

A Constrained Review of Safety Analyses of Electronic Medical Record Use and Recommendations for Enhanced Design

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Previous research has found that the use of properly designed and implemented Electronic Medical Records (EMRs) can promote safety culture in primary care providers. However, there remain concerns that such technology may also create new safety issues that could lead to patient harm. The objectives of the present research were to: (1) summarize studies that identified potential hazards in EMR use as well as those making use of safety analysis techniques for hazard identification; and (2) formulate a set of design recommendations and an enhanced design to mitigate user performance problems and potential patient safety hazards. Results revealed the main types of hazards in EMR use to be poor display of information and erroneous data entry and documentation methods. In addition, all hazard analyses conducted in previous studies employed inductive reasoning methods. It was also found that studies focusing on EMR system safety made no objective assessments and basically made use of descriptive and qualitative methods. We proposed an enhanced EMR interface design towards mitigating the safety issues identified in the literature. This research is complementary to other work we recently completed on EMR usability issues and enhanced design recommendations. We also recommended use of objective and deductive reasoning approaches to assess the frequency of potential hazards and to identify potential severity of outcomes for patients.

Practitioner Summary: An enhanced EMR interface design is proposed based on a review of literature and recognition of potential hazards to patients in use of existing designs. Results may be beneficial for companies developing EMRs for healthcare providers in order to design interfaces that effectively support safety in healthcare worker interaction with EMR systems.

Keywords: Electronic medical records, interface design, systems safety, fault tree analysis, literature review

1. Introduction

The introduction of information technology in healthcare has led to many changes in medical practice. One of the most important changes is the transition of paper-based health records to Electronic Medical Records (EMRs). The Office of the National Coordinator for Health Information Technology (ONC) defines an EMR as a digital version of paper charts in a clinician's office that contain the medical and treatment history of patients in one practice. Many studies have found EMRs to improve patient safety. For example, Mekhjian et al. (2002) found that EMRs and Computerized Physician Order Entry (CPOE) can reduce transcription errors and medication turnaround times. In addition, some other studies found that computerized documentation has improved legibility of notes and reduced documentation errors as compared to paper-based systems. (e.g., Pabst et al. 1996; Smith et al. 2005)

Although many previous studies have focused on the advantages of EMR use, there are still some concerns with the technology creating new hazards and safety issues that could lead to patient harm (Ammenwerth and Shaw, 2004). Some examples of possible hazards created by EMRs include: delayed feedback on user control actions, incomplete or incorrect process models, and failure to present "clean and relevant" and up-to-date patient information. (Weber-Jahnke & Mason-Blakely, 2012; Caudill-Slosberg & Weeks, 2005). Related to this, Bowman (2013) identified types of hazards posed by Electronic Health Records (EHRs) as system design flaws, poor system usability, inappropriate documentation capture, copy and paste (C/P) errors, in appropriate templates, and errors related to the use of Clinical Decision Support Systems (CDSS).

With respect to analysing the safety of EMRs, systems safety analysis techniques can be generally classified as being either inductive or deductive in methodology. Inductive reasoning is a logical process in which the proposed conclusion contains more information than the observation on which it was based. However, in deductive reasoning, a conclusion is drawn from a set of premises and has no more information than the premises taken collectively (Ericson, 2005). Applied to hazard analysis, inductive reasoning involves projecting a set of system failures or losses from sources of hazards in the workplace and mechanisms or events leading to exposures. Deductive methods involve hypothesizing a specific failure or loss state and deducing the events and objects in the work environment that might cause the failure state. Previous studies have used different safety analysis techniques in order to identify hazards in EMR use. For example, Singh et al. (2004) applied Failure Modes and Effects Analysis (FMEA; an inductive technique) for evaluating safety issues in EMR use. In addition, Caudill-Slosberg & Weeks (2005) suggested that hazards associated with EMR use could be identified by using techniques such as cause and effect diagrams or fishbone analysis.

Based on the literature of safety analyses of EMRs, the objectives of this study were to: (1) summarize studies that identified potential hazards in EMR use and those that have made use of safety analysis techniques for hazard identification; and (2) formulate a set of design guidelines and an enhanced EMR interface design to mitigate potential patient hazard exposure.

2. Method

A literature search was conducted using Compendex, PubMed, CINAHL and Web of Science (WOS) databases in order to find relevant research published since 2000. (It is important to note that PubMed supports searches on the previous 10 years of literature but does not allow for searches on specific date ranges.) Manual searches were also performed of lists of references concerning EMR safety analyses. Search terminology submitted to the databases included “Electronic Medical Records” combined with “Hazard”, “Safety”, and “Errors”. Inclusion criteria for the literature review were: (1) relevant, English-language papers with (2) subsets of the keywords as well as (3) any research studies (manually) identified with a focus on EMR safety analyses. (Articles appearing in databases without abstracts were excluded.) Initial search engine results were obtained in late 2014. Although hit counts were high, we reviewed for relevance the title (and often the abstract) of each and every hit from the databases. Subsequently, the abstracts of all related papers, identified based on the search strategy, were read and assessed for relevance. Full texts of articles considered relevant to the research objectives were obtained and reviewed. Articles were summarized as a basis for guideline formulation.

3. Results

In total, 9 unique studies were found to meet the inclusion criteria after accounting for overlap of hits across search engines. An annotated bibliography was developed, including the following subsections: (1) citation information, (2) study objective, (3) research methodology, (4) significant results, and (5) conclusions. It is important to note that some of the EMR safety studies did not make application of inductive or deductive systems safety analysis techniques for hazard recognition and control recommendations (discussed below). Based on the bibliography, studies that focused on safety analysis techniques were categorized into one of the two classifications, including: (1) inductive reasoning, or (2) deductive reasoning. Table 1 shows a list of the studies with none appearing in the deductive category.

Table 1. Studies focused on EMR safety.

Reference	Safety techniques	
	Inductive Reasoning	Deductive Reasoning
Singh et al. (2004)	P-FMEA (Preliminary FMEA)	N/A
Win et al. (2004)	FMEA	N/A
Caudill-Slosberg & Weeks (2005)	Cause and effect/ fishbone analysis	N/A
Belden et al. (2009)	FMEA, TRA (Topological Risk Analysis)	N/A
Kumar & Aldrich (2010)	Fishbone analysis	N/A
Weber-Jahnke & Mason-Blakely (2012)	STAMP (Systems-Theoretic Accident Model and Process)	N/A

3.1 Review findings on EMR safety

Several previous studies have linked EMR interface design features with safety issues (e.g. Caudill-Slosberg and Weeks 2005; Weber-Jahnke & Mason-Blakely 2012). In this section, we first summarize those studies (not listed in Table 1) that identified possible hazards created by EMR design and use. Subsequently, we summarize the studies listed in Table 1 that made use of safety analysis techniques to identify potential hazards in EMR use.

3.1.1 Potential hazards in EMR use

In a review of literature on EMR technology, Harrington et al. (2011) assessed performance with three components of EMRs, including CPOE systems, CDSS, and bar-coded medication administration (BCMA) systems. Based on several evaluations, they concluded that CPOE systems could be a new error source that could result in patient harm, or even mortality. They linked the potential sources of errors, in part, to poor EMR interface design. Some safety issues identified by Harrington et al. included: wrong selections from lists of physician orders, free text orders, changes in clinical communication patterns, and misidentification of patients due to poor display design. They suggested that effective planning and design of CPOE systems is critical for reducing such unintended consequences.

In yet another review, Bowman (2013) identified some of unintended hazards of using EHR systems. She also identified potential solutions to address those issues and promote patient safety and quality of care. Bowman (2013) classified types of EHR hazards as: system design flaws, poor usability and improper use, inappropriate documentation capture, C/P errors, inaccurate template use, and errors related to CDSS. Some of the specific hazards identified included: confusing screen displays, lack of consistency in design of data fields from one template to another, incomplete or inaccurate templates, patient note mismatches, outdated information as a result of inaccurate C/P function use, errors as a result of adjacency of fields, and over documentation. Some of the recommendations that the author suggested to address these problems include monitoring the C/P process to ensure appropriate case content and to implement EHR content design standards and guidelines.

In a more recent study, Meeks et al. (2014) performed a retrospective analysis of completed EHR reports as a basis for identifying safety issues within the Department of Veteran Affairs (VA). They found four main safety concerns including: unmet data display needs within the EHR, problems with software modifications and upgrades, errors occurring in transfer of patient information from one EHR component to another, and hidden dependencies within an EHR. The most common concerns were related to unmet display needs. Some specific examples of safety hazards in this category included: the need for reviewing multiple screens, EHRs allowing patient note mismatches and conflicting information entry, and inconsistent wording and functions among screens.

In summary, based on the above literature review, EMR related hazards can be categorized into two main categories including: (1) poor display of information, specifically failure to present up-to-date and meaningful information, failure to present coherent information, etc.; and (2) erroneous data entry and documentation methods, specifically inaccurate use of C/P functions and incomplete or inaccurate data entry.

3.1.2 Applying safety analysis techniques to EMRs

In this subsection, we summarize those studies that applied safety analysis techniques to EMR use. As identified in Table 1, all reviewed studies used inductive and qualitative methods for EMR analysis.

Singh et al. (2004) applied Failure Modes and Effects Analysis (FMEA) to evaluate safety issues in EMR use. FMEA is an engineering technique used to define, identify, and eliminate known and/or potential problems and/or errors in a system, design, process and/or service before they reach the customer (Omdahl, 1988; ASQC, 1983). Singh et al. found that EMRs may introduce new hazards in patient safety (over the use of conventional paper-based systems) due to changes in physician, nurse and patient interactions. Some identified hazards include: multiple different primary care errors in 12 different domains, such as physician-chart interaction, nurse-physician interaction, nurse-chart interaction, etc. They said that FMEA applied to specific practices can be used to identify changes related to EMR implementation, such as disruptions in doctor-patient communication due to EMR use.

Related to this, Win et al. (2004) also used the FMEA technique to identify potential failure modes in a health information system. They said in fault-tree analysis error sources are found after the event; however, with FMEA, failure modes can be predicted. In a case study at the Simpson Centre for Health Services, the

authors identified possible failure modes for processes. Based on the FMEA, the most hazardous failure modes included EMR forms not being marked appropriately (leading to incomplete data), missing forms, identical medical record numbers for different patients, and mismatches in data. Most concerning, in terms of a severity of hazard exposure, such errors have the potential to lead to patient mortality.

Caudill-Slosberg & Weeks (2005) suggested that hazards associated with EMR use could also be identified by using techniques such as cause and effect diagrams or fishbone analysis. A cause-and-effect diagram is a tool that helps identify, sort, and display possible causes of a specific problem or quality characteristic (Ben- Daya, 2009). They said that such methods could even be applied before EMR system implementation to project types of hazards. In their analysis of a specific healthcare operation, four entities contributing to hazards were identified, including patients, clinicians, pharmacy and EMRs. Some of their identified hazards related to EMRs included failure to present “clean and relevant” information, failure to present up-to-date and accurate patient information, coherent presentation of information, and inaccurate information and medication data entry. It was also shown that an EMR failure could lead to negative healthcare outcomes for patients.

In another review of literature, Belden et al. (2009) also identified FMEA as an appropriate risk analysis approach for evaluating the effectiveness of EMRs. In addition, they identified Topological Risk Analysis (TRA) as another applicable risk assessment technique. They said the TRA method describes a process in an in-depth manner, defines a layout (topological representation), and identifies risk elements such as “single-point” failures and “common-mode” failures. Subsequent to risk identification, detailed analysis and control efforts can be concentrated on these points. Having reviewed Belden et al. work, it is important to note that the TRA methodology is not commonly identified or detailed in system safety analysis references (e.g., Bahr, 1997).

In another study, Kumar and Aldrich (2010) analysed a case of failure in healthcare due to EMR system failure. They also used fishbone analysis to identify major contributing factors and specific conditions leading to negative patient outcomes. They found the causes of overall EMR system failures to include interface design, implementation strategy, and HCW errors. Some specific hazards they found in the technology design included alerts that could not be overridden, unidentified conflicts in drug interactions, too many fields for data entry, and no flexibility for custom entries.

Finally, in a more recent study, Weber-Jahnke & Mason-Blakely (2012) performed an analytical study using the systems-theoretic accident model and process (STAMP) approach to evaluate an EMR system. By definition, in the STAMP method, systems are considered as interrelated components that are maintained in a state of dynamic equilibrium by feedback loops of information and control (Leveson, 2004). The authors said that use of event-based safety analysis techniques, such as fault trees and event trees, may not be successful in complex socio-technical system such as EMRs. The STAMP approach was considered useful in that it attempts to consider non-technical as well as technical factors when assessing system safety. The authors applied STAMP to an EMR case study. Some types of hazards they identified included inconsistent, incomplete or incorrect process models, and delayed feedback on control actions. The authors recommended controls such as: allowing EMR pharmacy order dialogs to enforce limits on maximum dosages of medications, EMR injection order controls enforcing limits on volumes entered by physicians, EMR displays highlighting out-of-range order values, providing warnings to users about ‘stale’ results or the requirement for active drip infusions, as well as providing feedback on order administration.

3.2 Design guidelines

The above literature review leads to a set of EMR interface design guidelines for addressing safety concerns. These are listed in Table 2 along with the specific references identified as bases for each guideline. In addition, the design guidelines are grouped according to the hazard categories identified based on the literature which are poor display of information and erroneous data entry and documentation methods. As shown below, there were six recommendations that could address safety hazards related to poor display of information. In addition, there were seven other recommendations that could be used in order to address safety issues related to data entry and documentation methods.

Table 2. Summary of design guidelines for EMR interfaces based on literature review

Hazard category	Guideline	Reference
Poor display of information	1. Usability should be considered in EMR certification processes	Bowman (2013)
	2. Provide a limit on maximum dosage of medication; show out-of-range values, 'stale' results and provide feedback for EMR displays when data is out-of-range.	Weber-Jahnke & Mason-Blakely (2012)
	3. Ensure coherent information presentation	Caudill-Slosberg & Weeks (2005)
	4. Present "clean and relevant", up-to-date and accurate patient information	Caudill-Slosberg & Weeks (2005)
	5. Show unique patient identification information	Win et al. (2004)
	6. Inform users of conflicts in drug interactions	Kumar and Aldrich (2010)
Erroneous data entry and documentation methods	1. Have organizational policies for promoting ethical documentation practices	Bowman (2013)
	2. Minimize double-insertion of patient information and limit types of information that can be copied	
	3. Provide source attribution for copied data	
	4. Monitor C/P function use to ensure it is appropriate	
	5. Reduce the number of fields for data entry and provide the capability to override false alarms.	Kumar and Aldrich (2010)
	6. Ensure accurate information and medication data entry	Caudill-Slosberg & Weeks (2005)
	7. Ensure completeness of data entry forms	Win et al. (2004)

4. Discussion

4.1 Interface design concept

The above hazard research review and guidelines provide a basis for an enhanced EMR interface design concept. Previous research on EMR safety has shown that the use of templates is error prone mainly due to the lack of consistency of data fields and use of default values (e.g., Bowman, 2013). In our design, we recommend a basic but consistent template for all sections of the EMR interface. This approach dictates no default values for patient information. However, if a physician diagnoses that all systems are normal, (s)he can select an "all normal" option, which would be applied to all data entry fields in a particular section of the EMR. In addition, before moving to the next section of notes, the user would be informed of any incomplete data entry field in the previous section through a warning dialog or notification text at the top of the screen. In this way, the possibility of incomplete and inaccurate data entry would be reduced.

Since one of the major hazards found in the EMR literature was patient-note mismatch (e.g., Bowman, 2013; Meeks et al., 2014), in our enhanced design, we propose adding identification numbers for each patient with presentation at the top of each page of patient notes. In addition, this information can be displayed as a water mark in all patient information forms. In order to double-check the relevance of notes to patients, users should be presented with a confirmation page that includes patient identification before final note submission. This approach is expected to reduce the chance of patient-note mismatch. The final patient identification page would also inform a physician of any data conflicts in the patient's notes.

Previous studies also found that C/P function use in EMRs can cause safety concerns (e.g., Bowman, 2013). In order to address this issue, our interface design would include color-coding and time stamps to differentiate current data from dated information. Related to this, not all types of information can be copied

from notes. For example, information on patient test results or diagnoses cannot be copied because this is the most critical information in each note. The color-coding feature would also be used as a form of feedback to highlight out-of-range values in tests as well as any identified drug interactions. For example, if a physician enters a certain dosage of a drug that might interfere with other drugs the patient is currently taking, the offending drug would be highlighted in “red”. With this design, the physician can be aware of any conflicts among drugs in order to ensure patient safety.

In terms of displaying patient information, in our enhanced design, we would group relevant information on each screen, based on the proximity-compatibility principle described, as by Wickens & Carswell (1995). This principle recommends that displays with relevance to a common task or mental operation should be rendered close together in perceptual space. In addition, in order to reduce the mental workload of users, we recommend presenting only highly-ranked information in each section of notes and to provide “drill-down” capability, if needed.

Regarding data entry methods, since previous studies have found some hazards related to inconsistent use of methods (e.g., template vs. free-text format) in EMR interfaces or too many data entry methods, our new design would use a single method for entering data across all sections of notes. However, previous studies on the usability of EMR interfaces have found that both free-text and template formats can cause usability and safety issues (e.g., Bowman, 2013; Hagstedt et al., 2011). Therefore, in the proposed design, we would use an ecological interface design (EID) of the body with which the physician can select different segments and only those data entry fields related to that selection would be shown on the EMR display. In this way, we can also reduce the complexity of the display and reduce the mental workload of users, which is expected to increase patient safety.

In summary, the main advantages of this new interface concept over current EMR designs include: (1) reducing incomplete or inaccurate notes; (2) reducing the possibility of patient-note mismatch; (3) informing physicians of any conflicts in patient notes; and (4) reducing mental workload of physicians in order to allow more communication between the physician and the patient during review of systems, diagnosis, etc.

4.2 Safety analysis techniques

The review of previous studies on EMR safety (as listed in Table 1) revealed a focus on use of inductive and qualitative reasoning methods, including FMEA, TRA, STAMP, or fishbone diagrams/cause and effect analysis for hazard identification. As mentioned earlier, these methods identify sources and mechanisms of hazard exposure and project potential negative outcomes. Although inductive reasoning methods appear to be useful in order to recognize hazards related to EMR use, there is a need to apply other types of analyses employing deductive reasoning. As mentioned earlier, these methods hypothesize negative outcomes and deduce potential sources and mechanisms in EMR systems.

We recommend using deductive reasoning methods to identify certain EMR interface features (or manners of use) that could be root causes of specific HCW errors and potential negative patient outcomes. For example, Fault Tree Analysis (FTA) is a deductive system safety analysis technique that could be used for this purpose. This method traces the failure pathway from an undesirable event (called TOP event) to system, subsystem and component failures that could cause the event. Requirements for applying this method include description of an EMR use case along with identification of system elements that could fail or create hazards with the potential to lead to the negative patient outcome. The analysis does not require the existence of actual system and can be applied in the design phase. The FTA can link a top-event (e.g., “drug overdose”) to basic events in EMR use or component failures (e.g., “EMR fails to show out-of-range values”). In addition, FTA can be carried out either quantitatively or subjectively through the addition of system component failure probabilities or user error likelihoods to the analysis. For example, in order to assess the new EMR design, we can hypothesize a top event such as “patient has drug overdose after medical operation”. This fault consists of several component failures. Some of component failures might include: operator failure (the nurse fails to follow the prescription correctly), or EMR system failure (interface fails to present critical information). Since the EMR system failure is an intermediate event (dependent on other components), it can be further broken-down into basic events. In this case, the basic events might be that there was no color-coding method to show out-of-range values or there was no confirmation page to show any conflict in a patient’s prescriptions.

Despite Weber-Jahnke & Mason-Blakely’s contention that FTA is not applicable to EMR use, the majority of failures in healthcare involving EMRs are attributable to specific events (e.g., HCW data entry) and occur in specific use scenarios. Fault trees can be created for specific EMR failure modes and contexts

of use. It is also possible to develop a collection of fault trees (organized according to an event tree/scenario) for objective quantification of the frequency of potential hazards as well as identification of severity of outcomes for patients. The use of such methods may reveal additional causes of EMR failures and negative patient outcomes.

5. Conclusion

The objectives of this study were to: (1) summarize studies that identified potential hazards in EMR use as well as studies that have made use of safety analysis techniques to identify hazards; and (2) formulate a set of design guidelines and an enhanced EMR interface design towards reducing patient hazard exposure.

Our review of literature revealed that the main types of hazards in EMR use can be categorized as: (1) poor display of information; and (2) erroneous data entry and documentation methods. Although the literature review showed that inductive safety analysis techniques have been useful for identifying hazards associated with EMR use, there is a need to apply additional types of analyses, including objective assessments and deductive reasoning approaches to EMR systems. We recommend use of the FTA method to objectively assess the frequency of potential hazards as well as identify the potential severity of outcomes for patients.

In addition, the enhanced EMR design that we described addresses safety hazards identified in the literature through clear presentation of information on the basis of HCW goals and task priorities. The design emphasizes conflicts between previously entered and current information using display features and data tags. The enhanced EMR provides real-time feedback on erroneous input and informs HCWs of conflicts in data entries in order to reduce the total number of errors in records.

The limitations of this study include our focus on EMR interface design features and potential hazards of use to the exclusion of consideration of other aspects of EMR design. Many steps in EMR development can lead to safety concerns, such as how traditional paper-based workflows are modelled in EMRs and how specific paper records are transitioned to electronic forms. In addition, any complete analysis of human-computer interaction should consider the context of a user's task. The focus of the majority of the literature we have reviewed was on physicians and their requirements while interacting with EMRs in an examining room. Consequently, our design guidelines and the enhanced EMR design concept also focused on the processes that are primarily performed by physicians, physician assistants, etc. Consideration of other functions of EMRs (e.g., patient appointment scheduling, billing, etc.) would require review of literature in that context in order to identify specific design requirements and guidelines for other HCWs.

Finally, the proposed enhanced EMR is in the conceptual design phase and there is a need for further prototyping, usability testing and safety analysis in order to determine whether the design features we have recommended actually translate to reductions in safety hazards as compared with existing EMR interfaces. The results of the present study and interface design proposal may be useful for companies developing EMRs for healthcare providers in order to design an interface that effectively promotes safety in HCW interaction with EMR systems.

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