baseline and then I would tell him he could skip a year until he hits 50 and then we’ll do it every year. But I would get at least a baseline one, because I think that prostate cancer, they look at a trend and if suddenly you pop up like two points, that’s concerning. So I think it’s good to have a baseline.” [027]

“I will probably tell him to start at age 50, but if he really wants to start early, I’m okay with that too.” [053]

This clinical scenario also revealed the variety of ways that risk factors are considered. For some, the presence of a family history of prostate cancer was automatic grounds for screening earlier than would otherwise be recommended:

“Absolutely, I start screening at 40 [if there is a] family history.” [054]

“He has a family history, so he needs it done.” [049]

“Usually we start talking about screening at 50, but if there's a family history or if they are in a higher risk group then you could start screening like ten years earlier. So he would fit in that category.” [014]

For others, the increased risk merited consideration, but did not necessarily warrant screening:

“Based on evidence, that person would be a higher risk, but what that risk is I don't know. I can't tell that person what it is – just that it's greater.” [045]

“A subset of prostate cancers will be more aggressive and will be life-limiting but it is impossible to predict who will be among that small minority and I don't believe that that kind of family history is a very strong predictor. I don't think that the family history improves the incredibly poor test characteristics of the PSA or will be at all predictive at age 41 or 51 for someone who will develop prostate cancer in their 60s or 70s.” [043]

For one participant, the level of detail about the family history was insufficient:

“I would recommend screening no later than ten years before his father was diagnosed as opposed to having died from it. I would want to find out when he was diagnosed with it.” [100]

Organizational context

A common barrier to CDS is that “point of care” tools are not always used at the point of care.

For this reason, we sought to understand how orders for screening PSA tests fit within the clinical workflow. In the process, we discovered a number of workflow and organizational factors that influence screening.

We found that providers typically order PSA screening during a visit, with the patient in front of them, or sometimes immediately following a visit. However, there were a few providers who tend to place orders in advance of a visit, so that their results can be discussed in person:

“We order the lab tests—including PSA and other lab tests—a week before, so when the patient comes, we have his or her labs ahead of time, rather than doing it the same day or the day after.” [073]

Participants, all of whom were VA employees, also described the influence of providers outside the VA:

“It doesn't happen all the time, but probably every couple weeks I'll get something for an outsider provider with a list of labs that they want the patient to get. And I don't know if the patient has said, "Hey, I get my labs with VA, give me an order," or I don't know how that happens, but I just put the orders in if an outside provider has requested them.” [062]

“I had some coming from private practice, who come in, demanding [PSA screening]. Usually I try to get them away from it. But if they want it from outside, I tell them go get screened outside, if you want.” [054]

They also described ways in which the Veteran population might have a different risk profile (in addition to the previously-discussed agent orange exposure), or ways that practices at their medical center could change the risk/benefit ratio:

“I just want to make sure I can give them a complete evaluation. I just think that Veterans are the zebras of healthcare. There's always something unusual that's found in Veterans is just my general impression. If it's skin lesion, looks normal for somebody else, well, it turns out it's a rare kind of melanoma in a Veteran. So I've come across a lot of those kind of zebras and I don't want to be caught off guard.” [100]

“The VA, at least our educational venues from urology, has suggested that Veterans are generally at a higher risk, for whatever reason. We had stopped screening for a while, when the USPSTF came out with the D recommendation, and then urology kind of fought back and had several lectures given by some urology attendings and a couple of researchers, to suggest that that was a problem, because they are a population with a higher risk than the general population.” [090]

“The department of urology here has a fairly conservative approach, a non-aggressive approach, so the likelihood that they are going to get unnecessary morbidity is low, lower than probably the studies that were done previously.” [085]

Clinical Decision Support for PSA Screening

A substantial portion of the interviews concerned the electronic alert itself. We found surprising levels of agreement about the overall acceptability of the PSA screening alert, and starkly different examples of ways in which the alert is regarded as helpful.

Usefulness

Most of the participants said they consider the PSA screening alert useful, and about half said that the alert has sometimes made them decide against placing an order that they would have placed otherwise.

“It's definitely helpful because I have a couple of patients that are over 80 and for them it has popped up because by default I click on it and it tells me: ‘do you really need this?’ ... It's pretty informative. I mean, like I said, when I see it I react to it, so yes, it's actually good.” [097]

“It wants you to wake up and think what you're doing... you forget the age and then you just—yeah. I mean these reminders are many times very helpful because, you know, when you're very busy and you are considering multiple things going on. [It] just keeps things on track. So if you're asking me if that's a good thing to have there, yes, I think it is.” [084]

A small minority find the alert unhelpful and would prefer that it was not there.

“I already know this and if I order it, it's for some reason rather than screening, or the patient is insisting.” [042]

A few did not recall seeing the alert at all.

“I probably blew right past it. So if it did happen I probably didn't notice it, because my mind has probably already been made up. So I don't know if it's affecting how I practice” [029]

Several said the alert was unnecessary for them because they are already aware of and adherent to guidelines for PSA screening, but they appreciated its value for other providers.

“I don't think it has been helpful because we kind of know the screening guidelines. But maybe for new providers that may be helpful.” [073]

“It's not very helpful for providers who do not routinely order PSA like me. [It's more useful] for providers who are more inclined to order screening PSA for reasons such as they feel a liability issue” [053]

The most persuasive indication that the alert was effective came from the several participants who mentioned the alert's role in their decision-making process before they were asked about the alert itself.

[Explaining her decision not to screen a hypothetical 76-year-old patient in a clinical scenario:] “mostly because we have a little thing that pops up that says ‘PSA screening after the age of 74 is not recommended.’” [105]

Mechanisms of Alert Utility

Perhaps the most surprising finding was the considerable variety of ways that the alert was interpreted and used. For several providers, the alert functioned as intended: as a reminder when they forget that a patient has aged out of the optimal range for PSA screening, or when they forget that evidence does not support screening for older patients.

“You get used to just like clicking your normal labs and then when you get to that one, it will come up like, “Oh yeah, he just turned 75,” so then you take it—I take it off.” [027]

“I think it's sometimes we have an automatic thing of ordering different things, so sometimes people order nonchalantly just as a regular test order. So it's helpful for us to get that quick reminder, oh by the way, we actually don't need it for this patient.” [054]

By contrast, several providers said the alert is particularly useful as a tool to convince skeptical patients not to get screened.

“I, personally, like having that alert because it puts on the screen in front of me something that I can verbally tell the patient.” [100]

“It doesn't bother me that it comes up because sometimes it convinces a patient that they don't really need to have it. Probably in a blue moon I might inadvertently order a PSA and didn't really mean to and it'll come up and I'll go, oh, okay, I don't need to do that. But that doesn't happen often. But I don't mind the alert being there and I might miss it if it were gone.” [105]

Some providers primarily viewed the alert as educational: it made them aware of the guideline in the first place, and changed their future ordering habits such that they rarely saw the alert again. Or, if they were already aware of the guideline, the alert served to communicate that the VA considers this guideline credible and important.

“I’m trying to stay within the guidelines, so I guess the fact that it’s there, I kind of know about it, so I’m more careful with what I order, at least I think that. But overall the fact that it’s there has made me change my orders by knowing more about it.” [090]

We were also surprised that providers had markedly different expectations about how the PSA alert functioned: because the alert mentions age (it recommends against “screening for prostate cancer in men 75 or older”), most providers understood that the alert was triggered in response to the patient’s age, and many understood that the alert was intended to target screening PSA tests. However, few seemed aware that the alert had been programmed to be “highly specific,” i.e. to avoid firing when previous test results or diagnoses suggest that the PSA order might be for surveillance or some other non-screening purpose. One provider explained:

“I don’t feel like it ever pops up inappropriately. I think it just pops up based on the person’s age, to remind us of the guideline, but it’s not necessarily inappropriate. It would be inappropriate if we don’t order a test that we feel is clinically appropriate because of some indicator popping up.” [049]

These statements taken together suggest that users may interpret alerts differently based on their assumptions about the sophistication of CDS. Conversely, some participants voiced support for alerts to incorporate a wider variety of patient information and medical evidence.

“I mean, maybe if there was an alert that somehow factored in all the evidence and factored in all the risk factors of the patient and when I was about to do something else, you know, and finished the encounter and it showed me, ‘hold on a sec, do you want to consider screening this guy?’ Maybe that would be potentially more useful, but that would be hard.” [107]

Acceptability

In addition to speaking to the alert's utility, providers also explained their perspectives on its acceptability and convenience. They emphasized and responded positively to the fact that the alert takes only one click to dismiss, and requires no additional work on the part of the provider. *"What we have in the [VA's electronic health record system] is perfect. Number one, we don't have it as a mandatory check, which it should not be. It should only be with the discretion of the patient and the provider."* [006] In other words, the fact that the alert is a "soft stop" was highlighted as a factor in its acceptability.

Most providers said they do not mind the interruption, and view it as an inconsequential amount of time and attention. *"It's a good reminder. I don't mind it at all."* [042]; *"It's not bothersome or anything... ...It doesn't take any time out of our day or add any stress."* [049]

Counter-intuitively, frustrations with other types of clinical decision support may actually make the PSA alert seem less cumbersome by comparison. For example, providers explained that alerts notifying them of test results can be particularly burdensome. *"Every primary care provider's view alert box is filled, not just with all the tests you've ever ordered but all the tests that anyone has ever ordered for your patient."* [107]; *"I spend all of my Thursday afternoons answering alerts and two hours a night at home answering alerts. Yeah, I wish there weren't so many of them"* [105]

Alerts and reminders beyond PSA

Although discussing the example of the PSA alert helped elicit concrete feedback, we also discussed computerized alerts and reminders in general, beyond the PSA alert. As with the PSA alert, we were surprised by the overall positive regard for alerts and reminders, with a large

proportion of participants indicating approval, and some expressing particular appreciation for reminders related to needed preventive care, e.g. *“that’s really helpful, reminding when to order mammogram or colon cancer screening or pap smear,”* [049].

Despite this positive assessment of alerts and reminders, many discussed the importance and challenge of careful governance of the EHR system and the alerts and reminders therein. Some focused on the overall volume of alerts and reminders as indicative of insufficient governance of the system: *“I think 90% of the alerts out there, there’s no action needed and contributes to a lot of the alert fatigue and this really drowns out the 10% where something of importance comes up.”* [120]; *“If everything is important, nothing is important.”* [100]. Others spoke about governance directly, *“stewardship over the [VA’s EHR] system seems to be not the most rigorous,”* [107] and one provider identified a successful example of governance that had occurred for a period of time, whereby a clinician who was in charge of the EHR system consulted with PCPs before implementing an alert or reminder in order to get feedback from them and to let them know of the purpose of the CDS.

Providers also identified characteristics of alerts that improve their usefulness and acceptability. One provider emphasized that alerts should be well-targeted (i.e. highly specific, with minimal “misfires”), and must ensure that structured options are designed in a way that can accommodate complex and difficult-to-predict clinical scenarios:

They should not pop up inappropriately. They should have ways of escaping them, so they shouldn’t force you to choose an answer that’s going to be a lie. That can be a common pitfall. Because if you have to click them away, that means you have to click a statement that may not be true. So they should be optional and they should cover all of

the possible decision-making, including checking off some reason why you're not doing them. When these reminders are written, sometimes they're written by people that aren't thinking about all the possible clinical scenarios because maybe they haven't been there."

[043]

Providers also conveyed that alerts are most useful when they include a link to take the recommended action, e.g. "*I appreciate alerts that have links to orders directly,*" [002], or that link to relevant guidelines for more detailed information. However, providers also emphasized that guideline recommendations included in CDS must be kept current, again returning to the issue of governance and stewardship of CDS: "*A busy primary care provider would rather have it where you have the option to click on the link if you want to see [the guideline], read more about it. But then that takes work to make sure links are still working and that they're up to date.*" [045] Other providers suggested that alerts and reminders focus on *new* guideline recommendations, e.g. "*when new things come out, it's always helpful in terms of guidelines to put the reminders there,*" [084].

Guidelines and education

Participants also offered insight into their perceptions of different guidelines about PSA screening, and the ways that they learn about guidelines and best practices in general. A central component of these conversations was a comparison of participants' perspectives on guidelines from the United States Preventive Services Task Force (USPSTF) in comparison to guidelines from specialty societies, most notably the American Urological Association (AUA). A plurality of participants voiced the most support for, and familiarity with, guidelines from the USPSTF.

Those who place their trust in this guideline above others do so because it the most widely-recognized, and because they view specialty societies as relatively more likely to be influenced by guild incentives (to protect their members' financial interests).

“The Task Force, what they do is they digest and dissect information over a long period time, and they normally get it from several sources, versus American Urological Association, a lot of times you kind of tell that there is a little bit of a component of their job security that they're looking into.” [006]

One provider implied that primary care professional norms elevate the prominence of USPSTF guidance: “*USPSTF [is what] you always go by, at the primary care level,*” [110] and another suggested that the task force's federal imprimatur gives it particular credence at the VA: “*I'm a federal government employee and I work for a federal government hospital and so if I say I'm just using federal government guidelines here, most people accept that as a no-brainer.*”

A smaller group of providers prefer specialty society guidelines, in deference to urologists' expertise in prostate cancer, or based on the perception that those guidelines better reflect practice norms outside the VA:

I think I would want to do not just what the VA does, but what Joe Blow does when he goes to his private doctor across the street so that we all can agree to do it. Because I don't want him to go to his urologist and say, well, I'm doing this and it's different. So I'd like to be doing the same thing the guys in the community are doing. [029]

For some providers, their personal perspectives about guidelines were less influential than organizational endorsement, “*I think the [use of] guidelines should be based on what the chiefs of the department think are the most efficient and well-respected.*” [027] Several noted that the

PSA alert made them more familiar with the USPSTF guideline, and conveyed that the VA considers that recommendation credible: *“I usually stick with the VA guidelines. They’re my employers so I go by their guidelines. [I find out about them] in the alerts. It says ‘For Continued Guidance...’”* [100] This theme, of providers learning about guideline recommendations through the VA’s electronic health record system, extended beyond PSA screening, and was cited as a convenient source of learning in general, and highly salient for busy providers. *“[Some alerts have a link:] ‘For Continued Guidance.’ Or if I go to the consult order menu, if I’m referring someone to urology for prostate cancer, there may be a link that says, okay, here are the guidelines for this. Like microscopic hematuria, it’ll say something like that.”* [100] *“I try to keep up with the diabetes stuff and the hypertension... that’s like the meat and potatoes of internal medicine but when you start getting into subspecialties or prostate and all that, I don’t keep up with all that.”* [027].

However, the most frequently-cited source of information about guideline recommendations was the online service UpToDate, which compiles and distills medical knowledge from guidelines and primary research. *“I follow what’s in the UpToDate, which [I access] through the VA.”* [073] More traditional pathways for ongoing medical education, such as journals and conferences were also mentioned, though less frequently. Notably, organizational sources (besides the computer system) were also identified as important sources of learning:

“That’s one of the good things about working here is if there’s something that they really want us to do different, when there’s a major guideline change, we usually get an email about it... I don’t know where it originates but it’s things that we should know about, so they send it to us... And I actually think it’s helpful because it’s kind of hard to—

especially in primary care, we're responsible for so much information all the time. Everything has a guideline. So I'm not going to remember an individual guideline but it's helpful to get those reminders when there's something new, so you can kind of pull your head out of the sand like, "Okay, this is what I need to do different. This is a new thing coming down the pipeline." [049]

Discussion

Our study provides a rich contextual understanding of an alert to reduce unnecessary prostate cancer screening by elucidating providers' reasoning about prostate cancer screening, its organizational context, and the role of the alert in their decisions, along with insight into providers' perspectives on other CDS and on the guidelines that inform CDS. Below, we discuss the theoretical implications of our study for CDS by exploring connections between our findings and key CDS principles, and by examining the role of the sociotechnical model in our study. We also describe our study's implications for scholarship on decision-making about prostate cancer screening specifically.

Conceptual implications for CDS

The dimensions of the sociotechnical model for health IT (15) adeptly represent the scope and salient features of our findings. The model was developed with a focus on patient safety and error prevention, and was most informed by the implementation of tools to support orders of medication or diagnostic imaging. Our study represents a useful application of the model in a study not explicitly focused on medical errors, instead focused on the ordering of a lab test for cancer screening – a different part of the clinical workflow, and a distinct type of clinical decision with complex, personal, preference-sensitive dimensions.

While the sociotechnical model primarily influenced our interview guide, CDS-specific prescriptive frameworks are even more helpful for contextualizing our findings. The frameworks outline a great many principles that contribute to successful CDS. Among these principles, there were some that were surprisingly not evident in our study as explanations for the alert’s effectiveness or acceptability. For example, Bates (13) asserts that “physicians will strongly resist stopping” and that “changing directions [i.e. accepting an alternative] is easier than stopping”. You might expect these factors to constrain the effectiveness of the alert we studied, which a) urged physicians to stop an order *after* they had decided to place it, and b) did not recommend an alternative. But these principles were not prominent themes in our interviews. Instead, our study identified three principles that were particularly operative in the context of an alert to reduce unnecessary prostate cancer screening: workflow, trust, and governance (Table 9). We did not design the study to test hypotheses about these principles, but they emerged as important concepts for understanding the alert’s effectiveness, its positive reception (acceptability), and its potential limitations.

Table 9. Principles from Frameworks for Clinical Decision Support That Help Explain the Effectiveness, Acceptability and Limitations of an Alert to Reduce Unnecessary Screening for Prostate Cancer

CDS Principle	Bates 2003	Horsky 2012	GUIDES 2018
Attend to workflow carefully	<p>Commandment 3: “Fit into the user’s workflow”</p> <p>Details: “Only after bringing the guideline to the user on a single screen at the time the clinician was in the process of ordering [the target of the CDS] did we see an impact. Understanding clinician workflow, particularly when</p>	<p>Desirable system attribute: “Workflow integration”</p> <p>Related recommendations: “Appropriate sequence of screens, context, type and timing of advice by clinical task”</p>	<p>Checklist item 1.4: “[ensure that] CDS can be added to the existing workload, workflows and systems”</p> <p>Related questions: - Is it feasible to introduce CDS, given the current workload and the usual work processes? - If necessary, can the workload or the work</p>

	designing applications for the outpatient setting, is critical.”		processes be changed or can the CDS system improve the workload or work processes?
Foster trust	-	Desirable system attribute: “Presentation of advice in a way that cultivates trust over time”	Checklist item 2.1: “[ensure that] the content provides trustworthy evidence-based information”
		Related recommendations: “Avoid black box advice, maintain high specificity, context, justification”	Related questions: - Do the organization(s) and people that developed the decision support have credibility? - Is the advice supported by up-to-date scientific evidence and is the type and quality of this evidence clear to the user? - Is the decision support clear on the benefits and harms of the different management options?
			Checklist item 2.2: “[ensure that] the decision support is relevant and accurate
			Related questions: - Does the decision support contain accurate information that is pertinent to the care of the patient? - Does the decision support address the information needs of the users? - Is it clear to the users why the decision support information is provided for a given patient?
Maintain good governance	Commandment 10: Manage and maintain your knowledge-based systems	-	Checklist item 4.4: “Governance of the CDS implementation is appropriate”
	Details: “It is also critical to keep up with the pace of change of medical knowledge. We have attempted to assign each area of decision support to an individual, and require the individual to assess their assignment periodically to ensure that the knowledge base remains applicable.”		Related questions: - Are all the key stakeholders involved in the planning and implementation of the system? - Is the CDS initiative governed in an efficient, sustainable and equitable way?

Workflow

First among the principles that emerged as particularly salient was the importance of careful attention to workflow – a principle emphasized by all three CDS frameworks (Table 9). Alerts are frequently rendered ineffective when they cannot be easily integrated within the clinical workflow – for example, if providers postpone their computer-based documentation until after a patient visit, computer-based CDS cannot inform provider-patient interactions for that visit. Encouragingly, we found that the PSA alert is relatively well-integrated into the clinical workflow: most of the time, the alert is delivered to the provider (i.e. to the correct person, responsible for the decision), at a time when the provider can discuss prostate cancer screening with the patient. Only a small minority of participants reported placing PSA orders in advance of visits (so that results can be reviewed during the visit), and none reported a consistent pattern of postponing documentation until after a visit. These reports on whole suggest that the alert tends to reach the “right person and the right time” (27).

Beyond its timing, there are multiple features of the alert that help promote its easy integration into the provider workflow. A large proportion of CDS reminds providers of needed preventive care that may otherwise be overlooked, i.e. CDS intended to implement under-used practices. This type of CDS can be helpful, but it necessarily adds to providers’ workload for many or most patients. By contrast, the PSA alert is intended to “de-implement” an unnecessary and potentially harmful practice. By its very nature, this type of CDS often has a smaller footprint on providers’ workload because it is only invoked in response to a PSA order with certain characteristics. The

alert's workflow compatibility is also helped by its brevity: it presents a small amount of relevant information, and requires only one click to dismiss – features which several providers emphasized were critical to the alert's acceptability.

Trust

The second principle that was highly operative in our study was the importance and challenge of fostering trust in the CDS system. Horsky et al (14) suggest building trust by avoiding “black box” advice, and by maintaining “high specificity, context, and justification.” The alert was indeed designed to be “highly specific” i.e. to only appear when the EHR has no accessible evidence that may suggest that a given PSA order might have been ordered for a purpose other than screening. Our findings validated the value of this approach. However, we found the approach to be incomplete: the alert still occasionally “misfires” when PSA orders are placed, e.g. in response to symptoms (i.e. not screening) that cannot be detected by the alert's algorithm. The alert presents a succinct justification, but does not adequately convey its internal logic. For example, some participants assumed that the alert was not at all “context-sensitive” – i.e. that it appeared for every order for a patient over 74, without taking cancer diagnoses or previous elevated PSA levels into account. These provider impressions suggest that increased transparency could help foster greater trust in the alert, and deeper understanding of what it means when it appears.

Trust is also a function of the source of a given recommendation and accompanying CDS. The GUIDES checklist emphasizes the provenance of CDS as a determinant of trust, noting that the organizations and people who develop the CDS must be credible to the CDS users (16). Our

findings about the USPSTF – the organization identified in the alert – speak to this concern. Trust in and preference for USPSTF above other groups that offer PSA guidelines was not universal but was notably high. This is another important factor in the alert’s effectiveness: providers view the USPSTF recommendations as well-researched and well-accepted by the primary care community. Beyond the organizational provenance, there’s also the question of the credibility of the recommendation itself, i.e. to refrain from PSA screening for older men. For some, the very presence of the alert helped support the credibility of that recommendation because it implied endorsement by the VA or by local clinical leadership. Similarly, it helped convey the legitimacy of the recommendation to patients by providing visual evidence that external authorities endorse it.

Governance

The third key principle – related to trust, but not entirely defined by it – was diligent governance of the CDS system. GUIDES operationalizes one part of governance as engaging key stakeholders in planning and implementing CDS (16). This concept was addressed implicitly in discussions of alert fatigue, and was even addressed explicitly by a participant who noted being more receptive to CDS when the CDS developers discuss new alerts or reminders with providers before implementation.

Bates emphasizes another aspect of governance: the importance of keeping up with advancing medical knowledge (13). Participants articulated this need as well, and complained that some CDS rules reflect outdated guidelines. More broadly, some suggested that a particularly useful role for CDS would be to focus on new medical evidence, as opposed to the more typical focus

on relatively older, well-established medical evidence that is not universally recognized or acted upon.

Implications for PSA decision-making

In addition to the implications for CDS design and implementation, our study also sheds light on providers' reasoning about PSA screening in general. Our findings add credence to a set of profiles or "heuristics" describing primary care providers' reasoning about PSA screening, originally developed from interviews with general practitioners in Australia (11). Even though most providers tended to screen younger patients and avoid screening older patients, their membership in one of the four profiles defined by Pickles et al was relatively consistent: with rare exceptions, "avoids under-diagnosis," "avoids over-diagnosis," "doesn't consider over- or under-diagnosis," and "makes case-by-case decisions" were adequate descriptions of providers' reasoning across patient age groups. These heuristics were developed in the context of screening mostly younger men, for whom the evidence on PSA screening is less definitive; our study extends those findings to the population of older men for whom PSA screening is most consistently recommended against.

By contrast, Ilic's categories (10) of "proactive screeners" (who tend to screen as a matter of course) and "reactive screeners" (who tend to screen only at patients' request) had less explanatory power in our study. We observed substantial variation within these categories, e.g. in overall attitudes toward screening, locus of decision-making, and consideration of risk factors.

Conclusion

Our sample included primary care providers with diverse perspectives about CDS and prostate cancer screening. Because participation in the study was voluntary, providers with stronger opinions may have been more likely to participate. Fortunately, recruitment materials emphasized the opportunity to improve the VA's electronic health record system, and did not specify prostate cancer screening, which reduces the likelihood that participants with strong or unusual views about PSA screening were differentially included.

Our qualitative study revealed the heterogeneity in PCPs' approaches to PSA screening, including for older men who are highly unlikely to benefit from the screening. In doing so, it illustrated the continued need for CDS among several PCPs, who benefit from the alert in varied ways (e.g. as a reminder, as an educational tool). The study provides under-represented evidence on the use of CDS for lab-based cancer screening, for de-implementation, and using a "soft stop" approach. Even more importantly, the study identifies principles that help us understand *why* the alert has had its demonstrated effect: we found that attention to workflow (e.g. keeping it brief), fostering trust (e.g. citing trusted sources), and maintaining governance (e.g. engaging PCPs in implementation) were key principles that help explain its effectiveness and acceptability.

References

1. Grossman DC, Curry SJ, Owens DK, Bibbins-Domingo K, Caughey AB, Davidson KW, et al. Screening for Prostate Cancer: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2018;319(18):1901-13.

2. Qaseem A, Barry MJ, Denberg TD, Owens DK, Shekelle P, Clinical Guidelines Committee of the American College of P. Screening for prostate cancer: a guidance statement from the Clinical Guidelines Committee of the American College of Physicians. *Ann Intern Med.* 2013;158(10):761-9.
3. Carter HB, Albertsen PC, Barry MJ, Penson DF, Zietman AL. Early Detection of Prostate Cancer: AUA Guideline 2013 [Available from: <http://www.auanet.org/documents/education/clinical-guidance/Prostate-Cancer-Detection.pdf>].
4. Kicinski M, Vangronsveld J, Nawrot TS. An epidemiological reappraisal of the familial aggregation of prostate cancer: a meta-analysis. *PLoS One.* 2011;6(10):e27130.
5. National Cancer Institute. SEER Cancer Statistics Factsheets: prostate cancer 2018 [Available from: <https://seer.cancer.gov/statfacts/html/prost.html>].
6. Chamie K, DeVere White RW, Lee D, Ok JH, Ellison LM. Agent Orange exposure, Vietnam War veterans, and the risk of prostate cancer. *Cancer.* 2008;113(9):2464-70.
7. Chang ET, Boffetta P, Adami HO, Cole P, Mandel JS. A critical review of the epidemiology of Agent Orange/TCDD and prostate cancer. *Eur J Epidemiol.* 2014;29(10):667-723.
8. Fedewa SA, Gansler T, Smith R, Sauer AG, Wender R, Brawley OW, et al. Recent Patterns in Shared Decision Making for Prostate-Specific Antigen Testing in the United States. *Ann Fam Med.* 2018;16(2):139-44.
9. Pollack CE, Platz EA, Bhavsar NA, Noronha G, Green GE, Chen S, et al. Primary care providers' perspectives on discontinuing prostate cancer screening. *Cancer.* 2012;118(22):5518-24.
10. Ilic D, Murphy K, Green S. What do general practitioners think and do about prostate cancer screening in Australia? *Australian family physician.* 2013;42(12):904.
11. Pickles K, Carter SM, Rychetnik L, Entwistle VA. Doctors' perspectives on PSA testing illuminate established differences in prostate cancer screening rates between Australia and the UK: a qualitative study. *BMJ open.* 2016;6(12):e011932.
12. Shelton JB, Ochotorena L, Bennett C, Shekelle P, Kwan L, Skolarus T, et al. Reducing PSA-Based Prostate Cancer Screening in Men Aged 75 Years and Older with the Use of Highly Specific Computerized Clinical Decision Support. *J Gen Intern Med.* 2015;30(8):1133-9.
13. Bates DW, Kuperman GJ, Wang S, Gandhi T, Kittler A, Volk L, et al. Ten commandments for effective clinical decision support: making the practice of evidence-based medicine a reality. *Journal of the American Medical Informatics Association.* 2003;10(6):523-30.

14. Horsky J, Schiff GD, Johnston D, Mercincavage L, Bell D, Middleton B. Interface design principles for usable decision support: a targeted review of best practices for clinical prescribing interventions. *J Biomed Inform.* 2012;45(6):1202-16.
15. Sittig DF, Singh H. A new sociotechnical model for studying health information technology in complex adaptive healthcare systems. *Qual Saf Health Care.* 2010;19 Suppl 3:i68-74.
16. Van de Velde S, Kunnamo I, Roshanov P, Kortteisto T, Aertgeerts B, Vandvik PO, et al. The GUIDES checklist: development of a tool to improve the successful use of guideline-based computerised clinical decision support. *Implementation Science.* 2018;13(1):86.
17. Nilsen P. Making sense of implementation theories, models and frameworks. *Implementation Science.* 2015;10(1):53.
18. Prasad V, Ioannidis JP. Evidence-based de-implementation for contradicted, unproven, and aspiring healthcare practices. *BioMed Central*; 2014.
19. Blackmore CC, Mecklenburg RS, Kaplan GS. Effectiveness of clinical decision support in controlling inappropriate imaging. *Journal of the American College of Radiology.* 2011;8(1):19-25.
20. Hussey PS, Timbie JW, Burgette LF, Wenger NS, Nyweide DJ, Kahn KL. Appropriateness of advanced diagnostic imaging ordering before and after implementation of clinical decision support systems. *Jama.* 2015;313(21):2181-2.
21. Bright TJ, Wong A, Dhurjati R, Bristow E, Bastian L, Coeytaux RR, et al. Effect of clinical decision-support systems: a systematic review. *Ann Intern Med.* 2012;157(1):29-43.
22. Goldzweig CL, Orshansky G, Paige NM, Miake-Lye IM, Beroes JM, Ewing BA, et al. Electronic health record-based interventions for improving appropriate diagnostic imaging: a systematic review and meta-analysis. *Ann Intern Med.* 2015;162(8):557-65.
23. Strom BL, Schinnar R, Aberra F, Bilker W, Hennessy S, Leonard CE, et al. Unintended effects of a computerized physician order entry nearly hard-stop alert to prevent a drug interaction: a randomized controlled trial. *Arch Intern Med.* 2010;170(17):1578-83.
24. Lewis CL, Griffith J, Pignone MP, Golin C. Physicians' decisions about continuing or stopping colon cancer screening in the elderly: a qualitative study. *Journal of general internal medicine.* 2009;24(7):816-21.
25. Evans SC, Roberts MC, Keeley JW, Blossom JB, Amaro CM, Garcia AM, et al. Vignette methodologies for studying clinicians' decision-making: validity, utility, and application in ICD-11 field studies. *International Journal of Clinical and Health Psychology.* 2015;15(2):160-70.

26. Brooks J, McCluskey S, Turley E, King N. The Utility of Template Analysis in Qualitative Psychology Research. *Qual Res Psychol.* 2015;12(2):202-22.
27. Sirajuddin AM, Osheroff JA, Sittig DF, Chuo J, Velasco F, Collins DA. Implementation pearls from a new guidebook on improving medication use and outcomes with clinical decision support: effective CDS is essential for addressing healthcare performance improvement imperatives. *Journal of Healthcare Information Management.* 2009;23(4):38.

Dissertation Conclusion

In this dissertation I examined clinical decision support in VA primary care clinics using survey data, clinical quality measures, and interviews with primary care providers. Because a wealth of information is already available about the average efficacy of CDS interventions (1-7), I instead studied factors that can improve CDS, with an eye towards the way that CDS is implemented, and a particular emphasis on user-centered design.

In study 1, I examined the prevalence of four user-centered design strategies for CDS, and evaluated the association between those strategies and perceived utility of CDS. Of the strategies, I found that “analysis of impact on performance improvement” was the most common and was the only one statistically associated with perceived CDS utility.

In study 2, I assessed the relationship between CDS and quality of care, using the example of colorectal cancer screening. This study provided an opportunity to examine CDS in the context of other tools for supporting evidence-based practice, and included patient-level and site-level analyses. In this study, I did not find associations between a clinic’s use of CDS for colorectal cancer screening and the clinic’s colorectal cancer screening rates. In fact, no clinic-level characteristics, including other tools to support evidence-based practice, were associated with screening rates, perhaps reflecting a “ceiling” effect of high observed rates of colorectal cancer screening, and a prior organization-wide mandate to perform such screening.

In study 3, I explored primary care providers’ perspectives on an alert intended to reduce unnecessary prostate cancer screening, along with their approaches to the underlying clinical decision. I found diversity in providers’ approaches to prostate cancer screening, and high overall acceptance of the alert, with several different mechanisms of action for its influence on

screening decisions. I also identified factors that may explain the alert's effectiveness and acceptability, including attention to workflow (e.g. keeping it brief), fostering trust (e.g. citing trusted sources), and maintaining governance (e.g. engaging PCPs in implementation).

Conceptual and evidentiary landscape

The dissertation was organized around the sociotechnical model for health IT (8), and the dissertation's inclusion of multiple research modalities – of data from clinical records, surveys, and interviews – allowed the dissertation to more thoroughly span the 8 dimensions of the model. But health IT literature is growing and evolving quickly - so quickly, in fact, that novel frameworks have entered the literature while the dissertation was underway. A 2018 systematic review of factors promoting successful CDS interventions (9) helped produce a checklist for developing and implementing CDS (10), which joins a 2012 review with a narrower scope (focused on interface design) (11). These empirical studies and their accompanying recommendations add substantial detail that usefully complements the sociotechnical model, which was developed on the basis of diverse theoretical traditions but a narrower empirical base. For example, one of the dimensions of the sociotechnical model is "clinical content," which identifies underlying clinical knowledge or recommendations as an important factor in CDS. Recent frameworks supplement this dimension of the sociotechnical model by identifying specific, evidence-informed processes related to clinical content, e.g. ensuring that CDS content comes from sources credible to the user (10), making clear why CDS information is provided for a given patient (10), and "maintaining high specificity, context, and justification" (11).

Thus, the dissertation was organized around the sociotechnical model, whose level of specification was ideal for spanning three studies and providing a well-rounded view of CDS,

but the dissertation findings are most instructive in the context of more prescriptive frameworks. Some of the dissertation's relevance to aspects of these frameworks are explicated in study 3, which identified the framework-derived themes of “attention to workflow” and “fostering trust” as explanations for the efficacy of a given CDS alert. But the aspect of the frameworks that is best represented across the dissertation is CDS governance: the process of prioritizing, sustaining, and maintaining CDS.

CDS Governance

CDS governance encompasses several important aspects of CDS that are each necessary but insufficient components of successful CDS. For example, CDS *effectiveness* is a central outcome in most evaluations for good reason, but exclusive focus on effectiveness neglects the unintended consequences of CDS. Similarly, CDS *implementation* is a common object of study, but an exclusive focus on implementation typically underrepresents the ongoing work that must occur after CDS has been implemented to ensure that it reflects recent clinical knowledge and continues to fit changing clinical workflows and organizational contexts. CDS governance is inclusive of CDS effectiveness and implementation, but also emphasizes the externalities of CDS, the engagement of its stakeholders, and the continuous process of prioritizing, sustaining, and maintaining CDS.

CDS governance emerged as a consistent theme across the dissertation. This responsibility is an increasingly explicit, formal function, and some healthcare systems have convened committees to do away with existing alerts and reminders that are ineffective or insufficiently important, and to apply similar criteria to new proposals for CDS content. Each study in this dissertation is relevant to the decisions these groups must make, and each is instructive, in a different way, as to

how to balance the competing goals of encouraging certain clinical practices while minimizing burden and alert fatigue. Study 1 suggests that using an alert or reminder's impact on performance measures could be a useful way to evaluate and prioritize instances of CDS. Study 2 helps illustrate that CDS may not be necessary in the context of other strong incentives for a given clinical practice. Study 3 emphasizes the importance of engaging users in implementing CDS, and identifies CDS characteristics that may contribute to its success. Across studies, each of these implications are examples of CDS governance, and can be instructive for diverse CDS stakeholders, but especially those who are tasked with prioritizing across opportunities for CDS, maintaining and updating existing CDS, and implementing new CDS.

Future work

Each study illuminates an opportunity for related work - by extending my methods to additional clinical / operational areas, or building on my methods to support stronger inferences. For example, extending my approach to specialty care settings could bolster its generalizability, and could identify differences by setting. Similarly, extending my studies to clinical staff besides providers (e.g. nurses and other support personnel) could fill an important gap health IT research. Future work could build on the quantitative studies by including more direct measures of user acceptability, and could even draw on the growing discipline of "cognitive informatics" (12) that attends to the subtle thought processes and emotions elicited by technology, beyond simple measures of effectiveness.

More-applied opportunities for future work are suggested by individual study findings. For example, study 3 identifies challenges with CDS, several of which may be in part attributable to the fact that CDS is typically deployed semi-permanently - i.e. once a CDS tool is implemented,

it often stays in place for a long, unpredictable amount of time. The long duration makes CDS more likely to accumulate to create alert fatigue and necessitates an unconstructively high bar for CDS, while the unpredictable duration makes the *absence* of CDS a difficult-to-interpret signal for clinicians. This dissertation suggests an opportunity for research on approaches that can overcome these challenges, for example, by experimenting with shorter-term deployments of CDS with predictable extinction schedules.

In closing

Taken together, this dissertation illustrates the promise of judiciously implemented CDS. It identifies factors that can constrain CDS' usefulness, and points toward strategies for improving its impact.

References

1. Goldzweig CL, Orshansky G, Paige NM, Miake-Lye IM, Beroes JM, Ewing BA, et al. Electronic health record-based interventions for improving appropriate diagnostic imaging: a systematic review and meta-analysis. *Ann Intern Med.* 2015;162(8):557-65.
2. Bright TJ, Wong A, Dhurjati R, Bristow E, Bastian L, Coeytaux RR, et al. Effect of clinical decision-support systems: a systematic review. *Ann Intern Med.* 2012;157(1):29-43.
3. Garg AX, Adhikari NK, McDonald H, Rosas-Arellano MP, Devereaux P, Beyene J, et al. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review. *Jama.* 2005;293(10):1223-38.
4. Kaushal R, Shojania KG, Bates DW. Effects of computerized physician order entry and clinical decision support systems on medication safety: a systematic review. *Archives of internal medicine.* 2003;163(12):1409-16.
5. Wolfstadt JI, Gurwitz JH, Field TS, Lee M, Kalkar S, Wu W, et al. The effect of computerized physician order entry with clinical decision support on the rates of adverse drug events: a systematic review. *Journal of general internal medicine.* 2008;23(4):451-8.

6. Kuperman GJ, Bobb A, Payne TH, Avery AJ, Gandhi TK, Burns G, et al. Medication-related clinical decision support in computerized provider order entry systems: a review. *Journal of the American Medical Informatics Association*. 2007;14(1):29-40.
7. Moja L, Kwag KH, Lytras T, Bertizzolo L, Brandt L, Pecoraro V, et al. Effectiveness of computerized decision support systems linked to electronic health records: a systematic review and meta-analysis. *American journal of public health*. 2014;104(12):e12-e22.
8. Sittig DF, Singh H. A new sociotechnical model for studying health information technology in complex adaptive healthcare systems. *Qual Saf Health Care*. 2010;19 Suppl 3:i68-74.
9. Van de Velde S, Heselmans A, Delvaux N, Brandt L, Marco-Ruiz L, Spitaels D, et al. A systematic review of trials evaluating success factors of interventions with computerised clinical decision support. *Implementation Science*. 2018;13(1):114.
10. Van de Velde S, Kunnamo I, Roshanov P, Kortteisto T, Aertgeerts B, Vandvik PO, et al. The GUIDES checklist: development of a tool to improve the successful use of guideline-based computerised clinical decision support. *Implementation Science*. 2018;13(1):86.
11. Horsky J, Schiff GD, Johnston D, Mercincavage L, Bell D, Middleton B. Interface design principles for usable decision support: a targeted review of best practices for clinical prescribing interventions. *J Biomed Inform*. 2012;45(6):1202-16.
12. Patel VL, Kannampallil TG. Cognitive informatics in biomedicine and healthcare. *Journal of biomedical informatics*. 2015;53:3-14.

Appendices

Appendix 1: Constructs and Measures

<i>Domain</i>	<i>Construct</i>	<i>Source</i>	<i>Measures</i>
Perceived Utility of CDS	Perceived Utility of CDS	Primary Care Clinic Director	Mean of 3 items: “CPRS improves dissemination of new information” “CPRS improves clinical decision support” “CPRS reduces medical errors” (1=strongly disagree, 5=strongly agree)
User-Centered Design	User-Centered Design Practices	VA Medical Center Chief of Staff	Four indicators: 1) Test piloting reminders prior to full scale implementation 2) Post implementation assessment of provider satisfaction 3) Formal evaluation of reminder usability (human factors or usability assessment) 4) Analysis of reminder impact on performance improvement (1=yes, 0=no)
Structural Characteristics	Clinic type	Administrative Data	1 = Community-Based Outpatient Center 0 = VA Medical Center
	Academic affiliate	Administrative Data	Presence of a primary care training program (1=yes, 0=no)
	Size	Administrative Data	Number of unique patients, in 1000’s
Implementation Climate	Required Guideline Use	Primary Care Clinic Director	PCPs required to observe explicit practice guidelines when ordering specified tests or procedures (1=yes, 0=no)
	Health IT Use / Customization	VA Medical Center Chief of Staff	Providers sometimes turn guideline prompts off (1=yes, 0=no)
	Competing demands	Primary Care Clinic Director	2 items: 1) Hard to make any changes because so busy seeing patients 2) Competing demands across too many initiatives [serve as a barrier to improving performance] (1=strongly disagree, 5=strongly agree)
	Resistance to Performance Improvement	Primary Care Clinic Director	3 items: 1) Resistance from PCPs 2) Resistance from local managers 3) Resistance among local support staff (1=not a barrier, 4=large barrier)

Available Resources	IT staff sufficiency	Primary Care Clinic Director	Mean of 2 items: 1) Sufficiency of IRM or CPRS technical staff 2) Sufficiency of clinical application coordinators (1=not at all sufficient, 5=completely sufficient)
	HIT Expertise	VA Medical Center Chief of Staff	Access to medical informatics expertise (e.g. informatics-trained clinicians) (1=never sufficient, 5=always sufficient)
	HIT Training	Primary Care Clinic Director	Mean of 2 items: 1) Adequate types of HIT training 2) Adequate time for HIT training (1=strongly disagree, 5=strongly agree)

IRM = Information Resources Management; CPRS = Computerized Patient Record System; IT = Information Technology; CDS = Clinical Decision Support

Appendix 2-A: Study Constructs

Construct	Source	Measures
Outcomes		
Quality of Care	Chart Review	Receiving CRC screening Patient-level analysis: Dichotomous indicator (1=yes, 0=no) Clinic-level analysis: % of eligible patients at clinic screened
Primary Predictors		
Reminders	Primary Care Clinic Director	Use of a computerized reminder to support CRC screening Dichotomous indicator (1=yes, 0=no)
Templates	Primary Care Clinic Director	Use of a specialized CPRS template (eg pre-set standing orders or lab panel) to support CRC screening Dichotomous indicator (1=yes, 0=no)
Other Tools to Support CRC Screening		
Profiling and feedback	Primary Care Clinic Director	Performance profiling and feedback to providers Dichotomous indicator (1=yes, 0=no)
Incentives	Primary Care Clinic Director	Incentives (e.g. financial, protected time, perks, other) Dichotomous indicator (1=yes, 0=no)
Clinical champion	Primary Care Clinic Director	Designated local clinical champion Dichotomous indicator (1=yes, 0=no)
RN disease manager	Primary Care Clinic Director	Delegated RN for disease-specific management Dichotomous indicator (1=yes, 0=no)
Provider education	Primary Care Clinic Director	Provider education (e.g. seminars, newsletters, pocket guides) Dichotomous indicator (1=yes, 0=no)

Other clinic-level covariates

Clinic size	Administrative Data	Number of unique patients, in 1000's
Clinic type	Administrative Data	VA Medical Center (ref) vs. Community-Based Outpatient Center Dichotomous indicator
Local authority over clinical protocols	Primary Care Clinic Director	Mean of 3 items: 1) Establishing clinical procedures for PC 2) Establishing guidelines pertinent to PC 3) Implementing guidelines pertinent to PC Likert 1-4 (1=little or no authority, 4=complete authority)
Sufficiency of clinical support arrangements	Primary Care Clinic Director	Mean of 4 items: 1) Appropriately equipped examining rooms 2) Appropriately equipped treatment rooms (e.g. sigmoidoscopy, podiatry and other procedures) 3) Personal computers or workstations 4) Patient education spaces Likert scale 1-5 (1=Not at all Sufficient, 5=Completely Sufficient)

Patient-level covariates

Age	Administrative Data	Age 52-64 (ref); 65-74; or 75-85
Gender	Administrative Data	Male (ref) or Female
Income	Administrative Data	<\$10k (ref); \$10-19k; \$20-29k; or \$30k+ / year
Race / ethnicity	Administrative Data	White (ref); Black; Other race*
Number of visits	Administrative Data	(In the past 12 months): <6 (ref); 6-10; or more than 10 PC visits

*Combines Hispanic, Asian, and other race categories

CPRS = Computerized Patient Record System; PC = Primary Care; RN = Registered Nurse; CDS = Clinical Decision Support

Appendix 2-B: CRC Screening Measure Inclusion / Exclusion Criteria¹

Summary: Percent of patients receiving appropriate colorectal cancer screening

Numerator: Patients receiving appropriate colorectal cancer screening

Denominator: Patients 51-80 years old at the time of the qualifying visit

Exclusions:

- Terminal illness as indicated by documented diagnosis of cancer of the esophagus, liver or pancreas
- enrolled in a VHA or community-based hospice program
- documented in the medical record as having a life expectancy of less than 6 months on the PROBLEM LIST or as a Health Factor in CPRS
- diagnosis of colorectal cancer (ICD-9-CM Codes 153.x, 154.0, 154.1, 197.5, V10.05) or total colectomy (ICD-9-CM Code 45.8).

Cohort: Nexus clinic sample

Definitions:

Appropriate colorectal cancer screening consists of any of the following:

- Fecal occult blood test (FOBT) during the past year;
- Flexible sigmoidoscopy during the past 5 years;
- Colonoscopy during the past 10 years;
- Double contrast/air contrast barium enema during the past 5 years.

Past year: Period starting the 12th month prior to the “study interval” extending to last day of the month under study.

Past 5 years or past 10 years: A notation in the medical record must include a date reference that meets the timeline.

Fecal occult blood tests (FOBTs) must be noted in the medical record to be a screening test for colorectal cancer. The tests should be a series of 3 samples and may be either guaiac or immunochemical tests. Laboratory report of fewer than 3 cards, tests from digital rectal exam, or tests performed for reasons other than CRC screening are not accepted as adequate colorectal cancer screening for purposes of this measure.

Methodology:

- Data origin & extraction: EPRP from Medical Record
- Time frame: EPRP schedule, data collection monthly
- Interval: Compliance during the period beginning from the 1st day of the month of the study interval (month) and counted back to the stated interval prior to the ‘study interval’ beginning date and extending to the last day of the month under study.
- Scoring logic:
 - If test was completed in the VAMC, test results must be documented in the medical record or lab package. Where the returned FOBT cards are developed within the facility and results determined is not a factor for compliance in this measure (e.g. in AC as waived testing, satellite lab, main lab, etc). The critical data element is the documentation of the 3 FOBT results in the medical record or lab package.

¹ From EPRP Technical Manual

Facilities are encouraged to record results in the lab package regardless of where results are determined.

- If completed in the private sector or another VAMC, there is documentation indicating a test was accomplished and the result recorded, e.g. normal, negative, or positive. The date is documented closely enough to be able to determine if the test was accomplished within the acceptable time interval.
- $N / D * 100 = \%$

Appendix 2-C: Alternative Patient-Level Models of CRC Screening

	A	B	C	D
	OR	OR	OR	OR
	[95% CI]	[95% CI]	[95% CI]	[95% CI]
Primary Predictors				
Reminders	1.04 [0.85,1.27]	1.15 [0.88,1.52]	1.04 [0.84,1.28]	1.05 [0.87,1.26]
Templates	0.96 [0.86,1.07]	0.93 [0.83,1.05]	0.94 [0.84,1.05]	0.96 [0.87,1.06]
Other tools to support CRC screening				
Profiling and feedback	0.98 [0.87,1.09]	1.00 [0.88,1.13]	0.98 [0.87,1.10]	0.95 [0.85,1.07]
Incentives	0.99 [0.88,1.12]	0.96 [0.85,1.09]	1.00 [0.88,1.14]	1.00 [0.89,1.13]
Clinical champion	0.97 [0.87,1.09]	0.96 [0.84,1.09]	0.99 [0.87,1.11]	1.02 [0.91,1.14]
RN disease manager	1.12 [0.94,1.34]	1.14 [0.96,1.36]	1.14 [0.95,1.37]	1.22* [1.03,1.45]
Provider education	1.07 [0.96,1.19]	1.08 [0.96,1.21]	1.05 [0.95,1.17]	0.97 [0.87,1.07]
Other clinic-level covariates				
Community-based outpatient clinic	1.00 [0.89,1.12]	0.99 [0.88,1.11]	1.01 [0.90,1.13]	1.03 [0.92,1.14]
Local authority over clinical protocols (1-4)	1.00 [0.93,1.06]	1.02 [0.95,1.09]	1.00 [0.93,1.07]	0.99 [0.93,1.05]
Sufficiency of clinical support arrangements (1-5)	1.02 [0.95,1.08]	1.03 [0.96,1.09]	1.03 [0.96,1.11]	1.05 [0.98,1.11]
Clinic size (Unique patients, in 1,000s)	1.00 [1.00,1.00]	1.00 [1.00,1.00]	1.00 [1.00,1.00]	1.00 [1.00,1.00]
Patient-level covariates				
Female	0.98 [0.86,1.13]	0.99 [0.86,1.13]	0.98 [0.86,1.13]	0.98 [0.85,1.13]
Age (Ref: 50-65)				
65-75	1.77*** [1.67,1.87]	1.76*** [1.66,1.87]	1.78*** [1.68,1.88]	1.78*** [1.68,1.89]
75+	2.00*** [1.86,2.14]	1.99*** [1.85,2.15]	2.01*** [1.88,2.15]	2.01*** [1.88,2.16]
Number of Visits (past 12 months) (Ref: <6)				
6-10	1.32*** [1.25,1.39]	1.30*** [1.22,1.37]	1.32*** [1.25,1.40]	1.33*** [1.26,1.40]
11+	1.43*** [1.34,1.53]	1.37*** [1.27,1.47]	1.44*** [1.35,1.54]	1.46*** [1.37,1.56]
Income (Ref: <10k/year)				
\$10-19k/year	0.99 [0.93,1.05]	1.00 [0.93,1.07]	0.99 [0.93,1.05]	0.99 [0.93,1.05]
\$20-29k/year	1.11** [1.04,1.19]	1.12** [1.04,1.21]	1.11** [1.04,1.19]	1.11** [1.04,1.19]
\$30k+ / year	1.32*** [1.24,1.41]	1.34*** [1.24,1.45]	1.32*** [1.24,1.41]	1.32*** [1.24,1.41]
Observations	42,098	42,098	42,098	42,098

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Models:

- A: Primary analysis (GEE)
- B: Logistic regression with cluster-robust standard errors
- C: 2-level random intercept model
- D: 3-level random intercept model

(continued on next page)

	E	F	G	H	I
	OR	OR	OR	OR	OR
	[95% CI]	[95% CI]	[95% CI]	[95% CI]	[95% CI]
Primary Predictors					
Reminders	1.17 [0.92,1.48]	1.30* [1.01,1.69]	0.77 [0.56,1.04]	1.03 [0.84,1.26]	1.39 [0.79,2.45]
Templates	0.96 [0.85,1.09]	0.96 [0.84,1.10]	0.97 [0.82,1.15]	0.95 [0.86,1.06]	1.09 [0.79,1.50]
Other tools to support CRC screening					
Profiling and feedback	0.92 [0.80,1.05]	0.99 [0.86,1.15]	0.92 [0.78,1.10]	0.97 [0.87,1.09]	1.11 [0.77,1.61]
Incentives	1.06 [0.92,1.22]	0.91 [0.79,1.05]	1.15 [0.94,1.41]	1.00 [0.88,1.13]	0.82 [0.58,1.16]
Clinical champion	0.97 [0.85,1.11]	0.93 [0.81,1.06]	1.08 [0.89,1.33]	0.98 [0.87,1.10]	0.81 [0.58,1.14]
RN disease manager	1.09 [0.88,1.34]	1.08 [0.88,1.33]	1.19 [0.87,1.62]	1.11 [0.93,1.32]	1.81* [1.02,3.22]
Provider education	1.06 [0.94,1.20]	1.07 [0.94,1.22]	1.04 [0.88,1.22]	1.07 [0.96,1.19]	1.13 [0.82,1.55]
Other clinic-level covariates					
Community-based outpatient clinic	0.97 [0.85,1.10]	1.00 [1.00,1.00]	1.00 [1.00,1.00]	1.00 [0.89,1.11]	0.97 [0.67,1.39]
Local authority over clinical protocols (1-4)	0.99 [0.91,1.07]	0.98 [0.88,1.07]	1.02 [0.93,1.11]	1.00 [0.94,1.07]	0.89 [0.72,1.09]
Sufficiency of clinical support arrangements (1-5)	1.02 [0.94,1.10]	1.01 [0.93,1.10]	1.04 [0.94,1.14]	1.01 [0.95,1.08]	1.07 [0.88,1.29]
Clinic size (Unique patients, in 1,000s)	1.00 [1.00,1.00]	1.00 [0.99,1.00]	1.00 [1.00,1.01]	1.00 [1.00,1.00]	1.00 [0.99,1.01]
Patient-level covariates					
Female	1.05 [0.87,1.27]	0.99 [0.84,1.16]	0.98 [0.76,1.27]	-	-
Age (Ref: 50-65)					
65-75	1.77*** [1.63,1.92]	1.76*** [1.64,1.89]	1.77*** [1.59,1.96]	1.77*** [1.67,1.88]	1.55* [1.06,2.26]
75+	1.99*** [1.81,2.19]	2.03*** [1.86,2.21]	1.93*** [1.71,2.17]	1.99*** [1.86,2.13]	2.49** [1.38,4.47]
Race / ethnicity (Ref: White)					
Black	0.83*** [0.76,0.91]	-	-	-	-
Other Race	0.74*** [0.65,0.85]	-	-	-	-
Number of Visits (past 12 months) (Ref: <6)					
6-10	1.37*** [1.27,1.48]	1.34*** [1.25,1.43]	1.28*** [1.16,1.41]	1.31*** [1.24,1.39]	1.41* [1.02,1.95]
11+	1.49*** [1.36,1.62]	1.49*** [1.38,1.60]	1.33*** [1.19,1.49]	1.43*** [1.34,1.52]	1.52* [1.07,2.16]
Income (Ref: <10k/year)					
\$10-19k/year	1.07 [0.98,1.17]	1.03 [0.95,1.11]	0.92 [0.82,1.03]	0.99 [0.93,1.06]	0.95 [0.66,1.36]
\$20-29k/year	1.13** [1.03,1.24]	1.14** [1.05,1.24]	1.05 [0.93,1.18]	1.13*** [1.05,1.21]	0.70 [0.48,1.01]
\$30k+ / year	1.36*** [1.23,1.50]	1.32*** [1.22,1.43]	1.33*** [1.18,1.49]	1.33*** [1.25,1.43]	0.96 [0.65,1.43]
Observations	20,847	28,715	13,383	40,895	1,203

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Models:

E: Subset with race/ethnicity information available; **F:** VA medical center clinics;

G: Community-based outpatient clinics; **H:** Male patients; **I:** Female patients