Perceived usefulness of a usability issues reporting form to help understand "usability-induced use-errors": a preliminary study

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Perceived usefulness of a usability issues reporting form to help understand "usability-induced use-errors": a preliminary study

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Abstract. The Medical Device regulation requires manufacturers to anticipate and prevent risks of use errors of their medical device. However, manufacturers experience difficulties to understand the concept of "usability-induced use-errors". Based on a "usability framework" aiming at describing the relationship between usability design principles, usability flaws, usage problems, and outcomes, a usability evaluation reporting form had been designed to support understanding the use-error concept. This paper reports the preliminary evaluation of the perceived usefulness of this form. Results show that manufacturers found helpful the presentation of the results of a usability evaluation through this form for it supports the understanding of the usability origins and the consequences of use-errors. Even if the use of this reporting form should be made easier as usability experts experience difficulties to fill it, it seems a promising way to clearly present "usability-induced use-errors" to manufacturers.

Keywords. Human engineering; heuristic inspection; usability; pain monitor; use error;

Introduction

Manufacturers are asked by medical devices' (MD) regulatory authorities to anticipate and manage risks of use-errors related to poor design decision made during the design process [1]. Yet, manufacturers experience difficulties to understand what use-errors concretely refer to and how to prevent them. One reason for those difficulties may be found in a misunderstanding of the impact of their design choices on potential use-errors [2].

A use-error is an "act or omission of an act that results in a different medical device response than intended by the manufacturer or expected by the user" [3]. They are part of the "technology-induced errors", i.e. errors induced by the introduction of health information technology [4]. Amongst use-errors, a subset origins in the poor design of the device in terms of usability, namely "usability-induced use-errors".

Providing manufacturers with usability evaluation reporting forms that structure the description of potential use-errors may help them understand use-errors and their

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origin in usability. This paper proposes a preliminary evaluation of the perceived usefulness of such a usability study reporting form. We took the opportunity of a formative heuristic inspection of a medical device to gather perceptions of manufacturers and usability experts' on this form.

1. Background

The reporting form has been developed from a "usability framework" [5] aiming at describing the relationship between usability design principles, usability flaws, usage problems, and outcomes (cf. figure 1).

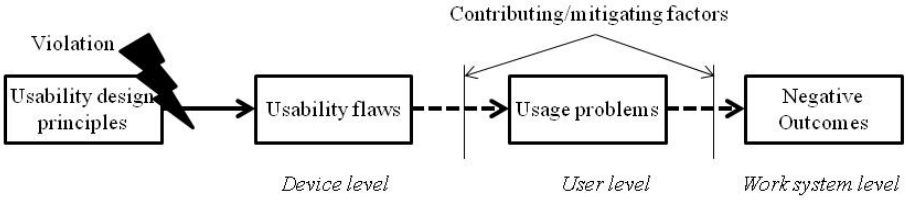

Figure 1. Schematic representation of the origin of usability flaws and of the propagation of their consequences towards the user and the work system in which it is implemented (adapted from [5])

Usability design principles (also usability heuristics/criteria) are recommendations for good practice in usability (e.g. [6]). When those principles are not applied during the design of a product, usability flaws appear. Those flaws are noticed from the device perspective. When the device is put in use, flaws may negatively impact users' experience. Those negative experiences are usage problems. Finally, usability flaws may also have consequences on the work system in terms of performance, workarounds and patient-safety (i.e. negative outcomes). The propagation of the infraction of the usability principles up to the work system is rather probabilistic than causal: mitigating factors independent from the device characteristics (e.g. high training, regular workload or adapted resilience) may prevent this propagation; au contraire, contributing factors (e.g. lack of training or high workload) may facilitate this propagation. In the framework, "usability-induced use-errors" are a specific type of usage problems which consequences are noticeable at the outcomes level.

2. Study context

NIPE® is a comfort monitor displaying graphically the result of an algorithmic transformation of the cardiac frequency retrieved from patient's monitoring [7]. It supports monitoring the well-being of newborns especially for babies born with delivery complications and preterm/ill babies. Usability experts have been solicited to ensure the device be compliant with usability requirements, i.e. safety use, to go to CE marking. Their intervention included applying the usability engineering process. The results of the present study were recorded during the first formative evaluation of this prototype through a heuristic evaluation.

3. Methods

3.1. Heuristic evaluation

Three usability experts independently performed a heuristic inspection of the NIPE® using Scapin and Bastien's list of usability principles [6]. They followed frequent and reasonably foreseeable worst use case scenarios based on the analysis of the intended context of use analysis (details in [8]). To stick to risk management requirements, for each usability flaw, the risk associated to their consequences was estimated (low, medium or high) as a function of their severity and frequency. Two involved experts (RM and CB) already took part in the intended context of use analysis; the third one (NL) read the detailed report of the analysis.

In contrast with usual heuristic inspections, this one was supported by a structured reporting form adapted by RM from the "usability framework" (table 1).

Table 1. Instances of reports of usability flaws through the proposed reporting form.

Usability principle	Violation (usability flaw)	Potential usage problem	Potential outcome	Probability x Severity = Risk
Significance of codes	There is no information about the meaning of the curve and the smiley (Figure 2, right)	Difficult to interpret, wasting time and inability to understand	Decision based on a wrongly understood information	Moderate x Moderate = Medium
Consistency	"Instantaneous" NIPE® index corresponds to the "averaged index" curve not to the "instantaneous index" one (Figure 2, left)	Inability to understand, wrong representation of the patient status, doubt about the reliability of the device decreasing confidence	Decision based on a wrongly understood information	Moderate x Minimal = Low

3.2. Perceived usefulness evaluation

Data on perceived usefulness of the reporting form has been recorded opportunistically via handwritten notes by RM. They were collected from four representatives of the manufacturers (chief executive, designer, engineer and quality control officer). To see the benefice-risk ratio of the structured reporting form, it was necessary to evaluate its perceived usefulness but also if difficulties were encountered filling it in. Therefore, comments from two usability experts (CB & NL) were also collected to get their perception on filling in the form.

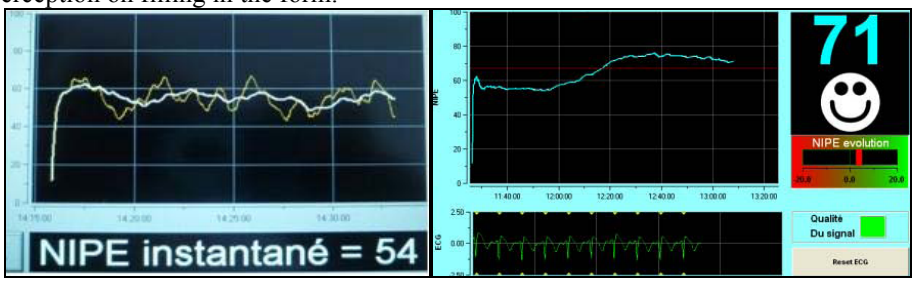

Figure 2. Screenshots of the "instantaneous" NIPE® screen (left) and of the main NIPE® screen (right)

Recorded comments were classified by RM as advantages and drawbacks either for filling in the form or for interpreting its content.

4. Results

A total of 46 usability flaws are uncovered. A huge majority (40) are assigned with a low risk: they mostly deal with non prompting icons and graphical elements along with the handling of the setting features. Six usability flaws are considered with a medium risk: they are related to the difficulty to interpret the NIPE index. For instance, there is a potential risk of use-error (usage problem) related to the misinterpretation of the valence of the NIPE index which could lead to a wrongly based therapeutic decision.

As for the perception of the usefulness of the reporting form, users' main comments are synthesized in Table 2. Manufacturers' representatives consider this way to present the results is useful to understand the origins and consequences of use-errors. As for usability experts, they think it can be useful to help readers to understand the origin of the use-errors because it presents more clearly and in a more structured way the results of the inspection. However, they reported also difficulties to fill in the form, e.g. it is sometimes difficult to anticipate the usage problems and outcomes. Nonetheless, they think this form could improve the consistency of their reports. In sum, whatever the profile of the user, no perceived drawback was reported about interpreting usability results through the form.

Concerning the filling in of the report, an important insight is that the usability expert who did not analyze the context of use (NL) was unable to anticipate potential usage problems and outcomes along with their related risks.

Table 2. Synthesis of the main comments from manufacturers' representatives and usability experts on the usefulness of the reporting form. Comments are sorted as perceived advantages or drawbacks and according to the potential function of the reporting form (support to report vs. support to interpretation).

		Usability experts	Manufacturers' representatives
Data reporting	Advantages	Compels to have the mind clear about the description of the usability flaw, the potential usage problems and outcomes.	Non applicable
	Drawbacks	Difficult to make easy-to-distinguish descriptions of usage problems and outcomes (hard "exercise in style"). Difficult to anticipate some usage problems/outcomes along with the risk level even more when the expert did not perform the context of use analysis. Not obvious whether the estimated risk is related to usage problem, outcome or both. It makes harder its estimation.	Non applicable
Data interpretation	Advantages	More precise description of the usability flaws: straight to the point. Clarify the consequences of the usability problems. Outcomes related to patient safety risks are clearly identifiable.	It is important distinguishing how the usability flaws can affect the users from the use-errors they can induced. Faster identification of the origins of potential use-errors.
	Drawbacks	/	/

5. Discussion

This paper presents a first attempt to clarify the concept of "usability-induced use-errors" during usability evaluation by turning a "usability framework" into a reporting form. This preliminary study focuses on the perceived usefulness of this form. Overall,

manufacturers and usability experts consider this form can be useful to understand "usability-induced use-errors"; however, usability experts reported difficulties to fill in it. Those difficulties could be fixed by explaining more clearly how to evaluate the severity of the consequences of a usability flaw. In sum, basing the usability evaluation reporting form on a framework linking usability principles, usability flaws, usage problems and negatives outcomes seems a promising way to help manufacturers understand "usability-induced use-errors". Another important result that could have been expected is the impossibility for a usability expert to anticipate usability flaws' consequences without having performed first an analysis of the intended context of use.

There is an increasing need for standardized descriptions of usability flaws related to use-errors [9] (a) to capitalize on them and build databases allowing comparisons across systems and (b) to use those databases to design in an informed way similar medical devices. Yet, databases of structured descriptions of "usability-induced use-errors" are currently often confidential or hardly accessible. Reporting forms can structure them: e.g. Peute *et al.* [10] developed an efficient scheme to capitalize unambiguously usability facts; however, this scheme is research-oriented and not adapted to manufacturers' needs. An important added-value of the present reporting form is that, besides providing a detailed report of potential use-errors, their underlying usability causes and their potential impact, manufacturers understand it.

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