3 Key Steps to Successfully Integrate Human Factors and Usability into Medical Device Design

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With the Food & Drug Administration’s (FDA) increased scrutiny on device usability, being able to understand and demonstrate the importance of human factors and intuitive use in device design has become a critical work tool. This paper shares best practice strategies of how to design and engineer innovative medical devices that successfully incorporate the needs of multiple users and influencers, complex, existing workflows and the challenges of their sensory and physically demanding use environments.
Introduction

The terms “usability” and “human factors engineering” have recently gained much attention in the medical device design community but the principles behind them are historically established and proven for good device development. Since October 2009 when the Association for the Advancement of Medical Instrumentation (AAMI) published its recommendation for human factors standard HE 75, [1, 2] the FDA has expected medical device manufacturers to identify, understand, assess and mitigate use error in the design of new products and, perhaps most importantly, document their risk management efforts throughout the development process.

The authors here believe that it is becoming increasingly important to demystify the process of understanding and incorporating the user’s perspective and context into medical device design and to share best practices in order to raise industry standards.

Definitions

For newcomers to this topic, the term “usability” refers to the process of understanding how a product will be used to achieve a desired task. Usability assessments seek to answer questions like: How difficult is it to use the product? How much time does it take to complete a task with the device? Does the product accommodate the user’s abilities and needs? How much re-learning is needed when there are gaps in use? How often are errors made during use? How serious are those errors? What can be done to reduce or eliminate user error? Is the product enjoyable or frustrating to use?

Intrinsically embedded in a robust usability process, human factors is explained by the International Ergonomics Association as “the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data, and other methods to design in order to optimize human well-being and overall system performance.” Simply put, it involves the study of how humans interact with the world around them, with a goal of improving performance, safety and adoption through improving the use experience.

Deploying principles from the sciences of psychology, engineering, industrial design, statistics, operations research and anthropometrics, human factors examines physical, cognitive, and social human abilities of the various user and stakeholder groups, their demographics, lines of communication and hierarchy, workload, fatigue and situational awareness. An evaluation of the use environment scrutinizes complicating cognitive factors such as physical dimensions, noise pollution, air temperature, lighting, material choices and electrical power availability. The functional series of tasks that revolve around preparing, operating and concluding the use of a device are also interrogated and deconstructed.
Brief History

Ergonomics, Human Factors and Usability Engineering (terms that are often used today interchangeably) have only recently become part of the cultural vernacular. The term “ergonomics” was first coined as a result of the work that psychologists and physiologists conducted to design and build safer World War II aircrafts. The practice was developed further by pioneers like Elias Porter, Ph.D. and others within the RAND Corporation. “As the thinking progressed, a new concept developed—that it was possible to view an organization such as an air-defense, man-machine system as a single organism and that it was possible to study the behavior of such an organism. It was the climate for a breakthrough.”[3]

The human factors/ergonomics profession has since grown, and now includes more modern-day applications, including device-specific usability and graphical user interaction (GUI) usability—both of which can be applied to the design of medical devices and technologies. The focused and deliberate use of these practices can lead directly to products that perform their function better, are safer, and ultimately improve people’s lives—including both practitioner and patient.
The Value of Usability

As the government body responsible for regulating medical devices, the FDA asserts that the responsibility of use error falls not on the user, but on device manufacturers. Instead of looking critically at the user as the cause of error, usability activities are advised to scrutinize device design for potential safety issues, focusing on how the product performs and how easy the device is to use repeatedly over time. Safety and efficacy are key device design criteria for the FDA because statistics reveal that medical error is reported to be the fifth leading cause of death in the United States (exceeding auto accidents, breast cancer and AIDS) and 44% of medical device recalls are attributed to preventable design problems. [4]

A device manufacturer today must be able to show the application of usability principles and human factors in its development process or otherwise face the prospect of having its regulatory submissions summarily rejected and launch plans stalled. It is worth noting that the AAMI guidelines apply to all new medical devices not just those with software screen interfaces or complex, high-risk protocols.

Applying the discipline of human factors alongside the deployment of a usability process not only promises a streamlined FDA application but also can address the diverse and changing needs of users groups. The evolving dynamics of the U.S. population across multiple demographic attributes presents a significant need for more thorough user evaluation. When new census data reports that for the first time in the nation’s history more than half of children under the age of 2 are of ethnic minority, [5] it can no longer be assumed that a future patient’s first language is English. With an aging clinician workforce—more than 41% of today’s registered nurses are now over 50 [6]—it is clear that healthcare professionals can no longer be expected to have the same physical capabilities as they had 10 years ago. With a 30% prevalence of 3 or more co-morbidities among the growing elderly population [7] the complexity of healthcare diagnosis and treatment becomes significantly more multi-faceted. The implications of statistics like these suggest that the diversity of users, their conditions and their cultural references make medical device development more challenging—a simple, common design solution that addresses multiple user needs is no longer as evident.

To further confound matters, use environments are also shifting. Many medical products that were initially approved for use by health professionals in high-touch clinical settings have evolved to be used in ambulatory settings. With the advancement of healthcare technologies and downward pressure on costs, more recovery time is being deferred to the home as patients get discharged sooner and are expected to undertake their own care, using products with minimal, if any, professional training.

In short, now more than ever, the usability process has value for device manufacturers. It can help define, minimize and mitigate development risk, improve product safety, build customer trust and user satisfaction, differentiate a product in its competitive market and ensure that the design of the device has sufficiently considered evolving macro trends.
Step 1: Understanding User Needs

To begin the usability process, the first step is to define the needs of use. With any medical device this involves understanding who will use it and where it will be used, across a continuum of users within a wide variety of use environments. All key user groups should be considered from clinicians to support staff, patient and caregiving members. All use environments should be evaluated, including secondary locations such as equipment utility storage rooms, biomedical work benches and different patient care spaces, as relevant. For example, a device that sits at the end of a patient’s bed can be easily crushed against a wall by a transporter when a patient is being moved to the MRI lab or can as easily become a playtoy for a visiting and curious child of the family. Below, Figure 1 illustrates as reference the myriad of factors that may need to be examined in this initial stage of needs gathering.

A wide range of research activities can be deployed in this initial exploratory phase to build foundational knowledge, from focus groups to team interviews, surveys, competitive research and ergonomic assessments. The authors’ preferred primary research methodology is a combination of in-depth user inquiry and in-field or simulated contextual observation. These two partnered approaches consistently generate an initial substantive bank of both articulated and latent needs, like no other. While focus groups do offer cost efficiencies by speaking to multiple users at once, the social dynamics and hierarchies of clinical seniority and experience can lead to misleading group consensus, biased feedback and less substantive understanding.

Armed with a loose questionnaire protocol, appropriate stimulus materials, an audio recorder and digital camera or video recorder, the hallmarks of an accomplished exploratory research team (whether that is ethnographers, industrial designers, human factors engineers or, ideally, a combination of multiple disciplines) lie in their ability to draw insights from intently listening to and acutely observing user frustrations, workarounds and as well as the limitations of predicate and competitor devices.
Step 2: Refinement & Iteration

During the analysis of the collected data, similar user needs are clustered and categorized. The detailed steps of use should be deconstructed and documented in task workflow mapping exercises (such as depicted in Figure 2) which will later become a framework for risk analysis. Working hypotheses, knowledge gaps and information conflicts are also exposed in this period, and typically debated within the project team.

Follow up round(s) of user research then should be conducted to refine and prioritize needs, quantify opportunity segments, resolve remaining ambiguities and inconsistencies and examine areas of potential use error. Industrial design concepting and rapid prototyping is optimally engaged at this stage initially as strawman stimulus but then quickly evolving to functional appearance models to uncover deeper usability insights and elicit feedback. The earlier that product samples can be introduced into the usability engineering process, the more effective learning will be since users are always able to better conceptualize likely use scenarios with three dimensional forms in their hands. Knowledge is further deepened when research is conducted in actual or simulated use environments, sparking more focused feedback and revealing more subtle risk and safety considerations. As Figure 3 indicates, interrogation at this stage includes graphic user interface templates and their controls, physical ergonomics, instructions for use and training plans. Individual studies of device components can be conducted to keep progress moving, despite the fact that the product may not yet be a holistic system. Each of these studies can be considered an exploratory study in the usability process and it is important that the findings be documented appropriately.
Step 2: Refinement & Iteration (Continued)

At the very crux of this investigation period is an ongoing, collaborative cross-pollination between the multiple disciplines of the project team. The field researchers and analysts must collaborate closely with industrial design and engineering. A shared project war-room space that encourages the posting of key themes, user experiences, industrial design concepts and engineering work ensures full and open information exchange as ideas quickly evolve and feature trade-offs are deliberated.

In parallel to the creative development process, the risk management process should also be underway. User needs have to be formulated into design inputs and product specification requirements. The task workflow map evolves into a reference tool for use and design failure modes and effects analysis (UFMEA and DFMEA) and risk hazard analysis. All risk management documentation is ideally drafted collaboratively between research, design and engineering and becomes the Design History File (DHF). The development and refinement of these risk management files is a critical component in the usability process. This foundation ultimately helps guide the prioritization of user tasks for summative validation as well as acceptance criteria and mitigation strategies.
Step 3: Verification & Validation

By the time the product development process has entered into Verification and Validation mode, a solid knowledge base has been gathered and a refined device design has been agreed upon. The team now shifts its focus to evaluate industrial design and engineering work to determine how well the operational and functional product features achieve benchmark goals and meet user needs. Usability research also shifts to measurement techniques that focus on high risk tasks, to evaluate user comprehension, ergonomic ease, dependence on Instructions For Use (IFUs), task completion, error frequency and close calls, successful timed tasks evaluation as well as subjective performance rankings.

The usability work typically culminates in a validation study (or series of studies) that tests a fully functional ‘looks-like, works-like’ model of the device in the approximate simulated use environments, replicating workflow distractions and delays between training and actual use. At least 15 participants from each distinct user group are pre-recruited to provide a sufficiently reliable sample; studies of this type are most often conducted in a solo interview format to avoid bias of one user’s responses influencing another. User input is gathered from close-ended interview questions and the data is tabulated for comparison against benchmark metrics. Particular emphasis at this stage is on potential error frequency and root cause analysis.

*Fig 4: Validation studies are conducted in medical simulation centers to mimic a real-life environment*
Cross Phase Usability Documentation

With the collected mass of data from exploratory user need identification, exploratory and validation studies as well as the risk management documentation, there is most likely a sizeable and potentially unwieldy paper trail now in existence. A big-picture perspective of the product history becomes helpful for new project team members or FDA inspectors. Figure 5 demonstrates how data accumulates through the development process, highlighting the value of managing all the documentation under one central source.

In our experience, when a single document, called the Cross Phase Usability Assessment, is constructed to summarize key knowledge and decision points on the project continuum citing the relevant supporting references, as needed, the usability process becomes more manageable. The user population and use environment parameters are outlined. Top line summaries of the identified use problems, hazard analyses and exploratory and validation study conclusions are reported. Prioritization and balancing of user needs and feature tradeoffs are also noted.
Case Study Example

In a corporate acquisition in 2002, Boston Scientific inherited a first-generation thermal ablation device, the HTA® System, which treats excessive uterine bleeding in premenopausal women. The underlying technology was sound but the device had a complex, unintuitive design. The original scope of work called for “a beautiful user experience” and improved design quality. What ensued was a collaborative research and development team effort between human factors industrial designers, mechanical and electrical engineers, regulatory experts and clinical advisors. Initial exploratory work revealed a variety of unmet user needs including a graphic user interface (GUI) that involved excessive steps to set up and use, functionality that required multiple component connections, continual visual monitoring and excessive mental and physical burden. Extensive training was needed to use the device and long gaps between physicians’ use of the device often required retraining. System components were heavy, bulky and awkward; angles and crevices made cleaning burdensome.

The project team set about a ground-up redesign. Human factors, design for manufacture and quality disciplines worked in concert with engineers and industrial designers. In a two-year iterative design process, a series of progressively refined prototypes were generated starting with concept sketches and evolving to production representative units. The product hardware was rescaled to a smaller footprint and the lighter weight made the device easy to maneuver in the use-environment. The GUI was deconstructed and rebuilt with clinician input to provide a more cognitively logical set-up with visually simpler navigation and reduced steps. The control panel during procedural use was re-aligned to focus on critical safety information to minimize physician distraction. A new disposable, cartridge component was engineered that further automated connection steps and improved reliability and accuracy. Less training was needed overall, cleaning time was dramatically reduced and risk factors were clearly mitigated. (See Figure 6).

The Ximedica team conducted the design verification, life-cycle testing and established the risk scores as part of the Design History File (DHF) while Boston Scientific completed the validation testing. Boston Scientific branded the device as the Genesys HTA™ System, collaboratively prepared the regulatory package with Ximedica for the FDA submission and secured timely approval.
Conclusion

Fully embracing human factors principles and usability guidelines as part of the development process is integral to optimizing product success, mitigating use-risk and enhancing performance. A collaborative team comprised of research, industrial design, engineering and regulatory experts from the get-go is critical to the successful development of a safe, user-centered medical device design. A lynchpin document built through the process is the Cross Phase Usability document which focuses the project team to centrally summarize the key learning and decision making points in the process. This process is optimized for risk mitigation and aligns with regulatory guidelines.
References

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Biographies

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