*Context Sensitive Health Informatics: Many Places, Many Users, Many Contexts, Many Uses*
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# Towards Evidence Based Usability in Health Informatics?

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**Abstract.** In a Health Information Technology (HIT) regulatory context in which the usability of this technology is more and more a critical issue, there is an increasing need for evidence based usability practice. However, a clear definition of evidence based usability practice and how to achieve it is still lacking. This paper underlines the need for evidence based HIT design and provides a definition of evidence based usability practice as the conscientious, explicit and judicious use of current best evidence in making decisions in design of interactive systems in health by applying usability engineering and usability design principles that have proven their value in practice. Current issues that hamper evidence based usability practice are highlighted and steps needed to achieve evidence are presented.

**Keywords.** Human engineering, ergonomics, evidence, evaluation, health informatics

## 1. Introduction

Health Information Technology (HIT) is increasingly disseminated and implemented to improve patient safety, performance and healthcare quality. Nonetheless, HIT applications face several acceptance issues, and because of these are often abandoned or fail their objective [1]. Their potential to improve healthcare is critically viewed upon due to the reports on induced medical errors [2] that may ultimately lead to patient harm or death [3-5]. A major cause of those problems has been attributed to problems in usability of HIT [4-5] where usability is the "extend to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specific context of use" [6]. Usability concerns the elements of the graphical user interface, their arrangement, navigational structures, the behavior of the system in response to users' actions along with the completeness of functions and the work model implemented in the system. A HIT with a high usability supports users achieving their tasks efficiently, effectively and with satisfaction in a safe context. When a HIT is poorly designed, users' interaction is negatively affected (e.g. increasing

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their workload). Ultimately, this can impact the work system in which the HIT is implemented, by causing usability-induced use-errors that may harm the patient [7].

To prevent consequences of usability issues, usability must be considered all along the design and evaluation process of HIT. This need has become part of the essential requirements governing the European Conformity marking of medical devices that also applies to certain categories of HIT [8], e.g., typically Decision Support Systems (DSS). To accomplish this, two types of usability knowledge are considered essential:

- Knowledge of the design engineering process and related usability methods;
- Knowledge of usability design principles that apply to the type of HIT[2] under consideration and of concrete instances of their violations (usability flaws).

This distinction is commonly made for clarity sake (e.g. separate ANSI/AAMI guidelines [9-10]), however both types are closely intertwined within design's practice: right design principles need the right engineering process for the HIT be effective.

To improve the integration of the usability knowledge within the HIT design team[3] practice, it is necessary to promote engineering and usability principles that have proven their value in practice. For this purpose, evidence regarding HIT usability knowledge needs to be recorded and provided to the design team in a usable way. Ultimately, such an evidence will be helpful in decreasing the risk of usability-induced use-errors with potential harmful consequences for patients.

Regarding HIT, the process of accumulating empirical data that evidently improve HIT design is still in its infancy. Even while international medical informatics associations consider usability as a dimension of HIT of which the design has to be evidence based [11], evidence based usability practice and how to achieve it are still lacking distinctive definitions. This paper provides a definition for evidence based usability practice in the context of interactive HIT and for the steps needed to achieve it.

## 2. Defining Evidence Based Usability Practice

The concept of evidence in medicine comes from Sackett et al. [12]. They defined evidence based medicine as “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patients”. According to this approach, clinicians' decision making process has to be fed by their expertise and by evidence from literature, applied to the patient case (Figure 1). Then, evidence based practice has been extended to other fields such as health informatics [13].

In the field of HIT design, decisions are made by the design team. This team has its own expertise in the development of HIT and adapt it to the intended type of technology. By analogy to medicine, evidence based usability practice can be defined as *the conscientious, explicit and judicious use of current best evidence in making decisions in design of interactive systems in health by applying usability engineering and usability design principles that have proven their value in practice*. This definition first implies that the HIT design team needs evidence demonstrating that the application of usability engineering and design principles is efficient and effective in

[2] In the absence of known taxonomy of HIT, "type of technology" refers to a homogenous category of technology supporting the same task (e.g. alerting systems, Computerized Physician Order Entry etc.)

[3] The design team includes designers, developers, project managers, sometimes informed by experts knowledgeable of Human Factors (HF) engineering and design principles.

preventing usability-induced use-errors. Second, they need to integrate this evidence within their design expertise to make informed decisions in HIT design (Figure 1).

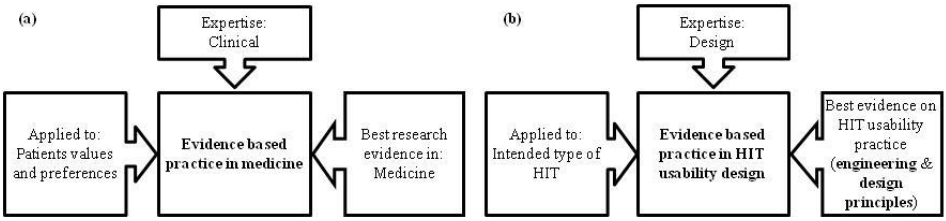


**Figure 1.** Schematic representation of (a) Evidence Based Medicine and (b) Evidence Based Usability.

## 3. Steps Needed to Achieve Evidence Based Usability Practice

Progress has been made in the field of evidence based usability engineering as a topic by the development of guidelines and standards aiming at design processes of HIT and/or medical devices [14-16]. However, developing a transversal evidence based usability design practice applicable to a given type of HIT and use context requires an approach. Inspired by [11] we propose the following steps to achieve this goal.

### *3.1. Perform High Quality Usability Evaluations*

Gathering best available evidence first requires extracting relevant data from high quality studies on the impact of HIT usability in certain use contexts. Performing high quality studies is the only way to ensure the validity of the results. Although not specifically dedicated to usability evaluation studies, the "Guidelines for Evaluation Practices in Health Informatics" (GEP-HI) [17] can be used to plan and perform high quality usability evaluations of HIT and analyze their results. Moreover, an increasing number of publications focuses on the (dis)advantages, requirements and pitfalls for applying usability evaluation methods (e.g. usability testing, heuristic evaluation, cognitive walkthrough [18-20]). Those good practices in usability evaluation of HIT must be promoted and HF experts and design teams should be encouraged to apply standardized relevant evaluation methods.

As in medicine where pathology of a patient evolves in a complex environment of genetic, cultural, societal and personal factors, usability-induced use-errors appear during complex interactions between the specific HIT, user(s) with specific profile(s), a given work system and a specific context of use. While HIT experimental evaluation studies in which context variables are controlled provide rich information on the short-term impact of usability characteristics on users, these studies do not provide insight into long-term and indirect consequences of HIT designs on users, their work processes and on the consequences of potential use-errors. Moreover, by controlling for biases, contextual variables interfering with the usage of a HIT technology are not considered. Case studies and post implementation surveillance provide richer and more nuanced data. Therefore, those types of studies should be promoted to get a deeper understanding of the interrelations between specific HIT designs, users' characteristics and contexts of use.

### *3.2. Publish and Identify Usability Studies*

Once those studies are performed, their publication must report on necessary data to seek evidence on HIT usability aspects that improve users' performance in certain working contexts. A recent Delphi study has identified various types of data that should be reported in publications on HIT usability studies, among which [21]:

- List of usability issues uncovered by the study,
- Description of the HIT to be able to merge data from similar HIT,
- Applied usability principles and methods, the contextual factors of HIT use,
- Context of evaluation, stage of the design process, purpose of the study.

However, most of the usability studies on HIT are poorly reported [22-23]. Only a limited number of uncovered usability issues are reported per publication; details on the HIT, user groups, methods and evaluation's context are weakly described.

Improving reports requires applying reporting standards. The "STAtement for Reporting of Evaluation studies in Health Informatics" (STARE-HI) [24] does not fully support reporting on HIT usability evaluation studies because it does not consider specificities of usability evaluations such as the iterative process. To help authors define, conduct and report on completely and accurately high quality HIT usability evaluations, a "Tool for the Reporting of Usability and human factors Evaluation of HIT" (TRUE-HIT) is under development that is based on the results of the Delphi study. Its use should be encouraged. In addition, journals' on-line appendices should be used to publish details on the full set of uncovered usability issues.

Finally, the referencing of usability studies should be improved: "Usability" or "Human Factors" are no MeSH terms. Few researchers know they must use synonyms instead ("Human Engineering", "Ergonomics"). Moreover, "usability" is not always mentioned in the title, abstract or keywords of studies including usability evaluations of HIT (e.g. [25]). It seems relevant to include "Usability" in the MeSH terms while encouraging authors to explicitly identify usability activities in their publications.

### *3.3. Gather Relevant Publications and Extract Relevant Data*

Gathering the best available evidence requires a systematically search, critically appraisal and synthesis of the usability literature for each type of HIT. To help researchers gather relevant usability publications, a HIT usability publications data base should be built on the model of the "IT evaluation database" [26] with adapted usability-related sorting features (e.g. type of usability method applied). Once the potential sources of evidence are identified and gathered, relevant detailed data must be extracted (e.g. type of HIT/method, usability issues and consequences, cf. section 3.2.).

### *3.4. Compare and Synthesize Publications' Findings*

Syntheses should allow (i) assessing the effectiveness of the evaluation methods to uncover usability issues (ii) identifying the specific usability characteristics (flaws or positive ones) reported for a given type of HIT (e.g. [23,27]) and (iii) highlighting what are the consequences of a specific usability characteristic for a given type of HIT on users and work system (e.g. [28]). Meta-analysis is the favored method to synthesize data from various sources. However, even if this method enables to describe the types

of usability characteristics uncovered for each HIT type, it does not provide insight into the consequences of usability for the user and the work system from a qualitative perspective. "Qualitative comparison analysis" [29] allows identifying the causal contribution of various conditions to an outcome of interest. This method should be favored to analyze the ongoing (positive/negative) consequences of usability characteristics of HIT on users and work systems,

### *3.5. Formulate Usability Design Principles and Develop a Usability Data Base*

Ultimately, the results of those syntheses should be used to formulate related usability design principles for each specific type of HIT. Since one better learns from one's mistake, it seems sensible to illustrate those principles with actual instances of their violations extracted from publications. An open usability data base should therefore be developed that present exhaustively and in a structured way usability design principles and related uncovered usability flaws and consequences. This data base could take for instance the shape of a usability ontology (e.g. [30-31]).

### *3.6. Disseminate Evidence Based Usability Knowledge*

Finally the evidence based knowledge should be provided to the HIT design team including HF experts, to support its design decisions. Presenting both usability design principles and actual examples of their violations will help the design team becoming aware of the good and bad usability practices for a given HIT in a specific context of use. This knowledge should be disseminated during the medical informatics curriculum or through seminars or training of HIT manufacturers.

## 4. Conclusion

In a context in which usability of HIT is more and more considered essential, evidence based usability knowledge is needed. This paper provides the first definition of evidence based usability practice. This topic is still in its infancy and several activities have to be realized in order to develop evidence based usability knowledge on HIT: improve the quality of HIT usability studies and of their report, perform systematic qualitative comparison analyses to identify the ongoing influence of usability characteristics of HIT, derive illustrated evidence based usability engineering and design principles and make available this knowledge to the design team so that it can integrate this evidence within its decision making process concerning HIT design.

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