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A framework for reporting on Human Factor/Usability studies of Health Information Technologies

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Abstract. Increasingly, studies are being published on the potential negative effect of introducing poor designed Health Information Technology (HIT) into clinical settings, relating to technology-induced errors and adverse events. Academic research on HIT design and evaluation is an extremely important source of information in providing new insights into factors contributing to successful system (re)design efforts, system user-friendliness and usability issues and safety critical aspects of HIT design. However, these studies have been inconsistent and incomprehensive in their reporting, complicating the appraisal of outcomes, generalizability of study findings, meta-analysis and harmonization of the available evidence. To improve identification of type of use errors and safety related issues regarding design and implementation of HIT, consensus on issues to be reported on in scientific publications is a necessary step forward. This study presents the first approach to a framework providing a set of principles to follow for comprehensive and unambiguous reporting of HIT design and usability evaluation studies with the objective to reduce variation, improve on the publication reporting quality and proper indexation of these studies. This framework may be helpful in expanding the knowledge base not only concerning the application of Human Factors (HF)/ Usability studies of HIT but also improve the knowledge base of how to (re)design and implement effective, efficient and safe HIT.

Keywords. Usability, Human Factors, Health Information Technology, Framework, Delphi study

Introduction

Though Health Information Technologies are advocated as one of the main strategies for enhancing safety in healthcare, concerns have arisen about the use errors and safety risks introduced by these technologies, some of which resulting from suboptimal designs and low usability [1, 2]. The evolving evidence on the negative impact of poorly designed HIT on daily healthcare practices has drawn attention to usability and user centered design (UCD) approaches of these technologies. The ultimate aims are to prevent use errors and minimize safety risks induced by these technologies.

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In the last few years the reporting of Human Factor (HF) and Usability evaluation studies of Health Information Technologies (HIT) has indeed increased vastly. The need to increase and extend the knowledge on HF usability studies in Healthcare is thus becoming more and more important [3]. Academic research on HIT design and evaluation is an extremely important source of information in providing new insights into factors contributing to successful system (re)design efforts, system user-friendliness and usability issues and safety critical aspects of HIT design. However, a systematic review on usability studies of Interactive Health Information Systems showed that scientific reports of these HF/Usability studies are not well structured and lacking in quality [4]. Application domains (e.g. the type of system evaluated), case study objectives, stages of development, research methods applied, and study outcomes in these scientific reports of HF/usability studies extremely differentiate. An even more important problem is that these studies have been inconsistent and incomprehensive in their reporting, complicating the appraisal of outcomes, generalizability of study findings, meta-analysis and harmonization of the available evidence. To build an evidence base of sound HIT design and usability principles, reporting of these kinds of academic studies should be of a certain degree of quality: complete, homogeneous and unambiguous.

Without a framework providing guidance of the reporting of HIT design and usability evaluation studies, the building of a proper evidence base of usability and design principles of HIT that lead to safe use in practice would remain hampered. In a collaborative effort of the IMIA and EFMI working groups, we therefore set out to develop a framework of good practice of reporting on HIT design, development and usability studies.

This paper describes the methods followed to establish the first version of this framework for reporting on HF/usability studies of interactive HIT. We aim to gain international consensus on the principles for reporting as defined in framework and have therefore developed an on-line survey to be delivered by means of a Delphi study.

1. Methods

1.1. Development of framework content

To develop the framework, an initial set of issues to be addressed in publications of HIT design and usability evaluation studies was drafted by analyzing all ISO (9241-11, 9241-21013407, 14155, ISO/IEC 14598-5, 9126-2,60601-1-6) and ANSI/HFES Standards (100) concerning usability and human factor engineering and/or evaluation within UCD processes of HIT. These standards include guidance on human centered design activities throughout the life cycle of computer-based interactive systems, how the usability of a system can be specified and evaluated, describe procedures and detailed user-based methods for assessing system usability and explain how measures of user performance and satisfaction can be used to assess how any component of a working system affect the whole working system in use. These standards were analyzed for activities (and related methods) to be undertaken in each phase of a user centered design approach of development of a computer-based interactive system.

These phases are 1) to understand and specify the context of system use, 2) to specify the user and organizational requirements, 3) to produce system design solutions, 4) to evaluate system designs against requirements. For example, to understand and speci-

fy the context of system use, relevant characteristics of users, of computer-supported tasks which may influence system usability, hardware and software attributes, and of the physical, social and cultural environment need to be described.

Existing standards such as STARE_HI [5] and SQUIRE [6] were also reviewed. For example, based on the review of SQUIRE, it was decided that a statement on compliance of the study to handling of ethical principles and statutory and legislative regulations should be included in publications on HIT design and usability evaluation. Finally, the initial list of issues to be addressed in scientific reports was expanded based on authors' experiences and on the HF/usability articles included in the systematic review [4]. The list of key words indicating type of system, type of study, research area and applied methods was drawn from the systematic review. Likewise, the systematic review revealed the need for a detailed description of the conduct of methods applied and their suitability in the context of the study aims in terms of their strengths and weaknesses.

In the further development of the content of the framework, iterative validation and feedback rounds consisting of multiple meetings with research team members of EVALAB and HITLAB, from Lille and Amsterdam, were organized. Six HF/usability experts of these centers were involved in these validation/feedback rounds. The first validation round started with the first version of the framework developed by the research team of HITLAB. This version consisted of the initial set of information items derived from the review of the ISO and ANSI standards, the STAR-HI and QUIRE standards, and the systematic review. It contained a definition of each item and the source the information element was extracted from. Each of these information items and their definition was discussed and confirmed by consensus.

In the second round the updated version of the framework was translated into an online survey. An online open source tool website 'Qualtrics.com' was applied to deliver the survey. This second iterative round aimed at validating the contents and design of the framework by the web survey. The six research team members of EVALAB and HITLAB pilot-tested the survey. The focus of the pilot testing was on debugging the online survey.

Finally, usability inspection was performed by 4 usability experts from the EVALAB team. The focus of the usability inspection was on clarity of information items, lay-out of information items, button functionality, and the login and logout procedure of the survey.

1.2. Participant identification Delphi study

To identify participants for the Delphi round we conducted a search on HF/Usability experts. We started our search for participants by reviewing the list of authors of the articles included in the systematic review [4]. We extended the list with participants of the pre-Medical Informatics in Europe (MIE) 2012 conference and IMIA and EFMI Working groups. We then used the following criteria for inclusion of participants in the Delphi study: 1. Participants should be well known and recognized for their HF/Usability expertise in the medical informatics community, 2. Participants should have published 2 or more articles about HF/Usability studies in Interactive Healthcare Technology and should have reviewing experience of these types of papers.

We identified 132 experts to invite for the Delphi study. The final list consists of experts from countries all over the world e.g. Netherlands, USA, Norway France, and Canada. The experts work in different fields and have different kinds of expertise (like

extensive experience in: requirements, design, usability evaluation, or implementation of HIT). There was a concluding Skype meeting to discuss the resulting list of participants.

1.3. Pilot study with seven experts

Seven experts from the list were invited through email to conduct the survey in a first pilot phase of the study. The participants were asked to provide background information on their fields of expertise and working experience and to rate each issue defined in framework delivered through the online survey on its relevancy for inclusion in reports of HF/usability studies of HIT. Each specific issue could therefore be rated on a Likert-scale ranging from 1-5 with 1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree, supplemented with a 'don't know' option. Participants were also invited to provide any additional comments they had in relation to each specific information element in a text box below each page of the survey. At the end of the survey, participants were asked whether they had missed any specific information item based on UCD phases as defined in ISO 9241-210:2010.

1.4. Data Analysis

Data was collected from the website Qualtrics.com in SPSS format and analyzed with the program: IBM SPSS Statistics v19. For each specific information item, the consensus by experts was assessed. Consensus was reached when at least 5 experts rated the relevance of an information element as 4 or 5.

2. Results

2.1. Framework

The first version of the framework consisted of 60 information items, divided over 5 sections similar to the structure of scientific publications. An abstracted version of the framework is presented in Table 1.

2.2. Pilot validation of framework

All seven experts participated in the pilot-study preceding the Delphi study aiming at validation of the framework. Table 2 provides an overview of the information items that did not reach consensus. Four answers regarding the relevance of the information items were missing for which participants failed to provide the reason or commentary. One participant mentioned that the question on added value of a system design or evaluation study in relation to return on investments was unclear.

Eight information items did not reach consensus, indicated by an agreement percentage lower than 75%. No commentary on these items was given by the participants. The participants rated the remaining 52 information items as relevant in scientific reporting of HF/usability evaluation studies of HIT.

Table 1. Abstract version of the framework

Heading	Items
Introduction	
Keywords	Type or functionality of the system, UCD phases, scientific domain, methods applied, usability as mesh term
Essential information	Conclusion or recommendations previous HF/usability studies, purpose and reason for study, scientific aims, potential health implications and ethical principles
Background information	
If HF/usability study is an integrated part in HIT development	Support for HF/usability activities within organization, system design/development team, UCD phases that are covered, system design principles or existing standards used specifications/goals/requirements depending on UCD phases.
If the study is scientifically oriented	User interface design principles applied or methods evaluated, theories underlying the interface design principles or methods evaluated
System type or its part/functionality	Version, release date, graphical view, system behavior view, the setting, the user tasks to be supported, main system functionalities, the ICT architecture, number of users, overview actual/intended users' profile, if the system is in use the context of the system, user characteristics, organizational and physical environment and equipment.
Method	
Method section	Applied method(s), suitability of each method, number of and expertise background of the study evaluators, description of study variables, outcome measures and quality metrics, if study used test scenarios or tasks, if the study participants are (representative) end users
Background study participants	Age, gender, linguistic and culture background, level of education, professional competence, potential disabilities, level of experience using IT, level of experience with similar system
Generalizability and reproducibility of the study	Setting of the study, study period and evaluation time, instructions provided to participants and the recruitment, resources required and their availability
Results	
Result section	If HF/usability methods have been applied, results are reported on per method, unexpected events encountered, unexpected results uncovered
If the study reports on usability problems	Presentation of results should rely on classification scheme, usability problems rated for their severity, usability problems rated for their potential impact on patient safety.
Discussion	
Discussion section	Intended purpose of the study is achieved, limitations of the study, contribution of the study to the UCD process, added value of method applied, knowledge/evidence gained in terms of HF/usability principles, added value of this paper

3. Discussion and conclusion

To improve identification of type of use errors and safety related issues regarding design and implementation of HIT, consensus on issues to be reported on in scientific publications is a necessary step forward. This study presents the first approach to a framework defining the structure and contents of scientific reports of HF/usability studies of HIT. The framework aims to provide a set of principles to follow for comprehensive and unambiguous reporting of HIT design and usability evaluation studies with the objective to reduce variation, improve on the publication reporting quality and

Table 2. Information items that did not reach consensus

Information item	Mean	Standard error	% Agreement
Scientific domain	3.57	0.79	42.86%
Compliance of ethical principles and statutory and legislative regulations	3.86	0.69	71.43%
Support of HF/Usability activities within organization, including the operational and financial support	4.00	0.82	71.43%
The system design and development project team should be described	4.00	1.00	57.14%
The description of a system type or functionality	3.71	0.76	57.14%
The system behavior view (UML model, task model)	3.71	0.76	57.14%
Description of the ICT architecture Number of users to be supported by a system	3.86	0.69	71.43%
The resources required and their availability	3.86	0.69	71.43%

proper indexation of these studies. Reviewers and/or authors of scientific publications will then be properly guided in judging the validity and generalizability of the study results that are reported on. Another aim of this framework is to assist readers in interpretation of the study results in the context of the system (re)engineering process. This framework may be helpful in expanding the knowledge base not only concerning the application of HF/ Usability studies of HIT but also improve the knowledge base of how to (re)design and implement effective, efficient and safe HIT. Further work on validating the framework to gain international and broad consensus will be performed by means of Delphi study approach with an online survey. Based on the results of the survey the framework will be adjusted.

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