MEDINFO 2010
C. Safran et al. (Eds.)
IOS Press, 2010

doi:10.3233/978-1-60750-588-4-719

The nature of unintended effects of health information systems concerning patient safety: A systematic review with thematic synthesis

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Abstract

In order to understand the nature and causes through which Health Information Systems (HIS) can affect patient safety negatively, a systematic review with thematic synthesis of the qualitative studies was performed. 26 papers met our criteria and were included into content analysis. 40 error contributing factors in working with HIS were recognized. Upon which, 4 main categories of contributing factors were defined. Analysis of the semantic relation between contributing reasons and common types of errors in healthcare practice revealed 6 mechanisms that can function as secondary contributing reasons. Results of this study can support care providers, system designers, and system implementers to avoid unintended negative effects for patient safety.

Keywords:

Health Information System, Patient safety, Medical Errors

Introduction

Health Information System (HIS) is strongly recommended for improving patient care quality [1]. Evidence concerning the effect of these systems on patient safety is very important. After many years of applying IT systems in healthcare services and despite many advances in the development of safe technology, there are still growing concern about the impact of these systems on patient safety [2]. Results from various studies in this area show how HIS can cause or contribute to medical errors. These studies, however, have mainly reported upon specific HIS and/or specific settings, making it difficult to generalize their findings. In order to learn more general lessons, there is a need to classify reasons for the unintended side effects of HIS and their related mechanisms. Such an understanding can benefit patient safety and increase positive impact of IT applications in healthcare. Thus the critical question here is: How can HIS cause or contribute to error producing conditions in inpatient settings? In this study, factors behind the unintended negative effects of HIS were presented and classified in order to support care providers, system designers, and system implementers and to provide them a better understanding of error mechanisms and consequences in healthcare practices.

Methods

We performed a systematic literature review to answer the research question. PubMed, EMBase, and Cocharan Library were searched for the relevant literature 1995 to September 2009. To select the relevant literature, the terms "patient safety", "medical error" or "medication error" were electronically searched in abstracts and titles of the literature. These terms were in turn combined with: information technology, information and communication technology, computerized provider order entry, computerized physician order entry, electronic patient record, electronic medical record, radiology reporting system, and laboratory reporting system.

Primary search refinement

The search hit 911 items. The result of the search was refined by manually examining the titles and the abstracts of the selected papers at the same time. The items that were related to patient safety concerns and the possible role of HIS in their creation were primarily selected. The literature that could not be judged based on their title and abstract, were examined by their full text. More refinement of selected literature was performed considering the research question. Trying to answer the "How" question, we needed to use in-depth qualitative studies for our review. The process of search refinement is presented in Figure 1; and the important primary exclusion and inclusion criteria provided in Tables 1 and 2.

Secondary search refinement: assessing quality of qualitative studies

There is yet much debate on whether or not to apply qualitative rigor to assess the quality of qualitative studies. In this review, however, we took the view that the quality of qualitative researches should be assessed to avoid drawing unreliable conclusions. In the literature, different sets of criteria have been proposed as rigour of qualitative studies. We developed our criteria by combining the commonly used

set of qualitative research criteria [3-6] with those which have commonly been considered in evaluating quality of IT evaluation studies [7]. In this study, qualitative literature was included if the authors could answer all of the presented questions in Table 3 (the secondary inclusion criteria) with *yes*. More literature was included by examining the reference lists of the literature resulted from the secondary search refinement.

Table 1- Important primary exclusion criteria

- Related to dental care
- Non-English papers
- Reviews (point of views), commentaries
- Conference proceedings Telemedicine or Telehealth related publications
- Papers related to ethical and legal issue on using IT for improving patient safety
- Papers without abstracts, except one case which was included into our study (they were either reports, point of views, news, editorials, or interviews).
- Related to primary care and outpatient setting.
- Systematic reviews which were not addressing related issue to our research question (in case the subject was relevant their reference list were searched to include appropriate studies)
- Simulation studies
- Merely quantitative researches were excluded on the ground that qualitative researches are more appropriate to understand a phenomenon in depth and to answer our "How" question.

Table 2- Important primary inclusion criteria

Original papers reporting empirical researches in inpatient setting were included if:

- They had qualitative research methodologies[1].
- Studies with mixed qualitative and quantitative method.
- Studies on voluntarily error reporting by the system users
- Case reports and case studies were included if they presented enough information about the system being studied and the error happened in using the system.

Data analysis and thematic synthesis

Campbell *et al.* [9] extracted what they called the 'key concepts' from the qualitative studies they found about patients' experiences of diabetes and diabetes care. In a similar attempt to a systematic review of qualitative studies, Thomas et al.[10] extracted all result sections of the included papers into qualitative data analyses software and analyzed the data based on an already prepared scheme of coding. In this study, we extracted the concepts from the included studies' findings that were reported about the direct, indirect, or potential role of HIT on medical errors. Following Thomas et al.'s method, we then assigned the extracted concepts into Atlas-ti 5.5.9 software for further qualitative data analysis. In case it was necessary, we used more information of the included literature to clarify the context of different pieces of extracted information.

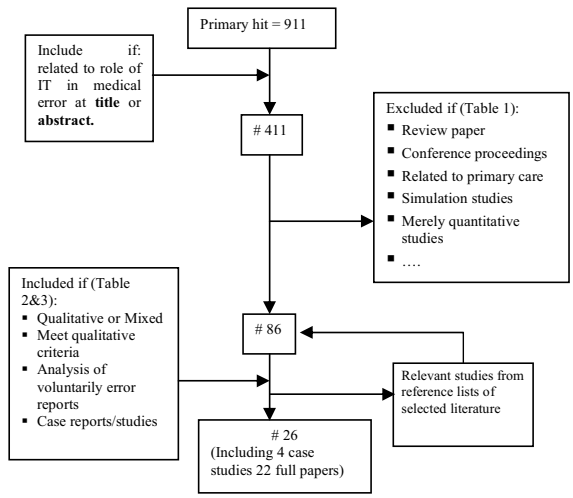

Figure 1- The search refinement process.

Table 3- Secondary inclusion criteria

1. Is there explicit theoretical framework and/or literature review?
2. Are aims and objectives clear?
3. Is the context of study clearly described (e.g., organizational setting, the evaluated system's detail and other systems in use)?
4. Is the study sample (e.g., system users) and how it recruited clearly described?
5. Is data collection method clear?
6. Is it possible to identify study findings from those of the other studies' in the paper?
7. Is the data analyses method clearly described?
8. Are attempts made to establish the reliability or validity of data analysis (e.g., reflexivity, triangulation, member checking, saturation in the field, and an audit trail)?
9. Are sufficient original data included to mediate between evidence and interpretation?

The extracted texts were coded for two types of contributing *reasons* (primary and secondary) of medical errors. More than 150 codes were created for the primary contributing reasons. In the process of thematic synthesis, the primary contributing reasons were reviewed frequently until 40 contributing *factors* (denoting the categories of similar primary contributing reasons that could be collected under specific causal themes) and 4 contributing *categories* (denoting the categories of family codes that could be organized under major causal

[1] Qualitative study was defined based on Strauss and Corbin [8] as "any kind of research that produces findings not arrived at by means of statistical procedures or other means of quantification".

themes of contributing factors) were created. The data was also coded with respect to identifying reported secondary contributing reasons (i.e., *mechanisms* through which primary contributing reasons were reported to produce error in healthcare practice). More contributing mechanisms were recognized by analyzing the semantic relation between the contributing factors and the common types of error in healthcare practice (i.e., mistakes, slips, and latent errors). In this study, we did not investigate the frequency and severity of the errors.

Results

Four case studies and 22 qualitative or mixed method studies were analyzed [11-36]. Four major categories were recognized out of 40 contributing factors: workflow problems, communication problems, technical problems, and user-related problems. Some of the contributing factors were reported to produce error directly (direct mechanism of error). The majority of the contributing factors however worked through *contributing mechanisms*. Figure 2 represents the semantic relation between the contributing factors at different levels with common medical errors.

Contributing categories

Workflow Problems

Working with HIS could hamper or block the normal flow of care work and as a result caused error in healthcare practice. Such workflow problems in working with HIS were reported due to increasing workload of care providers [11, 12, 20, 21, 25, 29-31, 35], or slowing down time intensive care work [11, 20, 21, 23, 25, 26, 28, 29, 31]. The use of information systems was reported to change inappropriately the structure of healthcare work and/or to increase the steps required to fulfill a healthcare task inappropriately [20, 21, 25, 35]. Many studies reported on HIS applications' failure to support intermediary tasks and shared responsibilities between care providers [16, 20, 25, 35]. Moreover, HIS reportedly failed to support non-routine and complex care processes [21, 31]; or it supported only a part of a care process and as a result created coordination problem between the automated part and paper-based part of the process [13, 25, 28, 29, 31, 34]. The workflow was also disrupted whenever a system forced its users to perform unnecessary extra-checks on one single part of a care process [11, 31, 32]. Extending the functionality of the software designed for one healthcare professional group (e.g., pharmacists) in order to support another group of professionals (e.g., physicians) also caused workflow problems [25, 35]. In the literature, many workflow problems were reported because of mismatches between the components of a process designed into HIS and the component of the process in the real care practice. Such mismatches were reported between HIS and its users in the way a care time [11, 20, 21, 26, 28, 35], a care unit [20], and a care process sequence [12, 25, 26] were defined. In addition a problem was reported when a system was not updated with new changes in healthcare practice [21]. Many recent studies have also reported the role of unsafe compensating strategies being adopted by care providers (i.e., workarounds) in order to improve problematic workflow as potential contributing factors for medical error [16, 17, 21, 25, 27-29, 31, 36].

Communication problems

HIS can contribute to or cause error by generating problems in the process of communication and information exchange between care providers. Working with information systems was reported to interfere with the communication between care providers [12, 18, 25, 28, 29, 35], or between the care providers and the patients [26, 35]. Information systems could also produce problems in the process of information mediation due to, for example, lack of feedback mechanisms between communicating care providers [12, 28, 29, 31, 34]. In addition, communication problems occurred in cases where HIS restricted appropriate registration of patient information, for example because of an insufficient /inflexible coding scheme [17, 21, 34]. Problematic information presentation was frequently reported as an important error contributing reason in the literature. Problems of this kind were reported due to fragmented presentation of data over different screens [20, 30] or over different patient care information systems [28-30], due to presenting too much information for systems users [28, 29], and because of problems in finding and retrieving already stored information [21, 29]. Moreover, interoperability problem between care providers as well as data loss were reported to happen in situations where care providers had to work with electronic and paper-based systems at the same time [28, 29, 33, 34]. Likewise, communication problems were reported in case patient information was not updated in information systems [17, 29, 35].

Technical Problems

Many studies have reported technical shortcomings with HIS that could directly or indirectly lead to error in healthcare practice. These problems were frequently reported to be in the form of a software glitch [13, 14, 18, 33] or due to applying outdated hardware [12, 33]. Problems in the design of user interface were also frequently reported in the literature. They were reported to be either in the form of inappropriate screen layout, forms, fonts, and colors [11, 18, 20, 24, 31], or inflexible data entry options [20, 21, 23, 35], or look alike on-screen forms [18]. Such design flaws could for example facilitate juxtaposition errors. Likewise, design problems such as inappropriate/insufficient order set [18, 20, 23], using inappropriate terminology in the system [18], unclear log in/off processes [20, 35], and unspecific alarms [21, 31] were also among the frequently reported error facilitating technical problems. Problematic ergonomics of HIS was reported as a contributing factor to erroneous practice [11, 21, 35] as well. Shortage of technical support in working with HIS, for example in case of networking problems or problems with system accessibility [21, 35], or when the system is down or has crashed [20] were of commonly recognized error contributing technical shortcomings in the literature. Moreover, working with nonintegrated or partially integrated information systems were reported to produce medical error [17, 19, 20, 30].

User-related problems

Some of the error contributing reasons were related to the way users worked with HIS and are hence called user-related

problems here. These problems were frequently reported to occur if users were not trained and educated enough with respect to the proper way of working with IT applications [12, 18, 21, 30, 31]. Another frequently reported problem of this kind was recognized to be system entry mistakes by users [11, 13, 14, 17, 20, 24, 33]. Users' cognitive ability to handle complex care processes was reported to be reduced or hampered if for any reason they developed negative emotions towards the IT systems [12, 21, 30-32]; or because they developed over-dependence to HIS [12, 21]; or because their social relationship with their colleagues and/or patients was intruded by HIS [11, 26, 31]. Users' role in error producing conditions dominated whenever they had to work with information systems in an interruption-driven and/or hectic environment [15, 22, 28]; or they had to work with paper-based and electronic systems at the same time [20, 29, 33]. User-related problems also reportedly took place if they did not comply with policy and procedure in working with HIS [13, 21, 26].

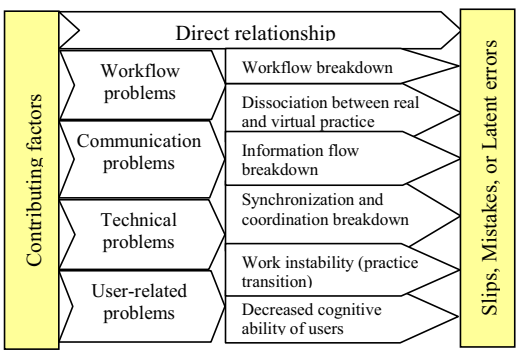

Figure 2- Semantic relation of medical errors with error producing mechanisms. Note that there is no one-to-one relation between the primary and secondary contributing factors.

Contributing mechanisms

Six error contributing mechanisms were recognized upon the contributing categories. The first mechanism, *workflow break down,* will be triggered if the construct of healthcare work is broken down as the result of applying HIS. The second mechanism works whenever *dissociation between real and virtual practice* happens. There should be a one-to-one connection between the components and stages of a care process designed into an information system (virtual practice) and the components and stages in real practice. The virtual-real connection is dissociated if for example patient information is not updated in the system or a wrong digital ID is allocated to a patient. The third mechanism will function if by using HIS *information flow is broken down* and the right information is not delivered to the right care providers at the right time and in the right place. The fourth mechanism will be initiated in case using HIS *hampers coordination and synchronization* between healthcare providers throughout the healthcare work. The fifth mechanism will be instigated if working with HIS *decreases the cognitive ability* of the care providers to cope with healthcare situations (e.g., due to increasing cognitive load). The sixth mechanism will work in case a care practice has developed a fragile and context specific configuration (*work instability*) as a result of interaction between a system and its users. In such a condition any unexpected change in practice can lead to error.

Discussion

The overview provided in this paper can benefit safe system design, implementation and use. The contributing factors and mechanisms are not specific for one system or one implementation site and hence important. More research however is required to point out where and how specific hands-on should be applied to decrease the unintended errors.

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