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The use of fault reporting of medical equipment to identify latent design flaws

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ABSTRACT

Background and purpose: Poor device design that fails to adequately account for user needs, cognition, and behavior is often responsible for use errors resulting in adverse events. This poor device design is also often latent, and could be responsible for "No Fault Found" (NFF) reporting, in which medical devices sent for repair by clinical users are found to be operating as intended. Unresolved NFF reports may contribute to incident under reporting, clinical user frustration, and biomedical engineering technologist inefficacy. This study uses human factors engineering methods to investigate the relationship between NFF reporting frequency and device usability.

Material and methods: An analysis of medical equipment maintenance data was conducted to identify devices with a high NFF reporting frequency. Subsequently, semi-structured interviews and heuristic evaluations were performed in order to identify potential usability issues. Finally, usability testing was conducted in order to validate that latent usability related design faults result in a higher frequency of NFF reporting.

Results: The analysis of medical equipment maintenance data identified six devices with a high NFF reporting frequency. Semi-structured interviews, heuristic evaluations and usability testing revealed that usability issues caused a significant portion of the NFF reports. Other factors suspected to contribute to increased NFF reporting include accessory issues, intermittent faults and environmental issues. Usability testing conducted on three of the devices revealed 23 latent usability related design faults.

Conclusions: These findings demonstrate that latent usability related design faults manifest themselves as an increase in NFF reporting and that devices containing usability related design faults can be identified through an analysis of medical equipment maintenance data.

1. Introduction

Evidence suggests that adverse events associated with medical devices are more often the result of use error than device malfunction [1]. One study found that 82% of all preventable errors involving anaesthesia devices were due to use error [2], while a study of infusion pump errors found that use errors were the most frequent cause of patient harm [3]. In some cases medical devices have poorly designed and difficult to use human system interfaces [4]. As a result, there is an increasing interest in incorporating human factors engineering (HFE) principles in the design and evaluation of medical devices. However, the use of HFE principles within healthcare is still not widespread [5]. There remain instances in which usability related design flaws are identified by users as a device malfunction. When investigated, conclusions of "No Fault Found" or "cannot replicate problem" are often reached. These outcomes cannot be used to mitigate the situation and may contribute to user frustration and incident under-reporting. In this study, we sought to identify devices that contain latent usability related design flaws using medical equipment maintenance data and human factors techniques.

Abbreviations: NFF, No Fault Found; UHN, University Health Network; WRHA, Winnipeg Regional Health Authority; NSAHO, Nova Scotia Association of Health Organizations; VIHA, Vancouver Island Health Authority; BMET, biomedical engineering technologist; HFE, human factors engineering.

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2. Background

Medical devices that are suspected by clinical users to be defective are typically sent to a hospital's biomedical engineering service department for troubleshooting and repair by biomedical engineering technologists and technicians (BMETs). Maintenance reports are routinely completed before returning the device back into service. The maintenance reporting data allow BMETs to categorize the device failure mode(s) and specify what repair actions were taken. One of the failure mode categories BMETs have the option of selecting is "No Fault Found" (NFF). The NFF category is used when a device sent for repair is found to be operating as intended. Usually in these instances the device is placed back into service without detailed investigation into the root cause [6]. Explanations for users believing devices to be defective include the failure of device designs to adequately account for user needs, cognition, and behavior, environmental factors, and intermittent faults.

Draper [7] provides a case study in which a usability related design flaw in a medical device was uncovered by an investigation initiated as a result of recurrent NFF reporting. An incident occurred at a hospital in which a syringe pump delivered a drug dose in half the anticipated time. When the nursing staff could not reproduce the error, the pump was sent to Biomedical Engineering where no problem was found. After recalling several similar NFF reports, BMETs subsequently performed a more detailed analysis. The analysis revealed that the user may have overridden the standard syringe size, instead programming the pump to expect a syringe size numerically equivalent to the dosage rate. It was demonstrated that this change results in an over infusion. The technologist concluded that this error could occur either through incorrect understanding of the difference between the dosage and syringe size or by accidentally pressing the up/down arrows on the pump thereby inadvertently changing the syringe size. While the design flaw was uncovered as a result of recurrent NFF reporting, the investigation was only initiated as a result of a technologist remembering previous incidents.

In this study we aimed to build on the premise of the case study by utilizing medical equipment maintenance data in order to proactively identify devices which may contain latent usability related design flaws that could lead to adverse events.

3. Methods and materials

3.1. Database analysis

In order to identify the devices most frequently associated with NFF reporting, a quantitative analysis of medical equipment maintenance data from University Health Network (UHN, Toronto, Canada), Nova Scotia Association of Health Organizations (NSAHO), Winnipeg Regional Health Authority (WRHA), and Vancouver Island Health Authority (VIHA) was conducted. UHN, NSAHO, WRHA and VIHA own approximately 2500, 3500, 7000 and 4000 equipment models respectively. Medical equipment maintenance data from 2003 to 2011 was analyzed in order to identify all reports of unscheduled equipment repair in which the BMET responsible for repair could find no fault. NFF reports were identified based on data contained within the failure mode field and free text comment field. Reports that contained "problem not found", "No Fault Found" (or variations thereof) as a fail mode were selected. Reports that contained free text comments indicating that no fault was found were also selected. Each NFF report was then associated with a particular equipment model so that the number of NFF reports per model could be determined.

The more frequently a device is used the greater the probability that it will be sent for repair. Therefore, in order to identify the devices with the greatest probability of containing latent usability related design flaws the NFF reporting rate was normalized in an attempt to account for frequency of device use. There are no hospital databases that outline the frequency of device use. As such, equipment inventory count was used in normalizing the reporting rate as there is presumed to be a correlation between frequency of device use and equipment inventory levels.

3.2. BMET semi-structured interviews

In order to contextualize and qualitatively confirm the results of the database analysis a series of semi-structured interviews with BMETs were conducted. Eight BMETs from UHN were recruited to participate in semi-structured interviews, which lasted between 30 and 60 min each. Participants work experience ranged from 5 to 25 years. BMETs were not made aware of the results of the database analysis. The interviews were recorded and transcribed by the investigator. The transcripts from each session were then thoroughly reviewed and initial specific low level codes were assigned to each word, phrase, or paragraph of text associated with an individual idea. The coded transcripts were then iteratively reread and reassessed allowing for codes to be combined, divided, added or removed. Inferences were then drawn about what the various codes might represent. Using these inferences, similar codes were grouped in order to form broad overarching thematic statements. Finally, each theme was compared to the original dataset in order to assess whether or not it appropriately described the data.

3.3. Heuristic evaluation

Next, heuristic evaluations were conducted in order to determine the likelihood that the devices identified as a result of the database analysis contain latent usability related design faults. The heuristic evaluations involved applying a set of usability principles to systematically evaluate each device. Two investigators, acting independently, evaluated each device, recording any heuristics violations. The usability heuristics used were: consistency and standards, visibility of system state, match between system and world, minimalism, minimizing memory load, informative feedback, flexibility and efficiency, good error messages, prevention of errors, clear closure, reversible actions, use of users' language, users are in control, and help and documentation [8]. After each device was evaluated, the lists of heuristics violations were combined and each investigator independently assessed the severity of the identified violations.

3.4. Usability testing

Three devices (a defibrillator, a feeding pump, and a thermometer) were selected for usability testing based on the findings from the database analysis, BMET interviews, and heuristic evaluations. The testing involved clinical users performing representative tasks with the devices in a simulated environment in order to reveal usability design flaws. The usability testing approach is strongly rooted in theories and methods from the field of cognitive science [9] and is recognized by the FDA as a method that should be used in identifying potential use related hazards [10]. For the purpose of this investigation, usability tests were conducted in order to assess whether the proposed methodology was successful in identifying devices with latent usability related design flaws. Eleven registered nurses and ten medical doctors from UHN participated in the evaluation of the defibrillator. Ten registered nurses from UHN participated in the evaluation of feeding pump and thermometer. Testing was conducted in a high fidelity simulation lab set up to resemble an intensive care unit. The environment contained three mannequins to simulate patients. Hospital sound effects were played

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