Operationalizing Sepsis Alert Design and Clinical Decision Support: Developing Enhanced Visual Display Models

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It is vital that health care providers have the tools needed for early diagnosis and treatment of sepsis to achieve improved survival outcomes. Despite advances in early warning system technology, providers still lack responsiveness in recognizing and treating septic patients. The recently introduced Centers for Medicare and Medicaid Services early management bundle for severe/septic shock highlights the need to promote bundles of care to improve guideline compliance and lower hospital mortality. Our objective is to determine the best way to provide a sepsis alert to drive compliance in the complex cognitive system that underlies the decision-making process in the dynamic and distributed health care work environment.

Alert and warning complexity is especially prevalent in health care information technology. Despite this issue, there is little consensus on how alerts and warnings should be generated and displayed to the user. Effective presentation of an alert, including how and what is displayed, may offer better cognitive support during busy patient encounters and may help providers extract information quickly. We are creating a framework to evaluate sepsis alert presentation models with enhanced visual elements integrating a textual, graphical, and figure display of the PIRO (predisposition, infection, response, organ dysfunction) classification. Our alert presentation framework is tailored to clinicians with the goal to better equip clinicians to understand their patients’ data through feature extraction and visualization embedded with different asynchronous alerts.

INTRODUCTION

A facility led initiative targets the development and evaluation of new technologies to trigger an electronic alert to providers at a point when appropriate clinical intervention can change the trajectory of a patient with a systemic infection. Alerts, a feature of electronic medical records (EMR), are increasingly recognized as valuable tools for providing clinical decision support (CDS), reducing adverse events, and improving patient safety. We propose to develop a framework to optimize EMR alert design to target sepsis, the most impactful disease process to our system. Our objective is to determine the best way to provide a sepsis alert to drive compliance in the complex cognitive system that underlies the decision-making process in the dynamic and distributed health care work environment. The planned approach includes addressing human factors issues inherent to implementation science along with the science of predictive analytics.

The health care environment represents a complex cognitive system based on the unpredictability of both patients’ clinical conditions and clinicians’ work patterns, the vast decision space and incomplete evidence that complicate clinical decision making, and the inherent unpredictability of the system as a whole (Kannampallil et al, 2011). CDS systems provide clinicians, staff, patients, and other key stakeholders with knowledge and person-specific information, intelligently filtered and presented at appropriate times, to enhance health and health care (Osheroff et al, 2006). The Institute of Medicine (IOM) has long recognized problems with health care quality in the U.S., and for more than a decade has advocated using health information technology, including electronic CDS, to improve quality (Dick et al, 1997; Chassin & Galvin, 1998; Kohn et al, 1999; IOM, 2011).

Effective presentation of an alert, including how and what is displayed, may offer better cognitive support during busy patient encounters and may help providers extract information quickly. Usability testing to assess the impact of enhanced visual display models is designed to understand more about the decision-making process based on provider response. Mistakes can be prevented by focusing on providers and studying how they interact with and as part of their clinical environments. Alert simulations orchestrated through our mobile usability lab will evaluate provider reactions, match human capabilities and limitations to the results, and proactively uncover hidden needs and unexpected interactions. Our methodology leverages expertise in the clinical aspects of sepsis, human factors, and industrial design, representing a unique usability testing approach supported by strong experimental design. The preliminary work discussed here includes the development of the enhanced visual display models.

BACKGROUND

Awareness of sepsis is low; many septic patients are under-diagnosed at an early stage when aggressive treatment could still reverse the course of the infection (Iwashyna et al, 2014). Treating septic patients early is the single most important element in their care. Early recognition and implementation of early goal directed therapy improves outcomes and decreases mortality (Ahrens & Tuggle, 2004). There is ample evidence that failure to initiate appropriate therapy correlates with increased morbidity and mortality (Dellinger et al, 2008). For every one-hour delay in treatment of severe sepsis or severe shock with antibiotics, there is an incremental decrease in patient survival. For example, a delay in antibiotics of five hours decreases survival to 50 percent (Kumar et al, 2006).
Diagnostic and therapeutic guidelines can significantly impact clinical care but timely and consistent implementation of these guidelines can be challenging and hospitals vary widely in their adherence to sepsis guidelines (Levy et al, 2010). Recently published data showed that protocolized sepsis care did not improve outcomes in patients as compared to individualized physician judgment (ProCESS Investigators, 2014). These findings show the importance of clinical attention to the septic population, demonstrating the importance of continual evaluation and intervention of patients and reinforce the absolute need for vigilance for early recognition and treatment of sepsis to ensure good outcomes. This research suggests that understanding and optimizing provider response through alert design is as important as the predictive tool itself.

National public reporting and pay-for-performance efforts, such as those implemented by CMS, have contributed to significant improvements for acute myocardial infarction, congestive heart failure, and pneumonia (Chassin et al, 2010; HCUPnet). By adding a specific focus on sepsis, CMS aims to achieve greater improvements in patient outcomes and advance the quality of hospital-based care. CMS has notified hospitals participating in the Inpatient Quality Reporting Program that data collection of the Severe Sepsis and Septic Shock: Management Bundle measure (NQF #0500) will begin with discharges on or after Oct. 1, 2015. CMS will attempt to regulate treatment by monitoring adherence to sepsis protocols that include recommendations for initial screening and resuscitation, hemodynamic support, and other supportive therapy for sepsis patients. The implementation of this effort will have significant impact on guideline dissemination and reimbursement.

There are a range of published alerts for sepsis, indicating various levels of Systemic Inflammatory Response Syndrome (SIRS) criteria and organ dysfunction. Mixed models, integrating organ failure assessment scores and general severity scores, have been published but have not gained widespread acceptance (Change et al, 1988; Timsit et al, 2001). Realizing that sepsis, like cancer, involves different disease etiologies that span a wide range of syndromes, the International Sepsis Definitions Conference proposed PIRO (Levy et al 2003; Howell et al, 2011). The PIRO (predisposition, infection, response, organ failure) classification system outlines a number of demographic, clinical, biological, and laboratory variables used to stratify patients with sepsis in categories with different outcomes, including mortality rates. The potential utility of the PIRO concept is the ability to predict not only adverse outcome but also the potential to respond to therapy as it incorporates assessment of pre-morbid baseline susceptibility (predisposition), the specific disorder responsible for illness (infection), the response of the host to infection, and the resulting degree of organ dysfunction. The definition of sepsis is evolving as we develop better methods of understanding the condition. However, it is rudimentary; extensive testing and further refinement are necessary before it can be considered ready for clinical practice (Vincent, 1997; Marshall, 2000).

The research team has developed three enhanced visual display models using human factors principles that integrate the PIRO classification system.

Currently, clinicians must rely on clues to sepsis progression in the patient’s medical history, vital signs, hemodynamic monitoring, lactate levels, and indications of organ dysfunction – all in the context of infection- to identify patients who have sepsis. There is mounting proof that evidence-based interventions decrease sepsis-related mortality through early diagnosis and initiation of evidence-based protocols for critically ill patients. Clinical trigger tools aim to identify and provide instruction to intervene before a patient deteriorates. Sepsis early alert systems have demonstrated increased compliance with sepsis resuscitation and management bundle elements (LaRosa et al, 2012). Early warning systems are multidimensional, complex, and require in-depth and interdisciplinary approaches to understand their impact. The interaction of poorly design technologies, organizational constraints, and functional capability has the risk of multiplying latent risks in health care technologies. This research represents a novel way to design and test alert systems that best support health care providers’ cognitive work.

**METHODS**

Traditionally, alerts are those components of a system that serve to direct a user’s attention to information related to some parameter which has been exceeded (Pritchett et al, 2002). Newer alerts, however, have advanced to the point of becoming a “type of automation that supplements the human powers of observation and decision”. Therefore, alerts are essential operating aids in health care, enabling providers to be kept aware of changes in the status of a patient and may indicated that intervention is necessary. Providers need help to detect, interpret and understand important operational information since they are not fully observant all the time, they are not omniscient, and they can make mistakes. How timely and effective providers actions are depends upon the nature of the alarm information displayed. Many different disciplines and research communities are concerned with questions of the design and effectiveness of visual displays. Alert and warning complexity is especially prevalent in health care information technology. Despite this issue, there is little consensus on how alerts and warning should be generated and displayed to the user (Phansalkar et al, 2010).

**Design Considerations**

The efficiency of alert design and provider response depends on several guidelines on design, implementation, and reengineering. These guidelines help providers to take the correct action at the correct time in response to recognition of the patient’s condition. Hollifield (2006) proposed the following guidelines for alert development: alarms are properly chosen and implemented; alerts are relevant, clear, and easy to understand; operators can rapidly assess the relative importance of alerts; operators can process alert
information during high frequency events; priority determination; and alert management enhances the operator’s ability to make a judgment based on experience and skill.

Easterby (1984) suggests seven psychological processes used by the human operator that should be considered in design of displays. He suggests that these processes determine the limits of the display formats. These have been adapted to consider the implications for the design of visual alarm displays, as illustrated in Table 1. In this way it should be possible to design alarm systems that are driven by human factors rather than technical capabilities. Stanton and Stammer (1998) give importance on prioritization and organization of alerts, which have impact on early detection of critical alerts.

Table 1. Psychological processes and implications for design of visual alarms (Stanton and Stammers, 1998).

<table>
<thead>
<tr>
<th>Psychological process</th>
<th>Implications for design of visual displays</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detection</td>
<td>Determining the presence of an alarm</td>
</tr>
<tr>
<td>Discrimination</td>
<td>Defining the differences between one alarm and another</td>
</tr>
<tr>
<td>Identification</td>
<td>Attributing a name of meaning to an alarm</td>
</tr>
<tr>
<td>Classification</td>
<td>Grouping the alarms with a similar purpose of function</td>
</tr>
<tr>
<td>Recognition</td>
<td>Knowing what an alarm purports to mean</td>
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<tr>
<td>Scaling</td>
<td>Assigning values to alarms</td>
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<tr>
<td>Ordering and Sequencing</td>
<td>Determining the relative order and priority of alarms</td>
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From Table 1 we consider aspects of display design in relation to taxonomy of psychological process of the provider. This serves to illustrate the different nature of the three types of enhanced visual display models.

Enhanced Visual Display Model Development

Research demonstrates that medical displays are often incompatible with practitioners’ workflow and unnecessarily fragment patient information (Ash et al, 2004). Information is often spread across multiple tabs and locations that require piecemeal information search and acquisition. This may confound practitioners’ ability to detect evolving changes, make it more difficult to attain a holistic view of a patient’s state, lead to care inefficiencies, and frustrate clinicians. Conversely, many alerts place the emphasis on detection of a single event, rather than on considering the implications of the alarm considering the patient condition as a whole (Stanton, 1993).

Implementation of computerized alert systems has been shown to enhance patient care and prevent adverse events (Bates et al, 1999; Kawamoto et al, 2005). The purpose of an alarm is to prompt an operator action, but poor alarm system design has been a contributing cause of upset severity in numerous health care systems worldwide. Additional displays that present together data that are considered for a particular decision reduce the reliance on human memory when needing to access separate tabs or screens (Koch et al, 2012). The appeal of access to a large amount of clinical data must be balanced against the real possibility of information overload. Our work focuses on improving the process of information display, reducing load on the working memory of the provider and improving usual care of fragmented, non-directed information gathering.

The various presentation models developed for this research seek to optimize provider recognition and identification of a septic patient. The alert system must provide useful information and functionality to support the providers’ tasks. Alerts should be integrated in process displays (EEMUA, 1999). Combining relevant process and alert information in the displays helps reduce the mental workload on providers. Attentional systematic and integrated approaches are required to select relevant information from among the vast display of information competing for visual processing. We began with an analysis phase that sought to identify the user-centered requirements for the design of the visual presentation models. The starting point for the analysis was the clinical care as it is performed today, with existing clinical practices and procedures (baseline). A number of human factors design guidelines and standards were used to streamline the process of developing alternative presentation models. Information must be presented and handled in a way that is compatible with human capabilities and limitations, so that the system remains usable for the providers in all situations.

Baseline: Medical chart review. The baseline presentation represents the usual care of fragmented, non-directed information gathering (Figure 1). As providers will be using their EMR system as normal, they will have access to all aspects of the patient record in order to identify information crucial to decision-making. There will be no alert or explicit CDS presented in this model. Interpretation in the usual care model can be difficult. Providers have to first identify which values are linked and then determine the meaning behind the sequence, linking information embedded in other information.
Model A: Enhanced text display. Model A integrates the alert into the text presentation of patient data. The use of alpha numeric and text has been the traditional way of representing alarm list to operators (Errington et al, 2006). The text display provides a list of important vitals and laboratory results for the patient, displaying information in ‘parallel’ rather than a ‘serial’ manner. Values are displayed in a set order with no prioritization to severity or urgency. The model is consistent with alarm design principles suggesting that the priority of alarms should be coded using colors (to properly and consistently facilitate the interpretation of the diagnostic information available from the alerts) (EEMUA, 1999). Color is said to be one of the most effective visual attributes for coding information in displays and is capable, when used correctly, of achieve powerful and memorable effects (MacDonald, 1999). This is to ensure that different priorities are visually separated in a way that makes it very quick and easy to spot the most important alert message. Symbols, location of information, font type, and blink frequency are among the available means for additional information coding. An alert will trigger to the provider as they use the EMR that indicates patient characteristics in text form including a summary of important vitals with color indicating values within range, and PIRO score and PIRO score associated mortality.

Figure 2. Model A: Enhanced text display.

Model B: Graphical display. Model B presents the same information to the provider as Model A, but uses a graphical display to illustrate each PIRO component by letter (similar to an annunciator panel), associated score illustrated graphically, and PIRO score associated mortality. While PIRO score is an important indicator, the score itself may not indicate individual components. The graphical display exposes providers to a meaningful presentation of data using discrimination, identification, classification, recognition, and sequencing properties. Over time, the provider may come to associate certain patterns of lit annunciators with certain prognoses or treatment as spatial information is presented within a panel of tiles according to PIRO letter. Thus frequent and familiar patient conditions are likely to be readily recognizable. However, the display may not be conductive to aiding the provider in discovery of infrequent and novel failures, due to the way in which the information is embedded.

The main benefits of presenting alarms using the visual channel are that they do not impose loads on operator memory. The presence of alarms within a visual display also offers consistency with display of general status information, which is generally presented visually. If the alert information is considered by the provider in conjunction with status information, one might postulate that from an information processing viewpoint it might be desirable to present all the information in the same format. This, one might hypothesize, would lead to the most efficient processing of information.

Figure 3. Model B: Enhanced graphic display.

Model C: Figure display. Expansion of the graphical display is a figure display illustrating individual components of PIRO, indicating which items added points to the total score and PIRO score associated mortality. The figure display represents characteristics of a patient with information overlaid. This model incorporates discrimination, identification, classification, recognition, ordering and sequencing, and scaling, assigning values to each PIRO category. This model addresses Woods (1983) suggestion that the relationship between displays and the big picture be made clear to preserve ‘visual momentum’ as providers make transitions between displays and extract patient information.

Figure 4. Model C: Enhanced figure display.
Enhanced Visual Displays with CDS

Meaningful Use, as defined by the Office of the National Coordinator for Health Information Technology, requires the implementation of at least one CDS rule in addition to prescription alerts (alerts that warn physicians of potential drug events such as interactions with other medications). The goal of CDS is to help physicians properly diagnose patients and identify gaps in care, prompting physicians to ask the right questions or run appropriate tests to prevent errors and improve patient outcomes. Human factors is concerned with reducing the probability that a human will make an error in the support of a system; and with the degree to which an individual is able to accomplish a task under specific conditions to meet a specified standard.

While the enhanced visual display models offer clinical decision support by synthesizing information, the models do not direct the provider to specific actions of care. We hypothesize that guided CDS delivered using information systems, with the EMR as the platform, will provide decision makers with tools making it possible to achieve large gains in performance, narrow gaps between knowledge and practice, and improve safety (Bates et al, 2001; Middletown et al, 1997). Exposing providers to CDS guiding diagnostic and therapeutic interventions could improve performance of key sepsis-related actions more often compared with the (control) enhanced visual display of a risk stratification score for sepsis and result in higher usability ranking compared with using the (control) enhanced visual display of a risk stratification score for sepsis.

If there is an incompatibility between the information display and the task the provider is required to perform, one might predict that this will lead to poorer performance, e.g. slower reaction times and greater errors. A second set of models addresses the suggestion that providing the health care team specific actions and guiding the treatment may be more important that the presentation of information. These models include the addition of guided CDS based on PIRO score and the CMS early management bundle for severe sepsis/septic shock.

RESULTS

Next Steps: Usability Testing

In health care systems, information display can influence providers’ ability to detect potentially critical changes in the patients’ condition. Medical displays are often incompatible with providers’ workflow and may present the patient information suboptimally (Ash et al, 2004). Kim et al. used repeated measures analysis to evaluate the impact of pilot- and display-related input factors, e.g., pilot experience level, display configuration, and flight task workload level. They found that both extremes of information presentation (i.e., high and low clutter) had negative effects on workload and performance measures (Kim et al, 2011). Anders et al. used similar methods to evaluate an integrated graphical information display (IGID) compared to a conventional tabular display with the goal of better supporting ICU nurses’ ability to synthesize information about patients’ clinical conditions (Andres et al, 2012). Their results showed that ICU nurses’ performance was better using the IGID compared to tabular display. In order to provide a basis for comparison between the enhanced display models, the research time will conduct usability testing using clinical scenarios that communicate the same patient condition. Alert simulations will evaluate provider reactions, match human capabilities and limitations to the results, and proactively uncover hidden needs and unexpected interactions. The definition of usability is sometimes reduced to “easy to use” but this over-simplifies the problem and provides little guidance for the user interface design. A more precise definition can be used to understand user requirements, formulate usability goals, and decide on the best techniques for usability evaluations.

Usability is measured relative to user’s performance on a given set of tasks as measured by (i) performance-related measures: success rate (correctness of alert interpretation, appropriate response regarding therapeutics, diagnostics, disposition, and diagnosis); and (ii) preference-related measures: participants’ subjective satisfaction and cognitive load. Although antibiotics and source control have proven beneficial for treating sepsis, virtually all attempts using targeted therapies for sepsis have failed and treatment remains mainly supportive in nature. Therefore, the main outcome of interest is therapeutic measures. Additional metrics will evaluate if the alert provides enough information for the participant to follow an optimal navigation path by evaluating their actions post alert using screen recording (e.g., user’s PC activities including key strokes, mouse clicks). Performance- and preference-related measures are captured through provider feedback and action during the usability test and a post-study usability evaluation survey.

Next Steps: Developing the Framework

Research has typically focused on how to get users to attend to warnings, but in this case, more research needs to be performed to determine best methods for getting users to respond. Early warning system products may be technically excellent, but if there is a problem with how they are used or applied, their effectiveness will be impaired. Guideline recommendations cannot direct outcome improvement if they are not translated into clinical practice. Until we have better understanding of how to support provider activities, and what information is optimum under particular circumstances, we cannot offer the designer sensible advice of how to present the visual alert information. Decision support systems need to be accepted by the workforce and properly integrated into the clinical environment to ensure that they are used effectively.

Effective presentation of the alert, including how and what is displayed, may help providers extract information quickly, offering better cognitive support during busy patient encounters. The following factors may be more relevant to the clinician user or those assisting with implementation: (1) the
primary need or problem and the target area of care for which the CDS is being considered (e.g., improve overall efficiency, identify disease early, aid in accurate diagnosis or protocol-based treatment, or prevent dangerous adverse events affecting the patient); (2) to whom and how the information from the CDS will be delivered; and (3) how much control the user will have in accessing and responding to the information. Key questions in designing or selecting CDS systems are whose decisions are being supported, what information is presented, when it is presented, and how it is presented to the user.

As more research is performed on health care alert usability and design, it is expected that the alerts will evolve to better facilitate providers’ decision in an efficient and effective manner by giving them proactive indicators and allowing them to direct patient care using information as needed. Further user-centered design development and testing of these applications should be undertaken to further establish their effect on provider action in health care settings.

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