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Identification of Patient Safety Risks Associated with Electronic Health Records: A Software Quality Perspective

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Abstract

Although Electronic Health Records (EHR) can offer benefits to the health care process, there is a growing body of evidence that these systems can also incur risks to patient safety when developed or used improperly. This work is a literature review to identify these risks from a software quality perspective. Therefore, the risks were classified based on the ISO/IEC 25010 software quality model. The risks identified were related mainly to the characteristics of "functional suitability" (i.e., software bugs) and "usability" (i.e., interface prone to user error). This work elucidates the fact that EHR quality problems can adversely affect patient safety, resulting in errors such as incorrect patient identification, incorrect calculation of medication dosages, and lack of access to patient data. Therefore, the risks presented here provide the basis for developers and EHR regulating bodies to pay attention to the quality aspects of these systems that can result in patient harm.

Keywords:

Electronic Health Records; Patient Safety; Quality Improvement.

Introduction

The progress of information technology has impacted the healthcare sector. Some of these impacts are caused by adoption of the Electronic Health Records (EHR) [1]. One of the main goals of EHR is to support continuity, efficiency, and quality in healthcare [2]. These systems can offer benefits, such as ease of access to patient data, research support [3], and greater completeness and documentation comprehensiveness [2]. In addition, these systems have shown a capacity for reducing medical errors and increasing patient safety, mainly by means of decision-making support mechanisms [1,4].

Despite these benefits, the literature also presents evidence that, when developed and/or used improperly, EHR can incur risks to patient safety [5–8]. Patient safety is understood as a reduction of damage risks to patients in the healthcare process [9].

For example, some real cases of problems associated with the use of EHR that jeopardized patient safety can be cited. In 2007, a maintenance error in the network configuration of the Veterans' Health Administration (VHA), one of the largest healthcare providers in the United States, caused the EHR to become inaccessible for more than nine hours. As a result, many consultations were conducted without access to any documentation, and surgeries had to be postponed because the doctors were uncertain about how to proceed without proper documentation [7].

An evaluation of adverse event database from the Food and Drug Administration (FDA) in the United States also revealed cases of incidents related to the use of EHR. Loss or corruption of data, association of information to the wrong patient, and lack of access to the EHR resulted in problems such as delays in diagnosis or treatment, incorrect administration of medication, and even death [5].

Despite the growing quantity of such evidence, there is a significant gap of initiatives that address patient safety issues associated with the use of EHR [10]. Therefore, there is a need for more research aimed at investigating the possible EHR quality problems that can negatively affect the healthcare process.

In this context, this work presents a literature review of the risks that EHR can cause regarding patient safety. The risks presented here are classified based on the software product quality characteristics specified by the 25010 standard by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) [11]. This classification allows EHR developers to have better traceability of the quality characteristics of their products that can affect patient safety. According to the authors' knowledge, such an approach has not been used by any published work in the literature.

Methods

In order to search the relevant databases, we used medical subject headings (MeSH) terms and free terms defined from the two main topics associated with the theme of this work: "EHR" and "Patient Safety Risks." The electronic databases consulted were PubMed, IEEE Xplore Digital Library, ACM Digital Library, and ScienceDirect. We selected only papers published between 2010 and 2014.

The electronic database searches returned 8,609 references, 17 of which were selected for review. The works were selected by an iterative scan of these references in order to eliminate duplicate records and select only those references relevant to the purpose of this work.

After the literature review, the selected articles were submitted to an in-depth reading for risk identification. The risks were then classified based on the software product quality model established by ISO/IEC 25010 - Systems and software engineering - Systems and software Quality Requirements and Evaluation (SQuaRE) - System and software quality models. This standard establishes a model composed of eight characteristics (divided into sub-characteristics) used to evaluate software product quality and evaluate how it can meet the needs of stakeholders [11].

Results

The works included in this literature review investigated the risks to patient safety associated with EHR using approaches such as: analysis of incident reports [5,12–16], application of interviews or questionnaires to experts or EHR users [17–19], literature review [20–23], and expert opinion [24–26].

In the next sections, we present the risks to patient safety associated with EHR identified by reading the articles included in the literature review. These risks are presented based on the characteristics and sub-characteristics of software product quality set out in ISO/IEC 25010, as listed in Table 1.

Table 1– Risks classified by ISO/IEC 25010 software quality model

Characteristics	Sub-characteristics	Risk
Functional Suitability	Functional completeness	R1 - Lack of functionalities that support clinical workflow [5,17,20]
		R2 - Lack of coding, standardization, and structuring data [24]
		R3 - Lack of features to detect duplicate patient records [19,27]
	Functional correctness	R4 - Inaccurate, outdated, or incomplete decision support rules [5,20,21]
		R5 - Software bugs [5,13,14,20,23]
	Functional appropriateness	R6 - Inadequate content import features [20,21,23,26]
		R7 - Pre-populated fields [20,23,25,26]
		R8 - Inadequate alerting [19,20,22,24]
		R9 - Allow tasks to be performed simultaneously [12,19]
Usability	Appropriateness recognizability	R10 - Inadequate display of information [5,12,14,16,18,19,22,25]
	Learnability	R11 - Difficulty in understanding current status of user actions [19]
	Operability	R12 - Difficulty in interacting with EHR [19,21]
	User error protection	R13 - Interface prone to user error [12,16,17,19–22,27]
	User interface aesthetics	-
	Accessibility	-
Performance Efficiency	Time behavior	R14 - Delay in system response [12]
	Resource utilization	-
	Capacity	-
Compatibility	Co-existence	-
	Interoperability	R15 - Communication errors between systems [5,12,14–16,19,24]
Reliability	Availability	R16 - EHR unavailability [13,15,17–19,24,25]
	Maturity	-
	Fault tolerance	-
	Recoverability	-
Security	Confidentiality	-
	Integrity	-
	Non-repudiation	-
	Authenticity	-
	Accountability	-
Maintainability	Modularity	-
	Reusability	-
	Analyzability	-
	Modifiability	-
	Testability	-
Portability	Adaptability	-
	Installability	-
	Replaceability	-

Functional Suitability

The quality characteristic "functional suitability" is related to the degree to which the features offered by the software are complete, accurate, and appropriate. Risks associated with all three sub-characteristics in this category were identified.

Functional Completeness

The sub-characteristic "functional completeness" is the degree to which the software provides necessary functions for users to achieve their goals. The following risks have been identified for this category:

- **R1** - Lack of functionalities that support clinical workflow [5,17,20].
- **R2** - Lack of coding, standardization, and structuring data [24].
- **R3** - Lack of features to detect duplicate patient records [19,27].

The absence of features that support clinical workflow can cause users to decide on workarounds that could jeopardize patient safety. For example, when the EHR does not allow registration of drug administration prior to registering its order (a common necessity in emergencies), the drug application documentation will occur after administration, which can result in medication being administered again because its administration was not registered previously [20].

The lack of codification, standardization, and data structure can result, for example, in failure to issue alerts [24], whereas the absence of mechanisms to detect double-patient records can result in documentation gaps because of information fragmentation [27].

Functional Correctness

The sub-characteristic "functional correctness" evaluates the degree of accuracy and correctness of the functionalities offered by the software. For this category, the following risks were found:

- **R4** - Inaccurate, outdated, or incomplete decision support rules [5,20,21].
- **R5** - Software bugs [5,13,14,20,23].

Supporting rules for incorrect, not current, or incomplete decisions can result in the issuance of a large amount of false-positive alerts, encouraging users to overlook alerts [21]. In addition, users with high confidence in technology can be mislead when making decisions based on incorrect recommendations issued by the system. This process is known as "automation bias," in which users perform actions recommended by technology when they have decision doubts, or even when such actions contradict their knowledge [20].

Software bugs can cause incorrect dosage calculations [5] or even the corruption, loss, or improper storage of data [20]. This risk was also associated with maintenance or updates to EHR that, when poorly managed, can introduce new bugs to the software [14].

Functional Appropriateness

The sub-characteristic "functional appropriateness" verifies how the functions offered by the software are appropriate and capable of facilitating task execution by users. The following risks were identified:

- **R6** - Inadequate content import features [20,21,23,26].
- **R7** - Pre-populated fields [20,23,25,26].
- **R8** - Inadequate alerting [19,20,22,24].
- **R9** - Allow tasks to be performed simultaneously [12,19].

Text import features (such as copy/paste) are often related to the propagation of incorrect information, loss of authority assignment, or even copy of outdated information [26]. Whereas these problems occur mainly from abusing the use of these features [17,20], the EHR can help avoid them by restricting the type of data that can be imported, and including the original text source for imported content [26].

Fields with default values (such as the establishment of standard doses [23,25]) can also incur risks to patients when not reviewed by users [26]. On the other hand, issuing alerts and reminders with low specificity or sensitivity, irrelevant, or excessive, encourages users to overlook alerts that could potentially be important [19,22] and interrupts the clinical workflow and thought process of health professionals [24],.

Allowing certain tasks to be performed simultaneously, such as opening two or more patient records on the same device [19] or simultaneously editing the same record by different users [12], can result in the registration of information to the wrong patient, or in information inconsistency [19].

Usability

The quality characteristic "usability" evaluates user interface in the context of ease of understanding, learning, ease of use, user attraction, and accessibility. For this category, risks were found in the sub-characteristics "appropriateness recognizability," "learnability," "operability," and "user error protection".

Appropriateness Recognizability

The sub-characteristic "appropriateness recognizability" verifies the degree to which users recognize the software suitable for their needs. The following risk for this category was identified:

- **R10** - Inadequate display of information [5,12,14,16,18,19,22,25].

The problems related to this risk are in regards to incomplete display of information [5,12,18,19,22,25], such as not displaying pre-existing medications or patient allergy data [12]; buttons with the same label, but different features [25]; and presentation of high information volume [5]. These problems are associated with patient misidentification (caused by not displaying key identifying data) [19] and incorrect interpretation of information [16].

Learnability

The sub-characteristic "learnability" evaluates how the software allows users to understand key software concepts, thus making the concepts effective for use. The following risk was identified:

- **R11** - Difficulty in understanding current status of user actions [19].

This risk is associated with the occurrence of open or incomplete orders caused by the failure to complete an order process, including signature or submission. This problem can be caused by the user interface when it becomes difficult to understand the current status of user's actions [19].

Operability

The sub-characteristic "operability" assesses the ease of using the software. The following risk was found for this category:

- Modelo de Qualidade ISO/IEC 25010 - Difficulty in interacting with EHR [19,21].

Interface problems, such as the display of information of the same context on multiple screens or tabs [19,21], can cause user interaction with EHR difficult. Difficulty in navigating, visualizing, understanding, and interacting with the user interface can cause failure to identify and/or use the most recent patient data, thus causing clinical decision errors and generating incorrect, unnecessary, or delayed tests, procedures, and therapies [19].

User Error Protection

The sub-characteristic "user error protection" evaluates the software's ability to prevent user errors. The following risk was identified:

- **R13** - Interface prone to user error [12,16,17,19–22,27].

Many of the selected studies reported that the way in which the user interface arranges information can facilitate the occurrence of user errors. The main problems regarding this risk are related to item selection lists (such as drug lists) or drop-down menus that often have very similar items [19–21], lack of item grouping [19], or a very large amount of items [19,21]. These design issues can result in the improper

selection of items (such as incorrect patient selection) [16,17,19,27].

Performance Efficiency, Compatibility, and Reliability

The quality characteristic "performance efficiency" evaluates software optimization in connection with processing time, resource consumption, and processing capacity. For this category, only the sub-characteristic "time behavior" presented a risk:

- **R14** - Delay in system response [12].

A delay in response to a particular EHR action can cause users to click the same action several times, thus generating duplicate prescriptions, for example [12].

The quality characteristic "compatibility" refers to the degree to which two or more systems or components of a system can exchange information. One risk was identified for the sub-characteristic "interoperability":

- **R15** - Communication errors between systems [5,12,14–16,19,24].

Communication errors between systems or components of a system are often caused by difficulties in EHR interoperability with other systems [22], or failures in network infrastructure [5,12,14,16,25]. Such errors can prevent patient context and status from being consistent between components/systems, leading mainly to delays in the healthcare process [14].

The quality characteristic "reliability" evaluates software in terms of maturity (frequency with which the software is defective over time), availability (degree to which the software is available for use), fault tolerance (the software's ability to operate in the presence of hardware or software failures), and recoverability (the software's ability to recover data and return to operate after the occurrence of a failure). For this category, we found one risk with respect to the sub-characteristic "availability":

- **R16** - EHR unavailability [13,15,17–19,24,25].

When EHR is not available for use, health professionals can lose access to the documentation required for healthcare processes, which can lead to such problems as delays in diagnosis and treatment [7].

The main causes of lack of access to EHR are failures or planned downtime of some infrastructural component [19]. Therefore, it is necessary for EHR to offer redundant devices [19,24], and a read-only version to access without connection [19].

Discussion

The software quality characteristics that presented more risks to patient safety were "functional suitability" (nine risks) and "usability" (four risks). On the other hand, the risks most discussed in the articles selected for this literature review were: "Inadequate display of information" (usability-appropriateness recognizability); "interface prone to user error" (usability-user error protection); "communication errors between systems" (compatibility-interoperability); and EHR unavailability (reliability-availability).

Once the major quantity of identified risks is related to the functions provided by the EHR (functional suitability) and its usability, it is noticed the importance of the integration of the end user to the product development process. A way for achieving such integration is the use of the principles of User-Centered Design (UCD) [28]. The UCD is an approach that involves the end users along all of the development process in order to enssure that the product is suitable to their needs. This approach also seeks to take into account the needs and expectations of any person that could be affected by the use of the product [29] (e.g. the patients). Therefore, UCD may help to building EHRs more compliant to the health professionals' needs and, at the same time, safer for patients.

No risks were found for the quality characteristics "security," "maintainability," and "portability." However, the authors consider that the attribute "security" (which evaluates how the software can protect its functions and data from unauthorized access) can also be important for patient safety because problems regarding confidentiality breaches of patient information could harm their psychological well-being.

In addition to the risks specifically related to EHR quality characteristics, we identified risks that arise because of improper EHR use, such as neglecting the use of structured fields to use only free text fields [24]; infrastructure problems, such as network failures [14]; and other contributing factors, such as gaps in regulations [20] and poor user training [16,23].

Therefore, it is clear that the EHR is part of a complex sociotechnical system in which patient safety incidents can occur because of the interaction of several factors [30]. However, this study aimed to present risks in an approach that was more focused on EHR quality characteristics, and therefore, risks relating to other aspects are not discussed.

Conclusion

This paper presented risks that EHR can incur to patient safety when developed improperly. The risks were presented according to the characteristics of software product quality set out in ISO/IEC 25010, thus allowing the developers of these systems to have a reference for identifying the quality attributes of their products that might pose risks to patient safety.

In addition, the risks presented can be used as reference for the specification of more stringent requirements in the EHR certification processes, once these processes still require more direct approaches to patient safety [10,31].

However, it is still necessary to investigate strategies to mitigate the risks presented here in order to provide techniques and recommendations that can be used by EHR developers to create a product that offers greater safety to the healthcare process.

It is also necessary to examine the risks to patient safety in a sociotechnical context in greater depth, thus allowing the identification of problems related to EHR process use, specification of regulations, supervision, infrastructure, and any other factors that interact with EHR throughout its lifecycle. The identification of these problems should be followed by the identification of their solutions, indicating the role of each actor involved in this sociotechnical system in mitigating the risks to patient safety.

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