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Combining situated Cognitive Engineering with a novel testing method in a case study comparing two infusion pump interfaces

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ABSTRACT

We validated the usability of a new infusion pump interface designed with a situated Cognitive Engineering approach by comparing it to a reference interface using a novel testing method employing repeated measurements and process measures, in addition to traditional outcome measures. The sample consisted of 25 nurses who performed eight critical tasks three times. Performance measures consisted of number and type of errors, deviations from a pre-established normative path solution, task completion times, number of keystrokes, mental effort and preferences in use. Results showed that interaction with the new interface resulted in 18% fewer errors, 90% fewer normative path deviations, 42% lower task completion times, 40% fewer keystrokes, 39% lower mental effort and 76% more subjective preferences in use. These outcomes suggest that within the scope of this case study, combining the situated Cognitive Engineering approach with a novel testing method addresses various shortcomings of earlier testing methods.

1. Introduction

While infusion pumps contribute to patient care, they are not without risks. From 2005 to 2009, around 56,000 adverse drug events associated with the use of infusion pumps were reported (Center for Devices and Radiological Health, 2011). Many of those use-related hazards were related to user-interface design deficiencies (Center for Devices and Radiological Health, 2010), the critical impact of which on the patient's safety is a well-known problem (Obradovich and Woods, 1996; Vicente et al., 2003). Approaching designs using Human Factors engineering has proven to be an effective means to enhance positive performance outcomes, such as fewer errors, less time to performance tasks and lower mental effort (Lin et al., 1998; Syroid et al., 2012).

Nevertheless, the current practice in studying medical device technology has methodological shortcomings, as evidenced by an extensive literature study in this field (Schraagen and Verhoeven, 2013). First, previous studies lack a profound analysis of the user-device interaction by mainly focusing on final task outcomes (errors) and completion time as primary performance measures (Schraagen and Verhoeven, 2013). It has been suggested that only 69.5% of the practitioners pressed keystrokes contributing towards the goal state that is aimed to be achieved (Nunnally et al., 2004). Hence, merely measuring erroneous task outcomes undervalues the impact of complex menu structures on the process of task completion, and thus the occurrence of near accidents. Secondly, past studies draw their conclusions upon single user-device interactions, and are therefore unable to investigate the impact of learning effects on the infusion pump's usability (Garmer, 2002; Schraagen and Verhoeven, 2013). Lastly, previous studies lack a combination of subjective and objective measures in order to gain a more complete picture of the user-device interaction (Hornbæk, 2006).

1.1. Goal of the present study

The aforementioned shortcomings in studying medical device

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technology potentially limit the informative value with respect to the effectiveness of Human Factors engineering in medical device design. The aim of this study is to evaluate the usefulness of a novel testing method, in a case study involving the comparison of two infusion pump interfaces. The study compared an existing infusion pump interface with a new infusion pump interface that has been designed with a situated Cognitive Engineering Human Factors approach. The novel testing method utilized in this study addresses the current limitations in the study of medical device design. Specifically, this study addresses these shortcomings by combining qualitative and quantitative analyses with objective and subjective measures in a usability validation study with repeated measures. Hence, the main aim of this study is to investigate whether this novel testing method would address shortcomings of previous methods.

1.2. Novel method for studying medical device technology

As reviewed by Schraagen and Verhoeven (2013), contemporary methods for studying medical device technology mostly report traditional outcome measures rather than 'process tracing techniques' placing emphasis on cognitive processes. To address this shortcoming, we introduce a novel, replicable method for a standardized representation of the user's task completion process. Our proposed method is feasible for qualitative or quantitative research, as well as mixed-method approaches. We applied the Goals, Operators, Methods, and Selection rules (GOMS) model (John and Kieras, 1996) as a framework for data coding to achieve a formal representation of task execution processes. In addition, introduction of novel interaction design requires initial learning (MacKenzie and Zhang, 1999) and may even be hampered by inappropriate transfer (Besnard and Cacitti, 2005). In order to capture performance differences beyond the first encounter, we explored the impact of task repetition on performance.

2. Methods

Designing interfaces of medical devices is a complex consideration of multiple aspects. Several frameworks, tools, methods, and case studies are available regarding the application of Human Factors to the design of medical devices (Furniss et al., 2014). Despite this, a recent study showed that development teams still face challenges in incorporating Human Factors when designing interactive medical devices (Vincent et al., 2014). An integrative framework, that addresses both users and the technology, and in which results from both theoretical and field research can account for choices in the design process could not be identified for medical device design. Therefore, we adopted a situation Cognitive Engineering systems perspective that has been successfully applied in other complex task environments such as space laboratories, ship control centers etc. (Neerincx and Lindenberg, 2008). This is a coherent three-phase-process (see Table 1 for a phase description) with accompanying methods to systematically arrive at validated user interface requirements. The core of the methodology is the theory-driven specification of claims (phase 1 and 2) and their empirical validation (phase 3).

Next to phases and methods, the methodology also provides a specific format to specify and validate user requirements. Fig. 1 depicts an example of this format. The key elements of the format are use cases, requirements and claims. Use cases describe the general behavior requirements for the device that is being designed. Nine use cases were formulated, eight of them describing an interaction between the infusion pump and a user: (1) start and stop infusion, (2) inserting and removing syringe, (3) pausing infusion, (4) alarms, (5) switching pump on and off, (6) bolus, (7) drug group, (8) occlusion. The ninth use case concerned a rest category containing requirements on a more general level, relevant for each user-pump interaction, such as font size, contrast, spacing and distinctiveness of buttons, etcetera, which we labeled "usability/ergonomics". Each use case referred to multiple requirements (indicating what the user should be able to do with the infusion pump) and to one or more claims, containing the evidence from literature or empirical research for the need of the particular requirement. Claims are included to justify design decisions, highlighting the upsides, downsides and trade-offs involved. If the claims are an adequate justification of the requirements, then a system adhering to the requirements will help reach the design objective. Claims have to be specific and testable, and defined in terms of outcome measures such as effectiveness (accurate and complete), efficiency (time), satisfaction, etc. In the end, the new interface (working prototype) was based on 41 validated user requirements. Fig. 1 depicts an example of a use case and one accompanying requirement. As can be seen, the "claim" requirement integrates evidence from literature and empirical research that we conducted to inform the interface design, facilitating the complex issues we had to consider when designing the new interface.

The working prototype we used as the test interface involved a dynamic simulation that users could interact with and that stored user key presses (see Fig. 2a). As reference, the interface of the Braun Perfusor® Space syringe pump was used (see Fig. 2b) which is a commonly used infusion pump in Dutch hospitals. The reference interface provides a completely different implementation of the same display design principles that were used for the development of the new interface. Table 2 lists five basic display design principles and shows how the reference interface scores more poorly in terms of the design principles compared to the new design. These are hypotheses to be tested in the qualitative analysis part of our results.

2.1. Experimental design

A 2 × 3 (type of interface x session) within-subjects design was employed. Each participant had to accomplish three task sets with both interfaces, each task set consisted of eight tasks. Thus, participants had to accomplish a total of six task sets. Each task session comprised two task sets; one regarding the new interface and one regarding the reference interface. All three task sessions were conducted directly after each other. Tasks were similar regarding the critical operations they tested and only differed in the precise medication doses that had to be administered. In order to control for order effects and systematic biases, the order of interaction with interfaces, task variations and tasks themselves was counterbalanced using a standardized protocol (see Table 3). Interaction with interfaces was counterbalanced by alternating the type of interface (new or reference) the participant started the experiment with. Each of the three succeeding measures included two task sets (for the new and control interface respectively). The sets of task variations were rotated; each participant completed each of the three task set variations with both interfaces, regardless with which interface they started. This, in turn, enabled a comparison between participants starting with either the reference or new interface.

In order to control for order effects *within* task set variations, the sequence of individual tasks was manually randomized for each set of task variations. An exception were the first (starting the infusion pump) and the last task (stopping the infusion pump). As they naturally occur in the beginning and ending, we did not include them in the randomizing order.