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ANALYSIS, REDESIGN, AND EVALUATION OF A PATIENT-CONTROLLED ANALGESIA MACHINE INTERFACE

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The hypothesis explored in this paper is that, by adopting human factors design principles, the use of medical equipment can be made safer and more efficient. We have selected a commercially available patient-controlled analgesia (PCA) machine as a vehicle to test this hypothesis. A cognitive task analysis of PCA usage, combined with a set of human factors design principles, led to a redesigned PCA interface. An experimental evaluation was conducted, comparing this new interface with the existing interface. The results show that the new interface leads to significantly faster, less effortful, and more reliable performance. These findings have implications for improving the design of other medical equipment.

INTRODUCTION

Human error plays a crucial role in the safety of medical equipment. For example, 60% of the deaths and serious injuries reported to the Medical Device Reporting system of the Food and Drug Administration's Center for Devices and Radiological Health have been attributed to operator error (Bogner, 1994). In part, this situation is due to the fact that human factors of medical equipment has received comparatively little attention, despite the fact that nurses and doctors, like operators in other human-machine systems, are dealing with complex situations where human lives are at stake.

The thesis of this paper is that, by adopting human factors principles, medical equipment can be made safer and more efficient as well. Patient-controlled analgesia (PCA) machines will serve as the focus for this study.

PCA

From the patient's perspective, PCA is easily understood. Whenever they are in pain, or are planning to do something likely to be painful (such as getting out of bed), they push the PCA push-button. If the patient is eligible to get the requested drug, as determined by the computer inside the pump, analgesic is given into the patient's IV over a few seconds. If there has not been enough elapsed time from the time of the last dose (the "lockout period"), the computer denies the request.

The action of the PCA machine is governed by a computer program which, in turn, is based on a PCA prescription. PCA prescriptions are written into the patient's chart using a standardized order form. Floor nurses use these orders to program the PCA machine. Typically, this involves opening up the machine (a special key is needed) and entering a series of numbers and other data through a keypad.

Previous studies have indicated that operator errors are the greatest threat to the safe use of PCA machines (White, 1987). This makes PCA a prime target for human factors analysis and design. Interestingly, with very few exceptions, the possibility of redesign is never acknowledged in the PCA literature. Instead, the most frequently mentioned solution to the problem of operator errors is to increase the amount of training (Smythe, 1992; Cohen, 1993). For example, White (1987) states: "If the nursing staff and patients are properly instructed in the use of the PCA device, these problems are preventable" (p. 82; see also Smythe, 1992). Clearly, the relevance and value of human factors has not been appreciated in the PCA literature. It is not surprising then, that several cases of PCA machine mis-programming have been reported in the medical literature (White, 1987; Cohen, 1993).

Interestingly, however, the comparative evaluations of PCA machines that have been reported in the literature have focused primarily on mechanical properties. Therefore, there is a strong unexplored need for evaluating PCA machines from a human factors perspective. This paper addresses this need by presenting a design and evaluation of a PCA interface based on human factors principles.

As a precursor to the redesign, a cognitive task analysis was conducted to understand the context in which PCA machines are used (Isla & Lin, 1993). This analysis, combined with a set of human factors design principles, led to a redesigned interface (Doniz & Harkness, 1994). The primary differences between the new and old interfaces was that the new interface had: improved layout of controls, labels which clearer and more meaningful to users, a more streamlined user dialogue, improved visual momentum showing where the user was in the programming procedure, more efficient methods for error recover, and better feedback for error detection. A detailed description and comparison of the two interfaces cannot be presented here due to space constraints but can be found in Doniz & Harkness (1994).

After the analysis and redesign efforts were completed, an experimental evaluation was conducted comparing the new interface with the existing PCA interface. This experiment will be described in the remainder of this paper.

METHOD

This section describes an empirical evaluation comparing the existing and redesigned PCA interface for the Abbott Lifecare Plus II PCA machine (Abbott Laboratories, 1989). The goal of the experiment was to evaluate the device from the viewpoint of the user who has to program the machine, not the patient.

Subjects

The principle focus of the experiment was to test both interfaces on novice users. Accordingly, the selection of subjects for the experiment was based on two important criteria. First, subjects had to have a background that was representative of the background of professional nurses. Second, subjects also had to have no experience with the current Abbott Lifecare Plus II interface, so as to eliminate any potential transfer effects. Thus, subjects were university students with medical professional backgrounds, including nursing, pharmacy, and rehabilitation medicine. A total of 24 participants volunteered to partake in the experiment, ranging in age from 18 to 45.

Experimental Design

A 2 x 3 x 2 mixed design was adopted for the experiment with Interface (Old vs. New) and Programming Task (PCA, Continuous, and PCA + Continuous) as within-subjects factors, and Interface Order (New First vs. Old First) as a between-subjects factor. The order of presentation of the interface and the tasks were counterbalanced. Thus, each subject performed a total of 6 trials.

Programming Tasks

For each trial, the subjects were given a copy of a doctor's order form filled in with the requested values to be programmed. The values requested depended on the task being performed. The subjects then proceeded to program the machine by following the directions presented to them on the respective interface.

As already mentioned, there were 3 programming tasks. The Continuous task required subjects to program the machine to deliver a continuous dosage of analgesia at a pre-specified rate. The PCA task required subjects to program the machine to deliver doses of analgesia of a given magnitude when requested by the patient (subject to lockout and 4 hour limits). Finally, the PCA+ Continuous task required subjects to program the machine to deliver both a continuous background dosage rate and added doses of analgesia when requested by the patient (again, subject to the appropriate limits).

Apparatus

A graphical simulation of both interface designs was developed using the Toolbook Openscript software package. The simulations ran on an IBM-compatible PC equipped with a mouse and a MegaImage colour monitor. Input data for the programming task were provided to subjects on standard PCA order forms used at the Toronto General Hospital (TGH).

Procedure

First, the purpose of the experiment was explained to the subject. Also, background information on the PCA machine and the tasks that subjects would be performing were explained. The subject was then provided with six PCA order sheets and was asked to begin the programming tasks. The test subject then proceeded through each stage, programming the required values. After each trial, subjects completed a mental workload rating scale (see below), and provided any comments they might have had on the preceding trial. The experimenter was present during the entire experiment. At the end of the experiment, informal comments were solicited from subjects to determine which of the two interfaces they preferred.

Performance Measures

There were three dependent variables. First, the total time to successfully complete each trial was recorded. Second, the number of errors made in completing each trial was recorded. Both of these measures were collected by the experimenter, who observed the subjects as they completed the required tasks. Third, subjective ratings of mental workload were also collected from subjects. The NASA-TLX method, a well accepted measure of subjective mental workload, was used for this purpose (Wickens, 1992).

RESULTS

The results for task completion time will be examined first. A three-way ANOVA with Interface, Task, and Order as the main factors was conducted. The Interface effect was highly significant ($F(1,22) = 54.71$, $p < 0.0001$). The mean time with the New interface was 3.9 minutes, whereas that with the Old interface was 5.2 minutes, 33% slower. However, this main effect can only be meaningfully interpreted within the context of the Order x Interface interaction, which was also statistically significant ($F(1,22) = 13.90$, $p < 0.0012$). As shown in Figure 1, the mean programming time on the new interface is always faster, but there is an asymmetrical transfer effect from one interface to the other. There are several ways to look at this effect. First, transferring from the New to the Old interface causes a larger performance change than going from the Old to the New (differences of +1.9 minutes and -0.6 minutes, respectively). Second, those subjects who have already had some experience at the task with the Old interface are slower with the New interface than subjects who are doing the task for the first time with the New interface. This suggests that subjects who have been exposed to the Old interface acquire behaviors that do not allow them to fully exploit the benefits of the New interface. Third, those subjects who have already had some experience at the task with the New interface are much slower with the Old interface than subjects who are doing the task for the first time with the Old interface. This suggests that subjects who have been exposed to the benefits of the New interface then have a more difficult time compensating for the deficiencies of the Old interface. Taken together, these results show the general superiority of the New interface, but they also point to the value of being exposed to such an interface right from the start.

The mental workload ratings were transformed into percentages, and a similar ANOVA was conducted. Again, the main effect for Interface was significant ($F(1,22) = 16.09$, $p < 0.0006$). The mean workload rating for the New interface was 10.8%, whereas that for the Old interface was more than twice as high, 23.8%. No other effects were statistically significant. Thus, the New interface led to significantly less workload than the Old interface.

A non-parametric statistical analysis was conducted on the number of errors. The New interface led to 28 errors, whereas the Old interface lead to a total of 43 errors, a difference of 54%. A chi-squared test indicated that this difference was statistically significant (chi-squared(1) = 3.1619, $p < 0.05$, one-tailed). Thus, the New interface led to significantly more reliable performance than the Old interface.

The informal comments expressed by subjects at the end of experiment were consistent with the results just presented. Twenty-three out of the twenty-four participants ($p < 0.001$, binomial test) expressed a preference for the New interface design. The one participant who did not prefer the new design recommended a completely different type of interface, similar to the doctor's order sheet, and therefore did not favor the old design either. A summary of the most common comments and suggestions provided by subjects can be found in Doniz & Harkness (1994).

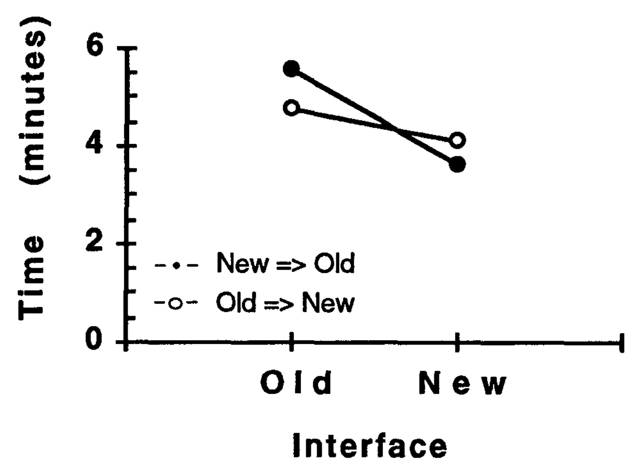

Figure 1. Interaction between Order and Interface for time to complete programming task.

DISCUSSION

This experimental evaluation sought to compare the performance obtained with the existing and redesigned interfaces for the Abbott Lifecare PCA Plus II. The informal comments obtained from subjects clearly show that the new interface was preferred by the participants. While it is certainly important to consider how the users felt about the interface, it is necessary to complement this anecdotal evidence with the results of the performance measures. All three of the other measures showed a statistically significant advantage for the New interface; the redesigned interface lead to faster programming times, lower ratings of mental workload, and fewer programming errors.

CONCLUSIONS

This paper was motivated by the fact that lack of attention to human factors in the design of medical equipment can lead to hazardous interfaces that induce human errors with potentially life-threatening consequences. The design of PCA machines was chosen as a focus for research, and several reports of mishaps associated with the use of PCA machines due to human error were cited. The PCA literature indicates that most authors recommend more training or simply "being more careful" as ways of reducing errors. Very rarely is redesign of the device mentioned as a way to improve safety. This shows a total lack of awareness of the impact of human factors on system safety.

This research has shown that the application of human factors design principles can lead to a PCA machine interface that is faster, less effortful, and more accurate to operate than a commercially available device. As far as we know, this is the first controlled study to empirically demonstrate this fact. If we are to improve the interfaces currently in operation, medical equipment manufacturers will need to adopt human factors analysis and design methods similar to those used in this research. Hopefully, providing empirical evidence of the benefits that can be realized by such methods, as we have done in this paper, will serve as a catalyst for change.

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