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INTEGRATING HUMAN FACTORS AND USABILITY TESTING INTO MEDICAL DEVICE RISK MANAGEMENT

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ABSTRACT

The application of human factors in medical device development is a required component of pre-market submission by regulatory bodies, including the US Food and Drug Administration (FDA). While manufacturers commonly manage product development with the risk management approach of standards such as ISO 14971, the integration of human factors and usability may not be as familiar and effectively integrated. However, the human factors process must communicate directly with risk management steps that companies already have in place. This paper provides an introduction to human factors for medical devices as an integrated component of risk management. Qualitative user research methods are presented that are useful in conducting this work, and are based on the authors' research on participatory design methods for medical devices in Uganda.

HUMAN FACTORS IN INDUSTRY

Human factors is "the application of knowledge about human capabilities (physical, sensory, emotional, and intellectual), and limitations to the design and development of tools, devices, systems, environments, and organizations" [1]. The practice originated in the aerospace industry in the early 20th century as more complex fighting machines shifted the focus of aviation psychology from the pilot, to the technology, and finally to a view of the user and device as a system. This latter User-Device Model (Fig. 1) now makes up a key perspective on human factors evaluation in healthcare [2].

In medical devices, the understanding and importance of this field has been growing for the past three decades [3], starting with a focus on anesthesia and expanding to more broadly encompass all areas of medical devices. The groundbreaking report *To Err is Human* released in 1999 by the US Institute of Medicine identified medical error as the 5th leading cause of mortality in the United States, with upwards of 98,000 deaths annually [4]. This further raised the importance of human factors and device usability in the industry.

Data on the effectiveness of current industry practice when it comes to human factors are not easily accessible, however the FDA acknowledges that recent years have seen an increase in the quality of submissions. Ongoing publishing by the FDA of common mistakes that manufacturers are making does indicate that industry has not yet reached a point of effective integration and strong enough capabilities in this area [5]. Anecdotal evidence shows that skewed perceptions toward human factors are also impacting results and approvals. For example, companies may assume that human factors is simply "common sense" in the design process, that it adds unnecessary cost and time to a project, or that lab testing and market research will be sufficient. The FDA clearly indicates otherwise.

The FDA's issuance of an updated guidance on human factors is reaching its third anniversary in draft form, with ongoing review of an extraordinary number of comments and interest from industry [6]. It is clear that the agency is continuing to work in partnership with manufacturers to build capacity in this area, while developing a guidance that is beneficial to all parties.

QUALITATIVE USER RESEARCH METHODS

Design for Expert Users

A major challenge in the design of medical devices is the asymmetry of information between expert users and designers. On one side the user has many years of training and experience in his or her field, having a highly

nuanced understanding of the physiology, ergonomic problems, and workflow. The designer on the other hand comes to the table with a depth of knowledge of the solution process and technology options that may be viable. It is precisely because neither party speaks the same language, that specially-trained human factors experts, qualitative user researchers, and industrial designers are required to bridge this gap. The skill lies not only in asking the right questions, but knowing how to listen, to interpret, and to look beyond the immediate data to hear what's not being said, and what actions are unknowingly being taken. This ability to translate factual observation into deep insight is the key to uncovering potential safety risks that would otherwise endanger patients and clinicians. It is this same skill set of human observation and interpretation that is unfortunately missing in the formal training of engineers – those who are often tasked with completing human factors work in small and medium sized companies.

The following methods are drawn from the authors' research on design methodology for medical device innovation in the developing world, a context where not only mismatched expertise gets in the way of communicating ideas, but so does culture, language, and value systems.

Contextual Inquiry and Ethnography

Ethnography is the non-intrusive study of people, cultures, and human systems through observation. Contextual inquiry on the other hand is also observation of users in their work environment, but involves a more active participation by both observer and user in a "think aloud" process or through questioning during the work process. These combined methods are valuable during formative and summative testing, although users should not be interrupted mid-task during testing.

Observation is key to this since users might not be aware of the errors they are making, or may have unconsciously found workarounds to challenges they face.

In our research, immersion in the Ugandan environment was key to seeing the difficulties in surgical practice. Treatment delays caused by limited resources led to significant biological tissue changes and a patient population with vastly different needs than those in Canada.

Cultural Probes

Cultural probes are a series of self-guided reflection tools such as journals, cameras, systems maps, audio recorders, and sketches that a designer may use to gain perspective on the challenges faced by users. The use of visual, auditory, and written means of communication provides a "valuable way to interact with a group of individuals who do not share the same language or demographic, in order to gauge perceptions, provide inspiration, and gain empathy for the users" [7].

In the Uganda research, reflection journals and disposable cameras were used by clinicians to communicate their challenges, values, and the concepts unique to their context of use that are otherwise difficult to convey in a formal interview. These data became invaluably rich sources of insight on technology use and differing roles among hospital stakeholders, highlighting the need for devices that allow lower-skilled users to perform advanced tasks.

Outcome-Driven Innovation

Outcome-Driven Innovation is a structured and rigorous process whereby users are engaged to identify and prioritize design opportunities based on the goals and outcomes they are trying to achieve at each step of a procedure [8].

Facilitated by a moderator, users are asked to break down a process into steps, and then identify 5-8 goals, or desired outcomes, per step. Each outcome is then ranked on importance and current level of satisfaction. This method is most useful in the early discovery phase when a company is searching for a disruptive innovation, or a problem that has yet to even be identified.

HUMAN FACTORS AND RISK MANAGEMENT

Human factors not only helps manufacturers to design products that are easier to use, more desirable, and will enjoy a competitive advantage in the marketplace, but is also a key component in the risk management process.

In the context of risk management, technology can be quite predictable. However, the way in which humans interact with it is much more complex. With adequate user testing and observation at every phase of the development process, it is possible to move towards predictable outcomes, even when humans are in the picture.

Discovery Phase

The discovery phase is where designers evaluate user needs and translate those into requirements and other design inputs. A deep understanding of the users, use environments, and the overall problem space is required at this stage.

The discovery phase may be the start of a design process where an opportunity has been identified, such as the case of designing the next generation of an existing device, or trying to solve a problem that is known by designers. In this case, skilled qualitative researchers can be engaged to help understand the challenges that are experienced in this problem space, or with existing devices.

Larger medical device manufacturers may have teams specifically focused on identifying latent or hidden challenges that are not readily visible to designers, or even users themselves, but are ripe for disruption. Christensen describes disruptive innovation as a product or service that is radically more affordable, simpler to use, and allows a whole new population of consumers to afford or gain access to what was previously limited to those with more money or higher skill [9]. By doing so, a disruptive innovation can change the market in which the old solution was operating, and even allow for previously "impossible" outcomes to be achieved. Orthopaedic fracture repair using implants can be considered such a disruptive innovation, which dramatically reduced hospital stays and immobilization, overall cost, and biological complications as compared to conservative treatment (traction) many decades ago.

Risk Analysis

In addition to traditional considerations that focus on technology failure alone, use error must be considered as a key initiating event and/or hazard. The design team must bring in information from the discovery phase, specifically an understanding of the intended users and their use environments. Safety-related and essential tasks must be identified based on the intended use of the device, instructions for use, and expert review. The User-Device Model can be applied to these tasks to identify where use errors may arise due to a user's failure in perception, cognition, and actions. Tangible usability criteria, or specifications, may be written based on these anticipated errors, as well as any other potential use errors that have been identified through a Failure Modes and Effects Analysis.

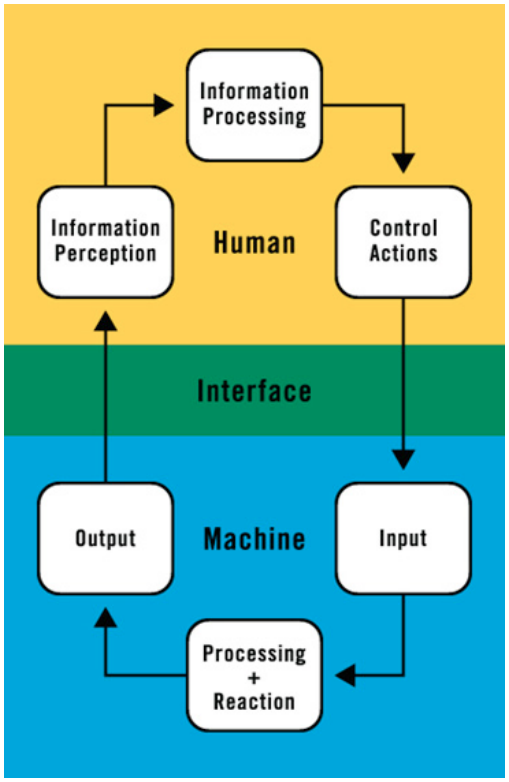

Fig. 1 – User-Device Model [2]

Utilization of the User-Device Model for performing this risk analysis increases the chances that use errors will be identified, however the evaluation phase is key to uncovering unanticipated use errors.

Risk Evaluation (Formative)

Formative testing begins early in the design process and can include general user feedback,

expert reviews, heuristic analysis, as well as testing of safety-related and essential tasks with representative users in a clinical or simulated environment using early prototypes.

It is during formative testing that many unexpected errors will arise, which analytical and lab-based techniques may fail to identify. Finding these early enough in the process allows for easy and low-cost mitigations, as well as re-testing to ensure safe use by the time summative testing occurs.

Risk Controls and Mitigations

Controls and mitigations may include, ranked in preferred order: safety mitigations designed into the device, alarms to notify users of hazards, and increased warnings, labeling, or instructions. Once such controls are implemented, it is critical that they be re-tested to determine whether the mitigation has proven effective at reducing use error, or possibly introduced a new set of risks. IEC 62366 offers an excellent visual aid indicating how information flow must take place between it and the ISO 14971 risk process [10][11].

The User-Device Model is here a useful tool to determine the root cause of use error during formative evaluations, and develop mitigations to address those specific causes.

Risk Evaluation (Summative)

Summative testing is part of the overall device validation phase. This testing must be performed with a finalized device, labeling, and instructions. Summative evaluation must be conducted in the clinical environment, or a simulated environment that adequately represents the expected lighting, noise, distraction, and other factors. Representative users from all user groups must be tested. For a device marketed in the US, the FDA requires a testing population to be representative, or inclusive of US residents.

While formative testing can be done with only 8-10 participants, the rule of thumb for summative validation testing is a sample size of 15 or above for each of the required user groups. Fewer than 15 participants may lead to evaluations that miss certain use errors, while a sample size too large will make difficult the depth of analysis required for pinpointing use error and root causes [12]. At the heart of this final evaluation is the ability to capture unanticipated errors, backed by subjective commentary from users in order to understand the root causes of failure and determine whether any residual risks can be deemed acceptable.

CONCLUSION

Human factors and usability testing is a key component for ensuring safety and efficacy of a medical device and should be integrated early in the development process. This need will only increase as international standards and guidelines further evolve and synchronize.

From a patient and user safety perspective, it is becoming clearer that use error may be as important, if not more so, a consideration for risk management as the failure of technological components. While the design team may be highly capable at predicting and designing out any technical problems, human use is much less predictable. Companies must invest in developing strong capabilities for observing, understanding, and interpreting human factors insights that will prevent use error from becoming a liability.

REFERENCES

[1] ANSI/AAMI HE75:2009 Human factors engineering – Design of medical devices, 2009.

[2] F. Redmill, J. Rajan, *Human Factors in Safety-Critical Systems,* Butterworth-Henemann, 1997.

[3] R. Kaye, "Human factors/usability for medical devices: A historical perspective," 2011, www.fda.gov.

[4] Institute of Medicine, "To err is human: Building a safer health system," 1999.

[5] R. Kaye, "What's new in human factors pre-market review?," 2013, www.fda.gov.

[6] H. Thompson "FDA sees 'extraordinary' interest in human factors guidance," *MDDI*, 2013.

[7] B. Gaver, T. Dunne, E. Pacenti, "Design: Cultural probes," *Interactions*, vol 6(1), pp. 21-29, 1999.

[8] A.W. Ulwick, "Turn customer input into innovation," *HBR*, vol. 80(1), pp. 91-97, 2002.

[9] C.M. Christensen, R. Bohmer, J. Kenagy, "Will disruptive innovation cure health care?," *HBR*, vol. 78(5), pp. 102-112, 2000.

[10] IEC 62366:2007 Medical devices – Application of usability engineering to medical devices, 2007.

[11] ISO 14971:2007 Medical devices – Application of risk management to medical devices, 2007.

[12] J. Nielsen, *Usability Engineering,* Morgan Kaufmann Publishers, 1994.