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Usability Validation of Medical Devices: Issues in Identifying Potential Use Errors

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Abstract. In order to prevent use errors with their medical devices, manufacturers have to integrate a safety-oriented usability engineering process in their product development lifecycle. A critical step of this process is the identification of potential use-errors. Standards and guidelines recommend to triangulate several sources of information e.g. scientific literature, incident reports, manufacturer's files and user's feedbacks. This paper presents lessons learned from applying these recommendations during an international project. We identify issues with (i) searching literature and databases, and (ii) interpreting collected data. Nevertheless triangulation of information sources allows to identify different types of use errors therefore providing valuable lists of potential use errors. Issuing recommendations aim at making easier this critical task.

Keywords. Human engineering, usability, CE marking, use-errors, validation

1. Introduction

In Europe, health authorities require the demonstration of the reliability and safety of medical devices (MD) before they are authorized to be put on the market (CE marking). Unfortunately, when a MD is poorly designed, usability flaws may induce dangerous use errors that may ultimately lead to patient's harm / death. "Use error" is considered here as *"user action or lack of user action while using MD that leads to a different result than that intended by the manufacturer or expected by the user"* [1].

In Europe, [1] but also in the United States [2], manufacturers have an obligation to integrate in their design and development lifecycle a safety-oriented usability engineering process. A critical step in this process is the identification of potential use errors. It is recommended to identify use errors that have been reported for similar devices in order to avoid those problems for the device under development. For that purpose, harmonized standards [1] and international guidelines [3] recommend to combine and integrate several sources of information:

- Literature: "journal articles, proceedings " [3], "pertinent literature" [1];
- Online databases: "performing online searches" [1] on "Relevant internet sites"[3] related to sentinel events and incident reports;
- Manufacturers' files: "previous Human Factor Engineering (HFE) / User Experience (UE) studies conducted on earlier versions of the device being

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developed or on similar existing devices" [3], " complaint files" [1; 3], and "interviews from trainers" [3];

- Users' feedbacks: interviews with "device users" [1, 3]

We took the opportunity of a research project focused on MD usability validation to identify benefits and issues when trying to apply these recommendations.

2. Study context: the USEVAL-DM project

USEVAL-DM (USability EVALuation of Medical Devices) is a Franco-Swiss project involving the Lille Academic Hospital, the Geneva University Hospital and three MD manufacturers. Its goal is to establish scientific evidence regarding critical methodological options of usability validation that are not precisely defined by regulatory documents. The project intends to deliver guidelines to optimize usability validation of MDs. Usability validation is a summative evaluation performed on the final version of the MD to be released on the market. It aims at ensuring that the MD presents no remaining risks of usability related use errors.

The first step of the USEVAL-DM project is to establish an as-exhaustive-as-possible list of such use errors for three medical devices developed by the SME partners. These MD differ in their technical characteristics and intended users:

- **Navigation aid system:** this MD is used to assist interventional radiologists during minimally invasive needle procedure performed under scanner. It is used in a very limited medical niche.
- **Non invasive monitor** providing an objective rating of patient pain and/or comfort. This device is the first of its kind.
- **Needle free disposable auto-injector device** for adrenaline to be used by patients for the treatment of an anaphylactic shock. Auto-injectors are well-known devices but the transdermal delivery is quite new in this field.

The methods used in the project comply as far as possible with recommendations.

Table 1. Overview of the USEVAL-DM methods to establish the list of potential use errors for each device.

	Literature search	Online databases	Manufacturers' feedbacks	Users' feedbacks
Navigation aid system	Pubmed and Scopus	FDA databases	Risk management files and users' feedbacks	Interviews and observations of actual use
Pain monitor	Pubmed and Scopus	FDA databases	Usability files of previous versions and users' feedbacks	Interviews and observations of actual use
Needle free auto-injector	Pubmed and Scopus	FDA databases	Risk management file and results of previous users interviews	Interviews and observations of simulated use

To establish the list of potential use-errors for each device, several sources of information are triangulated (cf. Table 1). We search (i) two scientific databases with queries adapted to each device: PubMed, the main literature database for medical studies and Scopus, the largest cover of literature for technologies; a snowball method is used to complete the literature result; (ii) relevant FDA's incident reports databases (MAUDE, Medsun, Recalls, Post Market Surveillance Studies); we analyzed (iii) files provided by manufacturers (e.g. risk analysis or compilation of users' feedbacks); and we collected (iv) users' feedbacks through users' interviews completed with usage

observations. This paper draws lessons learned during the project while instantiating those methods for the three medical devices under scrutiny.

3. Methods

Issues to apply the recommendations were regularly listed by the researchers of the USEVAL-DM project. All questions and discussions during debriefing meetings along with decisions to adjust the methods were documented. A content analysis of collected data identified recurrent themes.

4. Results

4.1. Lessons learned with the literature search

Overall, usability studies are poorly indexed. They are often part of larger studies and indexed as "evaluation" studies rather than "usability" studies. This makes it hard to identify them and leads to missing relevant publications. Regarding the auto-injector, a search query validated by an expert librarian resulted in selecting 24 papers. Still, the snowball method identified 9 additional papers; some of them were indexed in PubMed but did not match the initial query because of poor / incomplete indexation terms.

There are very few publications tackling usability and use errors for innovative MDs and MDs used in a restricted medical niche. We retrieved no papers on use errors for navigation aid systems used under scanners and only 2 for pain monitors. Similarly, no papers were found on use errors for needle free auto-injector devices: the query had to be extended to auto-injectors with needles, increasing at the same time the workload related to screening and analyzing papers. Besides, it was also necessary to adapt the results of the review to the characteristics of the needle free auto-injector under evaluation. In summary, narrow queries would likely provide no relevant information while larger queries provide too many irrelevant results.

In papers actually reporting on use errors, descriptions of the use errors and of their root causes are often incomplete (e.g. description of the difficulties to handle an injection device but no description of the physical properties of the device that may have led to this issue). It prevents from taking advantage of this knowledge.

4.2. Lessons learned with the search of incident reports databases

There are very few incident reports for innovative devices and for those used in a restricted medical niche. Besides, the classification of the incident reports is inconsistent: a given incident could be classified one way with a specific search option, and another way with another one, especially in MAUDE. For instance, to identify the category of device of the navigation aid system, it was necessary to search by the brand names of similar devices. By doing so, we found a few incidents (but not related to use errors): in the description of the incident, the category of devices is displayed (e.g. "electromagnetic navigation system"). However, this category did not exist in the drop-down menu to search by devices category. Those inconsistencies may have led to missing relevant reports. Finally, in the reports related to use errors (e.g. for the auto-

injector), descriptions of use errors are seldom precise enough (especially on the usability cause of the incident) to be interpreted unambiguously.

4.3. Lessons learned with the analysis of manufacturers' files and feedbacks

Understandably, there are no feedbacks from users for devices still under development. When a previous version of the device is already on-sale (i.e. pain monitor and navigation system), manufacturers may gather actual users feedbacks. However, the feedback forms are not standardized nor structured leading to heterogeneous and often not precise descriptions of the rare incidents reported. Those feedbacks are hardly reusable to identify use errors and their origin. Similarly, risk management files of previous or similar versions of the MD do not consider use errors and usability causes.

4.4. Lessons learned with users feedbacks' analysis (interviews and observations)

Standards and guidance documents highlight that the point of view of users of similar devices has to be considered. Considering "users' point of view" is best achieved through a standard analysis of the context of use, including use observations and users interviews. In the project, as this task was carried out by usability experts, no particular issue has been documented regarding the application of this method. Moreover, it proved an indispensable source of information to identify potential use errors, and even more important for innovative MDs (pain monitor) and for MDs targeting a restrictive medical niche (navigation aid system). Indeed, for those types of MDs, use errors are hardly reported nor collected by manufacturers. For those devices, direct feedbacks from users constitute the only opportunity to get useful insights on potential use errors. For the navigation aid system, the analysis of the context of use was the only source of information available besides manufacturer's feedbacks. For the pain monitor, most of the use errors were identified from a previous usability file (including a former context of use analysis) and from the current context of use analysis. For the auto-injector device, results from users' interviews and from the context of use analysis provided the knowledge necessary to adapt the instances of use errors found in the literature and in reports to the specific characteristics of the device (e.g. the absence of needle).

5. Discussion

Table 2 provides an overview of lessons learned in the USEVAL-DM project when applying regulatory recommendations for identifying potential use errors with MDs undergoing usability validation. Each method generates its share of difficulties, mostly in terms of searching relevant information within the literature and databases, and interpreting collected data. Other issues are more specific to the type of MD under evaluation: unavailable data or seldom data for innovative devices and those used in a restricted medical niche. In this context, recommendations to triangulate methods and to integrate users' interviews and observations are highly valuable. In the project, collating together several sources of data improved the scope of use errors in the final list, because some use errors are identified by only one specific source.

Another issue comes with the expertise required by the methods and the workload they engender. Those methods are time consuming and require usability expertise to identify actual use errors and their usability cause, or to properly carry out an analysis

of the context of use. In the USEVAL-DM project, all tasks have been performed by researchers familiar with databases search strategies and well trained in the context of use analysis. In a context where manufacturers have difficulties understanding the rationale behind the harmonized standards [4, 5] and suffer from poor usability maturity level, but at the same time are supposed to implement said standards on their own, it is likely that the difficulties listed in this paper could not be overcome. This would impact negatively the identification of the potential use errors while it is a critical step to perform correctly and efficiently a safety-oriented usability validation.

Table 2. Lessons learned from the USEVAL-DM project for identification of use errors.

	Application of the method	Specificity for each type of MD
Literature	Poor indexation of papers and description of use-errors' root-cause	No data for innovative devices and those used in a restricted medical niche
Incident reports databases	Inconsistent classification and poor description of use-errors	No data for innovative devices and those used in a restricted medical niche
Manufacturers' feedbacks	Lack of structured description of use-errors	No feedbacks for device under development
Users' feedbacks	Manufacturers' difficulties in integrating context of use analysis in the MD development lifecycle	Valuable source of information for innovative devices or those used in a restricted medical niche

Safety-oriented usability practices are still far from being routinely applied. This situation impedes the proper planning, budgeting, and running of the usability validation of MD and ultimately the prevention of use errors. To support the identification of use errors that have been reported for similar devices, there is a need for (i) more accessible sources of information to be explored (e.g. develop an open usability studies repository, make existing national databases accessible); (ii) more easy and reliable searches (e.g. improve the indexation of papers and reports: add "usability" as a MeSH term, use a unique technology categorization scheme in databases); (iii) improving the completeness of publications, reports, and manufacturers' files (e.g. use structured reporting forms including the description of usability issues). Those proposals are far from being easy to implement, they pose interesting research challenges that must be overcome.

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