Domain Specific User Centered Design for HCMDSS

Position Paper for HCMDSS 2005

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User Centered Design in Medical Practice

Research evidence suggests that the "*frequency and consequence of hazards* {potential sources of harm} *resulting from medical device use may far exceed those arising from device failures*" [6]. This in turn suggests that user centered design techniques have yet to have a significant impact on medical device design. Indeed, surveys have revealed that medical device manufacturers give variable attention to usability issues in device design [2].

In addition, modern medical practice continues to experience exponential increases in the already enormous amount of requisite knowledge clinicians must absorb and utilize [12]. Adding to this knowledge mastery burden are medical devices that have become increasingly sophisticated and rely on state-of-the-art and often fragile science and engineering. This trend decreases the probability that clinicians will understand the inner workings and essential mental models underlying the technologies used in complex medical devices.

Position

Our overall position is that the goals of HCMDSS cannot be achieved without significant input from usability research. In particular, *the usability of medical devices must be considered throughout the entire product lifecycle, from inception to deployment, maintenance, and use*. This assertion is supported by the medical community. AAMI [1] and FDA [6] sources cite evidence that medical device users consider usability to be amongst the most important considerations. Good usability design reduces cognitive overhead in already saturated intellectual settings while supporting the avoidance of errors. This in turn leads to improved efficacy and safety that enhances the prospects for satisfactory patient outcomes.

Our position is that a multi-dimensional approach of investigating techniques and methodologies spanning the design and development lifecycle for HCMDSS is needed. In addition, *the rapid pace of medical and device technology advances demands an approach that continually evolves to meet the emerging needs, trends, and empirical evidence on medical devices and patient outcomes*. We advocate investigating approaches that capture context-specific repositories that are continuously updated by software instrumentation and empirically-based evaluations throughout the development lifecycle.

This position paper is relevant for the *Medical Practice-Driven Models and Requirements, High-Confidence Medical Device Software Development & Assurance,* and *Foundations for Integration of Medical Device Systems/Model* topics for the workshop.

User-Centered Design Challenges for HCMDSS

Although research has been performed on *iatrogenic* (caused by a doctor or other caregiver) injuries, currently there is little research investigating incidences of medical errors involving

poor device design [11]. However, any study based on patient harm will vastly underestimate the systemic consequences and costs of poor interface design. In addition to patient injury, poor design causes other maladies, such as decreases in treatment efficiency and effectiveness, excessive training or maintenance costs, stress and confusion for users, and other attending complications [11]. Challenges for overcoming these issues for HCMDSS include:

Usability Impact for HCMDSS. While studies have shown that, for example, the average software program has 40 design flaws that result in lost productivity costing up to 720% [7], little work has been done to date on the impact of medical device design. Studies and data collection methods are needed to better understand the impact and costs associated with poor and suboptimal device design.

Capture and Dissemination of Usability Guidelines. A wealth of literature exists on design principles for medical devices [10]. But this knowledge is often rendered relatively useless without any information attaching principles/guidelines to usability contexts. In addition, many of these guidelines are not frequently updated [1, 6, 10]. Given the fast pace of technological change, more dynamic methods are needed that captures and disseminates emerging knowledge.

Adapting User-Centered Design Methods to HCMDSS. Adhering to even the best of usability guidelines and principles is not sufficient to guarantee appropriate device design. Diverse usability settings dictate that designers must work closely with users to match device design with specific practices and conditions of use. User centered design methods have been created for design stages including requirements and inception, summative evaluation, end-user support, and post release instrumentation and maintenance. What is missing is a means to *unify* these findings to better understand usability phenomena. In addition, existing user-centered techniques are not designed to address issues stemming from complex interacting systems (systems of systems) comprising users, devices and usage environments. Methods that integrate these concerns into a holistic approach to HCMDSS are needed.

Diverse Contexts of Use. In part, user interface design is difficult because the interface is influenced by many situational variables. These include environmental context (offices visits, surgery, emergency room, etc.), user populations (Doctors, nurse practitioners, nurses, anesthesiologists, etc.), devices (internal, monitoring, analysis, etc.), interface type (device controls, screens, handhelds, etc.), interaction type (selection sequences, parameterization, programming, etc.) just to name a few. Design methods must therefore possess the flexibility to accommodate the highly diverse and situation-dependent nature of interface design.

End-user Programming. In HCMDSS, interface diversity needs are a direct reflection of the diversity of individuals and their medical conditions. Medical devices are therefore designed with varying levels of end-user customizations, from parameter setup to tailoring environments involving forms of end-user programming that individualize therapies carried out by medical devices. As these devices become more flexible, the potential for error increases. HCMDSS interfaces must therefore be designed to minimize and avoid life threatening errors and parameter setting combinations by, for example, detecting anomalies or outliers in parameters or making sure programming directives do not break parameter invariants [9].

Technology Research Needs

Many of these techniques are well known and have been investigated in various user interface contexts. But the context of HCMDSS is unique in many respects and brings a degree of safety

and dependability concerns that have not been adequately researched to date. Empirical investigations are needed to better understand these specialized needs.

In general, there is no lack of information on user-centered design, interface design guidelines, HCI principles, and etc. What is missing are concerted efforts at unifying this information and capturing the "applicability conditions" for when particular usability concepts should be applied to address specific usability requirements. Such mappings would be an invaluable tool for both usability engineers and end users, particularly when coupled with methodologies and process technologies that disseminate this information throughout the lifecycle.

Because context is vitally important to the development of high confidence user interfaces, collecting and analyzing field data is crucial. Research is needed on technologies that capture data not only from laboratory studies, surveys, and interview techniques, but also from the field on operational software. Software instrumentation and profiling techniques [3], for example, could be applied to capture errant interaction sequences and information about how parameters are applied by user populations. Utilizing this information to improve understandings of usability issues for HCMDSS closes a knowledge improvement feedback loop where 1) designers and users draw on knowledge bases to perform their activities, 2) feedback is provided during these activities for knowledge enhancement [4], and 3) operational profiling is utilized to provide empirically-based knowledge improvements.

In the best of scenarios, this information would be shared by vendors and users through distributed ontologies capable of providing a medium not only for data sharing, but also intelligent analysis of data and usability knowledge. Utilization of Semantic Web technologies [8] is a promising approach needing further investigation as a medium for intelligent dissemination and enhancement of usability knowledge [5].

Roadmap

Addressing these challenges for HCMDSS involves a number of interrelated activities:

1) Years 1-2: Study usability issues for HCMDSS with an emphasis towards investigating the role of poor interface design in medical incidents involving medical device software, drawing on current studies from FDA and other institutions. Further studies may be needed to pinpoint the role of software defects in these incidents, and help answer questions on the type and frequency of problems caused by medical device software.
2) Years 2-3: Update current best practices and encode them in ontological forms that are specifically designed for HCMDSS contexts. This information would be packaged for dissemination to usability engineers and end users in their contexts of use.
3) Years 3-5: Build tailorable design methodologies that package empirically-based information on best practices into intelligent support systems that disseminate best practices for effective interface design.
4) Years 4-5: Based on empirical data, develop tools and techniques for helping end users (doctors, lab technicians, nurses, etc.) program or set parameters to devices in a high confidence manner.
5) Years 4-5: Instrumenting devices to capture user interface errors and/or parameters that are analyzed and integrated into the best practice ontologies.

Biographical Statement

Scott Henninger is an Associate Professor in the Department of Computer Science and Engineering (CSE) at the University of Nebraska at Lincoln (UNL) with expertise in software development environments, usability engineering, and usability design patterns. Sebastian Elbaum is an Associate Professor in CSE at UNL with expertise in end-user programming support for dependability, system profiling for behavioral testing, and empirical studies of software testing techniques. Gregg Rothermel is Professor and Jenson Chair of Software Engineering in CSE at UNL and is a recognized expert in software regression testing, empirical studies and end-user software engineering

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