Current Challenges and Opportunities for Better Integration of Human Factors Research with Development of Clinical Information Systems

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Summary

Objectives: Clinical information system (CIS) developers and implementers have begun to look to other scientific disciplines for new methods, tools, and techniques to help them better understand clinicians and their organizational structures, clinical work environments, capabilities of clinical information and communications technology, and the way these structures and processes interact. The goal of this article is to help CIS researchers, developers, implementers, and evaluators better understand the methods, tools, techniques, and literature of the field of human factors.

Methods: We developed a framework that explains how six key human factors topics relate to the design, implementation, and evaluation of CIS.

Results: Using this framework we discuss the following six topics: 1) informatics and patient safety, 2) user interface design and evaluation, 3) workflow and task analysis, 4) clinical decision making and decision support, 5) distributed cognition, and 6) mental workload and situation awareness.

Conclusions: Integrating the methods, tools, and lessons learned from each of these six areas of human factors research early in CIS design and incorporating them iteratively during development can improve user performance, user satisfaction, and integration into clinical workflow. Ultimately, this approach will improve clinical information systems and healthcare delivery.

Keywords
Human factors, clinical information systems, computerized medical record, human information processing, clinical decision support systems

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Introduction

Recently, there have been several articles in the scientific literature suggesting that simply implementing a state-of-the-art clinical information system (CIS) within the modern healthcare enterprise does not lead to improvements in the quality[1], safety[2] or even cost of healthcare[3]. When these reports are coupled with the increasing pressure on healthcare organizations to provide extensive data describing the quality of care delivered, the pressure on CIS developers and implementers to “get it right” as fast as possible has never been greater. Towards that end, CIS developers and implementers have begun to look outside their expertise to other scientific disciplines for new methods, tools, and techniques to help them better understand the following: clinicians and their organizational structures, clinical work environments, the capabilities of clinical information and communications technology, and how the above structures and processes interact[4].

The goal of this article is to help CIS researchers, developers, implementers, and evaluators better understand the methods, tools, techniques, and literature of the field of human factors. The six areas of current human factors activity within health informatics that we have selected cover the motivation for improving CIS and they provide an overview of current theories, methods, and measurements that are used by human factors within healthcare. Figure 1 provides an overview of these six areas. The caption and the following text explain what the areas represent, and describe how they relate to each other.

The overarching element in Figure 1 is the purpose of CIS, which is to provide information when and where it is needed in order to ensure satisfactory patient outcomes and patient safety. The extent to which CIS supports the demand for information determines whether the system will provide an effective vs. ineffective interface. The form and function of the interface contribute to whether clinical information can be accessed effectively and understood, and whether information can be entered and ordered undertaken with trust in the end result.

The above two factors—the information needed and the form of the interface— influence clinical activities that involve CIS. There are various ways to assess healthcare activities involving CIS: examples from the field of human factors include workflow
analysis and task analysis. These approaches can help designers better understand how CIS is actually used during clinical work and/or provide information on how CIS can be improved to aid work processes.

There are several work activities that need to be supported by CIS. One key activity is clinical decision-making. This activity may be supported by a clinical decision support system (CDSS) within a CIS. The CDSS may succeed or fail to support clinical decision-making depending upon whether the system interface provides the right information and allows the decision-maker to access and act upon that information in a manner that supports patient care.

Exactly what constitutes activity, and therefore what needs to be analyzed, is guided by different theoretical viewpoints. An influential viewpoint from human factors that has recently gained interest from health informatics is “distributed cognition”—the idea that cognitive activity is shared amongst different individuals and is spread across time and space.

Finally, CIS design influences the type and quality of interactions healthcare employees have with CIS, and also affects employees’ cognitive processes and productivity. These human experiences can be strong determinants of whether a clinical information system functions as intended. Two well-researched aspects of human experience are the level of mental workload that a healthcare worker experiences when using a CIS and the degree of situation awareness the clinical information system offers, such as a patient’s history, status, and treatment plan.

Although this article does not provide a comprehensive list of human factors topics, it presents some current human factors research topics and outlines opportunities to improve the design and implementation of CISs. Within each topic, we provide a short introduction followed by a brief overview of the key problems in that area; discuss, methods, tools and techniques that can be applied to CIS; and provide resources for additional information. The six topics areas presented in this paper represent key ideas, methods, and tools from human factors, which may be applied to improve CIS design, implementation, and associated patient care.

**Fig. 1** Framework for the human factors topics presented in this article, as they relate to CIS. The purpose of CIS is to improve patient outcomes and greater patient safety. The interface of the CIS can be informed by user-centered design and evaluation methods. Clinical activity can be analyzed with various human factors methods and supported with technology. For example, clinical decision making can be aided with a clinical decision support system. The analysis of activity is guided by theories of activity. Finally, the quality of the cognitive outcomes of activity can also be measured, human factors offers tools to measure the workload that employees experience during CIS use and their awareness of the patient status.

**Purpose: Informatics and Patient Safety**

As shown in Figure 1, a key purpose of informatics is to promote patient safety. Several human factors approaches can help improve the effectiveness of CIS while aiding efforts to reduce the risk of medical harm to patients. Clinical information technology, including the electronic health record (EHR), can be used to enhance patient safety and offers a wide range of novel mechanisms to achieve safety goals. In particular, computerized provider order entry (CPOE) and bar code medication administration (BCMA) have been implemented in hospitals with the intent of reducing the risk of medical harm to patients; research shows that, at least in some cases, these technologies have improved the safety of healthcare in measurable ways [5-7]. Information technologies can potentially aid patient safety by providing enhanced information availability and legibility, clinical decision support; safety alerts for physicians (e.g., medication order checks for drug-drug interactions), and mechanisms such as BCMA to help “double check” clinical procedures that pose greater risk to patients[5, 8]. These benefits notwithstanding, CIS’s potential to enhance patient care and patient safety has not been fully realized in many areas[9]. Moreover, information technologies can have unintended consequences, which may put patients’ health at risk and/or lead to medical harm [8, 10-12].

**Key Patient Safety Topics for Informatics**

For example, Koppel et al. 2005 found that one CPOE system facilitated 22 types of medication error risks[2]. In a different study, Horsky et al. 2005 analyzed a medication error and concluded that several aspects of CPOE...
design contributed to a serious, unintentional dosing event [13]. Several other relevant patient safety topics have begun to gain the attention of the informatics and human factors experts: inability to differentiate between truly new information and that which has been cut and pasted in progress notes [10, 14-16]; alert fatigue, i.e., a high frequency of electronic safety alerts leading to desensitization over time [17, 18]; and informatics over-automation and tight coupling, which can propagate inaccurate information or CIS errors to more healthcare employees more rapidly than traditional paper-based clinical processes [19, 20]. In addition, information technologies that inadequately support healthcare employees’ natural workflow processes are more likely to be associated with workarounds [8, 21]. While some workarounds may appropriately enhance patient safety, others can create unintended risks to patients’ well-being [6, 8, 22]. Workarounds have been reported for a variety of clinical informatics technologies including EHRs, CPOE, and BCMA [10, 23-26].

Methods and Tools for Assessing and Improving the Safety of Informatics

The field of human factors offers several theoretical frameworks and tools to facilitate patient safety goals. One that has received widespread attention in the medical literature, Reason’s Swiss cheese model for accident causation, illustrates how different “gaps” can align and lead to patient harm[27]. The more recent Systems Engineering Initiative for Patient Safety (SEIPS) model provides a framework for understanding how work system factors, including informatics technologies, can influence patient safety[4]. Human factors methods and techniques can be used to do the following: 1) prospectively identify potential safety problems with clinical information technology prior to implementation; 2) understand how informatics may promote or hinder patient safety within the context of clinical care and natural workflow processes; and 3) retrospectively evaluate the role of informatics in near misses, adverse events, etc. Table 1 outlines these three general approaches and lists some relevant tools and resources. Additional resources can be found in PubMed and engineering Compdex® literature search databases, the Handbook of Human Factors and Ergonomics in Health Care and Patient Safety, and are available elsewhere [28, 29].

There has been a lot of attention on how CIS can enhance patient safety; certainly, these technologies have much to offer. It is equally important to investigate how CISs may contribute to patient harm and identify what changes need to be made to ensure safer care. To enhance the safety of CISs, mechanisms need to be in place to receive rapid input from employees; prioritize issues related to patient safety; and provide timely responses to employees about how CIS safety issues were actively addressed[21]. If these mechanisms are unreliable or inefficient, then a valuable informatics resource (i.e., employee input) may diminish and, ultimately, patient safety could suffer[30]. Once safety concerns are identified, efforts should be made to address the problem via redesigns of the technology. In human factors, it is well known that removing patient safety hazards through redesigns is a much stronger and effective strategy than relying on warnings, protocols, and training, etc[31]. Human factors practice provides several tools to investigate how informatics influences patient safety. These tools, combined with iterative technology redesigns, can help ensure that information systems promote effective and safe medical care.

Table 1  Three general approaches to informatics and patient safety, their strengths and weaknesses, and corresponding tools and resources. All three of these approaches should be utilized to maximally strengthen patient safety. Some of the more commonly used tools are listed in the right hand column.

<table>
<thead>
<tr>
<th>Approach</th>
<th>Strengths &amp; Weaknesses</th>
<th>Tools and Resources</th>
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| Pre-implementation | * Identifies potential problems before patient harm occurs; can be rapid; redesigns may promote IT adoption by employees and minimize workarounds | - Usability testing [12, 32]  
- Heuristic evaluation [33]  
- Task analysis [34-36]  
- FMEA [37]  
- Think aloud  
- Cognitive walkthrough |
| Information technology use in the clinical context | * Identifies problems that result from complex socio-technical interactions; reveals how naturally-occurring workflow issues may influence patient safety  
* Some forms of data collection are limited by privacy restrictions; some methods can be time consuming; information may be complex to analyze | - Task analysis [34-36]  
- FMEA [37]  
- Analysis of workarounds and artifacts [21, 25]  
- Qualitative approaches: interviews, direct observations, focus groups [38] |
| Retrospective analysis of events (near misses, ADEs, ADRs, etc) | * Can inform changes to prevent similar, repeat events  
* Actual events may be difficult to reconstruct; does nothing to prevent the initial event from occurring | - Incident report analysis [39]  
- Root cause analysis (RCA) [40] |

Abbreviations: ADE – adverse drug event; ADR – adverse drug reaction; FMEA – failure modes and effects analysis
Interface: User Interface Design and Evaluation

Figure 1 shows that the user interface stands between the broader purpose of the CIS tool and the activity observed. The effectiveness and safety of clinical work processes are significantly shaped and influenced by how the interface is designed. The quality of the interface (e.g., how clear, understandable, and usable it is for employees’ work) can determine whether or not healthcare employees accept or reject an attempted CIS implementation. In fact, two of the five major barriers to adoption of healthcare information and communications technology in the U.S. are “lack of user-friendly, integrated technology solutions” and “lack of end-user acceptance” [41]. The CIS that healthcare delivery organizations acquire often fit poorly into actual work practices [42] and, therefore, are deemed inappropriate or unusable by end-users. In one estimate, 75% of healthcare CIS implementations were considered failures by their users [43].

Even the most motivated end-users in healthcare contexts do not necessarily know how to identify or explain what their information systems should deliver, or how to evaluate potential solutions to their problems [44]. Guidelines about the form that effective user interfaces should take can be difficult to translate into practice, and can even contradict each other [45, 46]. Following such guidelines does not guarantee effectiveness in rich sociotechnical contexts—a series of papers in health informatics whose titles include the words “unintended consequences” attests to the complexities [8, 10, 47, 48]. In the face of these problems, having an effective process for designing and evaluating the interface between user and system becomes very important.

Key Problems in User Interface Design and Evaluation

The healthcare industry cycles through enthusiasms for new platforms and applications. The well-known Gartner “hype cycles” [49] reveal a “peak of inflated expectations” and “trough of disillusionment” for emerging healthcare provider applications and systems. If the challenges that new CIS meet in practice could be identified earlier and more accurately, those peaks and troughs could be lessened. User-centered design techniques can help such assessments by providing broad principles (see [50]) to guide the process. Such principles, and challenges for applying them in healthcare, are as follows:

1. Early involvement of end-users and their contexts of use are needed. However, the scale of CIS often makes such involvement difficult [51]. Well-known user-centered design and evaluation methods sometimes do not handle the scale of time and space over which human-system integration takes place in healthcare.
2. System design should be an iterative process with formative (design-oriented) and summative (conclusion-oriented) phases of evaluation. Finding the right time to perform such evaluations, and making sure that the results influence development and rollout decisions, are key problems for large-scale CIS projects [52, 53].
3. Progress towards user experience goals should be measured objectively. Deciding upon criteria for the user experience, and finding measures that inform about progress towards those criteria, can be difficult given the scale of CIS applications and the need for a greater focus on safety than in many other contexts [54, 55].

Methods and Tools for User Interface Design and Evaluation

User-centered design and evaluation methods have come to the healthcare industry only relatively recently. Examples of such methods are shown in the first two rows of Table 1. Many papers covering these methods in the peer-reviewed literature are either tutorial in nature [32, 56], they recount case studies of applying such methods [57], or both [58, 59]. Nonetheless, taken together, such papers are informative about the wide range of methods and tools available for user interface design and evaluation.

Researchers distinguish between analytic methods, in which evaluations are made on the basis of formal models of interaction or on the basis of expert opinion, and empirical methods, in which evaluations depend on collecting data about user interactions. For example, analytic methods include heuristic evaluation and cognitive walkthroughs, whereas empirical methods include observation of representative users either in the field or in simulated contexts. Researchers are also concerned with different models of end-user participation; these range from strong participatory design methods, where users are also designers, to user testing, where users interact with prototype or production-level systems to reveal design flaws [51]. Healthcare is only slowly starting to be a source of innovation in such methods and tools, often driven by the need to design and evaluate handheld and embedded applications, web-based tools, Radio Frequency Identification (RFID) devices, and so on.

Key Literature and Resources

General user interface design and evaluation is covered pedagogically by several texts such as Preece et al. (2007) [50] and Benyon et al. (2005) [60]. Bias and Mayhew’s (2005) [61] edited volume on cost-justifying usability provides excellent support for those working in the organizational context, and the monograph by Dumas and Redish (1999) [62] provides invaluable support for user testing. Articles cited in the sections above show such methods being used for health applications. Reid et al., (2005) [63] outline how systems engineering and human factors processes might result in better healthcare systems. Fi
nally, health-related journals that cover user interface design and evaluation for clinical information systems include Journal of the American Medical Informatics Association, International Journal of Medical Informatics, Journal of Biomedical Informatics, Methods of Information in Medicine, and Quality and Safety in Healthcare.

**Activity: Workflow and Task Analysis**

As Figure 1 shows, the system purpose and the CIS interface shape activity. To promote CIS adoption, it is important that its interface and other aspects of its design should support work processes involved in patient care. Work processes can be described and better understood via a family of human factors methods known as workflow analysis[64] and task analysis[65]. With respect to CIS, workflow analysis and task analysis are typically done for either of the following two reasons: 1) to support workflow engineering by introducing changes to how work is accomplished with an existing CIS; or 2) to guide the design of new CIS features or functions that may change workflow and automate tasks. These analyses may be either prescriptive, indicating how work should be done, or descriptive, describing how work is actually done. Workflow analysis generally provides a more global, abstract view of how work moves across various components of a system, such as organizations, committees, people, and equipment. It describes how work is accomplished at each key point in the process. For example, a workflow analysis of an emergency department may indicate that a triage nurse enters triage data in an EHR. In contrast, task analysis usually gives a more detailed description of how each task in a workflow is accomplished. A task analysis would describe the detailed sequence of steps that the nurse needs to take to enter the data into the system.

**Methods and Tools to Assess Workflow and Task Analysis**

A number of methods are typically used for workflow and task analysis. For existing work domains or products, descriptive analyses are often performed using methods such as observational (e.g., time-motion) studies, interviews, surveys, and focus groups [64, 65]. For new work domains or products workflow and task analyses require more analytical approaches, but they typically start by addressing the high level goals of the work process, assessing constraints or limitations associated with work processes, and identifying tools that are currently available or must be created to complete the work.

There are several challenges to workflow and task analysis. First, it is often difficult and time consuming to get an accurate characterization of complex sociotechnical systems, such as an intensive care unit (ICU) or Emergency Department (ED). Workflow in such systems tends to emerge from the decisions of each worker as they respond to the highly dynamic demands of the workplace [66]. As a result, no single worker or even manager is likely to know the precise workflow of the entire system, and he or she is rarely completely aware of their own workflow. Interviews with employees or managers often reveal an idealized workflow that is often modified dynamically to work around problems, such as understaffing, missing or damaged equipment, emergency situations, and so on. Observational studies can help reveal these "workarounds" so that they can be incorporated into a more accurate analysis of the work processes. Many difficulties with CISs are due to the fact that designers failed to understand the true workflow, and especially the workarounds, that employees use to get their work done [67]. When a computer-based system, such as an EHR or BCMA, fails to support processes involved in workarounds, patient care can be impeded or completely undermined [23].

Another problem with workflow and task analysis is that they do not separate the work that needs to be done from the specific technology and methods currently available to do the work. They merely describe or analyze how the work is currently being done. An existing workflow is dependent upon the technology that is currently in use to help do the work; if we want to design new and better technology that allows employees to do a better job, we need to understand the hard constraints of the work, independent of the current tools. Work domain analysis (understanding the functional structure of the work context) is one method for doing this [68]. Work domain analysis takes a functional view of the work domain by considering its purpose, operational priorities, domain functions, physical functions, and physical objects or configurations. For instance, the purpose of an ambulance and its crew is to stabilize the patient and transport him or her to an ED, and operational priorities are to do so quickly and safely. The objects in the work domain include the patient’s physical location, and the location and status of EDs. These are all important objects in this work domain, regardless of the technology available to help accomplish the primary goals of the domain. Work domain analyses can help us design new technology and workflow processes that allow employees to do their work more safely and efficiently.

A number of tools are available to help with the analyses mentioned above. The Unified Modeling Language (UML) is often used to express workflow diagrams [69]. GOMS (Goal, Operator, Method, Selection) and the Keystroke Level Model (KLM) provide somewhat formal languages for expressing task analyses [70]. Abstraction hierarchies [68] and work domain ontologies [71] are tools for capturing properties of a work domain. Although the use of these techniques is increasing in healthcare, much of the primary literature appears in the fields of human computer interaction (HCI), hu-
human factors engineering, cognitive engineering, and change management.

**Activity Example: Clinical Decision Making and Decision Support**

Clinical decision making is an example of a clinical activity, as shown in Figure 1. The field of human factors has an extensive research base involving theories of decision making and how such theories can be applied to CIS design. A person is faced with a decision making task when: 1) s/he must select an option from a number of alternatives; 2) there is some amount of information available with respect to each option; and 3) the choice is associated with some uncertainty [72]. The classic human information processing model describes decision making as spanning three stages: 1) cue reception and integration (e.g., recognition that a decision needs to be made); 2) hypothesis generation and selection; and 3) plan generation and action choice [73]. Decision making models include rational, or “normative”, models and descriptive models [72]. Normative models are based on mathematical or statistical models of costs and benefits and represent what the human “should” do assuming that all the input data is available and correct. Descriptive models, such as naturalistic decision making [74], better capture how humans actually make decisions in real-world, complex environments, such as many clinical care situations.

CISs that incorporate well-designed clinical decision support system (CDSS) tools can support cue reception and integration; hypothesis formulation; data analysis and interpretation of information. They can also remind clinicians that a decision must be made at the point-of-care during the clinical decision making process. Well-formatted data displays, embedded calculations, and/or graphical elements can aid the clinician’s attempts to understand a patient’s current physiologic situation. Likewise, computer algorithms can be developed that improve the clinician’s hypothesis formation process. For example, systems such as DxPlain [75], Isabel [76], Illiad [77], and Quick Medical Reference (QMR) [77] were developed specifically to help clinicians formulate a comprehensive differential diagnosis. Likewise, the LDS Hospital in Salt Lake City, UT has developed various applications to help clinicians perform complex data analysis tasks including Evans et al.’s antibiotic advisor [78] and Gardner et al.’s blood gas interpreter [79]. In addition, Sittig et al. created a program that could interpret a patient’s current physiological state and use that information to recommend appropriate ventilator settings [80].

All of the CDSS applications described above help clinicians perform better than unaided clinicians in real-world clinical settings. However, the vast majority of CDSS interventions in use today are relatively simple applications whose sole purposes are to double check clinicians’ work, alert them about potential mistakes, or let them know that they have forgotten to order a specific test or medication that the patient should be receiving. It has been demonstrated that these simple CDSS tools can improve the quality of care by reducing providers’ reliance on memory and by helping clinicians as they attempt to manipulate large, oftentimes conflicting, data sources. In other words, effective tools can support clinicians during their decision making processes.

**Key Problems with Decision Making and Decision Support**

Decision making, in all domains, is subject to several human biases in every stage of the process. There are several examples of biases: generation of a limited number of hypotheses due to working memory limitations; cognitive tunneling, where the individual remains stuck in an initial hypothesis; and confirmation bias, where an individual only seeks confirming information to evaluate a working hypothesis [81]. CDSS can help reduce human biases, improve clinician decision-making, and support adherence with evidence-based guidelines. Ultimately, decision support can improve quality of care[63, 82-85]. However, the use of decision support tools in CISs is quite variable [86-90]. Overall, the implementation of CISs and their integration into clinical workflow has been slow and has not reached its full potential [88, 91]. This missed opportunity has been caused by inconsistent and incomplete implementation strategies and a failure to use approaches, such as usability testing, to integrate decision support effectively into clinical workflow [85, 88, 92].
including human factors assessment such as usability testing); and 6) measuring results and refining the clinical decision support tool [93]. Each of these six steps can be accomplished much more effectively if one or more of the human factors theories, tools, and techniques are employed. For example, work domain analysis can be helpful in selecting and specifying CDSS interventions, while careful task analysis studies can be used to identify the best point within the workflow to implement the particular type of CDSS intervention. Measuring and refining the CDSS should include assessing intervention use and usability on an ongoing basis, evaluating the intervention impact on target objectives, and continually enhancing the value of the CDSS to clinicians and its impact on target objectives [93].

In summary, CDSS tools can improve the ability of clinicians to make the right decision, given the right data, at the right point in time, and the right interpretation of the clinical knowledge. In addition to helping CIS developers better understand the underlying decision making process, human factors approaches, such as usability tests and workflow analyses, can also be used as part of the CDSS implementation process and may aid CIS adoption.

**Theory: Distributed Cognition**

Figure 1 shows that analyses of user activity can be guided by theories of different kinds. Distributed cognition has recently emerged as a theoretical framework for conducting analyses of human work. Researchers using this approach consider cognition as a system that goes beyond individuals. It is a distributed system approach originally conceptualized by Hutchins and colleagues and later expanded by others [94-102]. It has previously been applied to the study of cognitive systems underlying task performance on naval vessels [96] and in the airplane cockpit [97]. Distributed cognition studies show how cognitive activity is distributed across internal human minds, external cognitive artifacts, and groups of people, and how it is distributed across space and time (see Fig. 2) [96-98, 100-107].

Distributed cognition researchers consider people's intelligent behavior to be a result of their interactions with external cognitive artifacts and with other people; people's activities in concrete situations are guided, constrained, and to some extent, determined by the physical, cultural, social, and historical contexts in which they are situated [94, 108]. The unit of analysis is a distributed cognitive system composed of a group of people interacting with external cognitive artifacts (e.g., cockpit of a commercial airplane or the emergency department in a hospital). In general terms, the components of a distributed cognitive system can be described as internal and external representations. Internal representations are the knowledge and structure in individuals’ minds; external representations are the knowledge and structure in the external environment [104].

The expression “distributed cognition” does not simply refer to distributed information. Rather, it refers to an architecture through which information is propagated and represented. Furthermore, distributed cognition researchers do not claim that artifacts are cognizing entities. The theory simply models both humans and their artifacts as representational systems. Therefore, distributed cognition is concerned with representations inside and outside the individual’s head - and the transformation these structures undergo [109]. The focus is on the representations both internal to the individual and those created and displayed by artifacts [100]. With this viewpoint, distributed cognition researchers can help answer the question, “What information is required to carry out some task and where should it be located, as an interface object [hardware or software] or as something that is mentally represented by the user?” [110]. This type of knowledge is essential for effective CIS design.

Recently, there have been a growing number of studies of healthcare systems from...
the distributed cognition perspective [108, 111, 112]. These studies adopted a systems perspective to study the behaviors of complex teams in healthcare settings, such as EDs and ICUs (see [113] for examples). The distributed cognition framework has helped describe, explain, and predict the patterns of healthcare providers’ interactions with patients, computer systems, medical devices, and other artifacts in dynamic and complex healthcare settings. New methods, such as RFID tracking and agent based modeling, are now being applied to collect more data about team behavior and test informatics interventions in EDs and ICUs [111, 114]. The preliminary results have shown that these new tools allow researchers to study distributed cognition in ways that were not possible in the past.

Measurement: Mental Workload and Situation Awareness

Finally, Figure 1 shows that evaluation is performed via measurement of performance or subjective experience. Mental workload and situation awareness are two fundamental human factors constructs that can inform the development of well-designed CISs. Mental workload is related to the difference between the amount of finite resources (i.e., attention or mental effort) available within a person and the amount of resources demanded by the tasks being performed [73]. If the tasks required by a clinical information system demand excessive attention or mental effort, clinical performance may deteriorate, and the risk of committing an error will increase. Workload refers to the demand that tasks impose on a person’s limited resources. Although situation awareness (SA) is correlated with workload [115], they are distinct constructs. Researchers talking of SA make no reference to task demand variables, but they consider non-attentional factors relevant, such as domain knowledge [115]. SA is the perception and comprehension of elements in the environment and the projection of their status in the future [116, 117]; it is a person’s internal representation of what is happening. SA drives the decision making process and is a causal factor in human error. There are several types of SA: geographical, spatial, temporal, system, and environmental.

Key Problems with Workload and Situation Awareness

CISs should be designed so that clinicians can use them during the most complex tasks, with reasonable mental workload, and while maintaining situation awareness. If mental processing demands exceed available resource capacity, performance degradation will begin to occur, which may lead to errors while using the clinical information system. SA is an important framework from which to draw when designing a clinical work environment, such as an EHR-enabled exam room. A properly designed work environment will present the necessary information at the appropriate time, without requiring the clinician to divert his or her attention away from the patient. As with excessive mental workload, a reduction in one or more types of SA may lead to a deterioration of clinical performance and result in human error. Workload and SA should be considered together during the development and evaluation of a clinical information system since they are intimately linked constructs. For example, designing more automated functions in a CIS may reduce the workload of a clinician. However, the same automated functions may also reduce the clinician’s SA unless appropriate feedback is designed into the human-computer interface to keep the clinician in the loop.

Methods and Tools to Assess Workload and Situation Awareness

Measures of mental workload are typically classified as performance measures, physiological measures, and subjective measures [73, 118]. Subjective measures have been perhaps most commonly used to assess workload of CISs. The NASA Task Load Index (TLX) is one of the most popular subjective workload assessment scales in human factors research [119]. The NASA TLX scale can be used to assess perceived workload across several dimensions (e.g., mental demand, effort, frustration). The scale has been validated as being sensitive to detect changes in perceived workload across varying levels of task difficulty [120]. It has been used in several domains to assess workload in complex environments, including for the evaluation of CISs, such as a pulmonary display [121] and computerized clinical reminders [122].

Evaluation of situation awareness in healthcare environments has been gaining popularity. For example, SA has recently been applied to healthcare research as a guide to a better understanding of diagnostic errors in medicine [123]. The Situation Awareness Global Assessment Technique (SAGAT) is perhaps the most widely used measure of SA, originally developed to measure pilot SA in aviation [124]. SAGAT provides an objective measure of SA using simulated scenarios that are halted at random times. SAGAT has been adapted for use in healthcare to assess practical trauma skills for medical training [125] and could be readily adapted for use in evaluating CISs in a simulated environment or usability laboratory [126].

Key Literature for Workload and Situation Awareness

Most of the literature on mental workload and SA is not indexed in Medline, because these human factors constructs were predominately developed and refined in psychology and engineering fields. Therefore, databases such as PsycINFO and Compendex® are relevant places to search for this key literature, where many of the references in this section were obtained from, in combination with Medline / Pubmed.
In addition, the Handbook of Human Factors and Ergonomics [127] gives a comprehensive overview of this topic, with the latest material and references.

**Summary**

Human factors research and methods should be routinely used to support the design of CISs prior to implementation and also throughout the implementation of these complex systems. Adopting human factors input early and iteratively into CIS development can improve user performance, usability, and CIS integration into clinical workflow. Human factors can also reduce costs by addressing important human-computer interaction considerations pre-implementation, where redesign costs are much less than those post-implementation.

In this paper, we outlined some current opportunities for better integration of human factors in the development of CIs, covering six key topic areas: informatics and patient safety; user interface design and evaluation; workflow and task analysis; clinical decision making and decision support; distributed cognition; and mental workload and situation awareness. An overarching theme of these six areas is to help CIS designers better understand human cognition, as well as interactional capabilities and limitations of clinicians involved in performing clinical tasks involving CISs.

With this human factors design framework, technology does not drive work processes; rather, technological tools are designed with appropriate input from individuals working in the clinical environment. We strongly believe that such a human factors approach can engage clinicians in CIS design, help designers better incorporate the cognitive demands of clinical work tasks, and ultimately help improve clinical work processes and patient safety. The overall goal of this work is to better align the clinical workflow facilitated by the CISs with the required patient care tasks to improve the safety and efficiency of the healthcare delivery system.

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