Clinical Practice Improvement and Redesign: How Change in Workflow Can Be Supported by Clinical Decision Support

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Introduction

Research shows that automation is able to improve the quality and safety of care delivered by health care facilities. Recent advances in automation have the potential to improve all aspects of health care delivery, from diagnosis and treatment to administration and billing. Diagnostics have improved with the introduction of higher resolution functional magnetic resonance imaging (fMRI), positron emission tomography (PET), and computed tomography (CT) scans, not to mention advances in laboratory medicine technology for superior analysis of blood, urine, and cultures. Automation used for treatment spans the gamut—from new infusion devices such as smart IV pumps to surgical technologies such as endoscopic surgical tools, improved lasers, and even surgery assisting robots (e.g., da Vinci™).

The rapid pace of automation adoption in U.S. health care organizations will likely continue, owed in part to pressures from the government, purchasing groups, and consumers.[1-7] As a result, many health care organizations are functioning in a state of continuous technological change. Interestingly, the aforementioned diagnostic and laboratory automation is being implemented with relatively little fanfare or controversy. On the other hand, clinical decision support (CDS) automation, which provides clinicians and/or patients with computerized clinical information at the appropriate time and in an understandable format,[8] has been heralded as the savior of health care quality and patient safety yet remains controversial.

CDS systems are typically designed to aid decisionmaking for prevention, screening, diagnosis, treatment, drug dosing, test ordering, and/or chronic disease management, and "push" the information to the decisionmaker.[9] However, there is no agreement on the types of features or information technologies that constitute CDS. The broad definition above would include alerts, reminders, structured order forms, pick lists, patient-specific dose checking, guideline support, medication reference information, and "any other knowledge-driven interventions that can promote safety, education, workflow improvement, communication, and improved quality of care."[10] CDS includes any electronic or paper tool that facilitates clinical decisions. While this paper focuses primarily on electronic CDS, the concepts illustrated here can also be applied to paper-based tools. Electronic CDS includes computerized alerts and reminders, electronic medical records (EMR), electronic health records (EHR), computerized provider order entry (CPOE), electronic prescribing (eRx), bar-coded medication administration (BCMA), and stand-alone or integrated CDS systems. Paper CDS includes paper medication administration records (MARs), paper order sets, paper guidelines, and any other paper tools used to support clinical decisionmaking.

Although CPOE, EMRs, EHRs, and BCMA systems may not appear to have decision support, they do. They provide decision support, even if in subtle ways, because they help clinicians make clinical decisions.[11] BCMA, for example, provides an electronic medication administration record (eMAR), which supplies decision support to the nurse about the five rights of medication administration. CPOE and eRx also have decision support, in that formulary information is embedded in the order entry system, as are dose ranges and route options. Thus, even if a CPOE system does not include drug or dosing alerts, the fact that it constrains or forces choices is decision support.

Although CDS automation can be used to support patients or clinicians,[9] the focus of this white paper is on CDS to support clinicians. In outpatient settings, the most common CDS features are prevention / screening, drug dosing, and chronic disease management, respectively. Less frequent support is provided in outpatient settings for diagnosis, treatment, and test ordering.[9, 12] In inpatient settings, CDS automation can be used for other tasks, such as multidisciplinary rounds.[13] It is common that sources of CDS systems' clinical data are an EMR or paper chart, although the source may also be the clinician or patient.[12, 14]

CDS automation has been recommended for many reasons. As explained in a white paper[10] by the CDS Expert Review Panel, CDS has the potential to achieve the following objectives:

- Reduced medication errors and adverse medical events
- Improved management of specific acute and chronic conditions
- Improved personalization of care for patients
- Best clinical practices consistent with medical evidence
- Cost-effective and appropriate prescription medication use
- Effective professional and consumer education about medication use
- Effective communication and collaboration across clinical/prescribing/dispensing/administering settings
- Efficient and convenient clinical practice and self-care
- Better reporting and followup of adverse events
- Compliance with accreditation and regulatory requirements
- Improved dissemination of expert knowledge from government and professional bodies to clinicians and patients

Certain types of CDS automation have been shown to be effective. Computerized alerts may decrease error rates and improve therapy.[15] Computerized clinical reminders can increase compliance with guidelines[16] and preventive screening,[17] and may even save physicians time.[16] Some evidence suggests that CPOE can reduce medication prescribing errors, improve a variety of quality outcomes, and provide a return on investment; [15, 18-25] BCMA systems can reduce dispensing and administration medication errors;[26-30] and EHRs can improve a variety of physician and patient outcomes.[31-36] CDS automation may be effective for a variety of purposes in ambulatory settings[37] from treatment of depression[38] to care in nephrology clinics.[39] But, the evidence is not all good.

- "Currently, the clinical systems in routine use in health care in the United States leave a great deal to be desired. The health care industry spends less on information technology than do most other information-intensive industries; in part as a result, the dream of system integration has been realized in few organizations. For example, laboratory systems do not communicate directly with pharmacy systems. Even within medication systems, electronic links between parts of the system—prescribing, dispensing, and administering—typically do not exist today."[15]

- "Four benchmark institutions have demonstrated the efficacy of health information technologies in improving quality and efficiency. Whether and how other institutions can achieve similar benefits, and at what costs, are unclear."[40]

- "Nonetheless, there are few CDS implementations to date in routine clinical use that have substantially delivered on the promise to improve healthcare processes and

> outcomes, though there have been an array of successes at specific sites …Yet even these successes have generally not been widely replicated. There are many reasons for the lack of diffusion of these systems."[41]

These quoted broad brush stroke statements are backed by specific evidence. Drug safety alerts are overridden at rates over 90 percent[42, 43] and even allowing primary care physicians to customize drug alerts still resulted in 88 percent of alerts being ignored.[44] Evidence shows that ambulatory CDS automation has received mixed reviews from primary care physicians, with the often-cited criticisms being that the applications are time consuming and lack usability.[45] CPOE systems have been associated with increased rates of errors, adverse events, and mortality;[46-49] evidence does not support CPOE effectiveness in ambulatory settings;[50] and some CPOE systems have even been abandoned.[51] BCMA systems have led to many different workarounds, some of which involve not scanning and most of which can compromise safety.[52-58] EHRs are associated with concerns related to costs, poor usability, vendor problems, and poor consistency [34, 35, 59] and entire systems have been abandoned.[60] Even reviews that demonstrated that CDS can improve physician outcomes have not demonstrated improvements to patient outcomes.[61] Clearly, there are significant problems that must be overcome.

Recently two models have been offered to help explain why the data about CDS automation may be in such conflict. The first, Figure 1, is a human factors engineering model,[62] derived from the University of Wisconsin Systems Engineering Initiative for Patient Safety model.[63] Figure 1 shows how the structural elements of a health care system, which includes the clinician nested in a work system nested in a health care organization, determine the physical, cognitive, and sociobehavioral performance of the clinician.

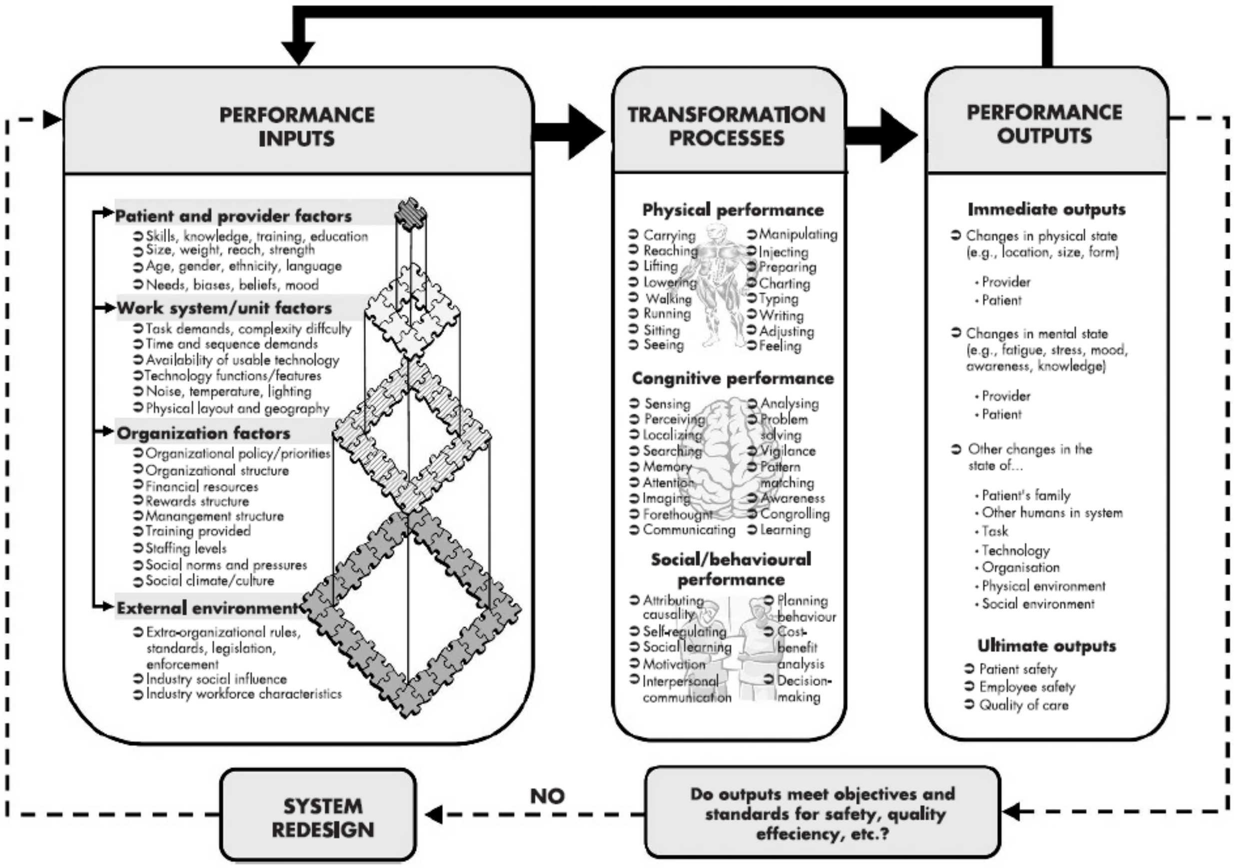

Figure 1. Human factors engineering model for patient safety. Reprinted with permission. Karsh B, Alper SJ, Holden RJ, Or KL. A human factors engineering paradigm for patient safety – designing to support the performance of the health care professional. *Qual Saf Healthc* 2006;15(Suppl I):i59-i65.

The clinician's performance subsequently helps to determine outputs such as patient safety and health care quality. This model helps to demonstrate that CDS automation must be designed to meet clinician performance needs such as sensation, perception, searching, memory, attention, decisionmaking and problem solving.[64, 65] If the design of the CDS is poor, then clinician performance suffers. If clinician performance suffers, patient care suffers.

Consider CDS such as an automated alert. A clinician must first sense the alert and perceive its meaning. As part of perception, the process of signal detection is used to determine if the alert is meaningful. Perception will be influenced both by the design of the alarm (knowledge in the world) and long-term memory (knowledge in the head).[66] Next, the clinician will make a decision about what to do about the alert, execute the decision, and monitor the outcome of the execution to determine if the outcome achieved the goal and if further action is needed. Depending on the ambient noise level or location of the alert system relative to the clinician, the alert may or may not be heard. Depending on the design of the alert, how similar it is to other alerts, where in the workflow it appears, what it says, and whether it is explained, the clinician will or will not perceive the alert to be meaningful – regardless of whether it is or not. Depending on whether the alert is designed to help guide the next steps, or is generic or patient specific, will determine how the clinician uses the alert for decisionmaking purposes. In other words, the design of a seemingly simple alert and its integration into clinic workflow, patient care workflow, and physician mental workflow all contribute to the impact of the alert on physician behavior, and subsequently, patient care. Some of the confusion regarding the efficacy of CDS could be due to variability in such design and implementation parameters.

The second model, show in Figure 2, is derived from Figure 1 but is specific to clinician interaction with health information technology (health IT) such as CDS.[67] The model shows that to achieve good outcomes with health IT, it is necessary to ensure that the health IT fits

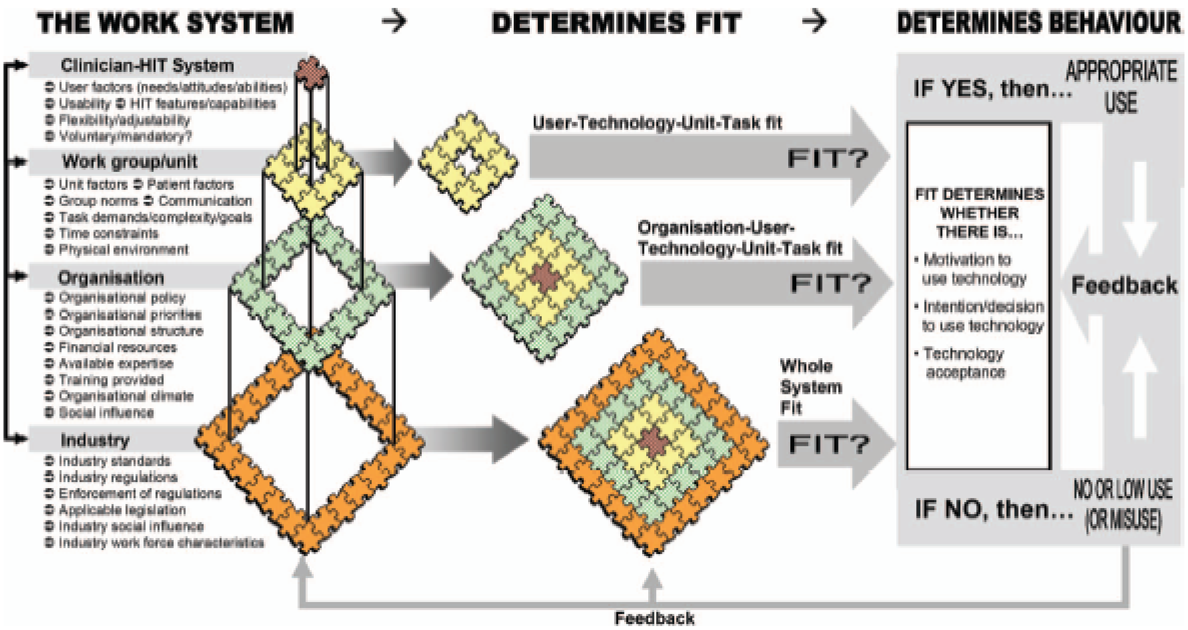

Figure 2. A theory-based multilevel model of health information technology behavior (from Holden RJ and Karsh BA theoretical model of health information technology behavior. Behav Inf Technol 2009;28(1): 21-38.

within the multiple levels of a health care organization, from the clinician to the industry. The model shows that the integration or fit of the clinician-health IT system into the higher level systems determines different kinds of fit, and how fit at different levels subsequently determines outcomes such as health IT acceptance and appropriate use. This model makes clear that the notion of “fit” or integration exists at multiple levels. The efficacy of CDS automation is thus determined in part by its integration with (a) the work of the clinician; (b) the policies, norms, constraints, and tasks of the next larger system, which might be a group of partners; (c) the policies, norms, practices, rules, layout and technology of the entire clinic; and (d) the larger health care industry.

The model in Figure 2 is consistent with several of the recently released grand challenges for clinical decision support,[41] which included human-computer interaction and best practices in CDS development and implementation. These ideas of design and implementation are important for all of the U.S. hospitals[68] and outpatient practices[69] that currently have CDS automation, as well as for all that are considering adopting CDS.

To better understand how CDS automation can fit within the multilevel health care system to support ambulatory care clinicians' workflow, this white paper will (1) explore why CDS is important for ambulatory care; (2) review evidence for the effectiveness of CDS in ambulatory settings; (3) discuss the relationship between CDS and workflow; (4) provide a framework for thinking about CDS-workflow fit; and (5) recommend steps for designing and implementing CDS to better fit the realities of clinical workflow.

Why is CDS in Ambulatory Settings Important?

The belief that CDS automation can improve health care delivery quality and safety is not new,[70, 71] but efforts to promote adoption of the technology have accelerated since the release of the Institute of Medicine (IOM) reports detailing the poor state of patient safety in the United States.[1-3, 72] Most patient safety research has focused on inpatient settings, though there is a growing amount of patient safety research being conducted in ambulatory settings, including general primary care, outpatient oncology, outpatient diagnostic testing, outpatient surgery, and ambulatory care of the elderly. [34, 42, 54, 63, 73-90] From those studies, we know that medical errors and preventable adverse events occur in ambulatory care settings and affect children, adults, and the elderly. [81, 91, 92] Like inpatient care, the incidence of preventable errors or adverse events in ambulatory settings such as primary care offices is high, and evidence suggests that over half, at least in primary care, may be preventable. [93-95]

Primary care offices are currently receiving the most attention when it comes to CDS automation. A recent U.S. Department of Health and Human Services national demonstration will provide 12 participating communities incentive payments to physicians in small- to medium-sized primary care physician practices to use electronic health records (EHR) to improve the quality of patient care.[96] The focus on primary care was justified by the slow pace of adoption combined with the large number of problems in primary care.[97, 93, 98, 99]

There are other reasons, too, to focus CDS efforts on ambulatory care settings. Consider, for example, primary care. The IOM [100] defines primary care as "the provision of integrated accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients and practicing in the context of family and the community." Primary care has been described as providing first contact care, longitudinal care, comprehensive care, and coordinated care. [100-102]

These four elements make primary care exceedingly complicated and put a great burden on the primary care clinician in terms of coordination, information seeking, information need, mental workload and decisionmaking.[103] In fact, Beasley et al.[73] recently found that primary care physicians dealt with an average of three problems per patient visit, and that figure rose with chronic diseases such as diabetes. Others have reported that physicians do not have access to all of the information available to adequately address patients' problems; it is estimated that physicians have about eight unanswered questions for every 10 ambulatory visits.[104] The need for clinicians and support staff to cope with a wide range of problems leads to more chances for diagnostic and therapeutic errors. As in the hospitals, these errors in ambulatory settings can have real consequences for patients such as delayed care, lost time, financial harm, physical harm, and emotional harm.[76-78, 80, 95] These results suggest that errors and risks in ambulatory care have consequences for patients that can be severe.

The most prevalent problems in ambulatory settings such as primary care[54, 77, 94, 105] are those related to medication management, laboratory and diagnostic testing, and medical records management. These ambulatory care hazards all have a common theme: information management. They therefore lend themselves well to CDS solutions. The National Alliance for Primary Care Informatics has stated that the delivery of excellent primary care demands that providers have the necessary information when they give care. [104] This need for information is why effective CDS automation is so needed in ambulatory settings; CDS automation should help to gather, analyze, and deliver information to clinicians, and aid them in managing the volumes of data points they deal with in a way that paper CDS cannot. Paper records are available to only one person at a time; they may be illegible and too thick to be accessible. [104] This fact had led to the belief that "the most serious problem with paper records is that they impede provision of clinical decision support; data stored in inaccessible formats cannot incorporate or trigger decision support tools."[104] This issue led a large coalition of groups, including the Ambulatory Pediatric Association, American Academy of Family Practice, and American Academy of Pediatrics, among others, to strongly recommend EMR adoption in primary care. [104] But, if CDS automation such as EMRs cannot be designed and implemented to support clinician workflow, then clinicians will be faced with an increasingly untenable situation.

Impact of Unmanageable Information on Clinicians

In the field of human factors engineering, problems of information management have been studied, and evidence shows that such problems directly contribute to at least two unwanted outcomes: a lack of situation awareness (SA)[106-113] and increased mental workload (MWL).[114-116] SA is defined as a person's awareness and understanding of his/her task-related situation. It has three levels: perception of elements in the environment (e.g., cues/stimuli from patient [pulse, color, weight change], chart, EHR, nurse), comprehension of the meaning of those elements (by integrating the disparate pieces of information and determining what is salient), and projection of future status so that decisions can be made.[106, 117] Whether or not an accurate SA ever arises is dependent on the timing and quality of the information obtained; if SA is poor, it directly results in impaired decisionmaking.[106, 108, 110, 113, 118] High MWL occurs when a person's mental capacity is exceeded.[114 116] That is, high clinician MWL occurs when the mental demands imposed on the clinician because of information overload, for example, exceed the clinician's ability to keep it all straight. Both poor SA and high MWL ultimately impair memory, problem identification, decisionmaking, and decision execution,[108, 114, 116, 118] and therefore have clear, negative impacts on safety.[118] High MWL and poor SA can result from the same underlying problem and they can influence each other.

Problems with information management can prevent clinicians from having real-time SA, which significantly reduces their ability to diagnose and treat. This has been demonstrated in health care delivery in surgical, trauma, and emergency settings.[109, 113, 119] Clinicians may be at special risk of poor SA and high MWL with elderly patients because this cohort has more medications,[81, 85] higher rates of many chronic conditions [120, 121], more problems per physician encounter,[73] and an increased risk of disorders affecting their decisionmaking capacity and memory, such as Alzheimer's disease.[122] This makes having effective CDS more important, perhaps, when caring for elderly patients.

Figure 1[62] presented the variety of cognitive work in which people engage. Types of cognitive work include, among many others, sensing, perceiving, searching, remembering, focusing attention, forethought, analyzing, problem solving, pattern matching, assessing, and learning. Clinicians rely on these cognitive activities to diagnose and treat their patients. For the cognitive activities to yield desired outcomes, the system in which the person is operating must support those activities. For example, clinicians might put patient information into EHRs to support searching, remembering and problem solving; however, if those EHRs are poorly designed, then clinicians struggle to find information, still have to rely on memory, and struggle to problem solve because they lack the information they need.[123] And, it is *information* that is central to the success of many cognitive tasks.[123] The mere existence of needed information is important, but more important is the easy availability, presentation, arrangement, and access of that information at the time it is needed to support task performance. The reason information is so central is that for a range of cognitive tasks, such as decisionmaking, information must be found, arranged, coordinated, communicated, and stored.[123, 124] So what effect does having problems with information management have on cognitive performance, and why?

Mental workload. As information management problems increase, MWL increases.[116] High MWL occurs when people do not have the capacity to deal with the demands imposed on them. In primary care, for example, this may be due to not having enough time for required tasks.[83, 125] In fact, one survey of primary care physicians found that 84 percent reported that they were more than 20 minutes behind schedule some, most, or all of the time.[126] Time pressure makes it all the more important that CDS automation be easy to use and useful, as those under time pressure have less time and patience to navigate through poorly designed technology.[127]

While under time pressure, people can adapt and still perform well by exerting more mental effort or by concentrating harder. Some refer to this ability to adapt and keep things in operation even in the face of stressors, such as too much information, as "resilience." [128] However, at some point, under more significant mental workload, individuals can no longer adapt or compensate in order to maintain cognitive performance. In such cases, the demands imposed by the system (e.g., clinician needing to remember the important facts of the most recent patient visit while starting the next patient's visit) exceed the attentional resources or mental capacity of the person. In such cases, cognitive performance suffers greatly; that means reduced ability to spot problems, treat, diagnose, remember, and understand information.

During high MWL, people focus, *involuntarily*, on fewer cues, consider fewer options, and consider fewer solutions because of a phenomenon called cognitive tunneling.[115] This is when people zoom in on a very narrow set of cues or options because mentally they cannot handle more. In such cases, people are at great risk for a variety of decision errors[129] because they miss things *they should have noticed* such as patient symptoms, patient weight loss, etc. What is needed to reduce MWL arising from information management problems is a mechanism to filter and present the needed information in a useable manner at the right time.[114] This is the goal CDS automation.[8, 10, 127]

As MWL increases, the effects on cognitive performance become more pronounced. As stressors such as mental workload increase, performance on detection tasks (diagnosis) and selection (treatment) start to become impaired and eventually both fail.[130] The more expertise a person has, the more MWL they can handle before failure. However, eventually even the experts are overwhelmed. In other words, in situations of high MWL, people operate with selective and reducing capacity.[115] Human factors engineering experts have warned that "expecting stressed [people] to seek and distinguish novel sources of information is a fallacy that should be avoided…"[115] Unfortunately, the reality is that clinicians working in ambulatory settings, from outpatient clinics to emergency departments (ED), have very high MWL, but still must diagnose and treat with a high level of accuracy.

Situation awareness. A related problem that occurs when a person cannot manage necessary information is reduced situation awareness (SA).[106, 117] SA can be thought of as "what must be known" in order to complete a cognitive task such as perception or decisionmaking. Decision support systems outside of health care, for example, in aviation, have explicit goals of reducing mental workload and providing the user with appropriate SA to support their work.[131-136] SA is dynamically produced based on the interaction of a person with his/her environment[116] (e.g., the interaction between a patient, clinician, and EHR).

This concept is quite relevant to ambulatory care. ED clinicians have to rapidly process information that is typically of varying certainty and all the while try to figure out what is going on; that "figuring out what is going on" is their attempt to establish situation awareness. Consider also a primary care office visit. At the start of an office visit, the clinician has some SA, but it may be incomplete. The clinician only knows what s/he remembers, if anything, from previous visits, from a brief look at the patient's chart, and from the short meeting with the nurse who roomed the patient. But, as soon as the clinician enters the room, SA is dynamically updated based on sensory inputs such as how the patient looks, feels, and sounds and from higher level processes such as communication with the patient and more searching in the medical record. Whether or not accurate SA ever arises is dependent on the timing and quality of the information obtained through sensation, perception, communication, and record searching. CDS, if designed effectively, can support those needs. However, if CDS does not meet the needs of the clinic, visit, and clinician workflow, then it will not support information processing needs.

SA has been studied in military operations, aviation, air traffic control, driving,[137-141] anesthesia,[142] hospital emergency response,[119] surgery,[113] and trauma care,[109] but not ambulatory settings (except in EDs[143]). The way to improve SA is to change the timing of information and the manner in which that information is displayed so as to give the clinicians a better understanding of the situation at hand. What is needed is integrated displays of information (whether electronic or paper) that help the clinician understand the right information at the right time.[115] CDS is supposed to do that. Does it deliver?

Effectiveness of CDS in Ambulatory Settings

The evidence for the effectiveness of CDS is far from clear, though many feel it has not lived up to its potential.[41] There is evidence that CDS *can* have positive outcomes, but the body of evidence is mixed. A brief review of that mixed evidence follows.

Alerts

Computerized alerts are specific types of CDS automation that are designed to notify clinicians about situations or information. There is evidence that alert CDS may decrease error rates and improve therapy.[15] On the other hand, a recent review of drug safety alerts[43] found they were overridden 49 to 96 percent of the time. The study also concluded that conditions such as low specificity, low sensitivity, unclear information content, and unnecessary workflow disruptions contributed to physician ignoring, misinterpreting, and mishandling drug alerts. Allowing primary care physicians to customize computer triggered drug alerts can improve compliance with alerts. But even then, most alerts are ignored (88 percent)[44] because physicians judge the benefits of ignoring alerts outweighed the risks; the drug problem presented by the system was already known; or the alert was not considered clinically relevant. Other systematic reviews have similarly found no impact of alerts on outcomes.[144] A study designed to improve EHR medication list accuracy between visits found no impact of electronically notifying physicians of discrepancies on having physicians update the medication lists.[145] Similarly, a recent study of primary care drug interaction alerts in two EMRs showed that the systems did a poor job of identifying severe clinically significant drug-drug interactions, but instead offered many spurious alerts.[146] Part of the problem was that knowledge in the system was not updated; if such systems are to be trusted and used, it is critical that they be kept up-to-date and tested.

Reminders

Computerized reminders are another type of CDS automation, in many ways similar to an alert. Computerized clinical reminders have been shown effective for increasing compliance with contact isolation guidelines[16] and can be time neutral or even save time if integrated appropriately into physician workflow.[16] VHA primary care physicians perceived their computerized clinical reminders, overall, in the midrange (50 on a 0-100 scale), with perceptions that reminders were situationally specific (29) and integrated into workflow (33) much lower. The design of the interface, or usability, was ranked at the midrange, 52. This was among a sample that rated their proficiency with the clinical reminders at 100.

Other studies have found the usefulness of reminder CDS to be impeded by a lack of coordination between nurses and providers, increased workload, and poor usability.[147] On the other hand, use of CDS can be facilitated by limiting the number of reminders, providing sufficient access to computer workstations, and integrating reminders into workflow.[147] These facilitators can be translated directly into improvements in the design of an alert system.[148,149]

Better integration of alerts and reminders into ambulatory care workflow can be achieved.[127, 150] In one ambulatory example, alerts were designed to either be interruptive, in that they required physician action, or noninterruptive, in that they presented a warning, but clinicians did not have to respond to it.[150] This was an innovative approach since several key considerations for implementing CDS automation are what content to provide, when to intervene in the clinical workflow, and how to intervene into the clinical workflow.[127, 151] Interruptive alerts were designed to be those that were critical or high severity, which meant that most alerts did not require the physician to respond since most were not interruptive. Sixty-seven percent of interruptive alerts were accepted.[150] CDS can be applied on a continuum of noninterrupting applications that incidentally display relevant information to completely interrupting applications that require the clinician to respond in order to continue.[127] To best support workflow, the degree of interruptiveness must match the severity of the situation.[127]

The timing of an interruption is also a critical factor for integrating alert and reminder CDS into workflow. Information specific to individual patients and information that is more global, related to guidelines and medical knowledge, both need to be available at the right time during clinical workflow or the CDS automation will not be useful.[127, 152-154] Consider that for CPOE, the right point to interject CDS might be at the start of the order, when selecting the patient, after selecting the patient and once the patient's data are loaded, when selecting the order, when constructing the order, when completing the order, or when completing the ordering session.[127]

CDS Systematic Reviews

Two recent systematic reviews of CDS effectiveness summarized the state of the evidence well. One found that overall, CDS can improve clinical practice[37] and the features that increased the likelihood of success were automatic provision of support as part of workflow, provision of recommendations and not just assessments, provision of support at the time and location of decisionmaking, and computer decision support.[37] The other review showed that the majority of studies that reported on clinician outcomes showed improvements (e.g., faster time to diagnosis, increased compliance with screening guidelines, or more disease management practices), but few of the studies that reported patient outcomes showed improvements.[61] Having CDS that automatically prompted use and systems that were developed by the authors reporting the study both predicted success on clinician outcomes.[61] Research is also starting to uncover patient and practice factors in ambulatory care that predict acceptance of CDS automation. For example, one study found that female and less experienced primary care physicians had more favorable perceptions of CDS automation than male or more experienced physicians.[126] Perhaps most interestingly was the finding that physicians reported they were more likely to accept alerts for elderly patients, those on more than five medications, and those with more than five chronic conditions. [126]

It is also important to realize that usability differences among CDS systems and differences in how they accommodate workflow at the different levels mean that it is nearly impossible to generalize the results from empirical studies.[12] CDS is not just technical content or technical design; CDS is also a workflow. Thus, even the same system can have different results depending on the workflow impact in the particular setting: "The same software in different contexts becomes different CDSs."[9] Thus, one cannot extrapolate the success or failure of a CDS system to another context (inpatient vs. outpatient), user (primary care physician vs. specialist), organization (solo practice or large HMO), or other set of features, as all might differently accommodate workflow.[9]

The data on the effectiveness of CDS automation are therefore both mixed and hard to generalize. Many studies have identified problems associated with CDS. As already mentioned, a recent paper by CDS experts explained:

> "Nonetheless, there are few CDS implementations to date in routine clinical use that have substantially delivered on the promise to improve healthcare processes and outcomes, though there have been an array of successes at specific sites …Yet even these successes have generally not been widely replicated. There are many reasons for the lack of diffusion of these systems."[41]

In the next section, one of the main reasons few CDS implementations have delivered on their promise to improve health care—CDS not supporting workflow—is explored in depth.

Relationship Between CDS and Workflow

The paper from which the previous quote was taken was entitled, “Grand Challenges in Clinical Decision Support.”[41] In it, 10 grand challenges for CDS were posed, in part because the authors argued that, as of 2008, there were few CDS implementations that had delivered on the promise to improve health care quality.[41, 155] The number one ranked challenge identified was improving the human-computer interface.[41] The justification for this challenge was, specifically, because the authors felt that CDS automation needed to be transformed into “one that supports and does not interrupt the clinical workflow.” The authors went on to explain that in contrast to current CDS automation, future CDS should be designed differently:

> “Rather, the CDS should unobtrusively, but effectively, remind clinicians of things they have truly overlooked and support corrections, or better yet, put key pieces of data and knowledge seamlessly into the context of the workflow…We need new HCIs (human computer interfaces) that will facilitate the process by which CDS is made available to clinicians to help them prevent both errors of omission and commission. Improved HCI design may include increased sensitivity to the needs of the current clinical scenario; provide clearer information displays, with intrusiveness proportional to the importance of the information; and make it easier for the clinician to take action on the information provided.”[41]

Others have made similar recommendations[156] such as:

- “All existing information of all types should be available within a clinical information system.”
- “Clinical systems should help clinicians to see the right amount of the right type of data wherever and whenever needed.”
- “A system should be learnable and usable for basic clinical functions with little or no formal training.”
- “Clinical information should be accessible in the shortest possible amount of time.”
- “Clinical systems should remain functional around the clock.”
- “Clinician access to clinical data should not be unnecessarily restricted.”
- “Data from disparate sources should be aggregated or joined for completeness whenever possible so that clinicians are not forced to go to multiple different systems to obtain important information.”
- “Clinical information systems should make all data and computer-supported activities available wherever and whenever needed…”
- “Clinical data should be accessible through a variety of…interfaces.”
- “Clinical systems should reduce to a reasonable minimum the number of steps required to obtain any information.”
- “A clinical system should meet the regularly recurring data needs of the clinician…”

Also, according to the aforementioned white paper by the CDS Expert Review Panel:

> "Clinical decision support (CDS): providing clinicians or patients with clinical knowledge and patient-related information, intelligently filtered and presented at appropriate times can improve the safety, quality, efficiency, and cost effectiveness of care when applied to electronic prescribing (eRx) systems. However, at present, these potential benefits have not been fully realized. Advances in the capabilities, usability, and customizability of CDS systems, new mechanisms to provide access to current knowledge, accelerated implementation of standards and coding systems, and appropriate incentives for use are all necessary to realize the full positive impact of CDS on health care. Advances in CDS system capabilities can be further divided into four areas: the state of the knowledge base (the set of rules, content, and workflow opportunities for intervention); necessary database elements to support CDS; operational features to promote usability and to measure performance; and organizational structures to help manage and govern current and new CDS interventions."[10]

These statements drive home the central importance of usability and workflow in the design of CDS automation. These ideas are repeated in nearly every study about every type of CDS.[144, 156] Consider computerized alerts, which have been criticized for high false positive rates. Such criticisms are levied not just because false positives are a problem, but also because they lead to disruptions in workflow. [43] Table 1, adapted from Van der Sijs et al. (2006), shows factors that promote effective alerts and demonstrates how central workflow is to alert success. [43] Even though only one header in the 1st column is labeled "workflow," and none of the 23 recommendations use the word "workflow," all of the issues are actually about the integration of CDS into workflow. For example, the recommendation under the heading, "specificity," has to do with providing the right alert in the right way so that the clinicians' workflow is not interrupted. Similarly, all of the issues under the heading, "information content," are designed to support clinical workflow (visit-level workflow or clinician mental workflow) or minimize disruptions to it. The same is true for all of the issues.

Studies that showed CDS could be effective emphasized workflow support and integration. For example, in one study, the researchers used rapid prototyping to obtain iterative feedback from users, incorporated the feedback, and continued to collect data from users on workflow.[157] By spending such time on usability and workflow integration, they created a CDS tool that integrated into routine clinical workflow. They also kept documentation and data entry to a minimum.

One of the systematic reviews of CDS stated that the features that increased the likelihood of success were automatic provision of support as part of workflow, provision of recommendations and not just assessments, provision of support at the time and location of decisionmaking, and computer decision support.[37] All four features demonstrate that usability and workflow are significant concerns for CDS effectiveness. Similar recommendations have followed from investigations of CDS in inpatient settings, where evidence shows CDS efficacy is predicted by the system being easy to learn, integrated into daily workflow, and helpful for learning about the practices the CDS was designed to target.[158]

One characteristic of CDS automation that makes it usable and useful is having the right information accessible at the right time. This seemingly straightforward notion is anything but straightforward considering that the “right time” may relate to clinic-level workflow, visit workflow, or clinician cognitive workflow. Cognitive work analyses and task analyses, and various forms of usability studies can be used to understand what constitutes the “right time.” The “right time” may also be complicated by the ambulatory setting.

Table 1. Factors for appropriate and useful alerts

Factor	Requirements / Suggestions
Specificity	1. Alerts should be clinically important for the patient
	2. Alerts should not be of minor importance
	3. Actions should follow the alert
	4. Alerts should be presented at the patient level
	5. Entering exceptions or mitigating circumstances should be easy to influence the number and accuracy of future alerts positively
Information content	6. Information must be clear and unambiguous
	7. Justification of the recommendations should be shown
	8. Amount of information should be limited
	9. More information should be easily accessible
	10. Seriousness of the alerts should be clear
	11. Alternative actions should be presented
Sensitivity	12. Alerts must be generated in all dangerous cases
Workflow	13. Alerts should be directed to the right person; low specificity alerts or administration alerts can be presented to nurses or pharmacy
	14. Specialists should receive fewer alerts than residents
	15. Specialists should receive no alerts on his own specialty
	16. Annoying repetition should be presented, turning off the alert should be possible if the user performs well
Safe and efficient handling	17. Overriding fatal alerts should not be easy
	18. Reasons for any noncompliance should be requested
	19. System should not ask for more data entry
	20. Promoting action rather than stopping intended action
	21. System must have speed
	22. Size and place of buttons should be logical, ensuring speed and error reduction
	23. Minimizing scrolling, keystrokes, typing, mouse clicks, steps to accomplish a task, screen or window changes, switching between keyboard and mouse

Adapted from: Van der Sijs H, Aarts J, Vulto A, Berg M. Overriding of drug safety alerts in computerized physician order entry. J Am Med Inform Assoc 2006;13(2):138-47.

For example, in the ED, clinicians “need access to large amounts of clinical information with the greatest possible speed and the widest possible context…The need for rapid access to complete data through a simple and reliable interface is particularly acute because the ED is the most disruptive and chaotic environment that exists in medicine.”[156]

CDS automation should not redefine the workflow of physicians,[159] but rather “to encourage clinician use, a CDS system must be functionally integrated into the workflow process, rather than being a stand-alone capability that requires a break from the routine.”[159] This is not an easy process, as “determining which workflow processes to automate and which ones to change presents a dilemma…changing the design of the paper chart would introduce a change to the way clinicians are used to working, which may create resistance to using a CDS system.”[159] And in fact, well designed CDS can be well integrated and lead to time savings for clinicians.[159]

In a recent white paper by the Joint CDS Work Group about integrating CDS into e-prescribing (eRx) systems, the authors offered recommendations in four core areas for allowing eRx systems to provide effective CDS: knowledge base / interventions, database elements, functionality, and organizational. [10] Within the over 70 recommendations, there is no mention of the word "workflow," though nearly all of the recommendations are about the integration of the CDS into the clinical workflow. For example, the first recommendation for each of the four areas is as follows:

- Knowledge base / intervention: "ability to select form and strength, dosage, duration, and frequency from lists"
- Database elements: "patient's medication and status of each"
- Functionality: "enforces generation of complete prescription"
- Organizational: "all rules and other knowledge and reviewed periodically for currency and appropriateness"

Each of those four recommendations, if *not* implemented, would lead to workflow problems. All of the "knowledge base / intervention" recommendations would allow a clinician to have the right information at the right time. All of the "database elements" would allow a clinician to be able to access patient specific and general data elements necessary to act on or interpret the CDS. The "functionality" recommendations all speak directly to workflow as they provide for functions a clinician would need for the CDS to be useful. Finally, the "organizational" recommendations provide for ways to make sure data are all current, and thus, facilitate workflow.

In a commentary[160] on the aforementioned Joint CDS Work Group white paper,[10] the importance of usability and workflow integration was further emphasized: "It is the authors' opinion that human (end-user) factors and electronic information interchanges among e-prescribing and other clinical systems play critically important roles in determining the success or failure of e-prescribing systems." The authors also pointed out that the realities of e-prescribing are more complicated than presented by the Joint CDS Workgroup. They noted:

> "In the outpatient setting, patients typically receive multiple prescriptions from multiple care providers and may fill them at different pharmacies. Each retail pharmacy store (or pharmacy chain) may have its own software system that provides various levels of alerts regarding doses and drug interactions to pharmacists as they fill prescriptions, but the same prescription taken to different pharmacies will generate different alerts. Electronic connectivity is rare between free-standing outpatient pharmacies and the hospital or clinic-based, patient information–rich practice settings where providers generate prescriptions."[160]

And they continued:

> "Systems that alter clinician workflow by not integrating all relevant information for informed decisionmaking into one place run the risk of distracting already busy clinicians. If the clinician must still check the traditional paper record (or a nonintegrated clinical results reporting

> system) as well as deal with an e-prescribing system simultaneously, the result can be more work and frustration for the clinician as well as more opportunities to err by missing important cues. Similarly, implementing a suboptimal system, or doing so with inadequate training, can cause a substantial risk of errors….. it is essential to consider end-users' workloads and expertise when implementing e-prescribing systems. For example, information should be collected from end users via keyboards only when the information will be used for important decisions. Furthermore, the data should be collected only once, from the individual most likely to know the correct information. Having a clinician type in patient diagnoses or laboratory results just so that the information can be displayed as indications or precautions on a written prescription may be less than useful. Preferably, the e-prescribing system should contain decision support logic that considers laboratory results or diagnoses immediately, if available, to provide informed, patient-specific dosing recommendations and warnings."[160]

It is clear from the empirical studies of CDS and current recommendations for their design that integration with workflow is a key for success. That it is key is not perceived by all clinic managers, however. Clinics transitioning from paper-based systems fear major problems related to workflow and productivity when CDS automation is implemented, whereas clinics transitioning from one electronic system to another worry much less about workflow impacts since the physicians have already experienced working with computers. [161] But, that does not mean that workflow is not an issue in the existing or soon to be installed systems. It only means clinic managers are less concerned about it. Also, no research exists to clarify whether workflow improves or stabilizes after a certain time post-CDS implementation.[162]

The bottom line is that the main challenge for CDS systems is integration into the wider workflow.[163] CDS automation must be designed to fit the specific context—practice and patient types—if it is to work.[62, 67, 163-165] Unfortunately, in health care delivery there are no industry standards for how care processes are completed; rather, every clinician has his or her own way of interacting with patients and executing tasks. Therefore, there are no standard descriptions of workflow for care processes to guide decisions about where and how to integrate CDS automation.[166] Because of that, the next two sections provide guidance on what it means to integrate CDS automation into workflow and how to fit CDS within workflow.

Frameworks for Integrating CDS Automation Into Workflow

In this section, four conceptual frameworks that are helpful to understanding what it means to integrate CDS automation into clinical workflow are reviewed. These frameworks come from research on (1) decision support systems (DSS) outside of health care, (2) human-automation interactions, (3) teams, collaborative work and distributive cognition, and (4) sociotechnical systems approaches to health information technology acceptance and use. All four contribute to an understanding of what CDS automation should be designed to accomplish and what it means to design and implement it effectively to achieve desired outcomes.

Decision Support System Performance

It is first important to understand that despite all of the research into decision support technology, the relationship between decision support and decision performance is poorly understood.[167] CDS automation falls under the more general heading of decision support systems (DSS). DSS, in general, and CDS, specifically, tend to be designed with two different goals in mind: helping users to implement normative decisionmaking strategies or helping users to extend their own decisionmaking capabilities.[167] An example of the former is the use of CDS automation to implement pathways or provide drug-drug alerts, while an example of the latter would be the integration of patient-specific data with guidelines to help inform treatment decisions.

Todd and Benbasat[167] provide an excellent review of the evolution of thinking about the relationship between DSS and decision performance. Originally, DSS were believed to have a direct effect on decisionmaking performance. That evolved to a task-technology fit perspective in which it was believed that the influence of DSS on decisionmaking performance was based on the degree to which the DSS capabilities matched the requirements of the task. That thinking further evolved to also include the internal problem representation of the decisionmaker, meaning that it was believed that, to the extent that DSS matched the task requirements (e.g., workflow) and represented the problem in a meaningful way to the user, it could improve performance.

Through studying more complex decisionmaking, the understanding evolved to suggest that DSS capabilities and the nature of the task influenced decisionmaking strategies, which directly influenced performance. But, studies then showed that it was likely that perceived accuracy and perceived effort further moderated the relationship between DSS capabilities and the task on the one hand, and strategy on the other. The strategies selected by decisionmakers involve trade-offs between accuracy and effort. Generally, effort is considered to be the more important factor, providing a direct explanation for why CDS automation with poor usability or poor workflow integration is rejected: it requires more effort. Therefore, for a given CDS to be used it should help clinicians achieve a more accurate decision in a way that is at least as easy as the less accurate path.[167]

Todd and Benbasat[167] further explain how incentives might influence both decision strategy and decision performance, in that incentives can increase decisionmakers' feelings of relevance of the decision, and therefore might motivate more effort to be put forth toward the decision. It would seem that a major incentive of CDS automation, compared to other types of DSS, is that a patient's health may be at stake. It might be assumed then that such a major incentive would lead clinicians to persevere in the face of difficult to use CDS in order to reach an optimal decision. However, research outside of health care shows that people will not put forth the extra effort to fight poorly designed DSS, even if highly motivated to do so because of incentives. Users only adopt the different decisionmaking strategies offered by DSS if the effort required to do so is very low;[167, 168] therefore, CDS usability and workflow integration are critical to the achievement of better patient care. Patient health and safety considerations are not likely to be a sufficient incentive for clinicians to utilize poorly designed and poorly integrated CDS. Poorly designed and integrated CDS may be rejected for at least two other reasons: (1) clinicians are highly trained experts who may feel they do not need to rely on CDS and (2) ambulatory health care delivery is provided under significant time constraints. Both factors further demand that CDS automation be designed so that it is easy to use and well integrated with workflow.

Principles for CDS design and integration with workflow that can be derived from DSS research are as follows:

- Clinicians may be unwilling to exert more effort to use CDS than was required to complete the same task without CDS, so make CDS easy to use and integrated into the multiple levels of workflow

Human-Automation Interaction

While the research on DSS elucidates the importance of design for ease of use and workflow accommodation, there are many other considerations. Much of what we know about those considerations stems from research on human-automation interaction. Automation is technology that executes a task or function previously done by humans.[169] Automation does not simply replace human activity; automation changes human activity in planned and unplanned ways.[136] What needs to be appreciated is that adding *automation is like adding another team member, but one who may not speak the same language or share the same cultural assumptions.*[170, 171] When automation is implemented that does not speak the same language as the user or share the same mental models, it results in what is called "automation surprises." [170, 171] These are events where the automation does something that the user does not expect (or does not do something expected) and the user (in this case a clinician), cannot figure out what the automation is doing. It is not surprising then that the design of decision automation can affect user information retrieval speed and accuracy, evaluation processes, and decision strategies.[172]

In human-automation research, automation has been classified in several ways and these classifications can be applied to CDS automation. What is common to the different classifications is they explain what types of functions are being automated and how much of the function is controlled by the automation or the human. For example, one classification shows that human functions that can be automated are monitoring, generating, selecting and implementing,[131] while another often cited classification describes automation as performing information acquisition, information analysis, decision selection and action implementation.[134-136] Information acquisition involves the sensing and registration of input data (e.g., patient vital monitors). Information analysis involves making sense of inputted data, such as CDS automation that forecasts, trends, and integrates data. Both classifications explain that automation (e.g., CDS) can perform any or all of those functions, and for each of the four functions, the "level of automation" can range from none at all (where the human is in full control) to total (where the automation executes the decision without any input from a human) and everywhere in between.[136] While the number of levels of automation have been debated, they recently have been described as:[136]

1. The human does everything manually
2. The computer suggests alternative ways to do the task
3. The computer selects one way to do the task, and
    4. Executes the suggestion of the human approves, or
    5. Allows the human a restricted time to veto before automatic execution, or

6. Executes the suggestion automatically, then necessarily informs the human, or
7. Executes the suggestion automatically, then informs the human only if asked.

8. The computer selects the method, executes it and ignores the human

Automation may increase or reduce mental workload, situation awareness, complacency, and skill, depending on what functions are automated, at what level of automation the function operates, and the reliability of the automation.[133, 134] Automation is supposed to lessen mental workload in order to reduce errors and improve accuracy,[169] though the most common complaint about CDS is that it takes more effort and more time. Some people under high workload, as is typical in ambulatory care, may rely more on automation, while others may rely less—the direction of the effect is unclear.[169] Other factors that might promote use of automation are the effort involved in using the automation, trust in the automation, and the risk of using or not using the automation.[169]

CDS automation has not been previously classified by the function it automates (information acquisition, information analysis, decision selection and action implementation) or the level of automation it provides, but this is necessary for understanding the relationship between CDS and workflow. Importantly, thinking about CDS in these terms helps to move designers and purchasers away from thinking about workflow only in terms of discrete, linear steps and more toward a dynamic cognitive workflow perspective.[173] That is, workflow is more than simply taking a history and physical, reconciling medications, deciding treatment, ordering treatment, and dictating. Workflow is also cognitive workflow[64, 65] where throughout the aforementioned steps, clinicians are dynamically updating their situation awareness about the patient based on their continuous attempts to acquire information from the patient, caregiver (if present), and paper or electronic medical record. This information is then analyzed in the clinician’s head, or with the help of a computer, and decisions are made and executed; each decision may require more information acquisition and analysis.

As mentioned, the extent to which the CDS automation is designed to provide the right type of assistance for the right function (information acquisition, information analysis, decision selection and action implementation) impacts the mental workload and situation awareness of the clinician, and even teams,[174] in positive or negative ways. If mental workload is high or situation awareness low, then memory, problem identification, decisionmaking, and decision execution may be impaired,[106, 108, 110, 113, 118] and, therefore, patient safety and clinical quality can be impaired.

Human-centered automation (more general human-centered design steps are discussed in the next section) is the idea that automation must be designed to *cooperate with* the users. In other words, just as humans must cooperate to get work done, so too must automation cooperate with humans. Human-automation cooperation requires shared representations[175] and cooperative displays and controls,[136] all of which seem to be lacking in currently used CDS. ***The notion that people should be expected, instead, to conform to automation, as is the case with much CDS, is antithetical to human-centered automation or user-centered design.*** A variety of principles have been developed and tested to help guide the design of automation, including CDS. Principles that the human (clinicians) and automation (CDS) need to have to effectively work together are:[176]

- Common grounding.
- The ability to model each others' intents and actions.
- Interpredictability.
- Amenability to direction.
- An effort to make intentions obvious.
- Observability.
- Goal negotiation.
- Planning and autonomy support.
- Attention management.
- Cost control.

Many of the CDS automation studies previously cited found an absence of these principles.

Research on human-automation interaction was driven in part by accidents that involved automation. The top five problems that have been identified over the years are feedback about systems states provided by the automation, misunderstandings of the automation, overreliance on automation, poor display design, and inadequate training,[136, 169] all of which have plagued CDS automation and medical technologies in general. This means that not only might CDS automation not improve decisionmaking, but it can lead to an entire new class of errors or problems.[168]

The first automation problem mentioned, problems with feedback about systems states, occurs when the CDS automation changes states (e.g., from logged on to logged off, or from one patient to another), but the automation does not communicate this to the user, or does not communicate it in a meaningful way. Such problems have been found with medical technologies and devices[177] and it seems clear from the CDS recommendations listed in previous sections that this a frequent occurrence with CDS automation as well.

A misunderstanding of automation occurs when the mental models of the users do not match the mental models of the designers. This is another problem commonly found with CDS automation.[177, 178] This happens when a designer builds automation in a way that makes sense to him/her, but unfortunately makes no sense to or misleads the end user. For example, a designer might use the color green to highlight a computerized drug alert, but to the end user, the clinician, the green might indicate "go," just like a traffic light. In this case, the designer's use of green was intended to alert the clinician, but the clinician instead assumes it means he or she can move on and ignore the alert. For successful automation-human collaboration, the user must have an understanding of how the automation operates and arrives at its recommendations.[179]

Overreliance, or automation complacency, a third most common human-automation problem, refers to users relying on the automation when they should not, because they inappropriately trust the automation.[169] It is unclear if this is a significant problem in ambulatory care. On the other hand, this may be a more significant problem in hospitals, where clinicians may rely on vital monitor alarms to alert them to a problem. While reliance is the decision to not act until told to do so, compliance is the act of doing what the automation suggests. Certainly there seems to be no problem of over-compliance in ambulatory care. Alerts and reminders are routinely ignored. The reason is likely because over-compliance stems from misplaced trust, and CDS automation in ambulatory settings simply is not yet considered very trust worthy.

When thresholds are set too low for alerts and reminders, false alarm rates are high, compliance drops,[180] and reliance may also drop.[181] When the threshold is set such that the automation misses events, then reliance on the automation drops.[181] False alarms may affect performance more negatively than misses, because they are more noticeable.[182] They also affect trust, which can mediate the impact of automation on outcomes (e.g., efficiency, productivity, quality and safety)[183, 184] because trust in automation helps to guide how much a person relies on automation.[183]

Principles for CDS design and integration with workflow that can be derived from human-automation interaction research are as follows:

- Adding automation is like adding another team member, but one who may not speak the same language or share the same cultural assumptions, so design CDS to speak the language and share the assumptions of the end users.
- When automation is implemented that does not speak the same language as the user or share the same mental models, it results in what is called “automation surprises,” which can slow work, or worse, cause errors.
- When designing CDS, consider which functions, among information acquisition, information analysis, decision selection and action implementation, need to be automated. CDS for the wrong function will lead to rejection.
- When designing CDS, consider to what level the CDS needs to be automated. Too much or too little automation can lead to rejection or errors.
- Poorly designed CDS will reduce clinician trust in the CDS, which will lead to inappropriate (too little) compliance and reliance.
- Poorly designed CDS can lead to increased mental workload and reduced situation awareness, both which can impair problem identification, decisionmaking and decision execution.
- CDS automation needs to be designed and integrated into workflow such that it *cooperates* with the clinicians that use it.
- Well-designed and integrated CDS should avoid automation problems related to feedback about systems states provided by the automation, misunderstandings of the automation, and overreliance on automation.

Teams, Collaborative Work, and Distributed Cognition

The fields of computer supported collaborative work (CSCW),[64, 185] teamwork,[111, 140, 186-192] and distributed cognition[110, 113, 193, 194] may also provide insights into how to study and conceptualize the workflow in ambulatory health care delivery for better CDS design and integration with workflow. CSCW research focuses on how people collaborate and how technology can mediate that collaboration effectively. In ambulatory settings—from primary care clinics to surgery-centers to emergency departments—a wide variety of people (clinicians, patients, and administrative staff) collaborate to achieve high quality and safe care.[195] When CDS automation is present, it may mediate or moderate the interactions of the individuals who must collaborate, and depending on how well the CDS automation meets the challenge, the interaction may be improved or degraded by the automation.

The science of teamwork provides evidence about the differences between the individual tasks that team members (e.g., physician, nurse, or pharmacist) must perform, called taskwork, and the teamwork, which involves communication, cooperation, and coordination. The skills needed for teamwork require as much training as the skills required for taskwork. Teamwork science also provides evidence about the types of knowledge, skills, and attitudes (KSAs) that are required for effective team function. CDS automation that is used in ambulatory settings will often be embedded into a team environment and therefore must be designed to facilitate the flow of task and teamwork required for safe and high-quality care.

Distributed cognition refers to how members of a group or team may have different, distributed cognitive roles in achieving an outcome, such as safe patient care. This is important for CDS automation design, because when work is distributed, as it is in a primary care clinic, surgery-center, or ED, each member of the team needs to have the right information to support their situation awareness (SA) and workflow. This leads to the idea of distributed SA, which is SA that is distributed among people, though not necessarily shared. For example, during a physician-patient care encounter, the physician's SA is in part due to the chart, patient appearance and knowledge of the patient. Patient SA may only be due to their knowledge of themselves. Patient and physician SA are therefore different and only partially overlapping. But, that may be appropriate as they have different goals. What is important in distributed SA is that the different people who rely on each other have the right SA for their goals. CDS automation that is implemented into a team environment, therefore, needs to provide the right support to each person.

Principles for CDS design and integration with workflow that can be derived from team science, distributed cognition, and computer supported cooperative work (CSCW) research are as follows:

- CDS must be designed to facilitate the necessary collaboration between health care clinicians and patients, not degrade them or make them more difficult.
- CDS must be designed to recognize that each member of the collaboration or team may have different mental models, SA needs, data entry needs, and data acquisition needs.
- CDS must support individual clinician task workflow and team workflow among the members.

Sociotechnical Systems of Information Technology

The final framework needed to understand what it means to design and implement CDS automation to support workflow is a sociotechnical systems theory of information technology.[62, 63, 67, 165, 196-202] Figure 2 provided a multilevel sociotechnical systems model of how the context or system of an ambulatory health care delivery clinic and the design of CDS automation interact to determine *fit*. The model shows that to achieve good outcomes with health IT, it is necessary to ensure that the health IT fits within the multiple levels of a health care organization, from the clinician to the industry.

For "fit" to exist requires an understanding of what system elements need to fit together and how to measure the fit. There is no consensus on what elements need to fit together, but examples of metrics and evidence from IT research provides some guidance.[67, 203-206] At the clinician-health IT level, fit involves usability and usefulness. Both can be measured quantitatively and qualitatively during testing and in the field. Quantitative measures can be subjective questionnaires, [203, 206-208] or, importantly, more objective measures of response time (i.e. productivity) and accuracy (i.e. quality and safety) of the clinicians doing the tasks the CDS is supposed to support. Qualitative measures can be based on interviews or focus groups.

At the work group or unit level, fit involves, among other things, integration with team or unit workflow, norms, rules, and other IT applications. Fit with workflow can be measured again with response time and accuracy, as well as with workflow models and questionnaires. Fit with norms or rules can be measured with techniques that assess whether using the CDS allows clinicians to still comply with existing rules or norms. This can be measured with a simple yes/no checklist. Fit with other IT applications can be measured also with yes/no checklists once all of the performance objectives of the IT integration have been listed and tested.

At the practice or clinic level, fit can involve integration with other clinic-wide applications, organizational culture, management structure, and reward systems. Fit with culture can be measured with a variety of culture surveys. Fit with structure and reward systems can be measured by conducting a formal work system analysis[209] and determining whether use of the CDS is in conflict with either. Finally at the industry level, fit might involve compliance with regulatory agencies such as the Joint Commission or the Centers for Medicare and Medicaid Services (CMS). Here, fit can be measured with a simple yes/no checklist once all of the performance objectives of the CDS and how it must comply with regulatory agencies is defined. Thus, health IT in general, or CDS automation specifically, must be well-*designed* and well-*implemented*; both are necessary, but neither is sufficient.[151, 155, 205, 210]

The model also implies that the concept of workflow, the central point of discussion in this White Paper, operates at different levels.[211] Workflow can be defined as the flow of work through space and time, where work is comprised of three components: *inputs* are *transformed* into *outputs*. For example, an input might be a medication order; the transformation is a pharmacy turning that order into a ready medication; and the output is the medication ready and available for the patient. Sometimes workflow is simplistically conceptualized as only the flow of observable processes, but workflow is much more complex.

At a macro-level, there is workflow among ambulatory settings, such as the workflow between a primary care physician and a community pharmacy to turn a prescription into a medication for a patient, or between an emergency department physician and a primary care physician to share information about a patient. There is clinic-level workflow related to the flow of a physician, nurse or patient through physical space and the flow of information, in paper or electronic formats, among people at the clinic. Then, there is the workflow during a patient visit, which involves the workflow of the visit (e.g., start by asking for a problem list, then take history and physical (H&P), then prescribe treatment).

Finally, at the most micro-level, there is clinician cognitive workflow during the visit, which is the flow of thoughts, questions, and decisions. Even though the observable step in the workflow might be "ask patient for problem list," the workflow in the clinician's head at that moment might be, "listen for any significant acute problems and deal with those first. Also, investigate my concern about spousal abuse. If I don't hear any, focus on the chronic problems." That is, the observable workflow may or may not perfectly match the workflow of ideas and thoughts in the clinician's head. There is also the flow of any given artifact, such as CDS software or a paper laboratory/diagnostic test order form. In those cases, flow relates to how information is presented and laid out. For example, the software workflow might force the clinician to log in, choose a patient, and complete a medication list before being able to enter data from the H&P. Whether the flow of the software matches the flow of the visit or the flow in the clinician's head is critical for the acceptance and use of that CDS automation.

It is also important to point out that the examples demonstrate that a variety of agents and information "flow" and the term "workflow" does not necessarily illuminate that. People flow through space and time. So does information in paper and electronic formats, and so do objects such as medications, sterile gloves, and wheelchairs. The flow of all of those, information, people, and products and the different levels of workflow are necessary to consider when designing CDS to support clinician workflow.

The left side of the model, the system inputs side, also demonstrates that the success or failure of CDS automation may only be partially attributed to technical reasons; success and failures are also often due to sociotechnical design failures, organizational misalignments, culture conflicts, poor implementation strategies, and misaligned incentives.[160, 164, 185, 196, 205, 212-214] That is, the fit of health IT into clinical work is the most important basic necessity, or certainly one of the most important necessities, to achieve any goal.[11, 37, 67, 153, 154, 166, 215-219] Further, the workflow of clinicians is not just driven by the IT, but the organization, its policies and procedures, management, resources and facilities, and patient needs.[62, 67, 205, 210, 211, 215] That makes clinical workflow complex; health IT like CDS that tries to fit complex, nonlinear clinical work into a linear workflow creates mismatches between the automation and the real workflows, which can result in errors.[173 165, 220]

In that same way, the model also emphasizes that context is also a critical variable[62, 63, 164, 196, 212, 213] and CDS testing must incorporate the appropriate context for there to be appropriate testing.[221-223] For example, the context of care in a primary care clinic is very different than that of an emergency department, where there is typically a higher degree of uncertainty, decisions are more time dependent, and more people are involved in providing care.[218] Context also relates to the degree of previous automation and the extent to which computer systems are connected, appropriately or not, because the way CDS systems interact with other systems can affect the performance under real circumstances.[213]

Principles for CDS design and integration with workflow that can be derived from sociotechnical systems research on health IT are as follows:

- CDS fit with workflow must occur at the multiple levels of workflow.
- The fit between CDS and various other system elements, including workflow, can be measured.
- People, information, and objects all flow. CDS automation must be designed and integrated such that it fits with the desired flows of all three.
- CDS automation is, necessarily, both a technical and an organization/social intervention. The organizational and social concerns regarding CDS are at least as important, if not more important, than the technical concerns.

- Context is key. Because of vast contextual differences between clinics in terms of operations, physical layout, rules, tasks and culture, the success or failure of a CDS automation in one practice may not be at all generalizable to another.

The lessons of these four areas of research on automation are not always heeded. For example, emergency rooms are highly complex and collaborative environments with variable individual and team workflows responding to the complexity.[143, 224] One noncomputerized CDS that provides individuals and team members with individual task information, team coordination, and communication, is the whiteboard. At first glance, the whiteboard appears to be a static CDS tool used to store data, but research demonstrates that this simple, noncomputerized tool supports collaboration and teamwork by facilitating task management, team attention management, task status tracking, task articulation, resource planning and tracking, synchronous and asynchronous communication, multidisciplinary problem solving and negotiation, and socialization and team building.[225-228]

So, what happens when emergency departments move to electronic whiteboards? For an electronic whiteboard to succeed, it too will have to support those same individual and team performance and workflow needs. However, initial evidence suggest that the design of electronic whiteboards does not support the same individual and team workflow needs as the manual boards, and so are largely ignored by clinical staff.[229] This CDS automation is rejected by staff, not out of resistance to change, but because the technology does not support their workflow, communication, and coordination needs. The type of work a non-electronic artifact (e.g., paper chart or whiteboard) supports is not often obvious by just looking at it; observations and studies of the way the artifacts are used in real world settings are needed to understand the ways people use them.[194] Understanding how people work is critical for ensuring new technologies implemented into a work setting integrate with user needs. To that end, the last section focuses on achieving workflow integration.

Achieving CDS-Workflow Integration: A User-Centered Design Approach

As the previous sections have illustrated, CDS automation needs to be integrated into multiple levels of workflow. It also needs to be designed to accommodate the range of users who will use it in the range of settings in which the CDS will be used. One method of achieving these challenging goals is referred to as human-centered design, or user-centered design. Human- or user-centered design methods, such as usability testing, for CDS automation have been strongly recommended[64, 65, 221, 222, 230, 231] because of the evidence to date that many CDS systems are not usable. Actual usability studies of medical technologies have been demonstrated to be useful[177, 223, 232-236] with some focusing on different types of CDS automation.[178, 237-242] User-centered design is more than simply the design of usable interfaces. It requires that IT—in this case CDS automation—be designed to fit into the larger social, workflow, organizational and environmental conditions into which it will be implemented.[62-65, 151, 155, 164, 195, 196, 205, 210, 212-214, 223, 243, 244] That means the development of CDS automation will require user, function, task, and system analyses to ensure the automation will fit into its context appropriately.

Human- or user-centered design is a larger process of studying the range of user needs in the varying context to the application of prototyping, testing, and iterative design. For best results it must be applied during the development phase of a CDS and not after implementation. Fixing problems in the development phase, or worse, after shipping, is much more costly (perhaps 10-100 times) than during the design phase. [152] Human-centered design starts with understanding the actual technical work of the clinicians under the variety of contexts of use. Cognitive work analysis, task analysis, [123, 195] function analysis, work system analysis,[209] flow charting, and many other methods can be used to understand the real clinical workflow at the different levels. If this step is missing, then the design process will be exponentially more challenging because the designers will not have realistic goals for which to design. Usability testing is but a part of user-centered design; it is the part that involves testing of a mock-up, prototype, or actual CDS automation. Even then, there are different types of usability tests that serve different purposes. Many of them have been tried, successfully, with CDS automation, although it is not clear how often this is done.

There are a host of resources that describe the plethora of user-centered design steps and methods,[245-248] including many specific to medical devices or health information technology.[232, 235, 236, 249-251] These include usability testing methods heuristic evaluations,[239] cognitive walkthroughs,[65, 178] think aloud protocols,[195, 231, 250] scenario testing,[177, 195, 241, 250] and other techniques. Examples of using these methods in inpatient and ambulatory settings have demonstrated that a variety of methods such as flow, sequence, cultural, artifact and physical models, think alouds, and cognitive evaluations can all be used to understand how to design CDS automation to match the real-world unit (or clinic) and clinician workflow for better acceptance.[238, 240] But, it is beyond the scope of this white paper to review all of the methods. Instead, this final section focuses on important concepts that will help ensure the successful application of user-centered design techniques.

First, user-centered design can uncover CDS design and workflow problems. These problems do not *just* lead to resistance or rejection; usability and workflow flaws can contribute directly to errors in data entry and data interpretation, as well as inefficiencies in data entry and data acquisition. Any of those can subsequently lead to patient harm or compromised quality.[178, 247, 252, 253] In one ambulatory setting study of CPOE usability, both cognitive walkthroughs by experts and think aloud protocols[1] by end users were undertaken to understand the CDS automation usability.[178] The cognitive walkthrough identified 25 potential usability problems, all of which were confirmed during end user think aloud testing.[178] These problems directly resulted in inefficiencies, omission errors, and inappropriately cancelled orders.[178] The think aloud testing with end users uncovered an additional eight problems not identified during the cognitive walkthrough because the analysts in the cognitive walkthrough did not have the local clinician mental models of how such a system should work.[178] These additional problems related to processes that did not adhere to current work practices or terminology that was foreign to the local clinic.[178] These problems also led to errors of omission, cancelled orders, and wasted time; they led to quality and safety problems.[178]

[1] A cognitive walkthrough is a usability testing method whereby end users or experts walk through the steps they will have to take to achieve their work goal. All the while, at each step, they ask themselves a series of questions to determine if the product or software will be usable. A think aloud protocol is another usability testing method that has end users use a product or software and verbalize their thoughts as they use the product so that problems can be identified.

Second, the usefulness of automation and its ease of use are both important determinants of end user acceptance and subsequent use of the technology.[175, 203, 204, 207, 254, 255] But, importantly, user-centered design of CDS automation should not focus on either usefulness or ease of use, but must address both. In a previous section, evidence was provided demonstrating that if automation requires effort above the status quo (i.e., it is not easy to use) that it will likely not be used, Evidence also makes clear that it is as important that the automation be designed to be useful. There are two related reasons for this: (1) evidence inside and outside of health care delivery consistently shows that perceived usefulness is a stronger predictor of acceptance than perceived ease of use[205, 210] (thought not always),[256, 257] and (2) evidence suggests that the question of ease of use may fade over time as users become more accustomed to a system, but the question of usefulness remains paramount in users minds.[206] Usefulness in the clinical sense may have a variety of meanings, but most importantly, it means that the automation helps clinicians care for patients.[258]

Some have argued that health IT cannot be simultaneously usable and useful. The rationale is that usable interfaces are necessarily simple, only solving simple trivial problems, whereas what is needed are systems that solve complex problems, which bring with them usability problems.[175] However, while this supposed paradox may seem to exist currently for CDS automation, it is far from a rule. Automation has been designed for highly complicated problems in aviation, nuclear power and other process industries that are both useful and usable, and there is no reason the same cannot be done in health care. Some have already demonstrated that it can be done[127] and human factors research is contributing to further developments.[259]

Third, drawing on the lessons from sociotechnical systems, during CDS testing it is critical that subjects represent all possible users, as testing may uncover certain features or problems for some users that are different from others. For example, residents and attending physicians find systems differently useful[65, 237] because, as experts and novices, they have different decisionmaking strategies, which translate to different information needs, and different analytical strategies.[231] Also, explanations of decisions in CDS may serve different functions for experts (attending physicians or experienced nurses) and novices; experts may use explanations more to understand unexpected events or recommendations contrary to their beliefs, while novices may use them more to learn.[260] Similarly, if the device or information technology will be used in environments with different lighting intensities and sources (fluorescent tube versus sunlight), different levels of noise (ED versus primary care office or surgery suite) and even different levels of distraction (ED versus nursing home), then testing should be conducted in those different environments to determine if and when the CDS is usable. Testing with the range of users and contexts helps to ensure the automation is designed such that it can be easy to use and useful for the entire range of users.

Different types of clinicians will also have different needs because of the different ways they work, different decisions they have to make, different data that are relevant, and different locations of their work.[127, 261] For example, Karsh and Scanlon note:

> "Putting a handful of subjects in a nice, clean, simulated patient care room and having them use the device there may not simulate the real environments of use, in which the alarms might not be audible, the displays easily visible, or buttons easily activated. The key point here is that usability is not proven by demonstrating that a handful of people can

> use the device in a given environment. Usability is determined by the *interaction* among users, the technology, the environment (lighting, noise, vibration, and distractions), the task characteristics (time pressure, need for concentration) and the organization (culture, policies). Good usability testing must attempt to mimic these interactions." [221]

It is also important to realize that a system that is considered usable and useful at a particular point in time may not be viewed the same way after users gain experience with the system.[261] It is therefore important that broad evaluations of the technology continue long after implementation to understand how the use of the technology evolves.[55, 56, 61]

Fourth, understanding the many human biases that can lead to incorrect conclusions during testing is another important consideration for good usability. Otherwise, if these biases are not understood, they can account for results being misinterpreted and misapplied. For example, hindsight bias (aka "hindsight is 20/20" or "armchair quarterbacking"), which is the bias that results when looking back at an event and believing the right course of action *should* have been obvious, may lead a tester to conclude that a user error during testing could "obviously" be corrected with better training.

Unfortunately, many decisionmakers, purchases and designers erroneously believe that design and user needs are common sense. Users (e.g., clinicians), often share the same erroneous assumption. "This leads to blaming (I can't believe that person can't figure it out) and even ironically leads to much self blaming (Why can't *I* figure this out? or If only *I* had been paying more attention, this wouldn't have happened) when in fact the real problem was poor design."[221] But, there is strong evidence that good design and integration is not common sense. That evidence comes from the fact that there is strong agreement that current CDS is not being used, and from evidence that when user-centered design approaches are applied to CDS automation, better products are designed. Thus, user-centered design is needed even if designers or purchases think the design is "obviously" good.

Software designed without attention to workflow and usability may fall victim to the "designer bias," which is when a designer's automation is designed based on what makes sense to him or her, and thinking that it must then make sense to the user. This is rarely the case. Designers have intimate knowledge of the inner workings of the automation that necessarily make everything about it "common sense." However, what is common sense to a designer often bears no resemblance to the "common sense" of the end users,[153, 169, 244] in this case ambulatory care clinicians, because they have their own mental models of their clinical work and of software in general.

Additionally, many in health care, from administrators and clinicians to manufacturers, believe proper training and compliance with correct use protocols are the needed "interventions" to increase CDS use.[221] This belief, which is not evidence based, brings with it many problems, as is clear from the evidence reviewed. Users get blamed for mistakes caused by bad design, even though the real problem is "designed-induced error."[251] Users themselves might even think that when they cannot figure out how to use CDS or when the CDS does not work for them that it is somehow their fault! Norman explains that this self-blame phenomenon is the result of misunderstanding in causality—that users think the automation must be right, and they wrong.[66] In fact, this is rarely the case, precisely because the hallmark of good design is that the automation works to support the user, not the reverse. Although training is crucial for effective use of automation, it cannot completely compensate for poor design:

> "Training is unlikely to overcome interfaces that do not conform to population stereotypes for where information is located or what colors mean or what "enter" or "return" means. And all the training in the world will not help someone hear an alert in a noisy environment or read a small display in a vibrating ambulance, especially during a time critical task. Each of these cases requires better system design."[221]

A well-trained tester must be aware of the many biases that exist and not fall victim to them. Because there exists a blame culture in health care, there is a knee-jerk bias to believe that human-CDS automation problems are user problems, not design problems.[221] Therefore, good user-centered design requires not only following prescribed methods, but also understanding the science of human-automation interactions, so that misinterpretations do not guide decisionmaking.

Fifth, while heuristic evaluations, cognitive walkthroughs and think aloud protocols can all reveal a large number of design problems, they *do not* substitute for experimental testing. Just as new drugs must be efficacy tested with robust experimental designs, so too should CDS automation. Testing, with externally valid scenarios, can yield hard data about which design options produce the fastest reaction time and highest levels of accuracy. That is, testing can produce quantifiable data about efficiency and safety. And testing can also demonstrate that what users *think* is better, may not be. A recent study of anesthesia alarm design[259] demonstrated that participants beliefs about which alarm design produced the best results did not match the actual test results. Had testing not been conducted and design decisions only relied on participant perceptions, the wrong design would have been chosen as superior. But, as with the other methods, the participants in the test and the scenarios under which the CDS is tested must carefully match the clinical realities of use.

However, because experimental testing cannot possibly mimic all situations under which all possible users might use the device, field usability testing[239] should also be part of human-centered design approaches. Field usability testing involves carefully evaluating the CDS automation in the field, during actual use, to further validate that the CDS is working as intended, providing the right information at the right time and therefore allowing for faster response for decisions with higher accuracy than before the CDS.

As mentioned, there is evidence that usability methods can help select a better CDS or design better CDS. For example, in a study evaluating five electronic bedside CDS tools, usability testing demonstrated that one of the CDS tools produced a larger number of correct answers, had the best usability ratings, and was rated the best at satisfying user needs; this was despite there being no perceived differences in the accuracy, amount of information, and timeliness of information among the five products.[262] This shows that usability testing outcomes must be broad to obtain a holistic evaluation. Usability tests in ambulatory care have uncovered CDS automation problems related to interface usability and workflow integration, and lessons learned from such tests have led to modifications of the CDS prior to implementation.[263] Using structured usability methods can lead to uncovering usability and workflow problems even when non-usability experts lead the studies,[263] though novices may miss problems experts can identify or misinterpret results and problems. In addition, it is likely that different types of usability evaluation methods are important, because while several methods may yield similar data, there is evidence that data from the other methods may be different.[264-267] However, which method or methods are best, and whether novices can perform as well as experts, is unclear.[268]

Conclusion

The promise of CDS automation in ambulatory care has not yet been met. Many reasons exist to explain this state of affairs, but none appear more critical than the fact that CDS applications have not been successfully integrated into the realities of clinical workflow. While such integration is challenging, methods exist for defining and measuring workflow fit and studying and improving upon existing workflows. These techniques can be implemented, along with user-centered design approaches, to better ensure that future CDS automation works at the right time for the range of users, their range of needs, and in their range of contexts of use.

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