Advances in Informatics, Management and Technology in Healthcare
J. Mantas et al. (Eds.)

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doi:10.3233/SHTI220787

Complexity and Health Technology Safety

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Abstract. In many ways health technology safety has improved significantly over the past few decades. Yet, we still have examples of incidents where safety of health technology systems of care have led to possible and actual safety incidents. In this paper we examine the complexity of errors in an increasingly complex and digitized system of care. Although safety incidents are decreasing over time due to improvements in the tools used to support care, they still occur. Simple safety incidents prevailed in the 2005. Today, incident reports suggest complexity has emerged as an important issue that needs to be addressed in order to make further healthcare industry safety gains.

Keywords. Patient safety, health technology, health technology safety, technology-induced error, complexity

1. Introduction

Publically available text based incident reports represent an important opportunity to learn about new and emerging types of safety issues involving software and medical devices. Incident reports may provide insights into the changing nature of health technology safety events (or technology-induced errors) and the factors that contribute to their occurrence [1, 2]. There is a need to understand the technologies and processes that lead to an error(s) so that future errors are prevented [3, 4]. In this paper we explore the nature of technology-induced errors in a modern health technology system from the perspective of complexity as the first step in a process of finding specific safety solutions. The objectives of this research are: (1) to identify the factors that contribute to a technology-induced error, and (2) to explore the nature of technology-induced errors in a modern, health technology system from the perspective of complexity.

2. Literature Review

Safety has emerged as an important issue for designers and developers of health technology systems. The digitization of healthcare systems has placed pressure on health informatics professionals to learn from safety events to improve the technologies they are designing, developing, implementing and maintaining to support patient care. Early research focused on proving that technology-induced errors exist [4]. A number of studies followed that described the phenomena [1-4]. Descriptions of technology-induced errors were translated into usable definitions; for example, some researchers defined technology-induced errors as those errors that have their origins in technology

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designs, the processes used to develop and implement technologies as well as those that allow for the exchange information between technologies used in healthcare [1-5]. An urgent need emerged to develop classification systems to codify and quantify such errors [1,2]. Many of these errors had their origins in user interface features and functions, technology workflows, and interoperability issues [1-6]. Early publications documented how a single technology issue could lead to an error (e.g. the wrong patient receiving a medication). As classification systems were more fully developed and applied in digitized healthcare systems, researchers foreshadowed the rise of potentially complex safety issues [2]. There emerged a need to understand these complex safety problems and to develop fulsome solutions. Methods began to be developed to understand technology-induced errors in an increasingly complex and digitized health system [8].

3. Method

To motivate this research, two years (2019-2020) of incident report data were extracted from the publically available MAUDE FDA database. The database provides data and access to medical device and software incident reports [7]. Incident report submissions from the top electronic health record (EHR) vendors (n=6) were identified (as they represent submissions from vendors that represent more than 90 percent of the EHR market) [9]. The reports were then reviewed by two researchers (EB, AF) and were included for further analysis if they were consistent with the definition of a technology-induced error as defined in [5]. Otherwise, the report was excluded. Once a final set of qualitative reports were identified, using the above described inclusion criteria, they were uploaded for analysis to NVivo12 Plus®. Two of the researchers (EB, AF), qualitatively coded each of the reports using a directed content analysis approach (i.e. using codes derived from the literature on health technology safety) [1-9]. Disagreements in qualitative codes were discussed until a consensus was reached.

4. Results

From 2019 to 2020, 2,900,950 incident reports were submitted to the MAUDE FDA database. 269 incident reports involved EHRs. Two researchers reviewed each of the reports for their fit with the definition of a technology-induced error [5]. Those reports that fit the definition were included, and the reports that did not fit the definition were excluded. Twenty eight reports remained for further analysis. It was found that coded reports revealed a great deal complexity in terms of the factors that contribute to a potential or actual safety issue. All of the reports had a minimum of two factors that contributed to the issue. Most of the reports had three to five factors that contributed to a safety issue. Eleven of the reports (40%) had five factors that contributed to an error. The reports suggest that the complexity associated with health technology safety issues involves multiple contributing factors (see Figure 1).

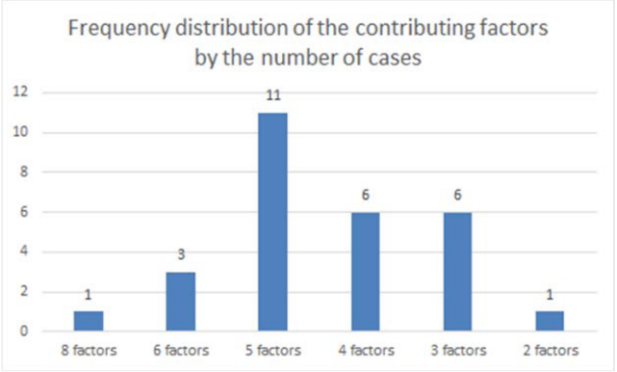

Figure 1: Frequency Distribution of the Contributing Factors by Number of Cases

Incident reports point to complexity being an important aspect of error. We sought to reason about technology system complexity by modelling an incident using Reason's Swiss Cheese Model [11], which has inspired our current line of work. Using this model, the errors' trajectory is modeled by viewing the system as failing, when there are "holes" that line up within the overall system's layers of defense, leading to the propagation of an error. Multiple contributing factors need to align for a user to experience an error. As noted above, in a number of the reports up to five factors contributed to a safety issue involving technology. As an example, Figure 2 represents our modelling of one such report using the Reason's Swiss Cheese Model [11]. In this example, a number of factors contributed to a possible incorrect opioid drug order. Software, databases, decision support systems that provide alerts (which are triggered by users'), socio-workflow issues (i.e. alerts) and data entry issues (i.e. such as incomplete information) were present. Such research reveals the numerous factors that need to be considered, when dealing with technology-induced errors. Future investigations may involve individuals, multiple organizations that may need to be considered in order to fully understand how systems were unable to prevent an error from propagating.

Figure 2: Example of a Complex Incident Modelled using the Swiss Cheese approach

5. Discussion and Conclusions

In our analysis of MAUDE FDA reports, the complexity of safety events involving technology-induced errors was found to typically involve multiple contributing factors. Early research reported on specific issues (e.g. orders being discontinued or lost, software reverting to a default, display visibility issues) leading to an error [1-6] Health technologies have become more complex and interconnected. It is expected that the complexity of errors will also increase. We found this to be the case in our research, when we considered our findings in the context of publications from ten or more years ago. The MAUDE FDA data has been analyzed by several researchers [e.g. 1]. Even so, there are several limitations associated with its use. The FDA states that reports submitted to MAUDE may be incomplete, inaccurate and/or biased. As well, the FDA identifies that submitted reports may be unverified and may not provide sufficient information about the event [7]. Future research will need to consider the impact of improving health technology development processes and new technologies upon technology error rates as well as studying how errors propagate and manifest across different technologies, digital ecosystems and digital organizational structures.

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