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Quality of Life through Quality of Information
J. Mantas et al. (Eds.)
IOS Press, 2012

doi:10.3233/978-1-61499-101-4-368

Patient safety-oriented usability testing: a pilot study

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Abstract. This paper focuses on the prevention of technology induced errors in Health Information Technology (HIT) applications through usability tests in which patient safety-oriented usability goals have been included. A case study presents the evaluation of a web-based medication-related Clinical Decision Support System (CDSS). Systematically defining beforehand usability goals according to the potential use errors is an objective and replicable approach to identify the strengths and weaknesses of an application in terms of patient safety.

Keywords. Use errors; usability test; usability goals; patient safety; CDSS

Introduction

CDSS have been shown to have a positive impact on patient safety by improving prescribing practices and reducing medications errors [1]. However, they remain difficult to implement and face acceptance problems. Moreover, they may also generate new safety problems, namely "technology induced errors" [2]. These difficulties are partly due to human factors and usability problems [3]. The application of User-Centered Design (UCD) principles [4] has been shown to enhance devices' usability, efficiency and safety. Standard UCD approach includes analysis of the work system, continuous support to the design and iterative usability evaluations in the form of heuristic inspections and users testing. This paper focuses on the users testing phase. This method allows evaluating a product by testing it with actual end-users: it aims at observing people using the product to identify usability problems and room for improvement [5]. It involves measuring how well test users respond in three main areas: effectiveness (e.g. could they complete the tasks using the system?), efficiency (e.g. were they able to carry out their tasks in a reasonable time?) and satisfaction. It is recommended that usability goals be defined *a priori* according to the critical characteristics of the tasks supported by the application. Completion of usability goals is used to objectively assess the usability of the tested device.

For safety sensitive HIT applications, it is mandatory that usability evaluation studies consider patient safety issues [6]. So, during usability tests, specific patient safety-oriented usability goals should be included amongst the usability goals. Few

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studies mention explicitly usability goals set beforehand: most often, participants' behaviors and verbalizations are analyzed without referring to any goal. In the field of medical devices, one study reports the explicit use of safety-oriented usability goals [7]. No such study could be found in the domain of HIT applications.

This study aims at presenting how patient safety-oriented usability goals could be applied to assess HIT applications. The tool under usability evaluation is a medication-related CDSS developed during the European project "Patient Safety through Intelligent Procedures in medication" (PSIP). This web-based application (see Figure 1) provides a summary of patients' hospitalization data (including lab test results) and allows simulating a prescription by entering a list of drug orders to check whether some PSIP alerts are triggered (cf. [8] for details). We describe here the users testing, with a special focus on the usability goals, which took place during the design iterations (formative usability testing). Those goals cover three objectives: to test (i) the usability of the critical and ancillary functions of the application, (ii) the accuracy and safety of the application and (iii) the information content displayed.

Figure 1. Screenshot of the drug entry page of the PSIP medication CDSS.

1. Methods

1.1. Participants

Existing standards recommend performing formative usability testing with 5 participants per category of users to detect 75% of the usability flaws of the system [9]. The prototype under evaluation is designed for physicians and pharmacists wanting to control medications' orders. Both categories of professionals can be considered as a homogeneous user group for this kind of task. Therefore, 3 hospital physicians and 3 pharmacists were invited to participate.

1.2. Usability goals, scenarios and patients' cases

Table 1 lists the usability goals corresponding to the objectives of the test. Scenarios of use inspired by actual tasks of physicians and pharmacists have been elaborated. Four real de-identified patients' cases have been used. The summaries of those cases (diagnoses, administration information and lab tests results), without the drugs lists, were implemented into the application and truncated at certain dates to make them appear as current stays. The history of the drugs administered before the day of

truncation and the list of medications to be ordered at the day of truncation were given to the clinicians on a printed form. Scenarios and patients' cases were balanced across the participants.

Table 1. Objectives of the test and corresponding usability goals.

Objectives	Corresponding usability goals
Test the usability of the critical (enter drugs and check alerts) and ancillary functions (remove one med, remove every med, change alerts' threshold)	1. **Efficiency**: at the end, 100% users should succeed in entering a list of drugs and in checking this list for PSIP alerts (without hesitation or help). No training phase is proposed before the test. So, we tolerated failures at the first trials at using it.
	2. **User Guidance**: at first attempt at entering a prescription, (2a) 80% of subjects should be able to enter a drug without help; when plotting together all drugs entered by all users, (2b) 90% of drugs should be entered successfully without help.
	3. **User Guidance**: 80% of subjects should succeed in performing the ancillary tasks at their first attempt.
Test the accuracy and safety of the application (especially the risk of getting false alert/not getting the due alerts due to usability problems, e.g. wrong entry of drugs)	4. **Accuracy, safety**: 0% users should end up checking a wrong list of medications (*i.e.* a list with a wrong drug name/with a drug missing)
	5. **Accuracy, safety**: plotting together all drugs entered by all users for all cases, there should be less than 5% of (recovered) errors in drug entry
	6. **Error recovery**: 100% errors in entering a drug should be identified and corrected by the user before checking the prescription (i.e. users spontaneously corrected errors they made before asking the system to check for PSIP alerts)
Test the information content displayed: understandable and unambiguous	7. **Appropriateness of the information content** (does it meet users' needs, is it clearly understandable?): assessment through the analysis of users' comments (not possible to set quantitative usability goals)

1.3. Material, study procedure and data gathering

The usability test took place in a French 416-bed hospital. We used a desktop connected to the hospital intranet to access the web-based CDSS. The computer was connected to a portable usability lab recording all users' interactions with the human-computer interface along with the users' verbalizations. Each test started with the presentation of the project and with a short description of the web-based CDSS. The general instructions were read and the consent signature fulfilled. Participants then performed the tasks defined by the scenarios with the 4 patients' cases. The session ended with participants fulfilling the System Usability Scale (SUS) questionnaire. Participants were asked to think aloud all along the test.

1.4. Data analysis

For each participant and each task concerned by the usability goals, levels of success (i.e. success, success with help, failure) have been documented. In cases of need of help or failure, in-depth analyses of the audio-video protocols have been performed. Moreover, as for any usability test, a standard qualitative analysis procedure has been applied to the verbalizations and behaviors of the participants.

2. Results

Two physicians and 3 pharmacists completed the test (the third physician unfortunately did not show for the test). Most of the usability goals (4/7) are fully achieved (cf. Table

2) and 3 are partially achieved (2a, 3 & 7). A supplementary qualitative analysis allows determining the usability problems that are responsible for the non-achievements. For usability goal 2a, problems concerning the procedure for the drug entry (critical function) have been detected: e.g., the participant types the complete name of the drug and then hits the "enter" key while he should have selected the drug name in the drop-down list. This problem causes difficulties in entering a drug only at the two first attempts. For usability goal 3, users encounter some problems to perform ancillary tasks: e.g., the "remove every medication" button is not used by 2 participants. For usability goal 7, users' comments reveal that the way the alert is displayed could cause erroneous interpretations and therefore could endanger patient safety. This problem is not related to the medical content of the alert but merely to its wording, not sufficiently elaborated to fit clinicians' language.

Comments analysis reveals that the clinicians like the principle of the application, its efficiency in terms of prescription checking and the simplicity of its functions. This result is supported by the high degree of satisfaction (SUS score: 80/100).

Table 2. Status of achievement for the 7 usability goals

Usability goals	Results	Achievement status
1	This goal is reached at the third iteration of the test and confirmed at the fourth one. Once the list of drugs entered, no user experienced any difficulty to check it for PSIP alerts.	Achieved
2 a	Two users (40 %) failed to enter a drug in the application at their first attempt at entering a prescription. After one or several attempts, s/he asked for help and was provided with instructions.	Partial achievement
2 b	Considering all 37 drugs entered by the users for the first iteration, two (5%) are considered as failure: 95% of the drugs could be entered without help.	Achieved
3	It is achieved for two secondary tasks (removing a drug from the list and changing the alert's threshold) out of 3: the test fails for the task "remove all drugs from the list". This did not prevent the users from achieving the task, with a slower procedure.	Partial achievement
4	No participant ended up checking a wrong list of medications (*i.e.* a list with a wrong drug name or with a drug missing).	Achieved
5	There are 3 recovered errors for the entire test (160 drugs entered), which represents less than 2% of errors.	Achieved
6	Users made errors in entering the drugs (3% and 5 % of entered drugs respectively for the 1st and 2d iteration; no error for the two last iterations), but they were able to catch all errors before checking the prescription.	Achieved
7	The qualitative analysis of participants' comments revealed 9 negative comments dealing with the content of the delivered information (scientific accuracy, alert triggering model, alerts' prioritization), its display (unclear) and its completeness (need for other information on the patient).	Partial achievement

3. Discussion

This paper has presented the application of patient safety-oriented usability goals to evaluate a web-based medication-related CDSS through user testing. Two quantitative usability goals are not achieved: they both are due to a typical problem of functions' intuitiveness that is rapidly overcome. The first unachieved usability goal (3) deals with the comfort of use of the application. As for the second one (2a), the difficulties to enter drugs without help in the system are compensated by the full achievement of the "error recovery" usability goal (4). This ultimately means that the application has a

good safety in entering the drugs. As for the qualitatively assessed usability goal, it shows that the information content requires re-engineering work in terms of information display to avoid misinterpretation. Due to the small sample of respondents, SUS questionnaire results should be carefully interpreted. They are nonetheless congruent with the other results: the application, in its tested version, is quite easy to use without training and is well-perceived. Once the identified usability flaws are fixed, a final summative evaluation should be performed on the new version to assess its usability and its safe use with a larger sample of end-users.

The European Union (EU) regulation on medical devices [10] considers stand-alone software contributing to diagnosis and treatment (e.g. CDSS) as a medical device, therefore subject to European Conformity marking. As a consequence, they must comply with the essential requirements of the directive, including "reducing, as far as possible, the risk of use error due to the ergonomic features". In this context, there is a need for objective and replicable methods to perform patient safety-oriented usability evaluations. In evaluation studies, systematically defining usability goals according to the use error risk analysis would facilitate the compliance with the abovementioned EU directive essential requirement.

Acknowledgments

The research leading to these results has received funding from the European Community's Seventh Framework Program (FP7/2007-2013) under Grant Agreement n°216130 – the PSIP project.

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