

2017

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Hautamäki E

Finnish Social and Health Informatics Association

article

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Health information systems' usability-related use errors in patient safety incidents

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Abstract

Health information systems contain usability issues that cause use errors, which may pose a risk to patient safety. The aim of this study was to identify what kind of usability issues in information systems cause use errors that lead to patient safety incidents. Patient safety incidents reported into an incident reporting system in a Finnish hospital district during the year 2014 (n=2500) were analyzed from the perspectives of usability and use errors. An inductive content analysis was carried out in order to gather information about the usability issues that may have led to a use error, thus causing patient safety incidents. The results showed that the main usability issues are the distribution of information into multiple views, identification problems with the selected patient, and basic daily tasks' reliance on users' memory. The results show that the relationship between usability, use errors, and patient safety should be understood and considered in the health information system design.

Keywords: electronic health records, health information systems, incident reporting, medical error, patient harm, patient safety, usability

Tiivistelmä

Terveydenhuollon tietojärjestelmissä esiintyy käyttövirheisiin johtavia käytettävyysoongelmia, mikä saattaa aiheuttaa riskin potilasturvallisuudelle. Tämän tutkimuksen tarkoituksena oli tunnistaa, millaiset tietojärjestelmän käytettävyysongelmat aiheuttavat käyttövirheitä, jotka johtavat vaaratapahtumaan. Tutkimuksessa analysoitiin yhdessä sairaanhoitopiirissä vuonna 2014 vaaratapahtumajärjestelmään raportoituja tapahtumia (n=2500) käytettävyyden ja käyttövirheiden näkökulmasta. Aineiston induktiivisella sisällönanalysillä kerättiin tietoa käytettävyysongelmista, jotka ovat johtaneet käyttövirheeseen ja siten aiheuttaneet vaaratapahtuman. Tulokset osoittivat merkittävimmitä käytettävyysongelmiksi tiedon jakautumisen usealle näkymälle, valitun potilaan tunnistamisen ongelmat, sekä päivittäisten perustoimintojen suorittamisen jättämisen käyttäjän muistin varaan. Tulokset osoittavat, että käytettävyyden, käyttövirheiden ja potilasturvallisuuden väliset suhteet tulisi ymmärtää ja huomioida terveydenhuollon tietojärjestelmien suunnittelussa.

Avainsanat: sähköinen potilaskertomus, terveydenhuollon tietojärjestelmät, vaaratapahtumien raportointi, lääketieteellinen virhe, potilasvahinko, potilasturvallisuus, käytettävyys

Introduction

Health information systems (HIS) used in health care are complex with multiple components, functionalities and interfaces, making their safe use challenging. Some reasons for the complexity include the demand for a large volume of heterogeneous information and the large number of interacting actors who must work effectively with the information. Safety issues also arise as a result of a failure to take appropriate actions in HIS design, development, deployment, and operation. [1] Many times manufacturers seek to differentiate themselves from competitors by providing functionalities that do not necessarily meet user needs. Irrelevant functionalities lead to more complex systems and use problems, such as users having difficulty accessing and using essential functions. [2]

Besides that the HISs are often complex, health care context contains multiple devices and information systems that the personnel have to operate daily. In addition, health care personnel often work under heavy workload and in critical, even life threatening, circumstances. Decisions and actions are often made in stressful environments and under time pressure. The issues that burden health care personnel reflect health care quality and patient safety. [1,2] Therefore, the safe and effective use of devices and information systems should be considered an outcome of interaction between the user, the user environment and the user interface [3]. From a safety perspective, an information system itself is neither safe nor unsafe. Instead, an information system should be considered as part of sociotechnical system and how it behaves in actual clinical use [1].

Previous studies have addressed various aspects of HISs that may cause safety issues [4-10]. Specifically, usability and use error related safety issues - the focus of this study - have also been identified in previous studies. Johnson et al. [4] indicated that the primary electronic health record (EHR) usability issues are poor organization and display of information, interference with practice workflow, increase in cognitive burden, and poor functional design. Some HIS use risks and safety concerns identified in previous studies include information passing and handling between different information systems, multiple screens and manual and electronic systems, finding and merging fragmented information, identification of valid and relevant information, and allowance of conflicting information input [5,6]. Other previously identified HIS usability or use error related safety issues are amongst other things the inconsistencies in used standards (e.g. units and date formats), wording and functions [5,6], patient identification issues [6,7,9], navigation difficulties [6,7], and wrong or missing data input [7,9,10]. To summarize, safety problems exist even in the context of broad experience in HIS implementations, and the increasing amount of implementations does not decrease the error rate.

Although usability of HISs has been widely studied, the relationship between usability, use errors and patient safety outcomes has not received much attention. Some models have been developed in order to identify and mitigate HIS usability issues that could potentially lead to patient harm [11,12]. Marcilly et al. framework links up usability principles, usability flaws, use problems and their potential outcomes (Figure 1) [11].

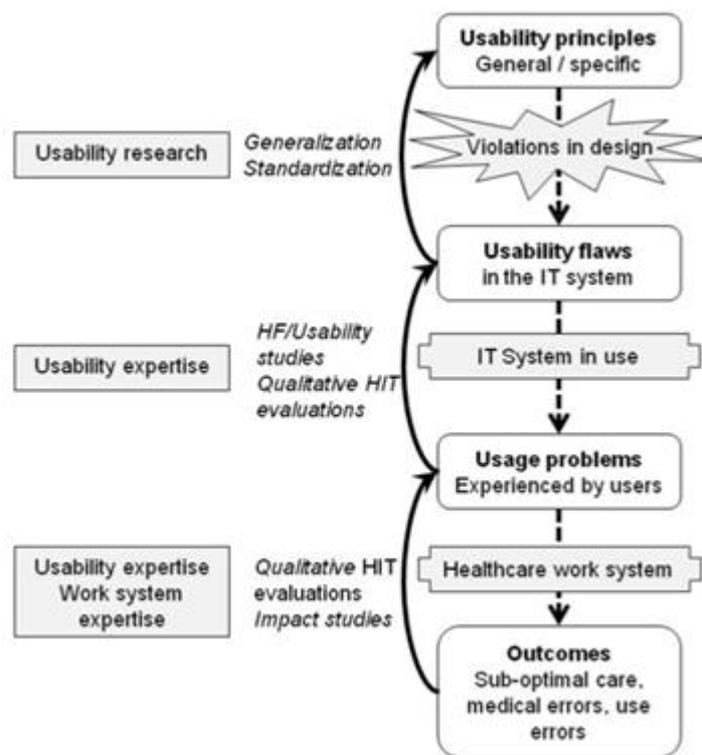


Figure 1. Emergent and identification of usability flaws [11].

The dotted arrow indicates the process from top to bottom and illustrates how violations in usability principles leads into usage problems and finally into unwanted outcome. The process indicated with solid upward arrows illustrates research and evaluation, in which usage problems of information system are identified, and then violation of usability principles are identified. This study focuses on identification of HIS usability issues that have led to user errors and that have risked patient safety.

Research aim and research question

The aim of this study was to analyze patient safety incident reports in order to define what type of usability issues in information systems cause use errors, and therefore risk patient safety. The research question was addressed from two perspectives: the use errors emerged from reported patient safety incidents and the usability issues causing the use errors. The research question was: What kind of usability issues in infor-

mation systems cause use errors that lead to patient safety incidents?

Materials and methods

Setting

Finland has a decentralized health care system with multiple funding sources (municipalities, households, state, employers, national health Insurance and voluntary private insurance). Primary care is provided by municipal health centers, occupational health care services, and private sector providers. The 20 regional hospital districts provide specialized care. [12] The EHR coverage in Finland is 100 percent, and hospitals in Finland are fully digital. Paper records are no longer in use. EHR's incorporate into the Finnish national health care archive, known as KanTa. [13]

According to the Finnish Act on Health Care from 2011, all health care organizations must maintain a patient

safety incident system as a part of their patient safety system [14]. The most commonly used safety incident reporting model and instrument in Finland is Haipro. The incident reports in Haipro consist of structured and free-text fields. Events are classified into 13 incident types (e.g. “Medication and Transfusions”, “Information Flow”, “Information Management”, “Laboratory”, “Imaging” and “Other Patient Treatment Procedures”) and their sub categories. Safety incidents are reported anonymously into Haipro database using an Internet-based user-friendly interface. [8,15]

Data collection and analyses

The data used in this study was collected from all patient safety incident reports in the Haipro system during 2014 in one Finnish district hospital. The textual descriptions of the reported incidents were analyzed. Marcilly et al. [11] model (Figure 1) from bottom to top was applied. First, use errors from patient safety incident reports were identified, and then preceding usability issues and violated usability principles were deduced.

An inductive approach for data analysis was used to identify and group relevant data and to establish theoretical concept. In the first phase of the analysis, textual descriptions of the data (n=2500) were reviewed, in order to pick up the significant data from the research question point of view, i.e. identify incidents where possible usability issues have led to use error. At this phase, 187 incidents were collected. During further

analysis of these 187 incidents, 45 incidents were excluded due to a variety of uncertainty factors. For example, incidents were excluded in which it was not possible to reliably evaluate during which stage the use error occurred or which factors caused the use error to occur, and when it was not clear whether the incident resulted from information system usage. The textual descriptions of the remaining 142 incidents were analyzed with the goal of finding similar incidents from the use error point of view. The similar incidents were grouped and given unified descriptions. For the grouped use errors, the possible cause and possible usability issue was determined. For each usability issue, also violated usability principles were determined from usability principles for health care domain by Jiajie Zhang et al. [16] and usability principles by Healthcare Information and Management Systems Society [17]. (Table 1)

Finally, the results were categorized, using Lowry et al.’s [18] EHR use error classification into the following categories: *patient identification error, mode error, data accuracy error, data availability error, interpretation error, recall error, feedback error, and data integrity error*. In addition a new *Input error* -category was created for clear input errors (e.g wrong value).

Results

The summary of the results are presented in a summary table 1.

Table 1. Usability related use errors (n=142) and violated usability principles.

Use error and outcome	Freq.	Possible use error cause	Possible usability issue (Usability principle)
Patient identification errors			
<i>User did not close the previously selected patient or did not select the new patient on the system. -> Documentation or other actions were performed, or were almost performed, on the wrong person.</i>	9	The system does not help the user identify the patient. The system does not lead the user in closing the previously selected patient.	Presentation of the selected person is not effective. Status of the selected person is unclear. (<i>Effective information presentation, Feedback</i>)
<i>User accidentally selected the wrong patient (e.g. keystroke error, selected adjacent). -> Documentation or other actions were performed, or were close to being performed on the wrong person.</i>	6	The positioning of the UI components (e.g. too dense) enables erroneous selection.	Layout of the UI creates use errors. (<i>Prevent errors</i>)
<i>User selected a patient with identical or similar name. -> Documentation or other actions were performed, or were close to being performed, on the wrong person.</i>	6	The system does not give hints, that similar names are present.	Presentation of the person information is not effective. (<i>Effective information presentation</i>)
<i>The action that led to an error is unknown. -> Documentation or other actions were performed on the wrong person.</i>	9	The system does not help the user identify the currently selected patient.	Presentation of the selected person is not effective. (<i>Effective information presentation</i>)
Mode errors			
<i>User did not notice an irregular system mode or setting. -> Treatment was placed at risk or was not fulfilled.</i>	3	The UI does not indicate when an irregular mode or setting is activated	The current state of the system is not clear for the user. (<i>Visibility</i>)
Data availability errors			
<i>User did not update medication (new orders/ dose changes/discontinuances/pauses) consistent in different views or the updating had been done erroneously. -> Actual medication of the patient was not evident or it was not fulfilled correctly.</i>	23	The system does not provide enough support for the user in keeping information consistent on different views.	Documentation of the same information is required in different views. (<i>Efficient and flexible interactions, Preservation of context</i>)
<i>User did not update order/request. -> Planned treatment/examination was not fulfilled.</i>	5	The system does not provide enough support for the user in verifying information consistency.	Documentation of the same information is required in different views. (<i>Efficient and flexible interactions, Preservation of context</i>)
Interpretation errors			
<i>User confused tablets and milligrams -> Medication was placed at risk or was not fulfilled with the correct unit.</i>	6	The system does not provide enough support for the user in keeping information consistent.	The system allows the use of conflicting units for the same medication. (<i>Consistency</i>)
<i>User confused medicine's commercial name and generic substance. -> Adequate medication was placed at risk or was not fulfilled.</i>	4	The system does not recognize different medication names. UI does not give hints of other possible names.	Recognizing different medication names relies on users' memory. (<i>Minimizing cognitive load</i>)
<i>User confused intravenous and oral medication because of the same medication name -> Medication route was placed at risk or was not fulfilled.</i>	2	The UI does not emphasize/differentiate the route of administration.	Presentation of the route of administration is not effective. (<i>Effective information presentation</i>)

Recall errors

<i>User did not print out changed medication list for the patient (new, ended or paused medicine, or changed dose). -> Medication was placed at risk or was not fulfilled.</i>	18	The system does not remind the user to print changed medication list.	Execution of the task relies on users' memory. Users are not notified about the incompleteness of the task. (<i>Minimizing cognitive load, Clear closure</i>)
<i>User did not set an indication for medicine(s) on medication list. -> Medicine was not added on printed medication list and was not administered or administration was placed at risk.</i>	14	The UI does not help the user notice that the indication is missing.	Execution of the task relies on users' memory. (<i>Minimizing cognitive load</i>)
<i>User did not document necessary information in the system (route of drug administration, laboratory samples to be collected). -> Unclear issues required identification.</i>	2	The UI does not lead the user in inputting all necessary information.	The content of the documented information (determination of the necessity) relies on users' memory. (<i>Minimizing cognitive load</i>)
<i>User did not enter, indicate, print out or send an order/referral/request, when it did not forward (to secretary or targeted ward/organization). -> E.g. examination, therapy or consultation was not fulfilled.</i>	12	The UI does not indicate unfulfilled orders.	Execution of the task relies on users' memory. Insufficient feedback. (<i>Minimizing cognitive load, Feedback</i>)
<i>User did not notice order/instruction. -> Ordered procedure was placed at risk or was not fulfilled.</i>	6	The UI does not indicate unfulfilled orders. The system does not help the user notice the issues that require user actions.	Insufficient feedback. The issues that require user attention, are not presented effectively. (<i>Feedback, Effective information presentation</i>)

Data input errors

<i>User did not document the alternate medication dosage or held medications adequately. -> Administered medication is not apparent or is in conflict with the documented medication.</i>	4	The UI is not intuitive enough for the user to engage in unusual use.	The UI does not encourage the user in learning unfamiliar features. (<i>Naturalness, Help and documentation</i>)
<i>User documented contradicting values for two samples into the system. -> Patient at risk of getting improper treatment.</i>	1	The UI does not help the user notice that the inputted values are out of range of the reference values.	The system does not prevent incorrect input. (<i>Prevent errors</i>)
<i>User documented same medicine twice on the medication list. -> Patient received or was at risk of receiving two doses of the same medication.</i>	3	The UI does not give hints regarding double medication.	The system does not give feedback of possible incorrect input. (<i>Feedback</i>)
<i>User documented a wrong medication dose, unit, administration route or schedule into the system. -> Actual medication of the patient was not apparent or it was not fulfilled correctly.</i>	9	The system does not help the user input the data in the correct format.	The content of the documented information relies on users' memory. (<i>Minimizing cognitive load</i>)

TOTAL **142**

Patient identification errors

User did not close the previously selected patient or did not select the new patient on the system. -> Documentation or other actions were performed, or were almost performed, on the wrong person. In some incidents the user initially had the correct patient information active in the system, but while checking another patient's information from the system, this wrong patient's information remained selected. In one incident the expected patient had already been selected actively in the system, but the patient was replaced with the other patient without notice, and the originally planned patient remained selected in the system. In one incident report concerning a wrong patient, multiple people working on the same computer was mentioned as the root cause for the incident. One identified root cause for this error was that the system does not lead to the user closing the previously selected patient. The more common identified error root cause was that the currently selected person is not clear for the user because the system does not help the user identify the currently selected patient.

User accidentally selected the wrong patient (e.g. key-stroke error, selected adjacent). -> Documentation or other actions were performed, or were close to being performed on the wrong person. Often the user had selected the wrong patient from patient list, most likely by a faulty mouse click. In one incident, the error was caused by a keystroke mistake, and in one incident the user had accidentally selected the adjacent patient row. The usability issue identified in this error was the positioning of the user interface (UI) components. For example, the list of patients is too dense or the rows are not clearly distinguished from each other, which easily leads to selecting the wrong row.

User selected a patient with identical or similar name. -> Documentation or other actions were performed, or were close to being performed, on the wrong person. The common factor in these incident descriptions was that the patient's social security number had not been checked. In most incidents two patients with same or similar names were in similar treatments or procedures at the same time (e.g. in the same task list or surgery

list). The identified usability issue was that the similar names are not presented efficiently, so that the user interface (UI) would help the user to recognize that similar names are present.

The action that led to an error is unknown. -> Documentation or other actions were performed on the wrong person. Some incident descriptions did not provide enough information to identify the actual use error. However, a use error had occurred because the wrong patient had been selected. In these cases actions leading to the wrong patient are unknown, but one identified usability issue was that the system does not help the user identify the currently selected patient.

Mode errors

User did not notice an irregular system mode or setting. -> Treatment was placed at risk or was not fulfilled. Patients had been given treatments without noticing that relevant settings were not on. In one incident the user missed a filter that was blocking access to view a research archive. Because the user had missed to notice the system mode or setting, the identified usability issue was that the user interface does not indicate well enough when an irregular mode or setting is activated.

Data availability errors

User did not update medication (new orders/ dose changes/discontinuances/pauses) consistent in different views or the updating had been done erroneously. -> Actual medication of the patient was not evident or it was not fulfilled correctly. In these incidents medication information differed between different views on the information system. A common error was that the medication list was not updated based on the medication order. In some incidents there was conflicting information also within texts in other views. Fragmented information was identified to be a serious usability issue, as the system does not help the user in keeping fragmented information consistent.

User did not update order/request. -> Planned treatment/examination was not fulfilled. In these incidents,

typically an order or request (e.g. checking results, collecting a sample, follow-up treatment) had been written in one view but had not been added into the order chart. Also in this error, the problem was identified to be fragmented information, and the system not helping the user keep information consistent.

Interpretation errors

User confused tablets and milligrams -> Medication was placed at risk or was not fulfilled with the correct unit. Two different units, tablet and mg, were used for the same medication. This issue appeared with medication orders, medication documentation from an order to the medication list, and in medication administration (although correct in medication list). Also, this error was identified to appear as the system does not help the user keep information consistent and allows the use of conflicting units for the same medication.

User confused medicine's commercial name and generic substance. -> Adequate medication was placed at risk or was not fulfilled. Using both the medication's commercial name and generic substance caused the patient to receive the same medicine twice, once for each name. In one incident, medication was ordered to pause with one name but the pause was documented into the medication list as a different name. Again, this error was identified to be caused by the system not helping users keep information consistent. Additionally, another identified usability issue is that the system does not recognize different medication names and give hints of other possible names, such as information about generic substances when using commercial names.

User confused intravenous and oral medication because of the same medication name -> Medication route was placed at risk or was not fulfilled. In one incident description, the reporter indicated that the error was caused because it allowed the user to select intravenous and subcutaneous medication into the printed medication list for oral drugs, but the route does not clearly stand out. This easily leads to the patient getting medication from both the oral and the intravenous and subcutaneous medication lists. In another incident, the

user searched the system for oral medication but instead gave the dose intravenously. In this error, the identified usability issue is that the user interface does not emphasize the route of administration and does not differentiate medication with different routes.

Recall errors

User did not print out changed medication list for the patient (new, ended or paused medicine, or changed dose). -> Medication was placed at risk or was not fulfilled. This was a common incident within the data. Patient's medication had been modified on the medication list, but the modified list had not been printed out, leading to medication administration using the old printout of the medication list. The identified usability issue is that printing relies on users' memory.

User did not set an indication for medicine(s) on medication list. -> Medicine was not added on printed medication list and was not administered or administration was placed at risk. These incidents appeared as the user simply forgot to set an indication (e.g. check-mark) for medicines to be included on printed medication list. In some incidents the indication had been removed because the medicine had been paused, but when the medicine was continued, the indication had not been re-entered. The identified usability issue is that the user interface does not help users notice that the indication is missing.

User did not document necessary information in the system (route of drug administration, laboratory samples to be collected). -> Unclear issues required identification. In one incident, the user had documented a medication order without a route of administration. In another incident, the user had entered a referral in textual format, which did not clearly articulate the needed samples. Missing information had to be uncovered. The identified root cause for these usability problems was the user interface not leading users to input all necessary information.

User did not enter, indicate, print out or send an order/referral/request, when it did not forward (to secre-

tary or targeted ward/organization). -> E.g. examination, therapy or consultation was not fulfilled. In these incidents the error had occurred when for some reason, the order, referral or request had not been forwarded. In some incidents, the user had not set an indication (e.g. check-mark) for orders. Sometimes an order, referral or request had not been printed out, and other times it was not delivered. The error in transferring information can be caused by many issues. However, the common usability problem identified for these errors was that the user interface does not indicate unfulfilled orders, and instead often times, the fulfillment of orders relies on the user's memory (setting an indication, printing, delivering etc.).

User did not notice order/instruction. -> Ordered procedure was placed at risk or was not fulfilled. In these incidents, the user had not noticed an order or other text related to the patient's treatment. Consequences were, for example, that nasal cannula was not started, a specimen was not collected, an immunization program was not started, or warfarin dosing was not documented in instructions for follow-up therapy. The identified usability issue was that the user interface does not indicate unfulfilled orders, and also that the system does not emphasize the issues that require user actions.

Data input errors

User did not document the alternate medication dosage or held medications adequately. -> Administered medication is not apparent or is in conflict with the documented medication. In two incident descriptions it appeared as though the user did not know how to document an alternate dose for the medication into the system. In both incidents the medication was administered correctly but the documentation to the system had not been done adequately. In one incident, the user had not documented that the medication was held, though the actual dose was written into textual section. It appears that managing alternate medication dosage within the information system is unclear for the user. One identified reason for this is that the user interface is not intuitive enough for the user to engage

in unusual use. Perhaps use instructions are not easily available or are insufficient.

User documented contradicting values for two samples into the system. -> Patient at risk of getting improper treatment. User had documented results of two laboratory samples that contradict each other. Both values were clearly out the range of reference values. The identified usability problem was that the user interface does not help the user notice that the inputted values are out of range of the reference values.

User documented same medicine twice on the medication list. -> Patient received or was at risk of receiving two doses of the same medication. In two of the incidents, the user had documented a changed medication order into the medication list but had not removed the old order from the list. In one incident, the user had accidentally re-documented already ongoing medicine into the medication list when the intention had been to document another order. The identified root cause was that the system does not help users keep medication data consistent. In this case, it appears that the system allows users to input inconsistent data and does not give hints regarding double medication.

User documented a wrong medication dose, unit, administration route or schedule into the system. -> Actual medication of the patient was not apparent or it was not fulfilled correctly. In some incidents, the user had selected the wrong medicine, which had the same name as the intended medicine. One incident stated that faulty selection had occurred because the intended medicine was not available in the system. In some incidents, the user had typed an erroneous unit or dose. Errors also occurred when the administration route or schedule was erroneously documented. These issues are diverse and can be caused by various usability issues. However, one identified issue is that the user has to recall information (e.g. the correct medication name, administration route and schedule) and the system does not help the user input the data in the correct format (e.g. using selection components, hierarchies, default values and example values).

Discussion

Use errors resulted primarily from three factors: users' requirement to manage and search for information on multiple views, the reliance of execution of basic daily tasks on users' memory, and identification issues with selecting patients. Use errors that led to a wrong patient or to wrong medication occurred many times when compared to the overall number of incidents. The HIS related usability issues identified in this study have also been addressed in prior studies. Information fragmentation into multiple views has been shown to be a common safety issue [5,6]. Use problems related to patient identification, selecting the wrong patient, and managing wrong patient data have occurred in earlier studies [5,7,9]. Additionally, usability issues related to medication have been addressed previously [7,9]. The results support previous research, and introduce new usability research perspectives on the relationship between usability, use errors, and patient safety.

In a recent Finnish study, EHR-related patient safety incidents at 23 hospitals during a 2-year period were analyzed, showing that 73 per cent (n=1755) of the incidents involved problems related to human-computer interactions [8]. The high frequency of human-computer interaction related incidents and large number of user error-related incidents identified in this study suggests that HIS usability should be improved in order to prevent safety incidents. From one perspective, HIS usability could be improved by searching usability design solutions for identified use errors. In a more detailed perspective, the emphasis should be on user involvement in the early phase of HIS usability design. However, presently there exist many shortcomings in users' abilities to contribute to development work [19].

Usability problems are symptoms of design flaws and poor integration of clinical work; they could be prevented by the application of a proper user-centered process and usability evaluations. Nevertheless, many do not acknowledge the relationship between usability and product safety. Designers, developers, and vendors of HISs are starting to become concerned about safety issues, but they usually doubt that their product per se

could generate safety problems related to usability flaws. Another hesitation is the idea that good usability directly results from the application of a proper usability engineering methodology during the design and development of systems [20].

While 100% elimination of use errors by usability design may sound unrealistic, user-centered approach to HIS design can lower the error-rate, as more usability issues are identified already during the design. How safe and effective a system is to use depends on the interaction between the user, the use environment, and the user interface [3]. Therefore, usability design concentrating only on user interface is not adequate. Sociotechnical approaches are required in order to ensure HIS fits into the complex health care context.

Limitations

There are some limitations to this study. First, the data was collected from one organization. Some issues indicated in the results might therefore apply only to the certain HISs that are implemented in this study organization. However, the analyzed data revealed that some of the issues occurred in various systems within the study organization, and added to the fact that previous studies have addressed similar results, supports generalizability of the results. Another limitation to the data is that in the analysis phase, some potential incidents were excluded from the final data as it was not clear whether they should have been included. This means that the results are affected by how detailed an incident description the reporter had written. Further, a common limitation to patient safety incident data is that it does not provide a complete picture of the threats to patient safety [21], which suggests that the amount and variety of the issues presented within the results are complex.

The usability issues presented with the results are determined by the researcher based on the textual descriptions of incident data. Actual HIS users could have different insight for determined usability issues. Within the results, some incidents are briefly described in order to promote transparency and to enable the reader

to assess the concluded usability issues. Despite the limitations, the data provided interesting and insightful results for a relatively lightly researched subject.

Conclusion

Finnish patient safety incidents analyzed in this study showed that HISs contain usability issues that lead to

use errors and endanger patient safety. For safer HISs, the relationship between usability, use errors, and patient safety should be understood and considered in the usability design. More studies of relationship between usability problems and usability design solutions are needed in order to prevent use errors by design.

References

- [1] Institute of Medicine. Health IT and Patient Safety: Building Safer Systems for Better Care. Washington, DC: The National Academies Press; 2012.
- [2] Gruchmann T, Borgert A. The effect of new standards on the global movement toward usable medical devices. In: Holzinger A (Editor). HCI and Usability for Medicine and Health Care: Third Symposium of the Workgroup Human-Computer Interaction and Usability Engineering of the Austrian Computer Society, USAB 2007 Lecture Notes in Computer Science (LNCS 4799). Berlin, Heidelberg, New York: Springer; 2007. p. 83-96. https://doi.org/10.1007/978-3-540-76805-0_6
- [3] U.S. Department of Health and Human Services Food and Drug Administration. Applying Human Factors and Usability Engineering to Medical Devices - Guidance for Industry and Food and Drug Administration Staff; Feb 2016. Available from: <http://www.fda.gov/downloads/MedicalDevices/.../UCM259760.pdf>. [cited 2017 Jan 12].
- [4] Johnson CM, Johnston D, Crowley PK, Culbertson H, Rippen HE, Damico DJ et al. EHR Usability Toolkit: A Background Report on Usability and Electronic Health Records. AHRQ Publication No. 11-0084-EF. Rockville, MD: Agency for Healthcare Research and Quality; Aug 2011. Available from: https://healthit.ahrq.gov/sites/default/files/docs/citation/EHR_Usability_Toolkit_Background_Report.pdf.
- [5] Lowry SZ, Ramaiah M, Taylor S, Patterson ES, Prettyman SS, Simmons D et al. Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Records: Empirically Based Use Cases for Validating Safety Enhanced Usability and Guidelines for Standardization (NISTIR 7804-1). National Institute of Standards and Technology, U.S. Department of Commerce; Oct 2015. <https://doi.org/10.6028/NIST.IR.7804-1>
- [6] Meeks DW, Smith MW, Taylor L, Sittig DF, Scott JM & Singh H. An analysis of electronic health record-related patient safety concerns. Journal of the American Medical Informatics Association 2014;21(6):1053–1059. <https://doi.org/10.1136/amiajnl-2013-002578>
- [7] Arvola T, Pommelin P, Inkinen R, Väyrynen S, Tamela O. Potilastietojärjestelmien turvallisuusriskit hallintaan [To control the security risks in patient information systems]. Finnish Medical Journal 2012;12:955-961.
- [8] Paljoki S, Mäkelä M, Lehtonen L, Saranto K. An analysis of electronic health record-related patient safety incidents. Health Informatics Journal 2016. <https://doi.org/10.1177/1460458216631072>
- [9] Magrabi F, Ong M-S, Runciman W, Coiera E. Using FDA reports to inform a classification for health information technology safety problems. Journal of the American Medical Informatics Association 2012;19:45-53. <https://doi.org/10.1136/amiajnl-2011-000369>
- [10] Warm D, Edwards P. Classifying health information technology patient safety related incidents – an approach used in Wales. Applied Clinical Informatics 2012;3(2):248–257. <https://doi.org/10.4338/ACI-2012-03-RA-0010>
- [11] Marcilly R, Beuscart-Zéphira M-C, Ammenwerth E, Pelayo S. Seeking evidence to support usability principles for medication-related clinical decision support (CDS) functions. In: Lehmann CU, Ammenwerth E, Nøhr C (Eds). MEDINFO 2013: Proceedings of the 14th World Congress on Medical and Health Informatics. Studies in

Health Technology and Informatics, Volume 192. Amsterdam, IOS Press; 2013. p. 427-431.

[12] Tynkkynen L-K, Chydenius M, Saloranta A, Keskimäki I. Expanding choice of primary care in Finland: much debate but little change so far. *Health Policy Volume* 2016;120(3):227-234. <https://doi.org/10.1016/j.healthpol.2016.01.015>

[13] Hyppönen H, Hämäläinen P, Reponen J (Eds.). *E-health and e-welfare of Finland - Check point 2015. Report 18/2015*. Helsinki, Finland: National Institute for Health and Welfare (THL); 2015. Available from: <http://urn.fi/URN:ISBN:978-952-302-563-9>. [cited 2017 Jan 12].

[14] Finnish Health Care Act 2010/1326. Ministry of Social Affairs and Health, Finland; Dec 2010. Available from: <https://www.finlex.fi/fi/laki/kaannokset/2010/en20101326.pdf>. [cited 2017 Jan 12].

[15] Doupi P. *National Reporting Systems for Patient Safety Incidents. A review of the situation in Europe. Report 13/2009*. Helsinki, Finland: National Institute for Health and Welfare (THL); 2009. Available from: <http://urn.fi/URN:NBN:fi-fe201205085214>. [cited 2017 Jan 12].

[16] Zhang J, Johnson TR., Patel VL., Paige DL, Kubose T. Using usability heuristics to evaluate patient safety of medical devices. *Journal of Biomedical Informatics* 2003;36:23-30. [https://doi.org/10.1016/S1532-0464\(03\)00060-1](https://doi.org/10.1016/S1532-0464(03)00060-1)

[17] Healthcare Information and Management Systems Society (HIMSS). *Defining and Testing EMR Usability: Principles and Proposed Methods of EMR Usability*

Evaluation and Rating. Jun 2009. Available from: http://s3.amazonaws.com/rdcms-himss/files/production/public/FileDownloads/HIMSS_DefiningandTestingEMRUsability.pdf. [cited 2017 Jan 12].

[18] Lowry SZ, Quinn MT, Ramaiah M, Schumacher RM, Patterson ES, North R et al. *Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Records (NISTIR 7804)*. National Institute of Standards and Technology, U.S. Department of Commerce; Feb 2012. Available from: https://www.nist.gov/node/592206?pub_id=909701. [cited 2017 Jan 12].

[19] Kaipio J. *Usability in healthcare: Overcoming the Mismatch between Information Systems and Clinical Work* [doctoral dissertation]. Espoo; Department of Computer Science and Engineering, Aalto University; 2011.

[20] Beuscart-Zéphir M-C, Pelayo S, Borycki E, Kushniruk A. *Human factors considerations in health IT design and development*. In: Carayon P (Eds). *Human Factors and Ergonomics: Handbook of Human Factors and Ergonomics in Health Care and Patient Safety, Second Edition (2)*. Baton Rouge, US: CRC Press; 2011. p. 650-668. <https://doi.org/10.1201/b11219-47>

[21] Shojania KG. *Reporting systems - The elephant of patient safety: What you see depends on how you look*. *The Joint Commission Journal on Quality and Patient Safety* 2010;36(9):399-401. [https://doi.org/10.1016/S1553-7250\(10\)36058-2](https://doi.org/10.1016/S1553-7250(10)36058-2)