VALIDATING HEURISTIC ANALYSIS AS AN EFFECTIVE METHOD FOR IDENTIFYING HUMAN FACTORS ISSUES IN THE MEDICAL TECHNOLOGY PROCUREMENT PROCESS

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INTRODUCTION

The introduction of human factors methods to the medical technology procurement process has been advocated as a means for improving patient safety, increasing the likelihood of successful technology adoption, and reducing financial risks associated with litigation and decreased time to obsolescence [1] As such, several human factors methods, including heuristic analysis (HA) have been employed by two medical institutions as described in [2,3] to influence procurement decisions. HA is a commonly employed usability method because it is inexpensive, does not require a lot of advanced planning, and can be done without acquiring formal usability facilities.

HA 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 in an existing design that may pose potential safety and usability problems. [4,5]

The objective of this study was to validate the effectiveness of HA as a method for identifying human factors issues as part of the medical device procurement process, and to evaluate the reproducibility of HA results, by comparing the results of two HAs. The HAs were each conducted by two different human factors engineers (HFEs) at two different Toronto area hospitals on the same IV Patient Controlled Analgesia (PCA) pump being considered for purchase. The hospitals that participated in this work were the University Health Network (UHN) and the Trillium Health Centre (THC). There was a three-year time period between the evaluations at each hospital as a result of different procurement cycles. During that time the product that both hospitals evaluated changed only slightly. For example, when UHN evaluated the pump the power cord was very snug and difficult to insert, THC found that it was too easily pulled out. Also, when UHN evaluated the pump the design allowed a patient to stop the pump and reprogram it but not re-start the pump. The version evaluated by THC required a key to unlock the cover before these actions could be taken.

A study by Karoulis and Pomportsis [6] shows that evaluator expertise is an important factor for identifying critical problems in a heuristic analysis. Both of the evaluators in this research are “double specialists”, meaning they have expertise in the development and evaluation of user interfaces as well as knowledge of the medical domain [7,8]. Both have three years of experience conducting human factors evaluations of medical devices using a variety of human factors methodologies.

METHODS

Each HFE used typical usage scenarios to guide a HA on several different IV infusion pumps for the purpose of informing the procurement process. The scenarios guiding the evaluation were slightly different at each site because the pumps are used by different clinical departments across the two hospitals (e.g., one hospital uses the pumps in labor and delivery, the other hospital does not have labor and delivery services).

Both institutions tested the pump against the same set of usability heuristics adapted specifically for the evaluation of medical devices by Zhang et al. [9]. A sample of the heuristics used includes:

- [Minimize Memory] users should not be required to memorize a lot of information to carry out tasks.
- [Informative Feedback] Users should be given prompt and informative feedback about their actions
- [User’s Language] The language should be always presented in a form understandable by the intended users.
- [Closure] Every task has a beginning and an end. Users should be clearly informed about the completion of a task.
- [Consistency] Users should not wonder whether different words, situations, or actions mean the same thing.

In addition to the HA, both institutions included other human factors methods, such a clinical walkthroughs and usability testing (described in [1]), as part of their evaluation process. However, this paper focuses on results of the HA aspect of the evaluation.

The effectiveness of the HA results was evaluated by testing whether or the not the design problems (violations of the heuristics) identified at each hospital would have a potential impact on the safety and usability of the device if that particular device was purchased. The reproducibility of the results was determined by the degree of similarity across the results of the two HAs.

RESULTS

The usability issues identified were mapped on to the heuristics they violated. The design problems and associated heuristic violations that were common to both hospitals are shown in Table 1. It can be seen that these issues negatively impact both safety and usability, indicating that HA is an effective means for discovering potential problems associated with the use of medical devices. Some of the most critical safety issues identified include:

- Users are not forced to review the settings entered before starting the pump. If any settings are selected incorrectly they are less likely to be noticed.
- The total volume delivered in mL is displayed on the pump but the dose is programmed in mg as is the amount of drug infused that is documented on the patient's chart. There is no option to change the units displayed
- There are two different task sequences for changing a syringe. One is used when the same drug is being re-loaded. The other when a different drug is loaded. If the first task sequence is used to change the syringe to a new drug the user never gets the option to change the drug protocol

Some of the usability issues identified that most impact ease of use include:

- No adjustments can be made to the protocol (e.g., changing the dose amount) once the pump is programmed. The user must re-program the pump.
- The 'Stop' and 'Suspend' functions share the same button. Users can easily stop the pump when they mean to suspend (pause) it and lose all the entered programming and history information
- When the pump is running, the screen reads "On Standby". This is not clear language to indicate it is ready to infuse.

THC identified 41 issues and UHN identified 30 issues. There were 16 common issues identified by the HFEs at both hospitals, meaning 55 unique issues were identified in total. Of the 25 issues that were identified in the HA by THC only, six issues could not have been identified by UHN. Two issues would not have been encountered by UHN because of different pump use protocols (e.g., it is the policy of one hospital not to use PCA pumps in a continuous mode). Two issues were not identified because the pump vendor made minor design changes that created new problems in between the time the each hospital did their evaluations. Two issues were not experienced by UHN even though the same conditions were tested (e.g., pump did not identify the correct brand of syringe loaded). Of the 14 issues identified by UHN only, six issues could not have been identified by THC. Two issues would not have been encountered by THC because of different pump use protocols. Four issues were not identified because the pump vendor made some design changes that eliminated problems during the three-year time period between when UHN and THC conducted their evaluations. When these 12 factors are eliminated from the total number of issues identified by both hospitals, there were 43 unique issues that could have been identified by both hospitals, meaning the commonality of issues found was 16 of 43 (37%). This level of commonality may seem low, however, the findings are higher than other comparative studies [10].

DISCUSSION

The results of this study clearly indicate that a HA conducted by an experienced HFE is an effective means of identifying potential safety and usability issues prior to making procurement decisions. The costs associated with this method include only the cost of hiring human factors expertise. If this cost is budgeted as part of the capital procurement process, it could result in cost savings when the potential litigation costs of an error or the cost of purchasing a more expensive but less usable product are factored in. This HA required approximately 7 hours of human factors expertise per hospital to identify the

usability issues and map them on to the heuristics.

There are several limitations to this study that help to explain the moderate number of common issues identified across the two evaluations. First, there was only one HFE conducting the analysis at each site. This is less than ideal considering three to five experts and two to three double specialists are required to discover 65-75% of the total design issues with any product [4,7]. It can be seen from this study that two HFEs enhance the number of problems identified; however, the cost associated with hiring two or more experts may not be feasible in a publicly funded healthcare institution. Regardless, the safety and usability issues identified by each institution alone served as valuable input to identifying the safest and more usable device.

Secondly, the results of only one pump were compared. Further comparisons are required to more accurately understand the level of reproducibility that is generally achieved when conducting a heuristic analysis on healthcare devices guided by the Zhang et al. [9] heuristics.

Another factor that may have contributed to the moderate number of common problems identified was that HA was not relied on as the sole method for extracting human factors data. Because each HFE could rely on the results of other methods such as formal usability testing, they may not have attempted to collect an exhaustive and comprehensive amount of heuristic analysis data knowing that the results of other types of testing could also be relied on to capture safety and usability issues.

CONCLUSIONS

This research demonstrates that HA is valuable as a means of gathering human factors data for the purpose of informing procurement decisions. When compared to the cost of most capital purchases, the relative cost of hiring a human factors consultant is minimal and the impact on safety and ease of use can be great. While the relationship between the usability and safety of a device can be easily inferred, there are additional benefits to selecting a device that is highly usable that may not be obvious. First, less training is required on devices that are intuitive. Second, users are more likely to want to adopt a new technology that is usable.

The combined benefits of incorporating human factors methods such as a HA into the procurement process strongly support their widespread adoption into hospital procurement decisions. Where possible, additional human factors methods should be used to supplement the findings to include a broader range of issues, particularly for complex and safety critical devices.

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