31st Annual International Conference of the IEEE EMBS
Minneapolis, Minnesota, USA, September 2-6, 2009

Applied Ergonomics: Determining User Needs in Medical Device Design

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***Abstract*— This paper describes methodology for determining user needs within the design process currently being used by the University of Cincinnati's Medical Device Innovation and Entrepreneurship Program. Topics such as ethnography (user observation and interviews), task analysis, and human factors for product embodiment are discussed. Specific tools for data gathering, analysis and synthesis towards determining design considerations, requirements and specifications are defined.**

I. Introduction

User centered design is prevalent during the pre-development and development phases of product design. The University of Cincinnati's Medical Device Innovation and Entrepreneurship Program (MDIEP) follows a product development methodology, which emphasizes the importance of the study of applied ergonomics, especially as it impacts the understanding of user needs. The MDIEP process places emphasis on applied ergonomics to gain better understanding of the user population as a means of deriving actionable design requirements [1]. This is reinforced by standards established in the Association for the Advancement of Medical Instrumentation: Human Factors Engineering (AAMI/CDV-3 HE 75) which seeks to provide human factors guidelines for the design of medical devices [2]. This new standard is intended to be a broad reaching referential guide for medical device development.

Applied ergonomics allows designers and engineers to develop solid information about user wants and needs, bypassing the frustrations of providing solutions to the wrong problems [1]. Through applied ergonomics, it is possible to identify problems which "may not yet be known or named by patients, physicians, or other stakeholders" [5] because many important user issues are not part of conscious awareness [1].

II. MDIEP Process

The International Ergonomics Association (IEA) defines ergonomics, or human factors, 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 methods to design in order to optimize human well-being and overall system performance" [3]. The practice of medicine is a system with many stakeholders and team players.

Medical device design has primarily been concerned with device efficacy, but now there is increasing understanding of the importance of human factors in designing and developing better medical devices. Through the optimization of the *entire* system, we can produce results that decrease operational time, minimize unintended device effects, and make it easier for the physician/caregiver to do the 'right thing' and harder to do the 'wrong thing.'

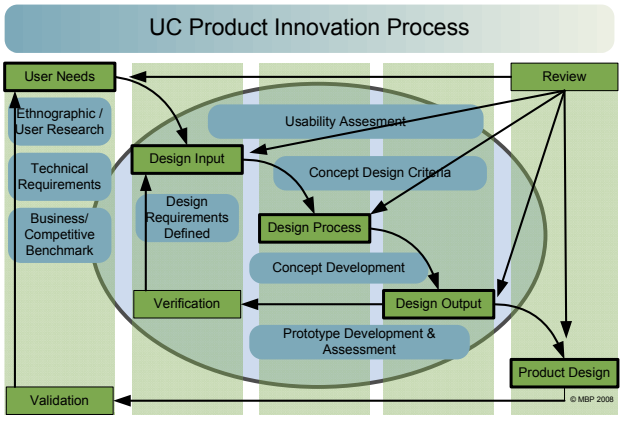

Fig. 1. Medical Device Innovation Process Map. Note the four required areas for determining user needs: user research (observation and interview), clinical, technical and business requirements. All are required for successful development.

The MDIEP process (see Fig. 1) requires all information gathered during the course of user observations, including the identification of clinical needs, technical studies and market research to be translated into actionable design requirements. This process ensures that the "design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the users and patient" [10]. It incorporates the requirements of the Food and Drug Administration's (FDA) Design Control requirements (commonly known as the waterfall diagram) for medical devices and is a holistic development approach which serves to ensure that the proposed solution meets all user needs and can be traced from discovery through verification.

III. Ethnography: User Observation and Interview

User experience with a device will determine the adoption of a device oriented clinical practice as a standard

Manuscript received April 22, 2009.

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of care as well as customer/brand loyalty. The environment of use, cultural background, education, training, and personal bias all influence the user experience and cannot be addressed by product design. However, recognizing behaviors, opinions, and fundamental tenets will inform the product design team of the priorities as determined by users. These can only be discovered through the process of ethnography; observation and interview. Dr. Thomas Fogarty commented, "You've got to learn the difference between what they say, what they want, what they'll pay for, [and] what they actually do" [8]. Another perspective is "the key is not only to observe what procedure was performed (or what device was used), but what the patient, provider, or system *experienced* as a result of the process" [5]. All user observations should focus on how the user acts and reacts to a situation, and will take notes of all the problems/mitigations which arise [5].

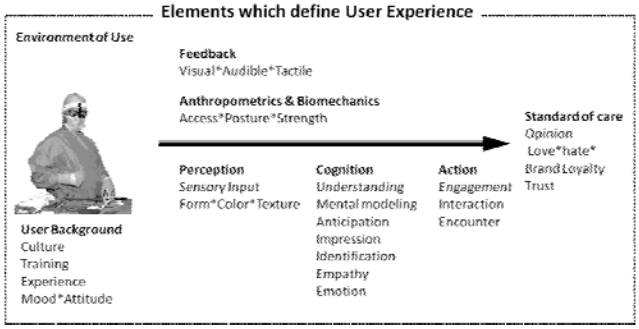

Fig. 2. Elements that define User Experience. The environment of use and the background of the user cannot be affected by device design must be taken into consideration whereas all other elements can be directly linked. The ultimate goal of any device design is the adoption of a device as the standard of care.

This goal of this process is to inform the team of critical issues, align the team with regard to the prioritization of device features and attributes from the viewpoint of the *user*, and inspire creative thoughtful solutions, with positive impact on the design of the device.

A. User Observation

The actual process of observing the user experience requires making consistent observations of the user in their *natural* environment. Ethnography, which is "concerned with the study of the 'ways of life of living human beings' [7]", is a process of observation that requires an established methodology, without which development teams run the risk of falling into two cycles of misunderstanding. These cycles consist of two observational mentalities: the "write everything" mentality, in which the observer will "write down everything, putting them into a situation where data analysis becomes a futile effort" due to quantity; and the "write what's interesting" mentality, in which the observer will "write only what they find interesting," whereby filtering the data with their own personal bias [6]. By implementing an observational protocol the product development team can avoid these pitfalls and will have improved ability to collect meaningful data, which serves their indentified end goal.

Data collection tools should include still and video recordings of observations which serve as a formal record and allow the team to complete further analysis of the user and device interactions at a more in-depth level and effective pace. In addition, the use of preliminary diaries by users can be helpful and can 'prime' users prior to an interview. These can capture demographics and procedural trends during a given time period. While this is readily accepted in consumer product development, it can be a challenge in compliancy for busy physicians.

During the observation data should be collected regarding the environment of use, the overall steps of the procedure (task analysis), and the lifecycle of the device. An inventory of all devices available for use, how they are arranged, any special needs or considerations, e.g. dimly lighted room, requirement of the user to wear lead aprons, etc. can be determined from the environment of use.

The exact user interaction from human input to device output can be tracked via *task analysis*. The goal of this analysis is to carefully observe a procedure and record: Who? Does what? With what? Why? And what went/can go wrong? Each of these steps can be examined further with regards to perception (sensory input), and cognition (understanding, mental modeling), which drive the actions of the user. It is often appropriate to extend the task analysis to include examination of the lifecycle of the device from its entry point into the point of care through the point of care, to determine any specific design implications with regards to packaging and disposal.

B. User Interview

Interviews can be used for several purposes, first to understand the current device and identify goals for the next iteration, and second to discover ideal solutions to the problems of an unmet need. In both instances, prior to conducting user interviews, the design team should collect information regarding the cultural background of the user. This is especially important in medical device design as typically a physician/healthcare personnel will have certain biases depending on where they were trained, their experience level, and/or research interests, etc.

Like observation, interviews should be approached in a methodical and planned manner. The interview should be held like a conversation allowing topics to flow freely with a written guide serving as reference to assure that all topics are covered. The emphasis of an initial interview should be one that focuses on building a relationship with the user and begins to elicit user responses that identify issues, challenges and/or problems. Forming the questions exactly should be carefully considered, approached in a thoughtful manner, and include various types of questions that are balanced in the types of responses they hope to elicit. Types of questions might include the following: open-ended questions (non-leading); relationship questions: "how does this relate to...?"; info questions: "what's going on here?" (leading to opinions); extension questions: "can you say more?"; challenge questions (a sharper, mean edge—serious or tongue in cheek); prioritizing questions: "rank—what's more

important…?"; action questions: "how are you going to do this?" (driving to specifics); prediction questions: "what do you think will happen?"; and summarizing questions: "would you summarize for us?" (after ideal has been described). In setting up interviews, it is important to obtain a broad cross section of users, including stakeholders from all aspects of the problem at hand, i.e. doctors, nurses, patients, sales personnel, procurement officials, etc.

IV. Data Analysis and Translation

Data analysis of the found information should focus on trends as observed or discovered. These trends can be organized into patterns and overall design themes, which emerge from the synthesized data. Tools commonly used in data analysis include spreadsheets and/or NVivo8 software, which assist in correlating the interview and observational data. Post-it note reminders of key quotes can also be helpful in keeping the user input at the forefront of design considerations. In this method, key opinions are recorded verbatim and their meaning is categorized visually across a large work surface. This allows the design team to capture these quotes on the fly and then rearrange them more freely than when captured in digital media.

The translation of the data capture into impactful meaning for the design is the most important step in a user-centered process. This synthesis will determine the design intent as organized into three distinct categories: design considerations, design requirements, and design specifications. Design considerations are those elements discovered which do not directly impact the design but are important to note, e.g. "30% of users have no experience." Design requirements are fundamental elements of a design which can be further broken down into needs, wants, and 'nice to haves.' These do not have to be measurable but provide important input for concept development and problem solving at the onset of the design/innovation process. Design specifications are completed once the final device design has been "frozen" or finalized. These are all measurable and according to FDA design control, require a design verification analysis. Design verification assures that all of the specifications documented in the device design meet the standards set forth by the design team.

V. Product Embodiment

Product embodiment refers to the giving of physical form to the object based on its technical requirements. Utilizing data collected and translated into device requirements, product embodiments can be explored to optimize technology application, form and user interaction. This requires adherence to human factors principles that are widely accepted as industry standards. As in traditional product design and development, mockups, models, and prototypes are used to test, revise, and improve the product in final stages of development.

A valuable document which is provided to assist design teams to better utilize human factors methodologies within the design development process, is the Association for the Advancement of Medical Instrumentation Guidance Document Human Engineering 75: Human Factors Design Guidelines for Medical Devices (AAMI HE75). This a compendium of standards touching on major relevant topics in the application of human factors in medical device design and provides relevant design criteria that are directly applicable to a product embodiment in early and advanced stages of development.

Specific references for anthropometric measurements allow designers to optimize overall sizes and ranges in the context of the use environment for targeted market share demographics e.g. 50% male etc. For control design and layout, it is helpful to determine the maximum and minimum limits a user is capable of producing. These force/torque ranges must be factored with user perception. For example the same physical sized hand/user may squeeze a trigger that has the same force requirement but both users perceive the acceptability of force production differently.

VI. Conclusion

Determining user needs is required by the FDA and reflects an optimum design process in the design of medical devices. As clinical therapies become increasingly more challenging and user interactions evolve with technology, so should the methodology for better understanding the needs and requirements of users with regards to device design.

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