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1 **BUILDING USABILITY KNOWLEDGE FOR HEALTH INFORMATION**
2 **TECHNOLOGY: A USABILITY ORIENTED ANALYSIS OF INCIDENT REPORTS**

3

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9

10 **Abstract**

11 **Background:** The contribution of usability flaws to patient safety issues is acknowledged
12 but not well-investigated. Free-text descriptions of incident reports may provide useful data to
13 identify the connection between health information technology (HIT) usability flaws and
14 patient safety.

15 **Objectives:** This paper examines the feasibility of using incident reports about HIT to learn
16 about the usability flaws that affect patient safety. We posed three questions: 1/ To what extent
17 can we gain knowledge about usability issues from incident reports? 2/ What types of usability
18 flaws, related usage problems and negative outcomes are reported in incidents reports? 3/ What
19 are the reported usability issues that give rise to patient safety issues?

20 **Methods:** A sample of 359 reports from the US Food and Drug Administration
21 Manufacturer and User Facility Device Experience database was examined. Descriptions of
22 usability flaws, usage problems and negative outcomes were extracted and categorized. A
23 supplementary analysis was performed on the incidents which contained the full chain going
24 from a usability flaw up to a patient safety issue to identify the usability issues that gave rise to
25 patient safety incidents.

1 **Results:** A total of 249 reports were included. We found that incident reports can provide
2 knowledge about usability flaws, usage problems and negative outcomes. Thirty-six incidents
3 report how usability flaws affected patient safety (ranging from incidents without consequence,
4 to death) involving electronic patient scales, imaging systems, and HIT for medication
5 management. The most significant class of involved usability flaws is related to the reliability,
6 the understandability and the availability of the clinical information.

7 **Conclusions:** Incidents reports involving HIT are an exploitable source of information to
8 learn about usability flaws and their effects on patient safety. Results can be used to convince
9 all stakeholders involved in the HIT system lifecycle that usability should be considered
10 seriously to prevent patient safety incidents.

11

12

13 **Keywords**

14 Information technology; Patient safety; Ergonomics; Databases, Factual; Software

15

1. BACKGROUND AND SIGNIFICANCE

Health information technology (HIT) promises to improve the safety, efficiency and overall quality of care delivery [1,2]. Yet, poor usability of HIT may lead to implementation failure or rejection [3], usage difficulties [4] and, even worse, to patient safety issues [5–7]. Poor usability is revealed by the presence of usability flaws, *i.e.* “*aspect[s] of the system and/or demand on the user which makes it unpleasant, inefficient, onerous, perturbing, or impossible for the user to achieve their [sic] goals in [a] typical usage situation*” [8]: these aspects may be related to the graphical user interface of the technology, its behavior, and the suitability of the knowledge implemented within and of the features available for users’ needs [9]. Usability flaws represent violations of usability design principles (also known as usability heuristics or usability criteria) when designing HIT [10].

The contribution of usability flaws to patient safety issues is well-acknowledged but there is little research on the effects of usability flaws on care delivery and patient safety. Common methods for usability evaluation do not enable this connection to be studied. Indeed, expert-based evaluations (e.g. heuristics evaluations [11], cognitive walkthrough [12]) and hazard-oriented analyses [13] enable identification of usability flaws. However, since there are no observations of technology in use, only hypotheses can be drawn about the effect of usability flaws [14]. As for user-based evaluations (e.g. user-testing [15], think-aloud protocols [16]) where representative end-users interact with the technology in a controlled environment, they offer insights about how usability flaws can impair work (*i.e.* usage problems): however, hypotheses must still be drawn on their potential negative outcomes on the work system (*incl.* patient safety) [14]. One way to examine the contribution of usability flaws to negative outcomes including patient harm is by field observations and interviews (e.g. [14,17–21]). These study designs enable connection of usability flaws with their effects on users and even with patient safety issues (e.g. [18]). However, such studies provide insights about a limited

1 range of situations. To get a deeper understanding on how usability flaws contribute to negative
2 outcomes it is necessary to analyze a variety of situations where HIT problems affected care
3 delivery and patient safety.

4 Incident reports are an accessible and significant source of information about patient safety
5 issues with health technology. Yet, biases and limitations give incident reports the reputation
6 for being an unexploitable material. Indeed, the blame culture may lead to underreporting and
7 may impact the accuracy of the reports [22,23]: relevant facts may be missed or presented with
8 less certainty [24]. In addition, the reports reflect the expertise of the reporters (e.g. vendors,
9 clinicians) [25] with all the inherent limitations of such a system. Despite those limitations and
10 biases, reports from a range of incident monitoring systems have been successfully investigated
11 to analyze patient safety issues with technologies [25–30]. By analyzing the free-text
12 descriptions provided in reports, those studies have highlighted that incident reports were a
13 valuable material to identify and categorize the types issues with technology issues that affected
14 patient safety. They have even described socio-technical factors affecting the use of technology,
15 including usability flaws that led to incidents.

16 Indeed, Magrabi et al. identified that such factors made up 4% of the patient safety issues
17 that were voluntarily reported by manufacturers to the US Food and Drug Administration
18 (FDA) Manufacturer and User Facility Device Experience (MAUDE) database [25]; this ratio
19 rose to 10% in [29] and 16.77% in [30]. The analysis of reports from MAUDE noted good
20 descriptions of technical issues and rich information about the types of software problems
21 encountered. Reports provided by manufacturers provided were found to provide insights into
22 how software and hardware systems were failing compared to those reported by health
23 professionals which emphasized issues with clinical workflow integration and training.

24 In another study by Magrabi et al. [27], 45% of the incidents reported involved socio-
25 technical factors. A study by Lyons and Blandford identified a few usability flaws which gave

1 rise to errors and affected patient safety [31]. These studies show that despite their limitations
2 and biases, incident reports, particularly those reported by manufacturers, may be a useful
3 source information to gain a deeper understanding about how usability flaws can affect care
4 delivery and patient safety. However, as far as we know, no previous studies have attempted to
5 explicitly analyze incident reports from a usability perspective.

6 **2. OBJECTIVES**

7 The present paper reports a study to examine the feasibility of using incident reports about
8 HIT to learn about the consequences of usability flaws, with a focus on patient safety. We posed
9 three questions:

10 1/ To what extent can we gain knowledge about usability issues from incident reports?

11 2/ What types of the usability flaws, related usage problems and negative outcomes are
12 reported in incidents reports?

13 3/ What are the reported usability issues that give rise to patient safety incidents?

14 **3. METHODS**

15 We performed a secondary analysis of a sample of incident reports that were previously
16 identified as involving human factors issues. The method involved three main steps. First, out
17 of this sample, we selected incident reports whose free-text descriptions presented a usability
18 flaw. Second, we used the definitions provided by a usability framework to extract from the
19 free-text descriptions three types of information: descriptions about (i) usability flaws (ii) usage
20 problems, and (iii) negative outcomes. Finally, we developed or reused coding schemes to
21 analyze in detail each type of information.

22 **3.1. Sample of incidents screened**

23 We examined incident reports involving HIT (excluding medical devices such as infusion

1 pumps and auto-injector devices) voluntarily reported by manufacturers to the US FDA's
2 MAUDE database that had been analyzed in a previous study [25]. That analysis identified broad
3 categories of issues with HIT using 678 reports that had been submitted to MAUDE from
4 January 2008 to July 2010. In the present study we performed a secondary analysis on a sub-
5 set of 359 reports that were previously identified as involving human factors issues. Some
6 incidents spanned two reports [25]: an initial description and additional information (labeled
7 hereafter “supplementary information”). Thus, the analyzed sample included a total of 359
8 reports corresponding to 242 different incidents (plus 117 “supplementary information”
9 reports).

10 **3.2. Eligibility criteria**

11 For a report to be included in the analysis, the free-text description must have presented at
12 least one meaningful semantic unit (i.e. sets of words representing a single idea that was
13 sufficiently self-explanatory to be analyzed) describing factually a usability flaw (cf.
14 background and significance section for definition). Reports not including usability flaws, or
15 where descriptions were too poor or incomplete (requiring hypothesis) or not factual (report of
16 hypotheses drawn by the reporter), were excluded from the analysis. “Supplementary
17 information” reports were included if they provided relevant information not mentioned in the
18 initial report of the incident; if not, they were excluded.

19 **3.3. Screening process**

20 The screening process was performed by three experts in human factors with a background
21 in medical devices and usability evaluation of HIT (JS, MCBZ, RM). The experts initially
22 trained on a randomly chosen set of reports to gain a common understanding about the
23 eligibility criteria and until agreement about the inclusion of reports could be easily reached
24 (n=18). Then, two human factors experts (JS, RM) independently examined 40% (n=142) of

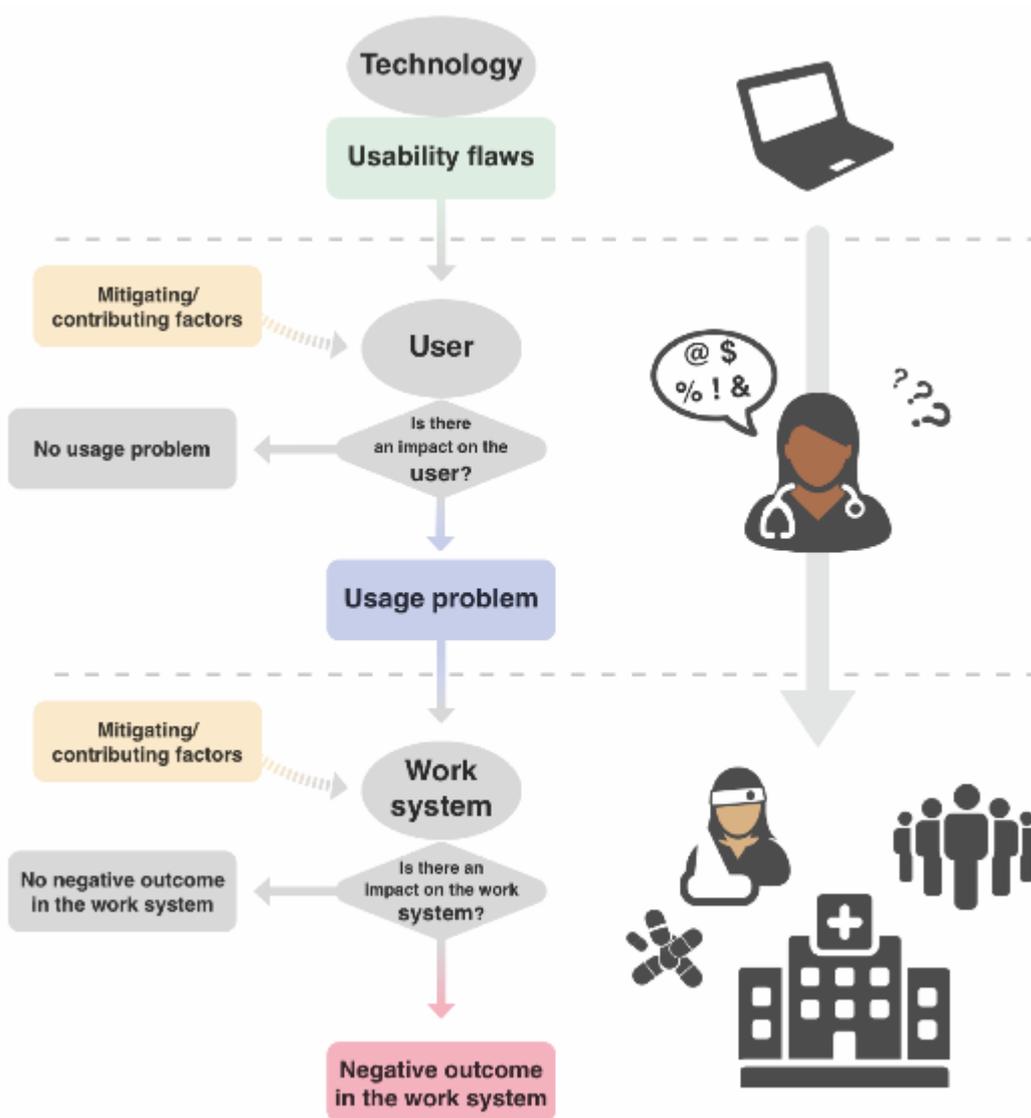
1 the remaining reports against the inclusion criteria. An inter-rater reliability analysis using
2 Cohen's Kappa score was performed showing good consistency among coders (Kappa=0.73).
3 The remaining 60% (n=199) were then examined by RM using the same categories; the results
4 were cross-checked by JS (Kappa=0.79). When experts disagreed on a report, or there were
5 doubts about inclusion, the report was re-examined during a meeting till consensus was reached.
6 Disagreements were resolved by consulting the third expert and were checked by FM.

7 **3.4. Data extraction and analysis**

8 **3.4.1. Data extraction**

9 The data extraction was based on an existing usability framework [14,32] that describes the
10 chain of latent consequences that leads from a usability flaw to a usage problem and then a
11 negative outcome (Figure 1). Usability flaws impair first the user work and the tasks to be
12 performed. These conscious or unconscious issues experienced by the user are referred to as
13 "usage problems". Other parts of the work systems, including the patient, are then impacted
14 through the user; those issues are referred as "negative outcomes", and include patient safety
15 issues. The chain is not linear and depends on several factors including factors independent of
16 the technology (e.g. training, clinical and technical skills, expertise, workload) that may either
17 favour or mitigate the impact of usability flaws at both levels of usage and negative outcomes.
18 We used the definitions of usability flaws, usage problems and negative outcomes provided by
19 this framework to extract those three types of data from the incident reports.

20 First, free-text from "supplementary information" was merged with the text of included
21 reports. In each free text description of the included incident, JS and RM extracted factual
22 descriptions about usability flaws.



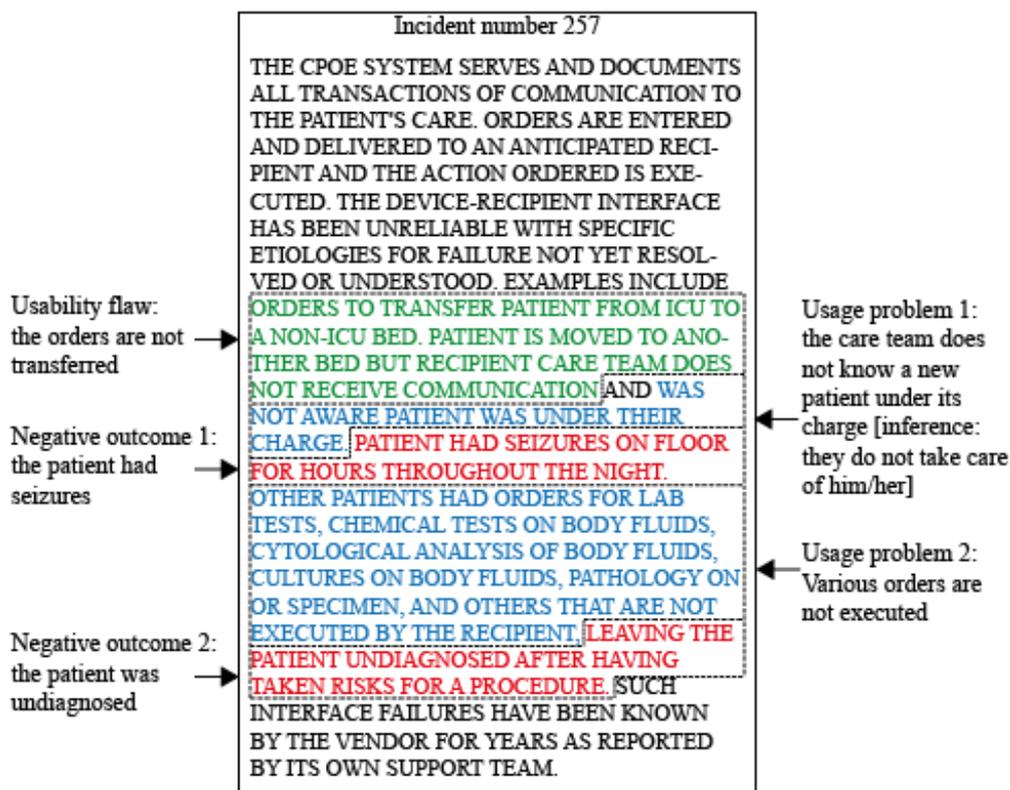
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2 **Figure 1.** Schematic representation of the consequences of violating a usability principle.

3 Then, for each included report, JS and RM independently examined consequences or
 4 absence of consequences of usability flaws, *i.e.* usage problems and/or negative outcomes. An
 5 inter-rater agreement was calculated ($Kappa = 0.74$). Disagreements were discussed till
 6 consensus arose. The following data were extracted from the reports that mentioned
 7 consequences of usability flaws:

- 8
- *Factual descriptions of usage problems:* any negative consequences of a usability
 9 flaw on the users and their tasks. Usage problems refer to the overall experience of

- 1 the users interacting with the technology including their cognitive processes,
 2 decisions, behaviors, feelings and emotions [32]. Usage problems include, but are
 3 not restricted to, use-errors as defined by [33](e.g. the user entered inadvertently the
 4 wrong dose).
- 5 • *Factual descriptions of negative outcomes*: any negative impacts of the usability
 6 flaws on the work system or care delivery including tools, technologies,
 7 environment, organization, performance, non-user person (e.g. patient) [32](e.g. the
 8 medication administration process was slowed down). Negative outcomes include
 9 patient safety (e.g. the patient got the wrong medication and experienced an adverse
 10 drug reaction).



11

12 **Figure 2.** Deconstructing the free-text of an incident report included in the analysis to
 13 identify usability flaws, usage problems and negative outcomes. Capitalization as written in the
 14 original report.

15 We also extracted information about the type of technology. It should be noted that a given

1 incident may be comprised of one or more usability flaws, and of none, one or several usage
2 problems and negative outcomes. Figure 2 provides an illustration of how an incident was
3 systematically deconstructed to identify the usability flaws and its consequences for the user
4 and the work system and patient.

5 **3.4.2. Classification process**

6 Data were analyzed by categorizing usability flaws, usage problems and negative
7 outcomes. For the usability flaws and usage problems, two separate coding schemes were
8 developed inductively by JS and RM so that descriptions that represented the same types of
9 issues were gathered together in unique classes. The coding schemes were developed to achieve
10 unambiguous, clear, and mutually exclusive subcategories with high internal consistency.
11 During the coding process, any disagreements were discussed till complete agreement was
12 reached. At the end of the process, each usability flaw and usage problem were assigned to a
13 unique category and subcategory of their respective coding scheme (cf. Figure 3, and
14 appendices 1 and 2 for the final coding schemes). Negative outcomes were examined using a
15 standard approach [25,27,34] and are as follows:

16 a) *Harm to a patient (an adverse event)*: An incident that reached the patient [35], for
17 example, a patient had a severe allergic reaction to prescribed medication even though
18 allergy was entered in the patient's electronic medical record.

19 b) *An arrested or interrupted sequence or a near miss*: An incident that was detected
20 before reaching the patient [35], for example, a prescription in a wrong name noticed and
21 corrected while printing.

22 c) *An incident with a noticeable consequence but no patient harm*: Issue that affected
23 the delivery of care but did not harm a patient, for example, time wasted waiting for a
24 printer to function correctly.

1 d) *An incident with no noticeable consequence*: Issue that did not directly affect the
 2 delivery of care, for example, an electronic backup copy of patient records was
 3 corrupted, but this was detected and the copy was not needed.

4 e) *A hazardous event or circumstance*: Issue that could potentially lead to an adverse
 5 event or a near miss, for example, a computerized physician order entry fails to display
 6 a patient's allergy status.

7 f) *A complaint*: An expression of user dissatisfaction, for example, a user found that
 8 training to use new software was inadequate.

9 New categories were developed when new themes emerged. As with the categorization
 10 process for usability flaws and usage problems, any disagreements were discussed till complete
 11 agreement was reached (cf. Figure 3 and appendix 3 for the final coding scheme).

12 Descriptive analyses of incidents were undertaken by the type of technology, usability
 13 flaws, usage problems and negative outcomes.

USABILITY FLAWS	USAGE PROBLEMS	NEGATIVE OUTCOMES
1. Graphical user Interface issues	1. Distrust in the system	1. Harm to patient
1.1. Close options	2. Error	1.1. No details
1.2. Lack of highlight	2.1. Diagnostic error	1.2. Without consequences
1.3. Load of information	2.2. Identification error	1.3. Non-lethal consequences
1.4. Typeface issue	2.3. Involuntarily validation/delete	1.4. Death
2. System behavior issues	2.4. Manipulation error	2. Arrested or interrupted sequence (near miss)
2.1. Lack of protection against errors	2.5. Order execution error	3. Incident with noticeable consequences with no harm
2.2. Lags	2.6. Ordering error	3.1. No details
3. System not supporting practices	2.7. Understanding error	3.2. Delay
3.1. Supporting information issues	3. Increased workload	3.3. Extra-costs
3.1.1. Missing information	3.1. Unspecified	4. Incident with no noticeable consequences
3.1.2. Information not up-to-date	3.2. Additional tasks	5. Hazardous event or circumstance
3.1.3. Data inconsistency	3.3. Increased cognitive load	6. Complaint
3.1.4. Inaccurate information	3.4. Task redone	7. Action in response to incidents
3.1.5. Data mixed up between patients' records	3.5. Time wasting	7.1. New procedure
3.1.6. Data mixed up within patient's record	4. Involuntarily missed information	7.2. Abandon of the technology
3.1.7. Unrequested data changes	5. Uncertainty	7.3. Drug diversion
3.2. Supporting features issues	6. Violation of safety procedures	
3.2.1. Inadequacy between the systems and the tasks of their users		
3.2.2. Inefficient functionality		
3.2.3. Issues in transmitting information		
4. Unspecified usability flaw		

1 **Figure 3.** Final coding schemes used to categorize the usability flaws (left), the usage
2 problems (centre), and the negative outcomes (right).

3 **3.4.3. Analysis of the usability issues that give rise to patient safety incidents**

4 We examined the subset of incidents which contained the full chain going from a usability
5 flaw through the usage of the technology up to the patient. To be included in this analysis,
6 reports needed to include:

- 7 1. Effects on patient safety that were objectively described for a patient or a group of
8 patients (excluding hypotheses).
- 9 2. A full chain of usability flaws, usage problems and negative outcomes that make sense
10 regarding the clinical work logic and the chronology of the incident reported. We
11 excluded incidents that required us to draw hypotheses to understand how the usability
12 flaw led to a usage problem and negative outcome. For instance, when the usage
13 problem is an emotion and it is not described how this emotion led to a negative
14 outcome, the incident was excluded.

15 Incidents which contained the full chain but whose negative outcome was not related to a
16 patient safety issue (ex. work organization, process) were excluded from this analysis.

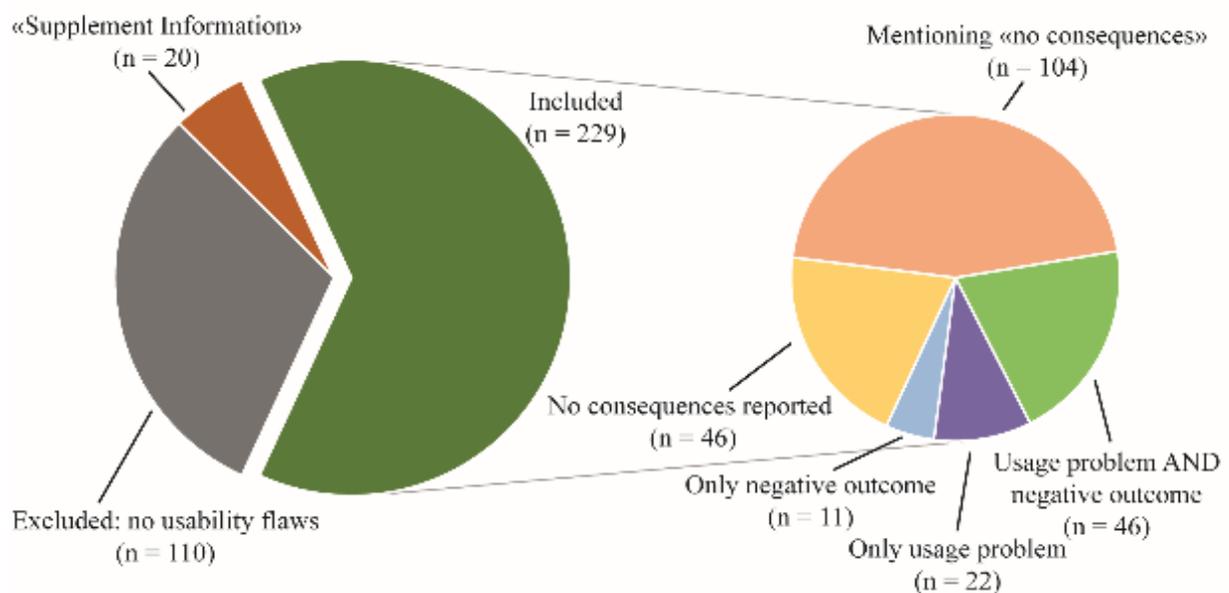
17 For each type of technology involved in the analyzed incidents, we performed a narrative
18 synthesis of the typical pathways of the propagation of the usability flaws up to the patient.
19 First, we gathered together incidents that shared similar kinds of usability flaws. Then, we
20 summarized the categories of usage problems and negative outcomes arising from this type of
21 flaw.

22 **4. RESULTS**

23 **4.1. Incident reports can provide knowledge about usability issues**

1 We found that incidents reports could be analyzed from a usability perspective. A total of
 2 249 reports out of 359 (69.3% inclusion) were included in the analysis, representing 229
 3 different incidents along with 20 “supplementary information” reports. While the incidents
 4 involved a large variety of technology, the majority were associated with imaging software
 5 (n=107, 46.7%). Computerized physician order entry, electronic health records, medication
 6 administration records and pharmacy clinical software accounted for 79 incidents (34.5%).
 7 Twenty-five dealt with laboratory information systems (10.9%). Thirteen involved blood bank
 8 software (5.7%). Anatomic pathology systems, archiving software, data management systems,
 9 radiation systems and electronic patient scales accounted for one incident each.

10 Of those 229 incidents analyzed, 46 did not report on any consequences, neither usage
 11 problems nor negative outcomes (20.1%), and 104 explicitly mentioned that there were no
 12 consequences (*i.e.* no error or no patient injury; 45.4%). In total, 46 incidents provided
 13 descriptions about usage problems and negative outcomes (20.1%) providing the full chain of
 14 propagation of the usability flaws. Twenty-two (9.6%) reported only usage problems while 11
 15 (4.8%) reported only negative outcomes. Figure 4 summarizes the distribution of the incidents
 16 analyzed according to their content.



1 **Figure 4.** Graphical representation of the distribution of the incidents analyzed according
2 to their eligibility (left) and their content in terms of usage problems and negative outcomes
3 (right).

4 **4.2. Reports provide information about usability flaws, related usage problems and** 5 **negative outcomes**

6 Our analyses successfully extracted usability flaws, usage problems and negative outcomes
7 from the free-text descriptions. Of the 229 incidents, 287 meaningful semantic units
8 representing usability flaws were extracted and classed into a hierarchy of four meta-categories,
9 eight categories, and 10 subcategories (cf. Figure 3 and appendix 1 for details). Usability issues
10 that were sufficiently described to be classified dealt with graphical user interface (GUI) issues,
11 or with the behavior of the system including lack of protection against errors that may lead to
12 preventable use errors. The last class dealt with violations of the needs of the users in terms of
13 information and of features including missing, non-updated, inconsistent, or inaccurate
14 information and features that do not support users' individual and collective tasks, failing
15 features, information transmission issues.

16 Of the 68 incidents mentioning usage problems, 103 different meaningful semantic units
17 were extracted and classed hierarchically into six categories and 12 subcategories (cf. Figure 3
18 and appendix 2 for details). Main classes dealt with the users distrusting the system, making
19 errors, being uncertain, missing relevant information, violating safety procedures, or seeing
20 their workload increased.

21 Of the 57 incidents mentioning negative outcomes, 64 meaningful semantic units were
22 extracted and classed into six categories and nine subcategories (cf. Figure 3 and appendix 3
23 for details). Main classes dealt with harm to patient (e.g. death, non-lethal consequences, no
24 consequences), incident with noticeable consequences with no harm (e.g. delay in the care

1 process), hazardous event or circumstance, arrested or interrupted sequence (near miss). Two
2 new categories were created: action in response to incidents (e.g. new procedures, abandon of
3 the technology) and drug diversion.

4 **4.3. Reported usability issues that gave rise to patient safety incidents**

5 Forty-six incidents report the full chain going from a usability flaw through the usage of the
6 technology (usage problem) up to the work system and or the patient (negative outcomes). Of
7 these, nine were excluded from the analysis because their negative outcomes were related only
8 to “actions in response to incidents”, “drug diversion” or to “delays” in the care process, not to
9 patient safety issues. Thirty-seven incidents reporting the full chain and leading to a patient
10 safety issue were considered for analysis; one (incident number 253) was excluded because the
11 link between the usage problem (“distrust for the functionality of the system by those using it”)
12 and the patient safety issue (“varying degrees of adversity for the patients”) must be
13 hypothesized (cf. Appendix 4). Table 1 presents the deconstruction of the 36 incidents analyzed.
14 These involved three types of technology: electronic patient scales (n=1), imaging systems
15 (n=4), Computerized Physician Order Entry (CPOE)/Electronic Health Record
16 (EHR)/Medication Administration Record (MAR)/Pharmacist Clinical Software (PCS) (n=31).
17 It should be noted that the usability flaw was not always the direct cause of the patient safety
18 issue but could also be a contributory factor. Overall the usability flaws were varied but a few
19 constants can be highlighted as we show below:

20 **Electronic patient scales:** The unit of measure could easily be changed causing an erroneous
21 measure and the administration of an inadequate dose of medication. This incident did not lead
22 to noticeable consequence.

23 **Imaging systems:** In the four incidents involving imaging systems, the unavailability and the
24 unreliability of the information provided on images were the causes of various errors (e.g.

1 patient identification, diagnostic, manipulation, order execution, understanding) that led to
2 patient harm and even death.

3 **CPOE, EHR, MAR, PCS:** Despite the great diversity existing in the types of usability flaws
4 identified and in the ways of their propagation up to the patient, five typical paths can be
5 identified in the 31 incidents concerning software related to the medication use process.

6 1/ If an information is erroneous, ambiguous, changed, missing (including, not transmitted),
7 illegible or nowhere to be found, it leads clinicians to miss it and prevent them from making a
8 correct order (e.g. duplicating medication) and from executing appropriately an order.
9 Consequences on patients range from incident without consequence, to harm to patient and
10 even death. (incident numbers 42, 92, 237, 247, 248, 252, 257, 265, 266, 269, 270, 271, 274,
11 249, 275, 280, 284, 290, 300, 305, 501, 313, 123, 239bis, 250, 266bis)

12 2/ Issues in patient or medication menus (e.g. items not sufficiently separated in a list of
13 medications) lead to erroneous orders (e.g. erroneous doses) and consequently to patient safety
14 incident with no consequences. (incident number 239)

15 3/ The system does not prevent multiple orders of medications of the same pharmaceutical
16 class or different doses and does not warn clinicians about duplicates. Therefore, clinicians
17 inadvertently order duplicate or more medications. Patients get the medications and are put in
18 harm's way. (incident numbers 249 & 304)

19 4/ Some unintuitive procedures to check or change medication orders do not respect
20 clinicians' way of thinking and logic. These procedures increase clinicians' workload and
21 dissuade clinicians to follow them. It leads to medication ordering errors and place patients at
22 risk. (incident numbers 251 & 293)

23 5/ A physician cannot enter an order as soon as the patient's record is opened by another
24 clinician even for a patient in an emergency condition. It compels the physician to delay the
25 order. Ultimately, the patient's treatment is delayed despite its emergency, endangering the

1 patient. (incident number 287)

2 **5. DISCUSSION**

3 **5.1. Answers to questions**

4 This study posed three questions to examine whether reports about incidents involving HIT
5 are an exploitable source of information to learn about the consequences of usability flaws,
6 including effects on patient safety.

7 1/ To what extent can we gain knowledge about usability issues from incident reports?

8 Our results show that 69.3% (n = 249) of the analyzed reports described a usability flaw as
9 one of the causes of the incident as perceived by the reporter. Amongst them, 20.1% (n = 46)
10 describe the full chain of propagation of the usability flaws through the user of the technology
11 up to negative outcomes (including effects on care delivery and patient safety). The usability
12 flaws extracted from the free-text descriptions form a coherent whole: no aberrant types of
13 flaws were found, and a number of flaws were found in several reports. For instance, in the
14 subcategory “Inaccurate information”, 17 separate incident reports mention that images were
15 flipped. Besides, the descriptions of usability flaws are consistent with those known in the
16 literature. For instance, the fact that “Options are too close” to each other on the screen
17 (subcategory “Close options”) is mentioned in Khajouei and Jaspers’ systematic review on the
18 usability characteristics of CPOE (table 5, page 12) [36]; this paper also highlights the problems
19 with “drop-down menu [having] numerous options” (subcategory “Information overload”).
20 Though the free-text descriptions in incident reports were provided by reporters who may not
21 have had expertise in usability, they were rich enough to provide information about the usability
22 flaws that contributed to the incident: thus, they are an exploitable source of information to get
23 knowledge about usability flaws with HIT.

24 2/ What types of the usability flaws, related usage problems and negative outcomes are

1 reported in incidents reports?

2 The descriptions of the usability flaws, usage problems and negative outcomes were
3 expressed in the reporters' own words (usually vendors). Nonetheless, it was possible for the
4 usability experts who performed the analysis to identify, understand, and class the reported
5 usability issues. Most of the usability flaws dealt with the GUI, the behavior of the system, and
6 the reliability and display of the information. As for the resulting usage problems, they were
7 mainly related to errors, missed information, increased workload, violated safety procedures,
8 and users distrusting the system. Finally, negative outcomes on the work system mainly ranged
9 from incident with noticeable consequences but no harm (e.g. "Delays" in the care process) up
10 to patient harm and even death.

11 The lack of usability background of the reporters impacted their investigation of the
12 usability flaws. Some types of flaws, more noticeable or easier to investigate (e.g. subcategories
13 of "Graphical user interface issues"), were more precisely and more completely described than
14 others, whose initial cause might have been more complex, deeper or less apparent (e.g.
15 subcategories of "System not supporting practice"). Therefore, based on the usability flaws'
16 description, it is possible to formulate recommendations to fix the more precisely described
17 flaws but not for all the complex ones. For instance, the complex usability flaw "computer
18 discontinuation of orders" (incident number 266) may have several technical causes: an expert-
19 based usability evaluation could be performed to get a deeper understanding of such flaws
20 before appropriate recommendations can be formulated to fix them.

21 3/ What are the reported usability issues that gave rise to patient safety incidents?

22 Free-text descriptions of incident reports are interesting in that the reporters make
23 themselves the connection between the usability flaws, the usage problems and the negative
24 outcome (cf. Figure 2). All in all, results tend to form a body of corroborating evidence that
25 usability flaws of HIT can pose risks to patient safety. A total of 36 incidents out of the 249

1 describing a usability flaw (14,46%) reported the full chain of propagation up to a patient safety
2 issue without requiring any hypotheses. These involved a variety of usability flaws (e.g. no
3 protection against changes and errors, issues in the menus, procedures not fitting clinicians'
4 way of thinking) but the most significant class is related to the reliability, the understandability
5 and the availability of the clinical information. The consequences of the latter range from
6 incidents that were a near miss, to those that reached patients, both with and without harm.

7 It must be kept in mind that the causal chain between the usability flaws, the usage problems
8 and the negative outcomes is not linear. A given usability flaw may lead to several usage
9 problems that, in turn, may give rise to several negative outcomes; furthermore, a given
10 negative outcome may be caused by several usage problems, themselves caused by several
11 usability flaws. It is therefore not possible to identify the relative contributions of different
12 usability flaws to a given patient safety incident.

13 **5.2. Benefits of usability-oriented analyses**

14 Published analyses of HIT incidents reports usually adopt a patient safety perspective and
15 try to uncover the broad types of issues associated with incidents (e.g. technical vs. human-
16 computer interaction [27,29]). Nonetheless, they do not look deeper into those causes to learn
17 how they propagate. To the best of our knowledge, this study is the first that systematically and
18 explicitly analyzes incident reports from a usability perspective with a standardized and
19 reproducible method to unveil the chain of propagation of the usability flaws through the user
20 up to the work system and the patient. The added value of analyzing incident reports is two-
21 fold. First, it enables analysts to make the connection between the usability flaws and their
22 consequences on the work system and the patient unlike expert-based, hazard-oriented analyses,
23 and user-based usability evaluation. Second, it enables analysts to examine a wider range of
24 situations than in-situ observational studies of usability.

1 Our results show that MAUDE's incident reports are an amenable material to make the
2 connection between HIT usability flaws and their consequences. In a practical way, results are
3 consistent with known literature and add to the body of work that aims to provide evidence that
4 poor usability negatively impairs users' work, their work system and puts patients at risk (e.g.
5 [7,32,36–38]). The results (especially Table 1) could be used to inform and convince all
6 stakeholders in HIT development, evaluation, procurement, and implementation processes (e.g.
7 designers, vendors, healthcare establishments' managers, certification bodies, healthcare
8 authorities) that usability flaws in HIT do pose risks to patient safety. The material gathered
9 highlights that usability of HIT must be taken seriously and that actions must be taken to
10 consider it all along the HIT lifecycle.

11 **5.3. Limitations**

12 U.S regulatory requirements on reporting medical device incidents in the MAUDE database
13 are not enforced with respect to HIT [39]. Consequently, the HIT incidents we examined are
14 unlikely to be representative of all systems and all incidents: HIT incidents may be
15 underreported. Therefore, the body of corroborating evidence that usability flaws of HIT
16 contribute to patient safety incidents may be even more significant.

17 As mentioned in the introduction, reporting biases may impact the accuracy of the incident
18 reports. Despite those biases, previous studies pointed out that incident reports were a valuable
19 material to identify the type of technology issues associated with the patient safety issues [25–
20 30] and to identify incidentally usability flaws and consequences [31]. Moreover, analyzing a
21 large collection of incidents enables identifying characteristic profiles [40]. In the present study,
22 we deconstructed the free-text descriptions of 359 reports corresponding to 242 incidents. From
23 previous studies [27,41], this sample size may be sufficient to gain an overview about the types
24 of usability issues reported and of their consequences. Besides, several usability flaws were

1 found in many reports and were consistent with the literature: the knowledge extracted from
2 incident reports has good internal and external consistency which underlines the reliability of
3 the results. Nonetheless, the results must be considered carefully: factors that may have
4 mitigated or favored the propagation of the usability flaws up to the patient were not identified.
5 Therefore, the fact that some types of flaws did not lead to patient harm does not mean this is
6 always true: in other contexts, their consequences might be more severe. The reverse is also
7 true: usability flaws that led to patient harm in the analyzed incidents may have less severe
8 consequences in other contexts.

9 Finally, the reports analyzed date back to 2008-2010. One could question the usefulness of
10 performing the analysis on old incidents. However, this paper aimed to examine the feasibility
11 of the proposed analysis and to test the method. This sample of reports was known to be related
12 to human factors issues: it was easier to use them to test the feasibility of the analysis. Now that
13 the feasibility of our method has been successfully demonstrated, the analysis can be extended
14 to more recent reports and to reports from other databases.

15 **5.4. Perspectives**

16 This study has shown that analyzing the free-text descriptions of incident reports is feasible
17 and effective to identify the usability flaws that led to patient safety incidents. Yet, to fully take
18 advantage of the MAUDE database, it is necessary to improve the accuracy and the
19 completeness of the reports by improving the guidance of reporting forms [23,42], especially
20 of the free-text entry. For instance, as recommended for the reporting of usability flaws in
21 software engineering [43], reporters should be assisted with question/wizard-based interaction
22 guiding them through the steps of the report. The free-text field to relate the incident can be
23 structured to encourage reporters to describe separately the usability flaws and resulting usage
24 problems and the negative outcomes. Besides, providing the opportunity to upload pictures or

1 screenshots of the technology and of annotating them would help describe more precisely the
2 usability flaw. For the more complex usability flaws (i.e. usability flaws requiring an
3 investigation in-depth to understand their causes, e.g. subcategory “Inaccurate information”),
4 vendors should trigger an investigation procedure including an expert-based evaluation by
5 usability experts to know precisely how to fix them.

6 The opportunity to automatize the analysis process to analyze larger samples of incident
7 reports must also be questioned. Automatic screening methods have been successfully tested
8 for extracting incidents and identifying broad types of incidents [44]. Yet, as far as we know
9 and regardless of the domain, there are no attempts aiming to extract descriptions of usability
10 flaws, related usage problems and negative outcomes: automatic methods still must be tested.
11 Besides, classifying the descriptions of the usability flaws, related usage problems and negative
12 outcomes requires a sound knowledge of the technology, of usability concepts, of the medical
13 specialties, and of the possible related work organizations and practices. As for the detailed
14 classification of incidents [44], this task cannot be allocated to automatic tools and needs to be
15 done by humans. Yet, it may take advantage of being supported by coding software (e.g. NVivo
16 [45]) to make data manipulation and exploration easier.

17 Finally, when several usability flaws are identified by the reporter of an incident as contributing
18 factors to the patient safety incident, the limited and focused information provided by the free-
19 text description does not allow examination of the relative contributions of each usability flaw.
20 Larger-scale investigations must be undertaken. For instance, combining methods inspired by
21 the fault tree analysis [46] with expert-based usability evaluations [11,12] of the HIT would
22 allow for identifying different kinds of factors (e.g. technical, organizational, usability-related)
23 that have contributed to the patient safety incident and to identify precisely the role of the
24 usability flaws in the incident. Unfortunately, such an approach would have the same limitations
25 as studies proceeding by field observations of HIT usage: they would allow the analysis of a

1 limited range of situations. A balance must still be found between the need for large amounts
2 of data to get evidence about the contribution of usability flaws to patient safety incidents and
3 the need for precise information to model the propagation of usability flaws up to the patient.

4 **6. CONCLUSIONS**

5 When complete, free-text descriptions of incident reports are an amenable material to make
6 the connection between the usability flaws and their consequences on the user, on the work
7 system and on the patient in a wide range of situations. Even if this knowledge must be
8 interpreted with caution, it can be used to convince stakeholders in the development, evaluation,
9 procurement, and implementation processes that usability flaws with HIT do pose risks to
10 patient safety and that actions are required to seriously consider usability throughout the HIT
11 lifecycle.

12 **7. CLINICAL RELEVANCE STATEMENT**

13 Be aware that problems with usability of HIT can put patients at the risk of harm.

14 Report problems with using HIT, particularly issues with the reliability, understandability
15 and availability of clinical information that is used to support decision-making.

16 Structure the description of incidents you report so that each step of the propagation from
17 the usability flaw, through the usage problem up to the negative outcome may easily be
18 identifiable for re-analysis.

19 **8. MULTIPLE CHOICE QUESTIONS**

20 1. Which element from the work system acts as an intermediary between a usability flaw
21 and its negative outcomes for the patient?

- 22 • The user
- 23 • The work organization

- 1 • The technology
- 2 • The environment

3 The correct answer is “the user”. A usability flaw is a physical characteristic of the
4 technology. If the technology is not used, it cannot have any consequence. As soon as the
5 technology is used (directly or remotely), the usability flaw may disrupt the interaction of the
6 user with the technology and then lead to use errors that may ultimately impact the work system
7 or the patient.

8 2. In the sample of analyzed incidents related to CPOE, EHR, MAR, and PCS, what is the
9 main type of usability flaws observed that led to patient safety issues?

- 10 • Menu issue
- 11 • System behavior issue
- 12 • Lack of feature
- 13 • Supporting information issue

14 The correct answer is “supporting information issue”. Out of the 31 incidents that led to
15 patient safety issues, 26 were related to “supporting information issues” (information erroneous,
16 ambiguous, changed, missing (including, not transmitted), illegible or nowhere to be found).

17 **9. CONFLICT OF INTEREST**

18 The authors declare that they have no conflicts of interest in the research.

19 **10. HUMAN SUBJECTS PROTECTIONS**

20 Human and/or animal subjects were not included in the project.

21 **11. ACKNOWLEDGEMENTS**

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24

1 **13. FIGURE CAPTIONS**

2 **Figure 1.** Schematic representation of the consequences of violating a usability principle.

3 **Figure 2.** Deconstructing the verbatim of an incident report included in the analysis to
4 identify usability flaws, usage problems and negative outcomes. Capitalization as written in
5 the original report.

6 **Figure 3.** Final coding schemes used to categorize the usability flaws (left), the usage
7 problems (centre), and the negative outcomes (right).

8 **Figure 4.** Graphical representation of the distribution of the incidents analysed according to
9 their eligibility (left) and their content in terms of usage problems and negative outcomes
10 (right).

14. TABLES

Table 1. Deconstruction of the 36 incidents analyzed to highlight the usability issues that gave rise to patient safety incidents: the usability flaws, usage problems and negative outcomes are summarized.

ID	Usability flaw(s)	Usage problem(s)	Negative outcome(s): patient safety issue(s)
	Electronic patient scale		
#242	A patient scale allowed users to switch easily between units (pounds vs. kilograms) while it is supposed to be kept in kilograms.	A nurse did not notice the change and weighed a patient incorrectly. Based on this erroneous measure, (s)he administered the wrong dose of medication.	Despite this incident, the patient was not harmed and did not require medical management.
	Imaging system		

ID	Usability flaw(s)	Usage problem(s)	Negative outcome(s): patient safety issue(s)
#202	The system merged the incorrect data and rejected the original images: images had the wrong patient tag. No further details were available about the usability flaw.	It led to the misidentification of a patient and the surgery (s)he had to undergo.	A surgery was performed on the wrong patient. No further details were available about patient outcome.
#229	The date of the image was not visible or was missing (not detailed).	The radiologist mistook an old image for a recent one and misdiagnosed the spreading of a metastatic disease.	The disease spread widely.
#163	The left-right markers of an image were not sufficiently visible.	The patient's image was flipped left-right unnoticedly. Based on this image, a surgeon operated on the wrong side.	The wrong side of the head of the patient was operated upon.

ID	Usability flaw(s)	Usage problem(s)	Negative outcome(s): patient safety issue(s)
#267	Images supporting the placement of a Peripherally Inserted Central Catheter (PICC) line did not show the line that was inserted too far.	A radiologist misunderstood the absence of the line on the image, thought it has been removed and did not check it.	This misunderstanding contributed to the death of the baby.
	CPOE/EHR/MAR/PCS¹		
#42	A medication was ordered but its prescription was not populated in the administration plan.	The medication was administered 3 days late.	The patient suffered from an ulcer that required a gastrectomy.
#92	A volume less than 0.01ML was not displayed with the order.	The nurse had to calculate the volume to be administered and miscalculated the dose.	A patient received almost a 10-fold overdose of insulin by injection.

¹ CPOE/EHR/MAR.PCS stand respectively for Computerized Physician Order Entry, Electronic Health Record, Medication Administration Record, and Pharmacist Clinical Software.

ID	Usability flaw(s)	Usage problem(s)	Negative outcome(s): patient safety issue(s)
#123	In the drug administration details screen, after a 30ml bottle of azithromycin 200mg/5ml was scanned, the screen displayed 200mg as the dose amount and 30ml as the volume: the volume to administer was incorrect.	A clinician miscalculated the dose and administered 1200mg of azithromycin instead of 250mg ordered	The patient received almost five times the ordered dose, but no adverse effect was reported.
#237	Manual entries of patient allergies were overwritten during automatic updates.	A clinician prescribed a medication ignoring that the patient was allergic.	The patient suffered a temporary allergic reaction (shortness of breath) to the medication but had no further effect.
#239	A drop-down menu for medication dosing frequency contained 225 options arranged in alphabetical order and included counterintuitively arranged items.	A user scrolled through the menu and selected the wrong frequency leading to a dosing error.	The patient received four times the expected dose of digoxin.

ID	Usability flaw(s)	Usage problem(s)	Negative outcome(s): patient safety issue(s)
#239bis	An update in the frequency field on an existing prescription was not transmitted to the pharmacy: the pharmacy received the order with the wrong frequency.	A clinician administered more than the prescribed dose.	An elderly patient received more than the ordered dose of blood thinner Levoxyl for 6 weeks but had no serious injury. Another patient received inappropriate dosage of carbamazepine and was admitted to hospital with atypical chest pains.
#247	The concentration of the medication was displayed amidst extraneous information in small font.	A clinician did not see the concentration and made a mistake in the dose administered to a patient.	The patient received 10 times the dose of epinephrine ordered and sustained a myocardial infarction (heart attack).
#248	An order to hold the sliding scale insulin at night time was delivered but without notification.	A nurse did not see the order and gave the patient the usual dose of insulin.	The patient endured hypoglycemia with severe symptoms.

ID	Usability flaw(s)	Usage problem(s)	Negative outcome(s): patient safety issue(s)
#249	A CPOE did not warn about duplicate medications; the font size was small; and the screen contained excess extraneous information.	<p>A physician ordered medications twice at different doses and schedules.</p> <p>A pharmacist missed the duplicate medications.</p> <p>Physicians delivered all medications ordered.</p>	The patient received all the medications ordered. No further details were available about patient outcome.
#250	Orders for stress tests were ambiguous and displayed over four lines	A clinician misunderstood the physician's order and gave the patient the incorrect pharmacological modality (<i>i.e.</i> wrong form).	The patient incorrectly received an infusion of adenosine which caused him/her a life threatening acute asthma attack.

ID	Usability flaw(s)	Usage problem(s)	Negative outcome(s): patient safety issue(s)
#251	To enter a post-operative order, physicians needed to delete orders that were no longer needed, <i>i.e.</i> inactive orders, leave orders that were still needed, and then add new ones. This was a time-consuming and unusual procedure.	Clinicians did not always perform this review due to the extra work and time it required. This led to commingling of the pre- and post-operative orders.	One patient got his/her clean postoperative abdomen irrigated based on a pre-operative order.
#252	The interface of a CPOE was unfriendly and displayed extensive extraneous information.	A physician did not see an existing order and ordered duplicate treatments for a patient.	The patient received duplicate treatments: infusion of total parenteral nutrition and concentrated dextrose solution. Their cumulative dose caused pulmonary edema.
#257	A patient was moved to another bed. But the order to transfer the patient was not received by the recipient care team.	The recipient care team was not aware that the patient was under their care.	The patient had seizures on floor for many hours throughout the night without the care team taking care of him/her.

ID	Usability flaw(s)	Usage problem(s)	Negative outcome(s): patient safety issue(s)
#265	The procedure to reconcile orders with the execution of the orders was complex.	A clinician did not execute the order. It was not known that the order was not executed. This led to a missed diagnosis opportunity.	A patient with a life-threatening disease was not treated appropriately, contributing to his/her death.
#266	On a CPOE interface, the orders were obfuscated by verbiage and the system discontinued them.	A clinician missed the orders, and therefore did not execute them.	A known consequence is that an order for a transcutaneous pacemaker with life-threatening consequences (no details) failed to be executed
#266bis	Once correctly ordered, the system switched doses of methadone syrup for two patients without informing the user.	A clinician gave a patient 5mg more of methadone syrup than initially ordered.	The patient received an excess dose of methadone but was not harmed.
#269	Test orders (hypercoagulability tests) were spuriously cancelled by the system without notifying ordering physicians.	Clinicians did not execute the hypercoagulability tests ordered for a patient having blood clots.	The blood clots remained unexplained. No further details were available about patient outcome.

ID	Usability flaw(s)	Usage problem(s)	Negative outcome(s): patient safety issue(s)
#270	The font size of the list of patients was small.	A clinician clicked on the wrong patient and entered an order of a test using radioactive tracers.	A patient received the radioactive injection intended for another patient.

ID	Usability flaw(s)	Usage problem(s)	Negative outcome(s): patient safety issue(s)
#271	<p>The interface does not specify the dose in mg of a combination medication (e.g. in the Acetaminophen-Oxycodone, the exact dose of Tylenol is not specified).</p> <p>Moreover, certain fields do not specify the volume, requiring users to open a pop-up screen to see this information.</p>	<p>A physician did not know the combination medication dose in the volume (s)he ordered.</p> <p>An excessive dose of Acetaminophen-Oxycodone was ordered for a patient.</p> <p>Neither the physician, the pharmacist, or the nurse recognized and intercepted this medication error.</p> <p>The combination medication was given to the patient.</p>	<p>10 ml of Acetaminophen-Oxycodone was given three times over 4 hours, meaning 1950g of Tylenol were administered in 4 hours to a patient in starvation receiving other medication increasing the effects of Tylenol. The patient developed acute renal failure and died.</p>

ID	Usability flaw(s)	Usage problem(s)	Negative outcome(s): patient safety issue(s)
#274	<p>A screen displayed vital information tintured with abundant clutter. There was no display of current treatments and what had been recently ordered.</p> <p>Moreover, the warning system was insufficient.</p>	<p>A clinician did not see the medications already ordered for the patient and ordered duplicate medications and intravenous fluids.</p> <p>(S)he was not warned by the system.</p> <p>At least two intravenous solutions were active simultaneously and given to the patient.</p>	<p>The patient received at least two intravenous fluids that were similar.</p>
#275	<p>A system variably changed the schedule of medications ordered daily at two distinct doses to be administered daily at two distinct times.</p> <p>The system scheduled both doses to be administered at the same time.</p>	<p>A nurse gave an excessive dose at once and skipped the second dose.</p>	<p>All patients treated at the facility were endangered.</p>

ID	Usability flaw(s)	Usage problem(s)	Negative outcome(s): patient safety issue(s)
#280	A system did not transfer an order to discontinue intravenous fluids in a post-operative setting to the task list of the nurse.	The nurse did not see the order and continued the intravenous fluids.	The patient was overloaded with fluid.
#284	A system did not provide an adequate representation of the current medications and orders, nor did it display what other members of the care team had ordered. The decision support module was also defective.	Physicians ordered four medications that increased the propensity for bleeding. They were not warned by the decision support system.	A patient was simultaneously given enoxaparin, unfractionated heparin, aspirin and warfarin.
#287	A system prevented physicians from ordering medications while another service had opened up the patient record.	The physician could not order critical medication immediately. The order was delayed.	The patient was in danger. No further details were available about patient outcome.

ID	Usability flaw(s)	Usage problem(s)	Negative outcome(s): patient safety issue(s)
#290	<p>A system did not transmit a transportation order.</p> <p>Additionally, the way orders were displayed was excessively lengthy.</p>	<p>An order to transport a patient with a monitor because of a heart risk was not seen and not executed.</p>	<p>The patient travelled to at least one test without a monitor.</p>
#293	<p>To transfer a patient after surgery, physicians must discontinue orders that are no longer needed. It was a counterintuitive function.</p>	<p>The physicians wasted time to perform this procedure leading them to neglect this medication reconciliation.</p> <p>A physician ordered medications that were already active, and prescriptions written after an operation contained duplicates and triplicates of five medications with distinct doses.</p>	<p>The patient was in danger. No further details were available about patient outcome.</p>

ID	Usability flaw(s)	Usage problem(s)	Negative outcome(s): patient safety issue(s)
#300	Medication labels for infusion bags that were created by a software labelling system were in a small and uniform font.	A nurse mistook two bags. She accidentally hung the bag of norepinephrine instead of the epinephrine one.	A patient was almost infused with norepinephrine instead of epinephrine.
#304	A system did not prevent pre-operative and post-operative orders from being commingled nor from allowing multiple orders and doses of the same medication.	Physicians had ordered up to six distinct acetaminophen doses, two distinct vancomycin doses, and two distinct famotidine doses concomitantly with pantoprazole in a post-op order.	The patient was in danger. No further details were available about patient outcome.

ID	Usability flaw(s)	Usage problem(s)	Negative outcome(s): patient safety issue(s)
#305	The function to discontinue medication orders was not working: the medication orders still appeared in the nurses' administration plan.	A physician who was aware of the problem wrote a note to the nurses. The nurses did not see the note and continued medications orders as they appear in the MAR: gentamicin was given to three patients despite instructions to discontinue the medication.	Three patients received gentamicin while it was discontinued. No immediate injury occurred.

ID	Usability flaw(s)	Usage problem(s)	Negative outcome(s): patient safety issue(s)
#501	<p>On the order entry screen intended for ancillary orders but not for medication orders, it was mentioned that no allergy information was recorded while there was a historical allergy entry.</p> <p>Allergy information from previous visits was not displayed without a specific medical record number.</p>	<p>Not being able to see this information, a physician used this order entry screen to order a medication to which the patient was allergic.</p>	<p>The patient received the medication to which (s)he was allergic resulting in an allergic reaction. The patient was discharged within 48 hours.</p>

ID	Usability flaw(s)	Usage problem(s)	Negative outcome(s): patient safety issue(s)
#313	<p>When a patient is transferred from a service to another, the system considered the patient to be discharged and to have a new admission.</p> <p>Therefore, during the stay of the patient in a second service, the system provided results related to the previous services only when a search was made on previous reactions to medications using large date constraints.</p> <p>Furthermore, the system did not alert users that the date constraints used to make the search were beyond the range of the “current admission”.</p>	<p>A clinician ordered a patient an infusion of famotidine while the patient had already suffered a reaction to this treatment during her/his “first admission”.</p> <p>A patient’s relative informed a nurse that famotidine was contraindicated. The nurse searched with large date constraints but did not find any previously infused famotidine.</p>	<p>The patient who was suffering from serious delirium received a medication which had previously resulted in an allergic reaction during her/his previous admission.</p> <p>The medication was stopped due the relative’s insistence.</p>