

Ergonomics in Medical Equipment Development and System Design

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Abstract— Utilizing ergonomics during medical equipment development and system design increases patient safety and efficiency in the working environment. The purpose of this report is to review the current literature on the use of ergonomics during medical equipment development and system design. To support the efficient use of existing ergonomics, there are techniques and methods that form an application for usage in the development process. The literature review will illustrate heuristics, design methods and design guidelines that ergonomists utilize during medical equipment development and system design.

Index Terms—Medical Equipment, Ergonomics, System, Design, Safety

I. ORIGIN AND SCOPE

The purpose of this report was to review the current literature on the use of ergonomics during medical equipment development and system design to ensure efficiency and patient safety. From the literature review future research needs were identified. The following 3 issues were examined in this report:

- 1) What are methods currently used in medical equipment and system design?
- 2) What medical equipment and system design issues have already been studied?
- 3) What guidelines already exist for medical equipment and system design?

II. FINDINGS

A. What are methods currently used in medical equipment and system design?

Heuristics: Zhang et. al., (2005) mention that heuristics are sets of evaluation techniques that individuals must utilize during a medical equipment design method. Heuristics are inspection methods that inspect medical equipment design, tool design and system software. Some heuristics are as follows: consistency, visibility, flexibility, closure and control.

Consistency involves sequence of action, organization of steps and design layout standards (Zhang et. al., 2005). Visibility allows the system to clearly display

feedback to the user. Zhang et. al., (2005) states that visibility answers the following:

What is the current state of the system? What can be done at current state?

What change is made after an action?

It's vital for the user to visualize and comprehend the brain of the tool or machine in process. As a result, the user can understand the capability and reaction which leads to efficiency during the process and the safety of patients.

Flexibility allows the user to customize and use short cuts to maximize performance (Zhang et. al., 2005). Medical equipment utilizes software that offers features for the user. The features allow the user to customize settings and short cuts to reduce time, therefore patient safety and efficiency increases.

Closure is a heuristic that provides feedback indicating the completion of a process. Medical tools and systems must provide a closure feature because it allows the user to proceed to the next step (Zhang et. al., 2005). A medical tool design process must contain a closure alert to avoid the prolonging of a procedure. As a result, patient safety increases due to the decrease in procedure length.

Control allows the user to take charge of the system or medical tool. Medical systems and equipment design must avoid surprising actions and unexpected outcomes that place the user in a vulnerable position (Zhang et. al., 2005). As a result, efficiency and patient safety decreases if control is not set in the user's hands.

Design Methods: Ergonomists utilize design methods during the development of medical equipment and system design to ensure user efficiency and patient safety. Design methods are as follows: contextual inquiry, cognitive task analysis, usability tests, cognitive walkthrough, delphi technique and field observations.

Martin et. al., (2008) mentions that contextual inquiry is an ethnographic research method that gathers information to inform the design of a new product or re-design of an existing product. Contextual inquiry offers the medical device sector specific data from real end users (Martin et. al., 2008). This method ensures that the designer inquires with the user in order to meet design needs. Understanding user needs is essential when designing medical equipment because it allows the designer to fulfill requirements benefiting the patient and providing efficiency for the user during operation.

Cognitive task analysis is a method for studying the mental process including behavior (Martin et. al., 2008). Understanding human behavior and mentality is crucial when designing a creation that a human will utilize. This

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method investigates strategies that humans use in order to complete a task successfully (Martin et. al., 2008). By understanding how one's brain operates during decision making, this method can take the findings into consideration while supporting the user in offering a technique that outputs successful results. As a result, designers utilize cognitive task analysis to aid the user in decision making and the patient benefits due to fast results from the operator.

Usability tests evaluate system errors and equipment performance. Martin et. al., (2008) points out that usability testing requires the user to perform the tasks on the system or equipment in order to monitor and measure errors during interactions between system and user. Usability tests increases the percentage of patient safety by decreasing user errors while entering and retrieving patient data from software systems (Martin et. al., 2008). The test measures efficiency and accuracy by checking if the "software misinterprets or fails to recognize clinical terms and whether the user of the program made an error while entering or retrieving data (Martin et. al., 2008).

Cognitive walkthrough predicts how user friendly a medical system would be for the average user. Martin et. al., (2008) mention that this method requires the designer to define a sequence of steps that allows the user to complete a successful task. Cognitive walkthrough requires the designer to think like a user because in order to determine the sequences and requirements of necessary steps, the designer must understand the order of the user's input to achieve a successful output. This process increases efficiency and patient safety due to the pre planning of the designer which simplifies the operation for the user to utilize the system.

The Delphi technique involves expert's opinions and ratings in order to expand on issues and ideas (Martin et. al., 2008). The process identifies issues by integrating rounds of questions between patients, operators, staff and users. Experts analyze the responses and form the basis for the next round of questions that will further the clarity of the issue (Martin et. al., 2008). At the end of all rounds of questions, the experts collect the findings to come up with recommendations for medical device design. Martin et. al., (2008) points out that this technique is useful when obtaining opinions on complex issues. The technique brings all parties together to brainstorm which aids in an efficient process that outputs successful results. The delphi technique is vital in medical equipment design because it involves the patient, users and all staff members who occupy and utilize the equipment to assist patients and ensures their safety.

Field observations illustrate the working environment to the designer. It's essential for designers to analyze the user's working conditions in order to design a system or equipment that accommodates the findings (Lin et. al., 2002). Lin et. al., (2002) points out that this is the first step a designer takes before initiating the process. An efficient design method must utilize field observations to customize a design approach to agree with the environment.

B. What medical equipment and system design issues have already been studied?

Previous Study: Several published applied ergonomics studies specific to issues in medical equipment and system design were found in the literature. The studies were conducted at Cambridge University. Buckle et. al., (2006) states that the covered topics were as follows:

- 1) Evaluating design process and how it influences the relationship between the designer and manufacturer
- 2) Consequences due to lack of training on medical equipment and systems
- 3) Challenges that face the user due to complexity of medical equipment
- 4) Tailoring and simplifying systems for all users and patients

5) What guidelines already exist for medical equipment and system design?

Guideline: The well known sets of guidelines are noted by the U.S Food and Drug Administration and the International Organization for Standardization. Martin et. al., (2008) mentions that ergonomics requirements use the following guidelines: IEC 62366 (2007), IEC 60601-1-8 (2006) and ANSI/AAMI HE74 (2001). Most of the guidelines tends to be self explanatory, topics include:

- 1) Risk management activity for device use
- 2) Human factors consideration for device-user system
- 3) Medical device use environment
- 4) Usability issues

III. CONCLUSION

Literature review data illustrate how the implementation of heuristics, design methods and design guidelines can lead to an efficient working environment and an increase in patient safety. Research points out heuristic methods that measure for consistency, visibility, flexibility, closure and control. The author highlights the necessity of heuristic measurements that benefits the user and patient due to design improvements and the redesigning of systems and equipment. The basis of design improvements and the redesign process is from the conclusion of heuristic measurements. In addition to heuristics, the author illustrates design methods that include contextual inquiry, cognitive task analysis, usability tests, cognitive walkthrough, delphi technique and field observations. The methods demonstrate a design approach that allows the designers to consult with users and patients during the process. Data illustrates how design methods allow the designer to customize systems and equipment to fit the patient and user environment. While utilizing design methods, patient safety increases including the efficiency of the working environment. Design guidelines highlight requirements for designers to follow during the development process. The guidelines direct designers on safety requirements and considerations during the design phase. As a result, heuristics, design methods and design guidelines allows designers to form and utilize a process in the ergonomics of medical equipment development and system design.

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