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USER CENTERED DESIGN OF MEDICAL DEVICES:
Managing Use-Related Hazards

This paper helps organizations who create medical technology understand how an effective user centered design (UCD) strategy can mitigate use-related hazards during the design of a medical device.

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There are safeguards that prevent medical devices that do not meet a rigid set of standards for safety and quality from reaching the market. The Food and Drug Administration (FDA) and Health Canada review, approve, monitor and regulate the medical device industries in the U.S. and Canada. Each agency has a rigid process to review and approve products for sale and use. In the approval process for each agency, applications are checked for adherence to standards, and guidelines regarding human factors and usability practices.

In no other industry does usability play as important a role as in health care. Products in a medical environment must be durable, easy to sanitize, but most of all they need to be easy to read, understand, set, maintain, and calibrate in the environment they are used. And the environment may include variations in light intensity, temperature, ambient noise, tactical sensory changes, and cognitive loads that affect use of the product.

SAFETY

"User errors" are made by users of a product who experience a problem due to a function of their actions with the product. User errors which have occurred many times or continue to occur frequently are often called use errors as they pertain to a group of users instead of a single user. Following human factors processes during development helps prevent user and use errors. The conditions of use of a product such as a medical device may include such things as:

- Information display
- Tasks a user performs with the product in the work context
- Environmental conditions like illumination, temperature, and noise
- Organizational parameters (competence, communication)

User Centered Design (UCD) ensures all relevant conditions of use have been accounted for in the design of a medical device. UCD accounts for these conditions through iterative analysis and evaluation. UCD maintains a continuous dialogue with users during the design, development, and rollout of a product to ensure:

- Potential use-related hazards are discovered and mitigated
- Needs of the Intended users are fulfilled

USE-RELATED HAZARDS

The FDA refers to 'use-related hazards' as a potential source of harm that arises through device use. The UCD process focuses on mitigating use-related hazards during the design of a medical device.

A process for addressing use-related hazards must first build an understanding of how a device will be used. Areas which must be understood include:

- Device users (e.g., patient, family member, physician, nurse, professional caregiver)
- Typical and atypical device use

- Device characteristics
- Characteristics of the environments in which the device will be used
- Interactions between users, devices, and use environments.

Each area will involve a different method for analysis including User Profiling, Task Analysis, Functional Analysis, Environmental Analysis, and Usability Analysis respectively.

Next, the risk associated with the use-related hazards must be evaluated to determine the likelihood the hazard will occur. The analyst develops and evaluates the use scenarios describing the circumstances under which the hazard might occur.

Finally, a defense analysis determines what defenses exist and whether or not those defenses are adequate for preventing or mitigating the use-related hazard.

User Centered Design (UCD) is ideal to analyze use-related hazards in the design process.

THE DISCIPLINE OF USER CENTERED DESIGN

User Centered Design (UCD) accounts for human factors of a system during the design process by talking to users during the design and evaluation of a product. The UCD process satisfies the requirements by Health Canada and the Food and Drug Administration to account for human factors in the design.

User Centered Design can be used to develop a wide range of products, including software, hardware, and web-based applications.

USER PROFILING

User profiling is a detailed study of the people expected to use your product. You can identify these groups by considering similar products that are in use today. User profiling includes all significant characteristics that might affect the use of the product. User profiling* adapted from Mayhew Includes:

Physical Characteristics
- Color-blind
- Handedness
- Age
- Gender

Psychological characteristics
- Cognitive style
- Attitude
- Motivation

Knowledge & Skills
- Reading level
- Typing skill
- Education
- System experience

Job Characteristics
- Frequency of use
- Training
- Job Role
- Turnover rate

- Other tools
- Task importance
- Task structure

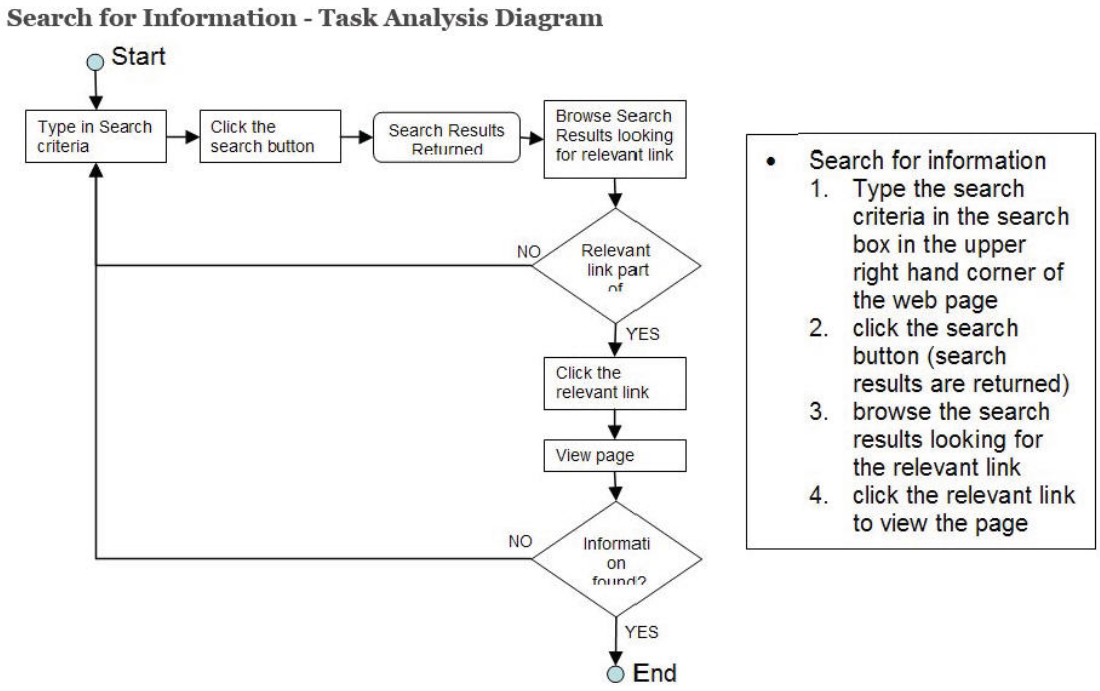
*Deborah J. Mayhew, Principles and Guidelines in Software User Interface Design, Prentice Hall, 1992

TASK ANALYSIS

Once a profile has been created for person and their characteristics, the next step is to understand the tasks each user will likely perform with your product. Task analysis captures such things as:

- Identify and quantify human operations performed and their relationship to system task and functions.
- Describe what users do within and around current the current product and what they are expected to do with the future product (task synthesis).
- Assess the critical nature of each task to the operation in terms of consequence of errors.

Task analysis is typically captured in data flow diagrams, or other similar graphics, to develop a complete model of the tasks of a system and how they are related.



FUNCTIONAL ANALYSIS

Functional analysis is used to develop a system description to define each function in the system. The description should include answers to the questions:

- What does the function do? (verb)
- What does the function act on? (noun)

Once a functional model is built based on the available technical specifications, it's compared to the functional models with results of the task models to locate primary and secondary functions. This also identifies gaps between tasks performed by the users and functions provided by the system.

ENVIRONMENTAL ANALYSIS

In this step, you build models for the environments in which the product will be used. Environmental models should include such things as:

- Temperature
- Clothing requirements
- Light intensity
- Sound
- Distractions
- Space requirements
- Placement of the product

Environmental models ensure the design will function effectively in the extremes of the environments which it will be used.

RISK ASSESSMENT

Risk assessment is based on usage scenarios developed through the careful consideration of users, tasks, functions and environments. These usage scenarios are used to describe the elements that make up a use-related hazard. Each usage scenario is rated according to the likelihood it will occur. The rating of each usage scenario is based on a set of subjective questions related to the users, tasks, functions, and environments as well as the potential outcome (inconvenience vs. injury, loss of life) of each scenario. The rating scale (high, medium, low) establishes priority for those use-related hazards that require further attention.

DEFENSE ANALYSIS

Defense analysis is used to analyze those use-related hazards and determine the defenses that would guard against such a hazard. The best defense is always prevention of the use-related hazard scenario. Where prevention is not possible, defenses include such things as physical defenses (i.e. covers, guards, insulation, railings, shields), cognitive defenses (i.e. warnings stickers, sirens, warning messages, confirmation messages), and process defenses (i.e. training, checklists, processes). For each scenario, determine the prevention strategy, estimated cost of prevention, technical feasibility as well as a prioritized list of defenses to guard against the use-related hazard scenario.

DESIGN

All of the analysis elements come together during the design phase. Design work focuses on the user interfaces for high priority tasks first and detail is added in iterations until all tasks/functions have been incorporated in the designs. It is important to use an iterative approach during design so that usability testing can be employed early. Use-related hazard testing takes priority over standard usability testing. All risk scenarios must be tested to ensure that the preventative measures or defenses function as they were designed.

Wireframe diagrams, screen shots, physical prototypes, and software prototypes are used to represent design elements which support the tasks. These design techniques allow for usability testing using a low-cost prototype. This way, usability testing can be performed early in the

design process because prototypes are quick to produce and modify, allowing for many iterations of a design to occur quickly at low cost.

USABILITY TESTING

User centered design emphasizes contact with users continuously throughout the process. Usability testing acts as the verification that the material collected in analysis was interpreted correctly when translated into a design prototype. Designs are tested with real users performing real tasks and where possible in the actual use environment. The results of usability testing may force a designer to revisit decisions made regarding use-related hazard in the design.

CONCLUSION

UCD de-risks design decisions, reduces churn during development, and is likely to reduce the time spent on design. User centered design is best used in quick, short iterations to deliver superior products. The UCD process satisfies the requirements by Health Canada and the Food and Drug Administration as a process to account for human factors during design.

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