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Using Publicly Available Recall and Safety Alert Reports for Learning from Technology-Induced Error

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Abstract

Information technologies have the potential to increase the safety of healthcare and advance safety science. However, it is now well known that health information systems may also inadvertently introduce new forms of error known as technology-induced error. Such errors may be difficult to detect as they may only appear under conditions of system use in real healthcare settings. In this paper, the authors explore the use and assessment of recall and safety alerts for both identifying and learning from technology-induced error. Publically available safety and recall reports from Canada were analyzed to identify opportunities to improve organizational learning from technology-induced errors. Although a range of error types were identified, it was found that none of the reports provided detailed information about the underlying technical circumstances that led to the need for a recall. Implications for future reporting systems to support learning from technology-induced error are discussed.

Keywords:

Safety, technology induced error, safety science

Introduction

The role of health technologies in patient safety remains an important and critical area of study for biomedical and health informatics researchers. There is substantial documented evidence that technologies can contribute to patient safety as well as detract from it [1-3]. With the introduction of each new technology to the healthcare marketplace we can also inadvertently introduce new types of errors (i.e. technology-induced errors) [4-6]. Both qualitative and quantitative data about technology-induced errors has been collected by safety researchers and healthcare organizations with a focus on safety [1-6]. Qualitative error data comes from interviews with key informants, clinical simulation studies, real-world observational and usability studies [7]. Quantitative error data has come from surveys and secondary analysis of incident reports submitted to national safety organizations [4, 6-9]. This research has been fundamental to the growth of Safety Science as a field of study in biomedical and health informatics. Safety Science in health informatics focuses on the quality and safety of health technologies used by consumers and health professionals to support healthcare.

Over the past two decades health professionals and individuals representing healthcare organizations have completed and submitted incident reports to local and national agencies [4, 6-9]. Researchers such as Magrabi [9] and Palojoki [4] have successfully analyzed these reports and identified the presence of technology-induced errors. However, there are other types of reports that could be of value in identifying and understanding the underlying reasons for the occurrence of technology-induced errors. In this research we explore the use of new sources of quantitative data about the quality and safety of technologies used in healthcare – i.e. the use and evaluation of publically available recall and safety alert reports [10] as a form of safety learning.

Research Objectives

The objectives of this research are to explore:

1. the feasibility of analyzing safety recalls and alerts for identifying technology-induced errors in healthcare.
2. the effectiveness of safety recalls and alerts from a health technology and quality perspective in communicating the underlying reasons for a safety issue.
3. the ability of the safety and recall reports to communicate information about how we might improve the quality and safety of technologies in Canada overall.

Background

Technology-induced errors emerged as an important safety science issue in biomedical and health informatics in 2005 with the publication of a number of papers focusing on this area of concern by researchers [5, 11-13]. Technology-induced errors "arise from: a) the design and development of technology, b) the implementation and customization of a technology, and c) the interactions between the operation of a technology and the new work processes that arise from a technology's use" ([14] p 154). Technology-induced errors may also arise in the exchange of information between two or more technologies [13]. Advances in safety science in health informatics involving the study of technology-induced errors has included the development of classification and analytic systems by Magrabi [9], Palojoki [4], Marcilly [7] and others [8-12]. The researchers have developed classification systems from incident reports found in databases, and have developed novel analytic approaches to better understand incident reports and to inform evidence-based system design [4, 8-12]. This has involved the development of methods for collecting data about technology-induced errors in an effort to improve system quality and safety. The conceptualization of new approaches and extension of safety models and frameworks from other disciplines has led to the use of models and frameworks to reason about software and technology safety for health. This research has also included a focus on determining the underlying reasons and contributing factors that lead to a technology-induced error [15-17]. More recently, we have also seen a shift towards understanding how health professionals conceptualize safety when using health

technologies [16,17]. Here, researchers have developed validated measurement tools that can be used to help understand health professional knowledge and application of safety practices in settings where healthcare is highly digitized such as intensive care units and emergency departments [15-18]. This research has made considerable advances to the field of safety science in health informatics.

Safety Science and the Learning Healthcare Systems

Over the past 20 years we have seen the safety research literature emerge and pivot towards identifying, describing and classifying technology-errors. After this initial burst of research activity, researchers focused on identifying solutions to industry recognized technology safety concerns [1-18]. Such research is critical to creating Learning Healthcare Systems (LHSs). LHSs focus on improving systems which include digital structures that affect organizational configurations, activities and outcomes (see Figure 1) [19].

Figure 1 – Learning Healthcare Systems in a Digitized Healthcare Setting

These continual improvements may take the form of radical changes and/or incremental improvements to digital structures and processes that support health professional work and patient health. The pressures to make these improvements have increased with the digitization of healthcare in response to the current COVID-19 pandemic. Technologies used in the process of healthcare have also come under these pressures and there has emerged a new need to understand how technology can be incrementally and radically improved to improve healthcare outcomes. To do this effectively there is a need to examine data that points to needed or necessary improvements and to understand the underlying causes of poor or unsafe healthcare performance [19]. As outlined earlier, incident reports, simulations and naturalistic observation have all contributed to technological improvements, where health technology safety is concerned [4, 6-9]. Yet, more research is needed to improve the safety of systems to improve their quality. Publically available data found in Safety Recall and Alert Information systems may provide additional knowledge about how we can improve health technologies. Such systems provide information about the type of hazard that is present and when the hazard emerges. More importantly they may provide insights into the types of solutions that have been developed to solve each type of safety issue. Understanding safety issues and developing solutions to these problems supports the development of LHSs [20].

Methods

In order to explore the feasibility, effectiveness and ability of recall and safety reports to support learning about technology-induced errors, we first identified a database of country level publicly available reports (see [20] https://healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php). The publicly available recall and safety alerts cover four areas: (1) consumer products, (2) vehicles, (3) food and (4) health products. To focus our search on health technologies, we conducted an advanced search focused on "health products", selecting for "medical devices" (i.e. software is classified as a medical device by Health Canada).

The researchers searched the recall and safety report database using the following search terms: "health products", "software" and "all types" of reports (i.e. advisory and recall reports). Following this, the researchers limited the search of the database to 1 year of recall and safety report data. The one year extraction period is consistent with prior published research [4, 6-9], where there has been an analysis of publicly available technology-induced error and/or medical device error incident reports.

Safety and recall reports were extracted from January 1 to December 31, 2020. The reports returned the following categories of information:

1. Start date
2. Posting date
3. Type of communication
4. Audience for the communication
5. Hazard classification
6. Affected products
7. Reason for the communication

The "Start date" refers to the day the recall or alert was enacted. The "Posting date" is the date the report was posted to the website. The type of communication is a "recall and alert". The audience for the communications included: (1) the general public, (2) healthcare professionals, and (3) general and healthcare professionals. The hazard classification for medical devices in Canada ranged from I to III (see Table 1 for Overview of Hazard Types). The definitions for each of the hazard classifications can be found in the below table. "Affected products" refers to the name of the product(s) that are included in the recall or alert. The "Reason for the Communication" provides details as to the product issue [21].

Table 1 – Overview of Hazard Types

Hazard Classification Type	Definition
I	"Probability that the use of (or exposure to) a recalled product will cause serious adverse health consequences or death."
II	"Use of, or exposure to, a recalled product may cause temporary adverse health consequences, or where the probability of serious adverse health consequences is remote."
III	"Where the use of (or exposure to) a recalled product is not likely to cause any adverse health consequences." [20-21]

The returned recall and safety alerts were downloaded and read by two researchers. Reports were included if it described an error. Reports were excluded if there was:

1. Not enough information to code the Reason.
2. Focused on hardware.
3. Focused on hardware packaging.
4. Involved a health professional modifying a device.
5. Did not provide sufficient detail to code for the type of error.

Taguette®, an open source qualitative research tool [22], was used to code the data. The recall and safety alerts were imported into the tool and the qualitative data in the "Reason for Communication" section was qualitatively coded using a direct coding approach (as outlined in Shannon and Hsieh) [24].

Each report was coded using concepts (and their associated definitions) from the software development and testing literature. The granularity of coded data was determined by the unit of analysis which included words, phrases, sentences and paragraphs. The data were coded for the smallest information unit that could be understood as a concept from the software development and testing literature and represented as a concept [24]. As each new unit of analysis was encountered, the segment was reviewed in the context of the codes from the software development and testing literature. Codes were assigned after each new segment or unit of data were read. If the new data segment was in keeping with concepts (and their associated definitions) from prior coded data or the published literature, the new segment was coded with that concept. If a new code emerged, then the segment was read, a new code and definition for that code was assigned. This was done until no new concepts emerged [24].

Results

Eighty six recall and safety alerts were returned. Nineteen reports were excluded and 67 reports were included and qualitatively coded. Nineteen of the remaining 67 reports identified one or more reasons for the alert or recall. Of the reports that identified software safety issues, 11 stated the safety issue was caused by software bugs or defects, 3 were caused by software updates and the remainder by varying other causes. Overall, there were many varied reports.

Several types of errors were identified through qualitative analysis of the reports. They included wrong patient errors, the rescanning of patients (or retesting of a patient), treatment delays, display errors, issues associated with system reliability, lost medication dose, notification failures, defaults or configuration issues, missing data or loss of information and issues associated with insufficient training for a health professional to undertake a task (see Table 2 – Types of Errors).

Table 2 – Types of Errors

Code	Frequency
Wrong patient	3
Rescanned patient	1
Diagnosis	
Misdiagnosis (led to a medical intervention)	1
Delayed diagnosis	1
Treatment Delays	
Time delays in image acquisition	1
Failure to start radiation treatment	2
Display Errors	
Incorrect image display	1
Cropping of images	1
Loss of images	1
Screen turns grey	1
Display freezing	2
Finding (output data) is obscured by error message	1
System Reliability	
Poor system stability	1
Poor system performance	1
System aborts	2
Lost Medication Doses	
Lost dose	1
Errors in custom concentration dose	1
Repeats medication administration (infusion)	1
Software calculations for threshold not correct	1
Notification Failures	
Alarms and alerts not passed on to health professional	2
Fails to generate error message after 100,000 samples	1
Defaults and Configurations	
Updates configurations incorrectly (reverts to system defaults)	1
Missing Data or Loss of Information	
Missing samples	1
No way to collect audio samples	1
Failed to anonymize patient name	2
Archives of results	1
Training	
No instructions to calibrate device	1

Little to no information was provided about the underlying causes of the errors in the safety alerts and recall information.

If a software programming issue such as a software bug or defect was present, a software interaction effect arising from a system update or an implementation issue such as a lack of instructions for those health professionals to use the technology, little to no information was provided as to the circumstances that lead to that safety issue. The recall and safety reports in some cases reported on issues that could affect patient safety such as a display screen freezing. In other cases the patient outcome that was considered a safety event, was briefly described (e.g. misdiagnosis, patient rescanned).

Discussion

None of the reports provided detailed information about the underlying technological circumstances that lead to the need for a recall or alert. As well, there was insufficient detail to inform software programmers as to how to prevent errors in the future (e.g. additional details might help the reader to understand how the programming error occurred, how the software updates that lead to configuration changes lead to an error). Therefore, it was difficult to understand the root causes, contributing factors and contextual issues that led to the safety recall or alert. As well, there was little information about understanding what lead to the safety recalls or alerts, making learning about technology-induced errors from the safety recalls limited. There is a need to have a more fulsome understanding of how the technology-induced error occurred, how it propagated and the activities and events that lead up to the error (e.g. organizational context, organizational specific configuration and/or implementation approach). Such detailed information would allow for identification of programming design and implementation, technology user interface designs, and implementation configuration strategies and approaches that are associated with higher levels of risk to healthcare organizations for the introduction of errors. Such knowledge could lead to systematized organizational learning and the development of LHSs strategies focused on digital health structures and processes.

Future research could investigate the circumstances that lead to a safety recall or alert to inform technology organizations, designers and implementers to avoid hazards associated with current technology processes. Such knowledge could be integrated into programming, software development and software implementation courses that are part of modern biomedical and health informatics programs.

This research identifies that the analysis of safety recalls and alerts is a useful approach to identifying specific errors associated with recalls. However, there is a need to more fully understand the events and investigations that lead to such recalls and alerts to inform technology design in the healthcare so that technologies are improved both incrementally and radically to prevent future technology-induced errors.

There are several limitations of this research. The research involves a qualitative analysis of safety and recall reports in Canada. Reports from other countries may provide more information about the digital structures and processes that lead to a technology being recalled. Canada has a robust reporting structure and system of investigation for safety alerts and recalls. Other countries may have more robust or less detailed organizational systems for addressing these types of safety issues. This would influence reporting.

Conclusions

In this paper the feasibility of analyzing safety recalls and alerts for identifying technology-induced errors in healthcare is explored. The use of safety recall and alert data is effective in understanding some aspects of technology-induced errors. However, there is a need for safety and recall reports to communicate more detailed information about the errors that arise. More detailed information about the context and factors that lead to the error needs to be provided to create LHSs, where incident reports lead to advances in the quality and safety of systems and safety science in health informatics.

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