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## Seeking Evidence to Support Usability Principles for Medication-Related Clinical Decision Support (CDS) Functions

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### Abstract

There is a need for evidence-based usability principles to support the design of usable medication-related computerized CDS functions and systems. Such evidence requires establishing scientific relationships between usability principles, their violation in terms of usability flaws, issuing usage problems and their consequences or outcomes in the clinical work and patient care. This kind of evidence is not currently directly available in scientific evaluation studies of medication CDS functions. A possible proxy to seek evidence is systematic review of existing scientific evaluation reports. We rely on a four-stage framework describing the chain of consequences and inferences linking usability principles to clinical outcomes to design the systematic review methodology and interpretation principles. This paper describes the four-stage framework and the resulting consequences for the systematic review design.

### Keywords:

Usability, Human Engineering, Decision Support Systems, Evaluation.

### Introduction

Computerized CDS with medication functions have been shown to have a positive impact on patient safety by improving prescribing practices [1] and reducing Adverse Drug Events [2]. However, they remain difficult to implement and difficult for users to accept [3]. Moreover, they may also generate technology induced errors, i.e., latent types of errors related to the usage of this technology [4]. The root causes of such problems are usually by human factor (HF) nature and more specifically related to usability features. However, the evidence of the relationship between the observed/reported outcomes, the usage problems experienced by the users, the usability flaws involved in the usage problems, and the usability principle whose violation led to the usability flaws remains unsubstantiated most of the time.

This paper presents a four-stage framework describing the chain of consequences and inferences linking usability principles to clinical outcomes. The consequences of the framework in terms of method and interpretive expertise are discussed and applied to the design of a systematic review of usability evaluation studies of medication related CDS functions.

### Background

Figure 1 shows the proposed four-stage framework to put together usability principles, usability flaws, usage problems and outcomes in the work system. It can be applied to any kind of Healthcare Information Technology (HIT) system. Two processes connect the four stages. The top-down process

describes the propagation of usability flaws until they finally impact the healthcare system's performance through deteriorated outcomes, e.g. medical errors. The bottom-up process describes the research, evaluation and expert consensus process which allows (i) identifying and characterizing actual usage problems and (ii) inferring from them elements of evidence to support usability principles for corresponding HIT systems.

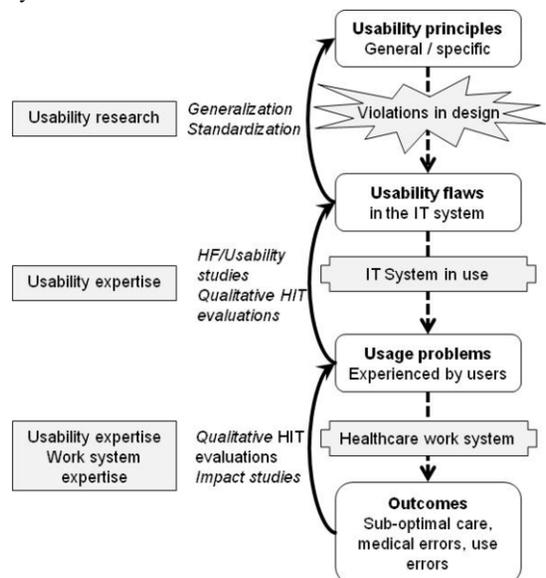


Figure 1 - Emergent and potential propagation (dotted lines) of usability flaws to healthcare outcomes and seeking evidence for usability principles.

Usability flaws of technical systems such as Computerized Prescriber Order Entry (CPOE), CDS functions, or medical devices result from violations of usability principles in the design of those systems. Most of those usability flaws create usage problems when the system is put into use. The importance of the usage problems experienced by the users depends on several variables (e.g., the nature of the usability feature violated or the type of task supported by the faulty function). Ultimately, these usage problems may actually negatively impact the healthcare system performance, e.g., by slowing down the clinical workflows or generating medical errors characterized as technology-induced errors [4]. Again, the scope and importance of the negative outcomes depend on several variables, e.g., the severity of the usage problems but also characteristics of the use and of the socio-technical organization in which the system has been implemented along with the capacity of adaptation ingrained in the work system.

The bottom-up process aims to link the outcomes identified by evaluation and impact studies back to usage problems and their usability root causes (usability flaws) and ultimately to the corresponding usability principles that have not been complied with. Given the multiplicity of other HF or technical factors that are intertwined with usability variables in the described top-down process, this inference work is far from trivial and requires a sound expertise in HF and usability of HIT applications. Moreover, most of impact studies such as clinical trials of CPOE or CDS functions lack qualitative analysis that would allow identifying the usage patterns of the HIT system that act as intermediate variables explaining the observed outcomes. Qualitative HIT evaluation studies might prove more informative but still require HF expertise in the analysis of work systems to differentiate organizational vs. usability issues, given that the report of the evaluation study provides enough details to make this inference. Usability studies that aim specifically to identify usage problems often fail linking the observed usage problems with causing usability flaws [5]. Such studies require usability expertise in HIT systems to properly infer the usability flaws. Finally, usability studies listing usability flaws of evaluated systems do not always provide the necessary level of details (e.g., screenshots) to establish clear links with violated usability principles and descriptions of potential related usage problems.

Usability principles are the core part of the framework. They can be divided into two categories: (1) methodological principles to apply the user centered design/usability engineering process (e.g., [6, 7]) and (2) usability principles and features of the targeted products (e.g., [8, 9]). This paper deals only with the latter category. The most important part of those principles is reported in standards elaborated on the basis of international expert consensus. They may be relatively general (e.g., usability principles for the design of Human-Computer Interface (HCI) [10] that would apply to all HIT applications) or they may be more specific to a category of product (e.g. medical devices of a certain kind). Unfortunately, most standards face several problems that prevent usability principles from an easy and unambiguous interpretation by non-experts [11].

During the last decade, there have been several initiatives to identify the most important usability principles for medication CDS systems. These attempts are mostly based on the experience of the authors in the domain and on lessons learned from medication CDS function design and implementation projects in which the authors participated [12-15], or derived from a specific theoretical approach of the cognitive processes involved in the interaction of the users with medication CDS functions [16].

## Rationale

Usability principles, whether recommended by standards or scientific publications, have great variety and their lack of comprehensible organization prevents developers, and even HF experts, from identifying those they should apply (and therefore from applying them completely and correctly). Moreover, the lack of evidence to support usability principles may also lead systems' developers to question the legitimacy of the stated principles. We aim to seek evidence supporting the organization and prioritizing those usability principles.

The systematic review method is a technique allowing the emergence of evidence from HIT evaluations' published reports. As far as we know, it has been used only once in the field of medical management systems to find evidence of usability flaws in CPOE systems [17], never for CDS functions. In order to seek evidence to support usability principles for

medication CDS functions, we designed a systematic review based on the four-stage framework. This review proposes to answer two main questions:

- What are the features characterizing medication CDSS usability?
- Do those features generate usage problems of the CDS function and ultimately outcomes in the work system?

Applying this framework allows identifying precisely the inferences necessary to jump from one stage of the framework to another. It also supports the search query through the delimitation of the scope of relevant evaluation studies, the definition of inclusion/exclusion criteria and the design of the interpretive grid for the analysis of final set of papers.

## Systematic Review Design and Process

The design of the systematic review follows as far as possible good practice recommendations [18-20]. The key concepts involved in the review, "medication CDS functions" and "usability", have been defined in the light of the framework. This supports the latter definition of inclusion/exclusion criteria of the papers.

### Concepts definition

#### Usability

Usability is defined as "the extent 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" [21]. Usability goes way beyond the features of the GUI (e.g. legibility of the texts, layout and prompting of information and tools), and deals more generally with the fitting between the system behavior and its users' needs. Considering medication CDS, one of the most important usability principle that, if violated, might engender critical usage problems and negative outcomes is the compatibility of the system with clinicians' activities, essentially of cognitive nature [16]. For our review (mostly the papers analysis phase) we consider four dimensions in the usability concepts:

- HCI characteristics,
- How the system responds to users' actions,
- Organization/accuracy of the knowledge incorporated,
- Availability of functions required to support users' tasks, especially of cognitive nature.

The analysis of retrieved papers, both for decision upon inclusion/exclusion and for final systematic analysis, requires a deep HF knowledge of intended users' needs, activities and working procedures.

#### Medication-related CDS functions

CDS functions include a very wide range of tools: documentation forms-templates, relevant data presentation, order-prescription creation facilitators (e.g. order sets), protocol/pathway support, reference information and guidance, and alerts and reminders (pushed or pulled) [16].

As this review focuses on HIT tools, medical devices in which medication CDS functions have been integrated are excluded from the analysis (e.g. auto-injectors pens, pumps). Only medication CDS software used in hospital or general practice in the internal medicine field is considered. To increase results' homogeneity, we focus on alert systems (alerts and reminders). As a result, the review includes studies of software supporting the management of e-prescriptions by physicians, pharmacists, and nurses. CDS functions integrated in Bar Coded Medication Administration and e-Medication Administration Records are excluded from the review.

## Consequences of the framework on the systematic review

### Queries definition

The biomedical literature was searched from 1980 to 2012 using PubMed, Scopus and Ergonomics Abstracts databases. Two semantic groups of key terms were constructed with the support of medical terminologies experts: terms related to CDS functions, alerts and CPOE and terms related to HF (cf. Table 1). As much as possible, MeSH terms were chosen for PubMed database thanks to the Health Multi-Terminology Portal [22]. The key terms have been slightly adapted for Scopus and Ergonomics Abstracts<sup>1</sup> databases. Key terms in each group were combined with the operator "OR". Then both groups were combined using the operator "AND".<sup>2</sup> Queries have been performed in March 2012 and updated on the 26th October 2012. The search retrieved a total of 5862 items.

Table 1 - Terms included in the queries according to their semantic category and to the queried database.

Databases	Terms related to CDSS, alerts & CPOE	Terms related to Human Factors
PubMed	"Medical order entry systems"; "Medication alert system"; "Computerized physician order entry system"; "CPOE"; "Decision Support Systems, Clinical"; "Clinical decision support systems"; "CDSS"	"User-computer interface"; "Human engineering"; "Risk factors"; "Usability"; "Humans"
Scopus & Ergonomics Abstracts	"Medical order entry"; "Medication alert"; "Computerized physician order entry"; "CPOE"; "Clinical decision support"; "CDSS"	"User-computer interface"; "Human engineering"; "Risk factor"; "Human factor"; "Usability"; "Human-computer interaction"

### Inclusion/exclusion criteria

Only studies published in English/French peer-reviewed journals and conference proceedings were considered. To be included the studies must report:

- The application of usability methods or of other qualitative methods aimed at evaluating CDS function(s) to report facts (not opinions) on usability flaws and usage problems.
- To specific standalone or integrated medication CDS functions. Functions that are not specifically dedicated to medications (e.g. care protocols/pathways) were included if at least one medication related feature was available.

Papers reporting evaluation of several systems without distinguishing results according to the systems were excluded.

### Selection and analysis of studies according to the evaluation methods applied

According to the four-stage framework, three kinds of data may be used to formalize usability principles: usability flaws,

usage problems, and their outcomes. These three kinds of data are retrievable through different sorts of methods.

Questionnaire and interview/focus group methods are usability methods [23]. However, they are often used to gather users' opinions about the system (perceived usability). Usually, such methods retrieve mostly feelings about a system, rarely usability facts. Therefore, studies based on those methods may be included only if they question explicitly specific usability features of the system to detect usability flaws or usage problems.

Usability flaws may be detected by classical usability evaluation methods resting on the standardized analysis of the system. During such evaluations, experts identify usability flaws by reference to a heuristic or to their knowledge about optimal human-machine interactions and to their knowledge of intended users work systems and procedures. Most known methods are expert evaluation and cognitive walkthrough. In those methods, usability flaws detection rests on hypothesizes about problems specific users may encounter.

Only making intended users actually use the system under evaluation might uncover usage problems. The most used methods are user testing with thinking-aloud and post-implementation surveillance. The former method aims to observe representative end-users using the test product in a simulated environment to identify usability flaws and rooms for improvement. The goal of the latter one is the same but either the users are observed during their actual use of the system once implemented in their work system, or users report by themselves usage problems they encounter.

Finally, the detection of the outcomes rests mainly on the socio-technical approach that proceeds by observation of the actual use of the system in the work system and by interviews of actual users of the system. To a lesser extent some outcomes can be detected in the results of impact evaluation studies including qualitative description of the system. Outcomes extracted by both methods may be reported with the usage problems that contribute to their appearance. There is often a need of usability expert inference to link them up together.

The identification of the methods resulting from the framework supports the process of papers' inclusion. Since the aim of this systematic review is to link up detected usability flaws, usage problems and their potential outcomes in the work system, papers relating the application of the aforementioned methods should be included. Nonetheless, data that can be extracted from each kind of papers are not the same and the analyses performed on them do not require the same type of skills and contextual information nor the same analyses to perform. (cf. Table 2). For instance, to understand socio-technical evaluation results, a description of the work system in which the system is implemented is required; such description is not required to understand expert evaluation's results. Therefore, the framework has also consequences on the construction of the grid through which each included paper is analyzed.

### Systematic review process and analysis

Publications' relevance was screened by one author (RM) to exclude dubbloons, posters and non-peer-reviewed papers. After a training session on 77 papers, two authors (RM & MCBZ) reviewed independently 471 papers' titles (Cohen's  $\kappa = 0.66$ ); remaining papers were shared-out for screening. Decision of inclusion/exclusion was based on the aforementioned criteria. If in doubt, the paper was included in the next step. The same process was applied for the screening at the abstracts (training on 44 papers, independent review on 73 papers, Cohen's  $\kappa = 0.69$ ; sharing-out remaining papers) and at the whole papers (training on 20 papers, independent review on 20 papers, Fleiss'  $\kappa = 0.95$ ; sharing-out remaining papers).

<sup>1</sup> This database is dedicated to Human Factors topics, therefore, only the first group of terms was searched.

<sup>2</sup> The full request is available on demand.

Table 2 – Methods applied, data to retrieve, analyses to perform on the data and requisites for the analyst and the analyzed papers according to the three stages of the framework that support the inference of elements of evidence to support usability principles.

	Usability flaws	Usage problems	Outcomes
Methods	Expert evaluation & cognitive walkthrough	User testing & post implementation surveillance	Socio-technical & impact evaluation methods whose results may be reinterpreted in terms of usability
Retrievable data	Description of usability flaws; hypotheses about their consequences	Description of usage problems; facts/hypotheses about their causes and their consequences in the work system	Description of facts consecutive to the implementation of the system; hypotheses about their causes
Analysis to perform	Organization of the usability flaws through a common frame	Organization of the usage problems and inference on their linkage to usability problems and outcomes	Organization of the outcomes and inference on their linkage to usage problems
Requisites for the analyst	Usability expertise	Usability expertise; Expertise of the work process	Usability expertise; expertise of the work process
Requisites for the analyzed paper	Description of the system under evaluation	Description of the system under evaluation and of the work system in which the system will be/is implemented	Description of the system under evaluation and of the work system in which the system is implemented

The latter step involved three authors (RM, MCBZ & SP). Twenty-seven papers were eventually included in the analysis process.

In each paper, descriptions of usability flaws, usage problems and outcomes were extracted and categorized by two authors (RM & MCBZ). A content analysis is used to identify classes of usability flaws related to medication CDS and their reported links with usage problems and outcomes in the work system.

## Discussion

This review describes a general framework linking up usability principles, usability flaws, usage problems and their potential outcomes in the work system. It presents also the application of this framework to the design of a systematic review on the usability features of medication CDS functions. The selection process of the systematic review is finished and will be reported along with the results in another paper.

First, comments about the advantages of the application of the framework can be drawn. The framework has consequences on the systematic review design at two levels. It supports the selection process by facilitating the identification of the kinds of methods the selected papers must apply. Second, it allows developing the final analysis grid with each included paper analyzed. As compared to previous similar work [17], the review framework's added value is that it allows establishing relations between usability flaws, usage problems and outcomes.

The analysis process is under progress. For now, only some papers have been identified that link up usability flaws, usage problems and their outcomes. Therefore, inferences have to be drawn to link up the retrieved usability flaws, usage problems, and their outcomes. By providing an architecture that articulates the different kinds of data, this framework allows reviewers be aware of those inferences. In sum, the review supported by the framework is informed and requires usability and work system expertise to draw inferences.

As noticed in Table 2, linking up usability/usage/outcomes results requires contextual information (e.g., description of the work system and of the system under evaluation). Yet, in most of published papers, this information is missing or ambiguous: most often the CDS functions is not clearly described, and the work system in which it is implemented is not described at all.

During the data analysis, an unexpected difficulty arose related to the level of description of the usability/usage/outcome results. Indeed, this level greatly varies from one paper to another: papers report either raw descriptions of unique usability flaws, or categories of similar usability flaws. This lack of homogeneity makes it difficult (1) to compare findings from a paper to another, and (2) to distinguish usability flaws from usage problems. Moreover, in most publications, place is limited forcing authors to report only a subset of issues that they found in their study. This makes quantitative comparison between studies or groups of studies impossible; only a qualitative synthesis can be performed.

To support more complete reports of usability/qualitative impact evaluation, we should consider elements to report for HF studies (especially the complete report of usability flaws or usage problems and system description in on-line appendices) and how to report them [24] as it has been done for general HIT evaluations [25].

## Conclusion

The proposed framework supports performing an informed systematic review in which drawn inferences and evidences are highlighted. It is used to find evidence to organize medication CDS functions' usability principles but it could be used to organize other usability principles requiring evidence.

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