



# User Centered Design of Medical Devices: Managing Use Related Hazards

by Ron Gagnier

Safe guards are in place to prevent medical devices from reaching the market which do not meet a rigid set of standards for safety and quality. The Food and Drug Administration (FDA) and Health Canada are agencies which, review, approve, monitor and regulate the medical device industries in each country respectively. Each agency has a rigid process by which products are reviewed and approved for sale and use. Within the approval process for each agency, applications for a product 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 the health care industry. Products in a medical environment need to be durable, easy to sanitize, but most of all they need to be easy to read, understand, set, maintain, and calibrate within the environment they are used. The environment is important to consider as there may be variations in light intensity, temperature, ambient noise, tactical sensory changes, and cognitive loads that must be accounted for during 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 or 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. The use of human factors processes during development is one way to help prevent user and use errors from occurring. The conditions of use of a product such as a medical device may include such things as:

- the display of information
- the tasks a user performs with the product in the work context
- environmental conditions such as illumination, temperature, and noise
- organizational parameters (competence, communication)

The role of user centered design (UCD) is to ensure that 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 that:

1. potential use-related hazards are discovered and mitigated
2. the intended users needs are fulfilled

The UCD process focuses on mitigating use-related hazards during the design of a medical device. The FDA refers to 'use-related hazards' as a potential source of harm that arises through device use. It is the role of Health Canada, the FDA and other such regulatory bodies to ensure that medical devices have been examined against use-related hazards and provide adequate defenses to guard against such hazards.

## Use-related Hazards

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, and
- The interaction 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 hazard must be evaluated to determine the likelihood the hazard will be expressed. Use scenarios describing the circumstances that allow each hazard to be expressed are developed and evaluated.

Finally a defense analysis is required to determine what defenses are in place and whether or not those defenses are adequate for preventing or mitigating the use-related hazard.

It is recommended that the User Centered Design (UCD) process be used for managing the analysis of use-related hazards in the design process.

## The Discipline of User Centered Design

User Centered Design (UCD) accounts for human factors of a system within the design process by maintaining dialogue with users during design and evaluation of a product. The UCD process satisfies the requirements by Health Canada and the Food and Drug Administration as a process through which human factors are accounted for during design.

User Centered Design process can be used to design and develop a wide range of products including software, hardware, internet based applications or some combination of these mediums.

When designing medical devices a multi-disciplinary team that includes persons who specialize in: user research, product design, human factors, and usability testing is preferred, due to the rigorous application of each of the analysis methodologies.



## User Profiling

User profiling is a detailed study of persons who are expected to use your product. It is simple to know who these people might be by considering similar products that are in use today. User profiling includes all significant characteristics they 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
- Task Experience
- Application Experience
- Native Languages
- Computer Literacy

### 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

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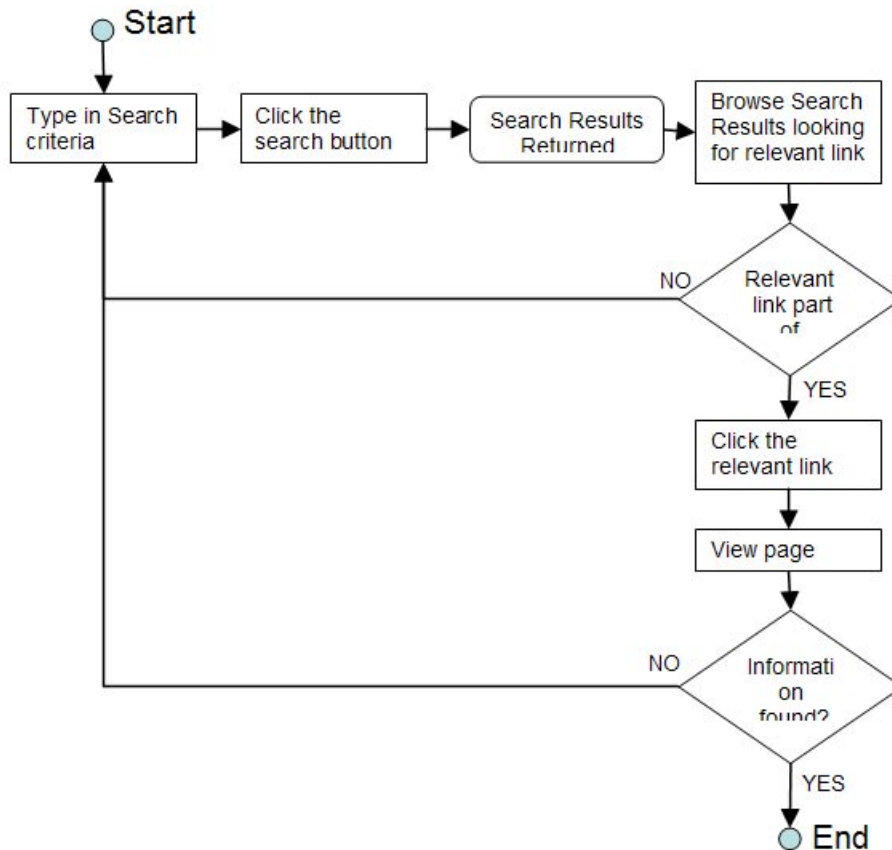
## Task Analysis

Once an understanding of the persons and their characteristics is performed through profiling it is necessary 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 product or what 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.

## Search for Information - Task Analysis Diagram



- Search for information
  1. Type the search criteria in the search box in the upper right hand corner of the web page
  2. click the search button (search results are returned)
  3. browse the search results looking for the relevant link
  4. click the relevant link to view the page

## 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)

Build a functional model based on the available technical specifications. Compare the functional models with results of the task models to locate primary and secondary functions. This will also identify any gaps between tasks performed by the users and functions provided by the system.

## Environmental Analysis

Build environmental models for the environments for 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 will be used to 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 describe the elements that make up a use-related hazard. Each usage scenario is rated as to the likelihood it will occur. The rating of each usage scenario is based on a set of subjective questions that are again 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) is used to establish priority to those use-related hazards that require further attention.

## **Defense Analysis**

Defense analysis is used to analyze those use-related hazards that require further attention (high, medium, low) to determine the defenses that would adequately 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) 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 take 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 to occur using a low-cost prototype. This allows for usability testing to 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 therefore 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 through which human factors are accounted for during design.