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Methodological Review

Usability flaws of medication-related alerting functions: A systematic qualitative review



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ABSTRACT

Introduction: Medication-related alerting functions may include usability flaws that limit their optimal use. A first step on the way to preventing usability flaws is to understand the characteristics of these usability flaws. This systematic qualitative review aims to analyze the type of usability flaws found in medication-related alerting functions.

Method: Papers were searched via PubMed, Scopus and Ergonomics Abstracts databases, along with references lists. Paper selection, data extraction and data analysis was performed by two to three Human Factors experts. Meaningful semantic units representing instances of usability flaws were the main data extracted. They were analyzed through qualitative methods: categorization following general usability heuristics and through an inductive process for the flaws specific to medication-related alerting functions.

Main results: From the 6380 papers initially identified, 26 met all eligibility criteria. The analysis of the papers identified a total of 168 instances of usability flaws that could be classified into 13 categories of usability flaws representing either violations of general usability principles (i.e. they could be found in any system, e.g. guidance and workload issues) or infractions specific to medication-related alerting functions. The latter refer to issues of low signal-to-noise ratio, incomplete content of alerts, transparency, presentation mode and timing, missing alert features, tasks and control distribution.

Main conclusion: The list of 168 instances of usability flaws of medication-related alerting functions provides a source of knowledge for checking the usability of medication-related alerting functions during their design and evaluation process and ultimately constructs evidence-based usability design principles for these functions.

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1. Introduction

Computerized Clinical Decision Support (CDS) functions may have a noteworthy impact on medication management safety [1]. Several studies have shown that they help to improve antibiotic use [2], drug dosing [3,4], clinical practice [5,6] and patient outcomes [7]. However, implemented systems may face acceptance

problems [8,9] that partly originate from poor usability. Poor usability may lead users to reject CDS functions or to adopt work-arounds even if the CDS functions are of benefit.

Usability is "the extent to which a product can be used by specified users to achieve specified goals effectively, efficiently and satisfactorily within a specific context of use" [10]. Usability goes beyond the features of the Graphical User Interface (GUI; e.g. legibility of texts), and deals with the functionalities of the product and with the fit between the system behavior and the needs of the users' [11].

Therefore, along with the study of the GUI characteristics, usability includes the analysis of the way in which the system responds to users' actions, of the organization and accuracy of the knowledge incorporated, and of the availability of functions

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supporting users' tasks. Poor usability of systems arises from the existence of usability flaws. Flaws are violations of usability design principles, and are additionally known as usability heuristics or usability criteria [12–15]. They may have an impact on users' experience with the system (usage problems) and generate negative outcomes in the work system (e.g. performance/patient safety issues) [16]. The present review focuses on usability flaws.

Improving the usability of CDS functions is a necessity [17]. In the broad sense, according to [18], computerized CDS interventions refer to a wide range of tools: forms and templates (e.g. to support proper drug order documentation), relevant data presentation (e.g. to support optimal decision making), proactive drug order suggestions and order sets (e.g. to ensure that a clinical situation is completely addressed), protocol supports/clinical pathways (e.g. to avoid omissions in the care process), reference information/guidance (e.g. to address known information needs) and alerts (e.g. to prevent errors due to lack of knowledge) [18,19]. These categories of tools are not exclusive, for instance, alerts may be integrated in order sets or in protocol supports. Within the whole range of available computerized medication CDS systems, alerting functions are known to face serious usability issues [17,20].

One way to prevent such usability issues is to provide manufacturers and Human Factors experts with evidence-based usability design principles [16]. Currently, existing lists of usability design principles regarding medication alerting functions are not based on evidence but rather on expert consensus (e.g. [17]) or targeted review (e.g. [19,20]). This study is part of a project that aims at contributing to the emerging knowledge on usability design principles to complete the existing lists and identify the usability design principles that are supported by evidence in the literature. A first step in that direction is to systematically comprehend the usability characteristics of medication-related alerting functions.

The present systematic review focuses on medication-related alerting functions and addresses the following question: "What are the usability flaws of medication-related alerting functions identified in published studies?"

2. Method

This systematic qualitative review complies as far as possible with international methodological guidelines [21,22] as well as with reporting recommendations [23].

2.1. Eligibility criteria

This review considered only original studies reporting usability flaws and published after 1980 in peer-reviewed journals or conference proceedings. Only English and French speaking papers were included. Three eligibility criteria were defined:

 Only medication-related alerting functions supporting the prescribing of medications and used in general hospital or in primary care general practice were included. Surgery, dentistry, anesthesiology, emergency were excluded because the organization of the medication management of those wards is different from the general hospital with respect to the types of clinicians involved and the nature of the work process. Pathology or diagnosis management alerting functions were excluded when they did not include features to support medication decision-making. Alerting functions dedicated to the patients as primary end-users were also excluded.

- Usability studies as well as socio-technical studies and impact studies addressing (at least partially) usability issues were included. Only papers judged to have high quality reporting of the study were kept (see Section 2.5 for details). Studies on more than one system were included if the results presented insights for each system separately.
- The review targeted studies that reported usability flaws in a descriptive and objective way. This excluded all studies reporting perceived usability assessment or feelings/opinions e.g. collected through usability questionnaires.

2.2. Information sources and search

Information was searched for in on-line references databases. Themes of searched papers are at the intersection of two domains: "health technologies" and "ergonomics". Therefore three databases dealing with those themes were chosen; PubMed, Scopus and Ergonomics Abstract. This search was completed by searching references in the reviewed papers.

Two sets of key terms were defined: on "alerting functions" and on "usability" (cf. Table 1). In each set, terms were combined with the "OR" operator. Both sets were then combined with the "AND" operator (cf. Appendix 1 for the complete queries). As the Ergonomics Abstracts database is dedicated to Human Factor topics, only the first set of terms was searched. The language was restricted to English/French, publication date after 1980, and type of journals to medical journals. Searches were performed on the 22th April 2012 and updated on the 25th June 2013.

2.3. Study selection process

The study selection was performed by usability experts with high expertise in Human Factors applied to health informatics and who had previous experience with medication management systems, CDS and alerting functions. The selection process is represented in Fig. 1. At each step of the selection, the review process was over-inclusive; if in doubt, the item was included for an analysis at the next step. Agreement scores were calculated between reviewers on their inclusion/exclusion decisions based on the eligibility criteria (cf. 2.2).

One reviewer (RM) excluded duplicate publications, non-original studies and non-peer-reviewed papers. Then, two reviewers (RM & MCBZ) screened the title of the papers, after a joint training session on 77 papers that were chosen at random from amongst all the papers, the reviewers screened 471 randomly selected papers

Table 1Key terms used in the queries according the database searched.

	PubMed	Scopus	Ergonomics abstracts
Alerting functions terms	Medical order entry systems, Medication alert system, Computerized physician order entry system, CPOE, Decision Support Systems, Clinical, Clinical decision support systems, CDSS	Medical order entry, Medication alert, Computerized physician order entry, CPOE, Clinical decision support, CDSS	
Human Factors terms	User-computer interface, Human engineering, Risk factors, Humans, Usability	User-computer interface, Human engineering, Risk factor, Human factor, Usability, Human-computer interaction	Not applicable

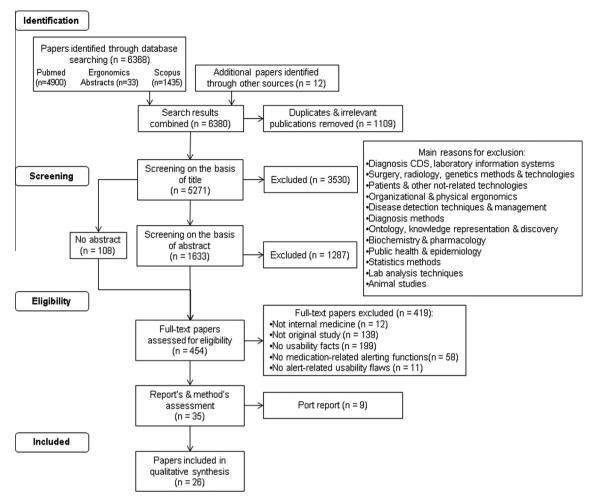


Fig. 1. Study flow.

individually. The agreement score calculated on the review of the 471 papers was good (Cohen's κ = 0.67) and discrepancies were solved through reconciliation meetings. After the review of the 471 papers, considering the amount of papers to review, all remaining papers were divided between both reviewers to be screened individually by title. At this step, only papers that were obviously out of the scope of the review (e.g. genetics or data mining investigations) were excluded.

In the next step, the same two reviewers screened the abstracts of the selected papers. For papers without abstracts (n=108), the full texts were screened directly. A joint training session on 44 randomly selected papers was performed and followed by parallel individual review on the abstract of 73 papers. The agreement score was again good (Cohen's $\kappa=0.69$). Considering the amount of papers to review, the remaining papers were divided between both reviewers to complete the screening of the abstracts. As for the previous step, only papers obviously out of the scope of the study were excluded.

Once the screening of abstracts was completed, the full-texts of the selected papers were screened by three reviewers (MCBZ, SP and RM): after a training session on 20 randomly selected papers, reviewers individually analyzed 20 other papers. The agreement score was almost perfect (Fleiss' κ = .95) and thus each reviewer screened a subset of the remaining papers. The excellent agreement score shows that the eligibility criteria, including the definition of objective usability flaws, were sufficiently well-described to support non ambiguous decision-making. The motive for rejecting a paper was documented.

2.4. Data extraction and analysis

Data was collected for all included papers by two reviewers through several independent readings (MCBZ & RM). Where available, on-line appendices of the papers were also analyzed. During the data collection process any disagreement was solved by discussion. Authors of [24–28] were e-mailed to get more information.

A review reporting form was used for data extraction that included three sections:

• Description of alerting function:

- Alerting function may either be used standalone, or be integrated into a larger information system such as a CPOE or an Electronic Medical Record (EMR).
- Medication-related alerting functions may target several kinds of clinical information. Kuperman et al's [9] classes of medication-related decision support were used to categorize the functions: drug allergy checking, basic and advanced dosing guidance, formulary decision support, duplicate therapy checking, drug-drug interaction checking, advanced guidance for medication-associated laboratory testing, advanced checking for drug-disease interactions and contraindications, and finally advanced drug-pregnancy alerting. Those classes are non-exclusive: a single alerting function may include several classes of clinical information.
- Alerting functions may issue different modes of alerts [19] and were accordingly categorized as (a) interruptive (active, pushed alerts), i.e. alerts designed as modal dialog boxes

requiring an action to dismiss, (b) non-interruptive (passive, pulled alerts), *i.e.* alerts displayed in a non-intrusive asynchronous presentation format or (c) mixed, *i.e.* combining both interruptive and non-interruptive formats of alerts.

- Moreover, we considered the stage of development of the alerting function either during the design process ("under development") or when it is in use.
- Description of methods: The methods applied in the studies to collect usability data were extracted. This extraction was supported by a checklist of methods listed in usability standards [29] and in a focused review [30]. The checklist included the following items of observation, interviews, user-testing (including think-aloud), heuristic evaluation, focus groups, retrospective data analysis (expert review), cognitive walkthrough, questionnaires, telephone and e-survey, log files analysis, experimental design and performance measurement, critical incident analysis, creativity methods, contextual inquiry, collaborative evaluation, automated evaluation, brainstorming, document analysis, document-based methods, model-based methods, parallel design.
- Objective descriptions of usability flaws: Any violations of a usability principle described from the system's perspective. Usability flaws are descriptions of the characteristics of the systems that do not adhere to usability principles. They may concern the system's GUI, its behavior and the suitability of the knowledge implemented within it for users' needs and the availability of features needed to perform a task. Therefore the objective descriptions may describe all of the above mentioned dimensions. Items representing instances of usability flaws were searched for in the results and discussion sections of the included papers. Only items reported in a descriptive, objective and reproducible way were retained in the analysis process in order to get reliable data; hypotheses drawn by the authors of the included studies were not analyzed.

"Duplicate instances" of flaws, *i.e.* descriptions of usability flaws detected in a given function and that were reported in several papers on the same study, as well as instances described several times in the same paper, were presented together in a single instance

Once the data extraction was complete, each extracted usability flaw was categorized according to the usability design principle it violated. Design principles can be described in a variety of different ways (e.g. [12–15]) however it has been identified that differently named principles can reflect the same inherent usability concepts [31]. The main differences reside in their construction, in the precision level of the principles and in the instructions on how they should be applied. Scapin and Bastien's usability design principles

[14] were chosen for this review as unlike other sets of design principles, they were based on a review of recommendations published in the literature and in standards and then reviewed by experts, not only from experience. Additionally, Scapin and Bastien's usability design principles [14] were considered by both reviewers as being most precise with easy to apply instructions.

Scapin and Bastien's [14] set of heuristics is composed of eight main usability design principles and 18 sub-principles (cf. Table 2). The first seven principles (guidance, workload, explicit control, adaptability, error management, consistency and significance of codes) are applicable to any kind of computerized system. The eighth principle, "compatibility", considers how the characteristics of the system under design/evaluation fit:

- The characteristics of the tasks to be performed with/supported by the system.
- The characteristics of the typical end-user(s) (mental model, knowledge organization, cognitive tasks) and.
- The characteristics of the typical end-user(s) workflow.

The compatibility principle accounts for the specificity of the task to perform, *i.e.* in the present context, the interaction of the clinicians with the alerting function. It is not a principle that has previously been divided into sub-categories. Therefore, to account for the different dimensions of the flaws specific to the medication alerting functions, sub-categories of "compatibility" flaws were developed by both reviewers (RM & MCBZ) in an interactive and inductive manner. During this process any difficulties and disagreements were discussed between both reviewers to achieve clear, unambiguous, and mutually exclusive sub-categories with a high internal consistency and on which both reviewers were in complete agreement. At the end of the categorization process, each usability flaw was assigned to a unique category and sub-category.

2.5. Bias assessment

To ensure the validity of the eligible studies, two eligibility criteria concerning the report and the method of the studies were defined. Both criteria were selected because they were necessary if the study was to be reproduced. During the analysis process, two reviewers (RM & MCBZ) scored each paper individually on two 5-point Likert scales (from 1 = poor report/method to 5 = very good report/method) regarding the following criteria:

 Report: completeness and clarity in the description of the aim of evaluation study, the context of evaluation, the function under evaluation (including type of system, stage of development), the setting in which it is (to be) implemented, and in the results.

Table 2Main Scapin and Bastien's usability principles (cf. [14] for sub-criteria's description).

Usability criteria	Definition
Guidance	Refers to the means available to advise, orient, inform, instruct, and guide the users throughout their interactions with a computer (messages, alarms, labels, etc.), including from a lexical point of view
Workload	Concerns all interface elements that play a role in the reduction of the users' perceptual or cognitive load, and in the increase of the dialogue efficiency
Explicit control	Refers to the system processing of explicit user actions, and to the control users have on the processing of their actions by the system
Adaptability	Refers to system's capacity to behave contextually and according to the users' needs and preferences
Error management	Refers to the means available to prevent or reduce errors and to recover from them when they occur. Errors are defined in this context as invalid data entry, invalid format for data entry, incorrect command syntax, etc.
Consistency	Refers to the way interface design choices (codes, naming, formats, procedures, etc.) are maintained in similar contexts, and are different when applied to different contexts
Significance of codes	Qualifies the relationship between a term and/or a sign and its reference. Codes and names are significant to the users when there is a strong semantic relationship between such codes and the items or actions they refer to
Compatibility	Refers to the match between users' characteristics (memory, perceptions, customs, skills, age, expectations, etc.) and task characteristics on the one hand, and the organization of the output, input, and dialogue for a given application, on the other hand

• Method: completeness and clarity of the applied methods. This included an assessment of the method(s) applied, a description of participants (number, profile and experience in the setting and/or with the system), and examination of the study design (i.e. single evaluation, comparison between systems and/or pre- post- re-engineering).

When any of the two scores was equal to one on the 5-point Likert scale, the paper was excluded. The usability flaws reported in the included studies may have differing description levels, creating a risk of bias across studies. By selecting studies reporting on usability flaws that were sufficiently self-explanatory (i.e. usability flaws' descriptions that do not need supplementary information to be understood), the potential for bias was mitigated.

Moreover, publication and selective reporting biases had an impact on the review. Firstly, conference proceedings do not provide as much space for describing usability flaws as do journal papers with on-line appendices. Secondly, the focus of the study, e.g. alerting function vs. EMR/CPOE that includes an alerting function or pure evaluation study vs. entire design cycle study, could also have an impact on the report of usability flaws. Since the aim of the review is to achieve a comprehensive description of all usability flaws reported in previous studies on medication-related alerting functions, those biases were handled by performing only qualitative analysis.

3. Results

3.1. Study selection

The study design is schematically described in Fig. 1. The database searches and the searches within publication references identified 6380 publications. After the removal of duplicate publications, non-original studies and non- peer-reviewed publications (n = 1109), screening of the titles and of the abstracts excluded 4817 publications and rendered 454 papers eligible for further full-text review. Based on the full-text review, 428 papers were also excluded. Nine publications were excluded due to quality concerns in the reporting style: either the usability flaws and the method applied were not precisely described, or the discussion of the results confused flaws of different systems [32-40]. Finally, a total of 26 papers met our inclusion criteria and were used for detailed analysis. One [28] out of the two papers claiming to have on-line appendices did not provide them despite emailing the authors. On-line appendices of only one paper were analyzed [41].

3.2. Results of the bias assessment

Only studies judged to have acceptable validity were included in the analysis: after rating the validity of the included papers, nine papers were excluded due to quality concerns in the reporting style. Overall, the report quality was average (mean score = 3.46, median = 3.5) and the method quality was relatively good (mean score = 3.88; median = 4) for the included publications.

For the differing levels of description in the reported usability flaws, only studies reporting self-explanatory usability flaws were selected. Amongst the 168 instances of usability flaws identified in the studies, 155 are verbatim from the papers and only 13 (7.74%) needed rephrasing to make the usability flaws clearer. Rephrasing was based on complementary information provided in the papers, screenshots of the functions along with users' and designers' comments.

3.3. Characteristics of included papers

The set of 26 included papers comprises ten conference proceedings and sixteen journal papers. These papers report evaluations of 19 different systems integrating alerting. For two instances, two papers reported separate evaluations of the same system ([26,27] and [42,43]). Seven papers report evaluations of a CPOE that contains both non-interruptive and interruptive alerting functions. It was not identifiable whether both functions worked similarly or not therefore each of the seven papers was analyzed separately. Amongst these papers, three report different evaluations of non-interruptive alerts [14,44,45] and four report a unique study on interruptive alerts [41,46–48]. Since the latter four papers provide the same results, "duplicate instances" of usability flaws are presented together.

The main characteristics of analyzed papers are summarized in Table 3. In the following paragraphs, when the number of studies does not total 26 (or 19 functions), papers do not report on the presented issue.

There is no clear mention in any of the papers of the functions' design/implementation stage therefore deductions, based on the context of the studies, have been made to obtain this information. The large majority of the functions (16 in 23 papers) belong to system already in use, amongst them one paper reports an evaluation during a redesign process [49,50] and one an evaluation without real patient data [51]. Two other systems were still under development at the time of evaluation [52] and one was acquired by the hospital but not yet implemented [28].

Two alerting functions are standalone software [52]. The other 17 functions (in 24 papers) are integrated either into EMR, CPOE or into electronic patient records.

Classes of medical information targeted by the alerting functions [9] are not reported in a systematic manner. The most reported class is "drug-drug interaction checking" (for 10 alerting functions in 15 papers). There are also six alerting functions that include "drug-allergy checking", "duplicate therapeutic checking" or "basic dosing guidance" (respectively in 9, 11 and 8 papers). Evaluations of "advanced guidance for medication-associated laboratory testing" are reported in two alerting functions (in 6 papers). Evaluations of "advanced dosing guidance", "formulary decision support" and "advanced drug-pregnancy" alert are reported once.

Twelve alerting functions (17 papers) are interruptive, three are non-interruptive (5 papers) and three are mixed systems (3 papers).

Each paper included a detailed description of the methodology applied and the data collection methods used. The included papers proposed a great variety of methods. Eighteen papers combine at least two methods such as observations [24,41,44–48,50,53–55], interviews [24,41–48,50,52–56], focus groups [54,57–59], user testing [26,51,52], simulation [43,49,50], cognitive walkthrough [27,51], heuristics evaluation [28,60], questionnaire [49,50,52,58], survey [50,54], retrospective analysis [25,42,61] and log files analysis [50]. Eight papers apply one method amongst the above mentioned [25,27,28,56,57,59–61].

3.4. Categories of identified usability flaws

Overall, 168 instances of usability flaws are reported and categorized. No inter-experts agreement score was calculated because both experts performed this categorization process, including the development of the sub-categories, together.

The subsequent sections of this review describe the categories and sub-categories of usability flaws. The ultimate aim of this research is to look for evidence for usability design principles dedicated to medication alerting functions, therefore a focus is drawn

Table 3Main characteristics of the selected papers.

System		Mode of alerting	Integration	Class ^a	Design stage	Methods
VA Computerized Patient Record	[48]	Interruptive	In CPOE	DA, DT, DDI, AGML	In use	Observations, interviews
System	[46]	Interruptive	In CPOE	DA, DT, DDI, AGML	In use	Observations, interviews
	[41]	Interruptive	In CPOE	DA, DT, DDI, AGML	In use	Observations, interviews
	[47]	Interruptive	In CPOE	DA, DT, DDI, AGML	In use	Observations, interviews
	[45]	Non-interruptive	In CPOE	No data	In use	Observations, interviews
	[49]	Non-interruptive	In CPOE	No data	Redesign of system in use	User testing, simulation, questionnaire
	[44]	Non-interruptive	In CPOE	No data	In use	Observations, interviews
Medicator ©	[26]	Interruptive	In CPOE	BDG, DT, DDI	In use	Heuristics evaluation, user testing, experimental design
	[27]	Interruptive	In CPOE	BDG, DT, DDI	In use	Cognitive walkthrough
Medicatie/EVS ©	[42]	Interruptive	In CPOE	BDG, DT, DDI, AGML	In use	Retrospective analysis, interviews
	[43]	Interruptive	In CPOE	BDG, DT, DDI, AGML	In use	Simulation
Other	[24]	Non-interruptive	In patient record	BDG, DDI, ADG	In use	Observations, interviews
	[61]	Interruptive	In CPOE	DA, DT, DDI	In use	Retrospective analysis
	[57]	Interruptive	In CPOE	DA, DDI, ADP	In use	Focus group, Interviews
	[53]	Interruptive	In CPOE	No data	In use	Observations, interviews
	[59]	Mixed	In EMR	No data	In use	Focus group
	[51]	Interruptive	In CPOE	BDG	In use but evaluated with fake patients' data	Cognitive walkthrough, user testing
	[25]	No data	In CPOE	DA, DT	In use	Retrospective analysis
	[60]	Interruptive	In EMR	DDI	In use	Heuristics evaluation
	[50]	Non-interruptive	Standalone	No data	Under development	Observation, interviews, log files analysis, simulation, questionnaire, e-survey, telephone survey
	[56]	Mixed	In EMR/CPOE	DDI	In use	Interviews
	[54]	Interruptive	In CPOE	DA, BDG; FDS	In use	Observations, interviews, focus groups
	[52]	Interruptive	Standalone	DDI	Under development	Interviews, user testing, questionnaire
	[55]	Interruptive	In CPOE	DA, DT, ADP	In use	Observations, Interviews, e-survey, telephone survey
	[28]	Interruptive	In CPOE	BDG	Prior to implementation	Heuristics evaluation
	[58]	Mixed	In patient record	DDI	In use	Focus groups, questionnaire

^a Acronyms for the classes [9]: DA, "drug allergy"; DT, "duplicate therapy"; DDI," drug-drug interaction"; BDG, "basic dosing guidance"; ADG, "advanced dosing guidance"; ADP, "advanced drug-pregnancy alert"; AGML, "advanced guidance for medication-associated laboratory testing"; FDS, "formulary decision support".

to the categories of flaws specific to those functions. Table 4 proposes a synthesis of the categories of reported usability flaws. For more details, the reader may refer to Appendix 2 that presents the complete list of instances of usability flaws.

3.4.1. General usability flaws

Guidance infractions refer to issues related to prompting the user(s): important information is not highlighted, information is displayed in the visual periphery and instructions are unclear. There are also instances of the lack of distinction of alerts according to format: alerts with different severity levels are not visually distinguished as well as alerts of different types. There are also legibility issues along with lack of immediate feedback and heterogeneous presentation of alerts presenting the same severity level.

Workload-related usability flaws are mainly related to the excessive number of actions to be performed either to obtain information or to enter data. Other workload infractions refer to dense information and to non-concise information.

Violations of the significance of codes criterion are related to non-intuitive icons and wording. There are also issues with the consistency of the behavior of the system; it does not work the same way across use and according to the data it analyzes. Instances of explicit control issues are related to the fact that the system does not act as the user required and due to the lack of user

control; there is no way to undo an action. An instance of adaptability flaw is also observed, as the system does not support all types of users. Finally, an instance of error management flaw is reported; the message that is supposed to explain a problem related to the alerting function is not clear.

3.4.2. Medication-related alerting functions-specific usability flaws
Six categories of CDS-specific usability flaws are identified.

3.4.2.1. Low signal-to-noise ratio. The category of "low signal-to-noise ratio of alerts" deal with the failure to consider the context of use including the clinical context (patient clinical case), the setting context (user's expertise or ward habits, clinicians' priority, good practices and pharmacist knowledge), logistical context (care logic) or the care context (actions already taken by the clinicians). The category also deals with problems of reliability of the data triggering the alerts, there are several instances are reported of alerts that appear erroneously due to clinical data not being up-to-date. Seven issues of alert redundancy are observed. They include problems of re-appearance of the same alert throughout the same order entry, problems of system logic that does not consider the relevant solutions proposed by the users, and finally problems of the impossibility of de-activating a specific alert for a specific patient.

3.4.2.2. Alert content issue. This category refers to missing information in the alert and to the wrong content, rendering the alert useless. The missing information is related to one of three topics: the purpose of the alert (clinicians are facing alerts containing only the name of incriminated medications, without the reason why they are triggered, their severity and supporting scientific evidence), contextual information (patient's condition of importance regarding the alert, information necessary to interpret data within the alert such as lab results), and suggestions of actions to be taken to avoid (or to manage) the detected potential problem. Other instances are related to suggested actions that are "clinically erroneous" as stated in the studies analyzed.

3.4.2.3. Function is not transparent enough for the user. Flaws in this category refer to the fact that the system does not provide sufficient information for the user to know how it works. Instances deal with a lack of transparency about the way the alerting function is operating: what knowledge is applied to trigger the alerts (and if it is up-to-date), how alerts are categorized by severity or what actions users can perform on the system. Some instances reveal a lack of information about the data that is used by the system to trigger alerts. Clinicians are not informed that some data is screened while other data is not, and that the medications' mapping implemented in the alerting function does not consider all possible usages of a medication.

3.4.2.4. Alert appearance issues: timing and mode. This category illustrates alert appearance timing issues: the alert appears after the decision is made or the alert appears before the decision-making process is started or just at the wrong moment. There are also instances of low processing, slowing down the appearance of the alert. Finally, there are issues with the mode of presentation of the alert, *i.e.* their level of intrusiveness: alerts are either too intrusive, distracting the clinician from the decision-making process, or not sufficiently intrusive being unnoticed.

3.4.2.5. Tasks and control distribution issues. This category identifies that tasks and control distribution flaws are related to alerting functions' behavior that is unsuitable for the cooperative and distributed aspects of the medication use process. The alert is displayed to the clinicians who are not concerned by it (e.g. physiotherapist or psychologist). It is displayed once to a single clinician, not to the whole team. The alert and users' comments on it may also not be transferrable between clinicians who take care of the patient.

3.4.2.6. Alert features issues. This category deals with the lack of alert features adapted to support decision-making or the instantiation of a decision. Some instances are related to the volatility of alerts: the clinician cannot choose to reconsider an alert later in the decision making process. Moreover, the user cannot access additional information directly from the alert nor can they act to solve the problem highlighted by the alert through actions featured in the alert. The clinician must go back to the patient's record/ordering system to find information or to take action. Finally, there is an instance of a feature that does not suit clinicians' workflow and so the alert is recorded in the patient's progress note outside the template compelling clinicians to search for it in the entire note.

4. Discussion

This review fits into a project aiming at contributing to the emerging knowledge on usability design principles to complete the existing lists and identify those that are supported by evidence in the literature. The present systematic review aimed at answering the question "what are the usability flaws in medication-related alerting functions identified in published studies?" to provide comprehensive knowledge on the usability flaws already reported for those functions.

Two main kinds of usability flaws have been observed: general usability flaws and specific usability flaws. General usability flaws are related to infractions of good guidance practices, workload, significance of codes, explicit control, adaptability, error management and consistency (Table 4). General usability flaws can be observed whatever the type of computerized system. They are known for potentially making the use of the system harder [14]. The results also highlight types of usability flaws that are specific to medication-related alerting functions (Table 4): low signal-to-noise ratio, content issues, transparency issues, appearance (timing and mode) issues, tasks and control distribution issues and alert features issues. Those flaws are not only dealing with the GUI of the function but concern all components of the alerting functions including the knowledge implemented in it, its triggering model and the behavior of the function.

When this system is put in use, those usability flaws may negatively affect the quality of the physicians' interaction. Therefore, it is interesting to discuss the potential links between the categories of flaws that have been observed in medication-related alerting functions and the steps of the interaction. A structured model of user's interaction with a tool is needed to support this discussion. Norman's 7-stage model of action [62] presents the interaction process as two phases: action phase and evaluation phase (cf. Fig. 2, top). Adapted to the interaction of a physician with a medication-related alerting function, the first step of the model, the goal of the interaction, is to check the appropriateness of the prescriptions. Two action/evaluation loops may be described. The core one deals with the "display/reading" of the alert. The second one, "acknowledgment", depends on the alerting function model (sometimes, no acknowledgment is required). For the "display/ reading" loop (loop a, Fig. 2, top left), when forming the intention to use the alerting function, physicians may be plagued with "low signal-to-noise ratio", "alert content" and "alert appearance" issues. By affecting frequently other steps of the interaction, those issues may ultimately create "alert fatigue" and even rejection of the alerting function [5,63]. At the following step, "guidance issues" may bother physicians to specify the sequence of actions to notice and retrieve an alert (e.g. unclear guidance). The execution of specified sequence of action may be greatly affected by "guidance", "significance of codes", "workload", "explicit control" and "alert features" issues (e.g. confused terminology in labeling of buttons). Once the alert has been displayed on the screen of the alerting function, physicians have to read it: "guidance", "workload", "significance of codes" and "alert appearance" issues may hamper this step (e.g. users must use vertical scrolling and go through several tabs to get complete information). Then, "significance of codes", "consistency", "error management", "alert content" and "transparency" issues (e.g. relevant data to interpret the alert are missing) may impact the interpretation of alert's content. Finally, "low signal-to-noise ratio" issues might hinder the assessment of alert's relevance according to patient's prescription (e.g. the multiplication of irrelevant alerts prevents physicians from finding the relevant ones). Once the alert is interpreted, physicians may have to acknowledge the alert (loop b, Fig. 2, top right). No type of flaw has been found that hinder the intention of acknowledging the alert while "guidance" issues may impact the step of specification of the action "accept/override" the alert (e.g. acknowledgment requirement is not always marked). However, physicians may be hampered to actually acknowledge the alert by "guidance", "workload", "explicit control", "significance of codes" and "alert features" issues (e.g. several actions

 Table 4

 General and medication-related alerting functions' specific categories of usability flaws and references of the papers from which they were retrieved.

General usability flaws	Studies
Guidance issues Prompting issues: unclear text, information highlight deficiency, alert/information far from the center of the screen, no detail No distinction by format (shape, color) of different severity alerts, types of alerts or types of message (system vs. medical alerts) Legibility issues: not sufficient inter-line space, font in capital letters, size of elements too small No feedback to inform the user that (s)he has just missed an alert Too much distinction by location: no grouping of same severity alerts	[24,43,46,50,52,56,58,61] [41,48,57,60] [41,48,52] [43] [60]
Workload issues Minimal action: too many actions for entering information or obtaining information (e.g. scrolling, tabs) Information density: too much information of different kinds in the window, several alerts in the same window, alert content displayed in a one-paragraph format Lack of concision	[42,44,46,50,53,59,61] [24,41,46,48,50,51] [55–57]
Significance of codes issues Non-intuitive wording Non-intuitive icons	[26,42,49,50,59] [44,50]
Consistency issues Inconsistency of behavior of the system across use or according to data analyzed	[28,46]
Explicit control issues Explicit user actions: system's action does not correspond to the action requested by the user User control: there is no way to undo an action	[44] [45]
Adaptability issues Lack of flexibility: the system does not support all user types	[41]
Error management issues Quality of error message: problem messages are unclear	[41]
Usability flaws specific to medication-related alerting functions	
Low signal to-noise-ratio Alerts are irrelevant regarding: expertise/ward habits, existing validated good practices, pharmaceutical knowledge, data considered, patient case, actions engaged, clinician's interest for at risk situations, care logic, no detail Low signal-to-noise ratio without specific description Alerts are redundant: alerts appear very frequently/several times during the decision making, clinically relevant solutions from the clinicians are not accepted, no feature for turning-off a specific alert in a specific context	[24,26,41–43,45–48,57–59] [41–44,46,48,53,55,57,59] [41,44,45,48,55,56,59]
Alert content issues Information required to make a decision is missing: the actions that could be taken, patient data, the problem detected its evidence and its severity and information for interpreting data within the alert The alert's content proposes erroneous suggestions: the proposed action does not suit the clinical context, no detail	[42,43,47,49,51,53,61] [26,44]
Function is not transparent enough for the user The alerting function is not transparent about the way it works: no information about the alert severity scale, about the up-to-dateness of the alerts' rules or no detail	[24,41,45,46,51,60]
The alerting function is not transparent about the data it uses: all available data is not used to trigger the alert or incomplete mapping Alert appearance issues: timing and mode Alert does not appear at the right moment to support the decision making process: before the decision process starts, at the wrong moment, after the decision is made	[25,28,41,48,59] [24,27,51,54–56,59]
Data processing is slow The alert's display mode does not suit the decision making process: not sufficiently intrusive, too intrusive	[41,44] [59]
Tasks and control distribution issues Alert not displayed to the right clinician or only to the pharmacist The alerting function allows users to enter comments that are displayed to no one Alert not transferable from one clinician to another	[43,54,58] [41,61] [44]
Alert features issues Alert features are missing: no feature for reconsidering an alert later, no access to additional information from the alert, no action tool to solve the problem from the alert	[41,43-45,50,60]
Alert features are not adequately designed to suit users' needs	[44]

needed to justify the irrelevance of the alert). Once the alert is acknowledged, "guidance" and "workload" issues may affect reading the alert acknowledgment status (e.g. no feedback after hitting a button). "Significance of codes", "consistency" and "error management" issues may prevent from interpreting this status (e.g. non intuitive status icons). Finally, no type of flaw has been observed that may impact the assessment of the acknowledgment.

In summary, usability flaws may impact both action and evaluation stages. This highlights that the design of the interaction and the design of the information have to be improved. Both "display/reading" and "acknowledgment" loops may be affected by those flaws even if it appears that flaws specific to medication-related

alerting functions are more likely to impact the "display/reading" loop (except "alert features issue").

It has to be noticed that not all types of flaws match the interaction model (Fig. 2, bottom). Indeed, Norman's model reports the individual interaction with the alerting function, not the workflow nor the collaborative characteristics of the work. Yet the workflow may be deeply impacted by "alert appearance" issues (e.g. high intrusiveness of alerts) and collaborative tasks may be hampered by "adaptability" and "tasks and control distribution" issues (e.g. features missing to transfer an alert to a colleague).

This systematic review has limits and biases that must be considered. In the reviewed papers, the description of the functions

under evaluation is not complete, preventing the analysis of whether usability flaws are related to a specific type of the alerting function. Another limitation is restricting the review process to peer-reviewed papers, potentially putting aside institutional or companies' reports. Relevant usability studies could have been missed. However, only a peer-reviewed publication process could guarantee that the methods applied in those studies are of sufficient quality. The quality of the review method reflects this, with only nine of the included papers excluded.

Publication and selective reporting biases could have potentially impacted the representativeness of the results. Moreover, some types of flaws are easier to picture in a few words or with a screenshot (e.g. guidance) while others require long descriptions of a system's behavior to be understood (e.g. error management). This may have impacted, at least partially, the representativeness of the results (e.g. one instance for error management but twenty-nine for guidance). This representativeness bias may have impacted the diversity of the usability flaws reported as compared to those actually existing in alerting functions. However, all categories of flaws identified included instances that come from different papers: the overlapping of data from various sources ensures the reliability of these results.

The systematic review process highlighted papers that initially met the inclusion criteria but further examination revealed that significant data was missing from the methods and/or the results section of the papers. This problem has been identified by previous systematic reviews on usability characteristics of medical software (e.g. [64] for CPOE). In this review, only papers with sufficient data in the study method have been analyzed; nine papers were excluded after initial acceptance due to missing data. This represents a loss of about a fourth of the total number of papers that could have been analyzed. Moreover, even in the included papers,

some information non-essential for the topic of the review (e.g. the class of CDS, the context of use) was often briefly described. There is an actual need for reporting guidelines for usability-related papers [65] as has been done for HIT evaluations [66]. Moreover, this review has also illustrated the advantages of on-line appendices to describe usability flaws [41] exhaustively and in detail provides much useful data. The use of on-line appendices has to be encouraged for the reporting of the whole set of usability flaws uncovered by the study and the precise description of the system. This proposal is currently under examination in an international Delphi study [67]. A demand for high quality reports for Human Factor evaluation will enable a repository of high quality studies to be created. However, this repository is necessary to capitalize on usability data in order to ultimately look for evidence for usability principles.

The results of this review provide insight on the topic of usability flaws in alerting functions by precisely detailing the types of usability flaws reported for alerting functions. Moreover, in their current state they are directly useful, a list of 168 actual concrete instances of usability flaws that characterize those functions is now available. Even though it may not be representative of the entire set of usability flaws that could possibly be found in medication alerting functions, it is exhaustive considering what has been published on this topic.

As far as we know, it is the first time that such a list based on empirical illustrated knowledge has been proposed for medical software. This list could be used as an illustrated check-list for usability mistakes not to be made by Human Factor experts, designers and health informatics project managers to facilitate the identification and correction of potential usability flaws during the design, evaluation, procurement and implementation processes.

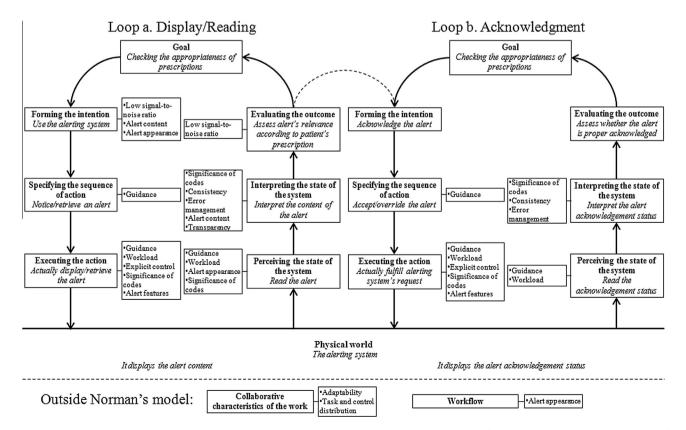


Fig. 2. Top: Norman 7-stage model of action adapted to the interaction of a physician with an medication-related alerting function and potentially impacting usability flaws. Loop a "display/reading" the alert (left) represents the core interaction of the physician with the system. Loop b "acknowledgment" represents a second order interaction: not all alerting functions allow acknowledging alerts. Bottom: characteristics of physician's interaction not matched by Norman's model and potentially impacting usability flaws.

This work should be regularly updated to consider the evolution of the usability features of medication-related alerting functions for the present list represent the current state of knowledge on usability flaws problematic for those functions. Moreover, those data should also be completed by searching incident reports for medication-related alerting functions [68]. This will enable us to identify new kinds of flaws not yet reported in the literature and enhance the database developed by the current review.

This study reports the first mandatory step to seek evidence for usability design principles for medication-related alerting functions. The flaws identified may have an impact on users' experience with the system and negatively affect the work system (e.g. generating patient safety issues). This impact may have different severity levels considering its object from low to potentially harmful. Therefore, further studies must endeavor to identify the consequences of those flaws in terms of usage problems and usabilityrelated outcomes in the work system. This will help us to weight the usability flaw categories in order to find out which ones are more dangerous and should be set as a priority and ultimately support the construction of evidence for related usability design principles that take clearly into account the consequences of the infractions of those principles [16]. The required next step will consist in developing usability design principles to help fix the usability flaws. For now, only preliminary tracks of recommendations can be proposed:

- Improve the design of the interaction: reduce the gap between
 the way the system actually works and users' mental model of
 the system, guide users to understand the limits of the alerting
 function and how to act upon it properly, consider the various
 profiles of users in terms of features needed and terminology.
- Improve the design of the information: reduce the effort required for users to perceive and interpret alerts, reduce the number of irrelevant alerts, provide relevant and structured data within each alert, the alerting system must correctly perform actions required by the user.
- Design the system as a team player and as a clinician's partner: the design of the alerting system must support physicians' actual workflow and the existing cooperation between clinicians. The model of work implementing in the alerting system must take into account the various profiles of users and their interactions.

In order not to reinvent existing principles, categories of usability flaws in medication alerting functions will be matched with existing related usability design principles. The results of this operation will enable the identification of existing lists of usability design principles that are supported be evidence of the literature.

5. Conclusion

The present systematic review aimed at identifying the usability flaws that have been reported in previous studies on medication-related alerting functions. Results identified 168 instances of usability flaws that were categorized into eight categories of general flaws completed by six categories of flaws specific to medication-related alerting functions. The 168 instances represent 168 usability mistakes not to be made. This list can be used as a usability check-list during the design, the evaluation, the procurement and the implementation process of medication-related alerting functions

Knowing those flaws is a first step to provide recommendations for improving the usability of medication-related alerting functions. Further studies are needed to identify the known potential consequences of those flaws in terms of usage problems and outcomes in the work system and to provide suitable and precise usability design principles.

Authors' contribution

Romaric Marcilly designed the study, retrieved the data, performed the analysis and wrote the paper. Marie-Catherine Beuscart-Zéphir retrieved the data, performed the analysis and supported the writing of the paper by reading it several times and providing advice to improve the report of the study. Elske Ammenwerth designed the study, provided a methodological support and supported the writing of the paper by reading it several times and providing advice to improve the report of the study. Francis Vasseur and Erin Roehrer supported the writing of the paper by reading it several times and validated it. Additionally Erin Roehrer checked English spelling and grammar.

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Conflicts of Interest

The authors declare they have no conflict of interests.

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Appendix A. Supplementary material

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