HUMAN FACTORS IN PROCUREMENT: INFORMING THE PROCESS FOR THE SAFE SELECTION OF MEDICAL TECHNOLOGY

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INTRODUCTION

Introducing new medical technologies into the healthcare environment poses potential risks. Technology that does not consider the capabilities and limitations of users can result in human error, leading to patient safety risks. Technology that does not meet functional and system integration requirements can affect an organization's ability to provide efficient care, which poses adoption risks. [1] Finally, purchasing medical technologies that pose safety or adoption risks can lead to financial risks from litigation and shortened time to obsolescence.

Human factors engineering is a discipline concerned with the interaction between people and the systems they use. Recently, human factors engineering has contributed to patient safety improvement efforts through medical device evaluation and design. [2-6] The medical technology procurement process provides an opportunity to further improve the safety of devices and systems used by healthcare organizations. By selecting medical technology that conforms to human factors principles and evaluating how a particular technology will interact with all elements of its environment, the safest available technology can be purchased. Biomedical engineers and technologists are key players in procurement decisions, and can be instrumental in introducing human factors methods to the procurement process.

This paper presents a human factors informed procurement (HFIP) process model that introduces human factors methods to the traditional procurement process. It outlines the quantitative and qualitative data that can be gathered using this process and how this data reduces the risks associated with procurement decisions, resulting in the selection of safer decisions.

THE HUMAN FACTORS INFORMED PROCUREMENT (HFIP) PROCESS

The HFIP process evolved from the inclusion of human factors methods into the procurement process for a variety of medical devices at the University Health Network (UHN). After studying a number of human factors informed procurement decisions to see which methods most contributed to an understanding of the safety and adoption implications of each product, the HFIP shown in Figure 1 was arrived at. This paper details each step of the HFIP process with a specific focus on the contributions that can be made by biomedical engineering professionals.

Step 1: Assemble a multi-disciplinary team

The first step in making an informed purchasing decision is to assemble a team comprised of all relevant hospital stakeholders. Depending on the type of medical technology being attained, this might include representatives from: clinical practice areas, pharmacy, medical engineering, purchasing, risk management, information technology, and human factors. The role of this committee is to consider all necessary requirements for the safe selection and implementation of a particular medical technology.

Biomedical engineers are often called upon to lead a procurement decision because of their knowledge of how medical technology works, technical problems with the current technology being used, requirements to maintain technology, what products are available on the market and their existing relationships with medical technology companies. Additionally, biomedical engineers are often well informed of a hospital's overall plan for expanding IT capabilities and can factor IT requirements into the decision process. As a leader in the process of procuring new medical technology, biomedical engineers should invite as many relevant stakeholders as possible to join a team responsible for making the final purchasing decision.

Step 2: Identify the function needs

Before specific products can be identified for evaluation, the multi-disciplinary team must decide on product requirements and inclusion criteria. This is best achieved by conducting a functional needs assessment. A functional needs assessment is an assessment of the functions a product must be able to perform to meet clinical, safety, and system integration needs both now and for the duration that the technology will be in use. There are several tools to guide a functional needs assessment including task analysis (to better understand the range of tasks the technology is used for), workflow analysis (to understand how the technology fits into the order in

which work is conducted), information flow mapping (to understand what information is required to use the technology and how the technology influences decision making in its use) and a market scan (to understand the capabilities of products on the market). Important safety information can also come from use alerts, warnings and guidelines provided by regulators and advisory boards (e.g., FDA, JCAHO, ECRI , ISMP, and Health Canada). The results of a functional needs assessment provide a checklist of necessary clinical functions, safety functions, and system integration requirements that can be weighted in terms of importance by the decision committee. The list of required functions serves as input to the request for proposals (RFP) document, and the function priorities guide an objective comparison of product performance later in the evaluation process.

The suggested tools to guide a functional needs assessment are primarily used by human factors practitioners. The role of a biomedical engineer in this step is to suggest required product functions, particularly those related to maintenance and system integration, and to contribute to the discussion of weighted priorities.

Step 3: Draft RFP

Once the functional needs are identified, a request for proposals RFP can be drafted. Biomedical engineers sometimes take the lead in drafting these proposals and then send it to the procurement committee for feedback before sending it to vendors (via the purchasing department). The RFP should include the function requirements identified in the previous stage, and demand that proposals identify any human factors methods employed during the development of the product and how the findings were incorporated into the product's final design.

Step 4: Select a short list of vendors to evaluate

After proposals are received, the procurement committee can create a short list of proposals they would like to consider further. The short list should be based on each product's ability to meet the functional criteria identified. Very rarely does any product meet every requirement. In these instances the criteria priorities can help to eliminate products that do not meet established minimum standards.

Step 5: Product setup, customization & installation

It is important to evaluate each product in a way that closely resembles how it will function in the purchaser's environment. For this to happen the product must arrive customized for the purchaser's environment (e.g., a smart pump should come with drug templates matching hospital drugs and protocols). The human factors specialist will gather this information with help from representative clinical staff and will communicate it to the short-listed vendors either directly or through the purchasing department. If the biomedical engineering is the sole point of contact to the vendor they will be responsible for communicating this information and ensuring vendor compliance

Step 6: Product training

The human factors specialist and a biomedical engineer should receive in-depth training on each product being evaluated. Upon completing the training the human factors practitioner should be capable of training clinical staff on how to use the technology, and the biomedical engineer should be capable of understanding how to test the performance of the device with respect to its specifications. Using the human factors professional to train clinical staff during the evaluation process has several benefits. First, it removes the vendor from participating in the evaluation; reducing any bias introduced by their involvement. Second, it increases testing efficiency because there is no need to include the vendor in scheduling efforts. Finally, it increases the consistency of training across users because the human factors specialist will develop a training program and ensure that training is delivered consistently.

Step 7: Conduct a heuristic analysis

The following three steps comprise the plurality of the human factors evaluation work in the HFIP process. These steps primarily involve the participation of a human factors practitioner and clinical users.

A heuristic analysis refers to the evaluation of an interface by a human factors expert against a standard set of known usability principles. It facilitates the identification of design flaws that may pose potential safety and usability problems. It is useful for identifying design elements that users may find difficult to use, but is not very useful for identifying system problems that results from the interaction of the technology with a particular environment. There are a variety of different heuristics used in various industries. Zhang et al. [7] adapted a set of heuristics used commonly to evaluate web-based interfaces so they would apply more directly to the evaluation of medical devices.

The knowledge gained from a heuristic analysis is useful for identifying and eliminating products that clearly pose safety risks early on in the process before other, more resource intensive, human factors methods are employed. The output from this step will also inform the development of evaluation tools used to collect data during clinical walkthroughs.

Step 8: Clinical walkthroughs

A clinical walkthrough refers to the evaluation of an interface by a group of clinician users by performing a set of pre-determined tasks and evaluating the understandability and ease of performing each task. The primary purpose is to get detailed information from users about how well each product meets the identified functional needs. Clinical walkthroughs help to identify design flaws that may not be identified during usability testing and allow more users to be involved in the evaluation process, further enhancing the likelihood of user acceptance and successful product adoption.

Step 9: Conduct usability testing

Usability testing refers to an observational research technique where representative end users are recruited to participate in realistic scenarios in a simulated environment in order to assess the appropriateness and ease of use of a system prior to its introduction into the real world. It allows product deficiencies that could affect the overall usability of the product to be identified.

Both quantitative and qualitative data representing user performance are collected to reveal design flaws that affect a many aspects of the system including interface design issues as well as in technology-environment (e.g., pump is too large to fit in workspace), technology-tool (e.g., the pump programming task sequence indicated by the order of parameters on a drug order form does not match the task sequence prompted by the pump), technology-workflow (e.g., pump does not allow for advance set-up) , and technology-policy issues (e.g., policy requires a double check but pump does not display the information for confirmation after initial settings are selected). During usability testing these deficiencies usually result in user-errors, the inability to complete tasks, and increased task time. Measuring these parameters allows for an understanding of what errors can occur, the severity and impact of these errors, and what can be done to reduce the likelihood of these errors.

Step 10: Gathering additional information

In addition to gathering human factors data, technical performance, cost, information systems requirements, and maintenance related information also needs to feed into the purchasing decision. Gathering this information comprises the bulk of the traditional procurement process and is primarily the responsibility of biomedical engineers.

Step 11: Making the final purchasing decision

Depending on the findings of the data gathered using the HFIP process the final purchasing decision might be an obvious choice, or a tough decision. Safety, cost, usability, technical proficiency, maintenance agreement, propriety and other contractual agreement parameters are all competing priorities that must be satisfied. The output of the HFIP process does not assist in this prioritization, but it does provide safety and usability information so that those parameters can contribute to the final decision.

DISCUSSION

The application of human factors methods to the procurement process facilitates the collection of explicit safety and usability data. Organizations that place a strong importance on patient safety and quality of worker life have much to gain by introducing these methods. Biomedical engineers can play an important role in introducing human factors methods to procurement in several ways. Primarily, as leaders of the procurement process, they can seek out and bring human factors expertise to the procurement team. The biomedical engineering department is a natural fit for a human factors practitioner because, in addition to participating in procurement evaluations, they can assist in accident investigations, develop training programs that reflect the lessons learned during usability testing, and provide insight into workflow and job design.

The second role that biomedical engineers can play in bringing human factors to their organization is that they can develop an understanding of the underlying principles of human factors engineering to help identify usability issues with medical technology already in use. When problems are identified they can help to find modifications that might reduce the impact of the problem and/or prepare a case to purchase new technology to eliminate device-use errors that impact negatively on safety.

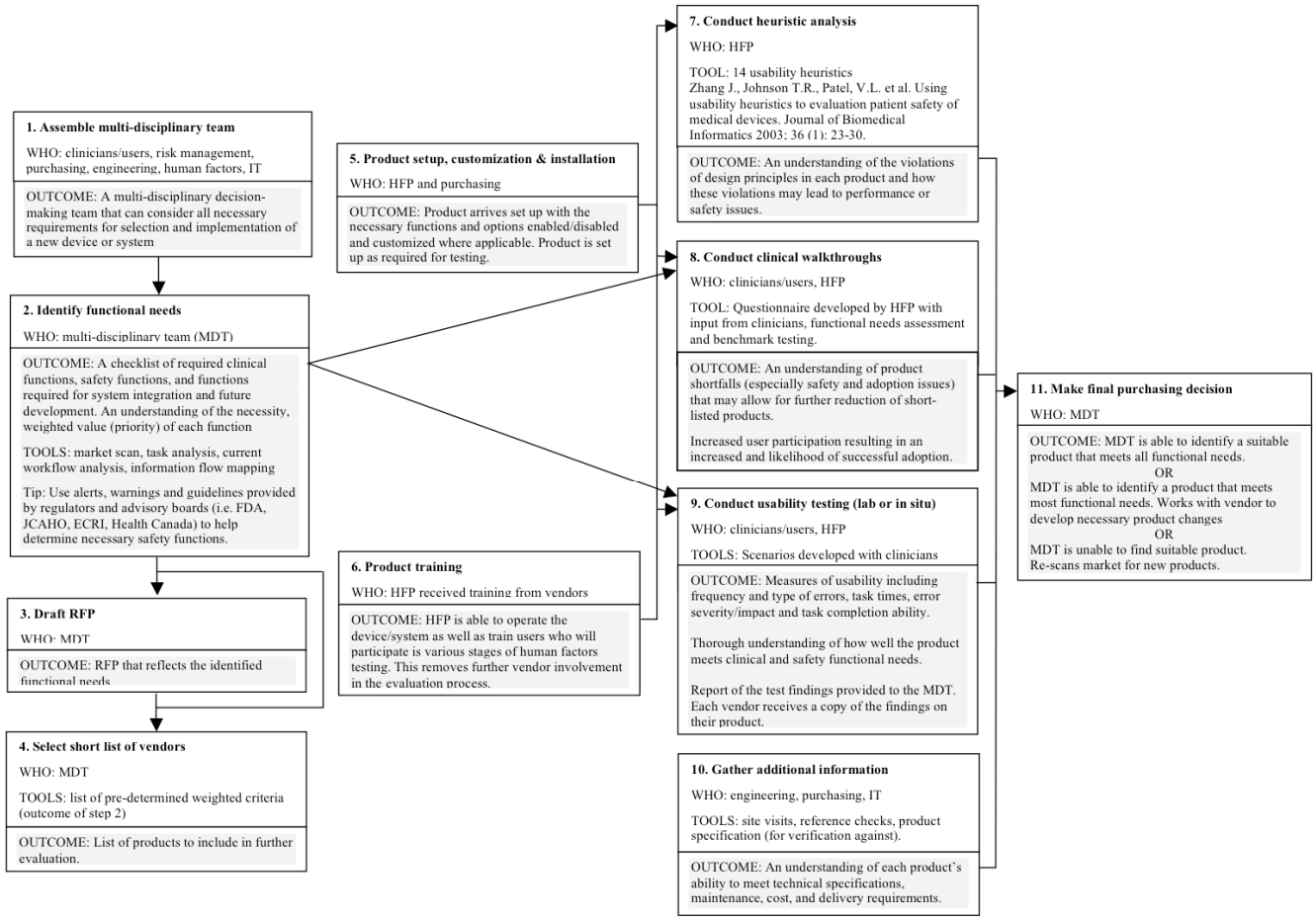

Figure 1. The human factors informed procurement (HFIP) process

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