An analysis of health information technology-related adverse events: Technology-induced errors and vendor reported solutions

by

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BHSc, University of Ontario Institute of Technology, 2014

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Abstract

Health information technology has been widely accepted as having the potential to decrease the prevalence of adverse events and improve workflows and communication between healthcare workers. However, the emergence of health technologies has introduced a new type of medical error. Technology-induced errors are a type of medical error that can result from the use of health information technology in all stages of the health information systems life cycle. The purpose of this study is to identify what types of technology-induced errors are present in the key health information technology vendors in the United States, determine if there are any similarities and differences in technology-induced errors present among the key health information technology vendors in the United States, and determine what methods are utilized, if any, by the key vendors of health information technologies to address and/or resolve reported technology-induced errors. This study found that the most commonly reported technology-induced errors are those related to unexpected system behaviours, either through their direct use or through the communication between systems. It was also found that there is a large difference in the number of adverse events being reported by the key health information technology vendors. Just three vendors represent 85% of the adverse events included in this study. Finally, this study found that there are vendors who are posting responses to reported technology-induced errors and these vendors are most commonly following up with software updates and notifications of safety incidents. This study highlights the importance of analyzing adverse event reports in order to understand the types of technology-induced errors that are present in health information technology.

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Chapter 1: Introduction

1.1 Introduction

As the level of complexity involved in healthcare increases, so does the demand for more suitable health information technologies. Health information technology (HIT) has the potential to improve the efficiency and effectiveness of healthcare delivery, while reducing associated costs (Salzberg et al., 2012). HIT is defined as "hardware or software that is used to electronically create, maintain, analyze, store, receive, or otherwise aid in the diagnosis, cure, mitigation, treatment, or prevention of disease" (Magrabi, Ong, Runciman & Coiera, 2012). Healthcare is an information-intensive industry, so the use of HIT can help facilitate care delivery by allowing for the digitization of health information to electronically track patient information (Snowdon, Shell, Leitch, Ont & Park, 2011). A common example of HIT is the electronic health record (EHR). EHRs were originally developed for the collection, storage and easy retrieval of health information that would replace traditional paper-based medical records. Modern EHRs have more potential than just completing simple transactions related to information storage as paper-based records have been used for. EHRs can deliver clinical decision support that is becoming an expectation of high-quality patient care and includes tools that can be utilized to help with the reduction of medical errors. The number of vendors that have developed EHRs has increased substantially over the past 30 years from approximately 60 in the early 1980s to over 1000 in 2013 (Salyer, 2014). This substantial growth has since slowed, with approximately 1,100 vendors in 2016 due to a number of acquisitions and mergers between companies (Coustasse, Andresen, Schussler, Sowards & Kimble, 2018). The EHR began simply as a tool for the

collection and storage of health information and as an alternative to the traditional paper record. It has since evolved into a tool that is becoming essential to improving the quality of care and increasing patient safety by reducing the amount of medical errors (Salyer, 2014). Studies have shown that there are many benefits associated with the adoption of HIT. When designed and utilized correctly, these technologies have the potential to increase patient safety, improve workflow and communication and improve upon the quality of care delivered (Salyer, 2014). However, there has also been considerable research showing the potential negative consequences of HIT use when there has not been enough thought involved in the design, development, programming, testing, implementation and maintenance of the technology. While there is a potential to eliminate many medical errors, the introduction of any new technology also creates potential for new types of medical errors to arise (Borycki & Kushniruk, 2008).

'Technology-induced error' is a term that was first used only a short time ago as awareness of this new type of error only began to emerge in the early 2000s (Borycki, 2013). As there are no standardized terms for these type of errors, there have been many variations used such as 'unintended consequences' (Harrison, Koppel & Bar-Lev, 2007; Ash, Berg & Coiera, 2004) and 'e-iatrogenesis' (Palmieri, Peterson & Ford, 2007). To maintain clarity, the term technology-induced error will be used in this thesis to refer to these types of medical error. A medical error is defined as "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim" (National Research Council, 2000). Technology-induced errors are a subset of medical errors and are defined as errors that can "arise from: (a) the design and development of technology, (b) the implementation and customization of a technology, (c) the

interactions between the operation of the new technology and the new work processes that arise from a technology's use" (Borycki & Kushniruk, 2008), and d) the transfer of data from one system to another (Kushniruk, Surich & Borycki, 2012). The possibility for these technology-induced errors arising is present at every stage in a health information systems life cycle, from development to implementation. The potential for these errors rises as technology is being increasingly implemented and used in health care and information systems are constantly changing (Borycki & Kushniruk, 2008). Technology is seen as both an effective way of reducing medical errors and as a factor that leads to adverse events (Balka, Doyle-Waters, Lecznarowicz & Fitzgerald, 2007). Although there has already been a significant amount of research surrounding the emergence of this new type of medical error, it is still unclear how HIT can be fully improved to ensure the safety of patients.

1.2 Technology-Induced Errors

Since the publication of the Institute of Medicine's report *To Err is Human*, there has been increased focus on medical errors and the improvement of patient safety (Balka, et al., 2007). It was found that medical errors are a leading cause of death and injury in healthcare (National Research Council, 2000) and in the United States, the cost of medical errors is projected to be approximately $17 billion per year (Salyer, 2014). It is estimated that in the United States, medical error is the third leading cause of death following heart disease and cancer (Makary & Daniel, 2016). The desire to utilize technology to support patient safety initiatives began with the report *To Err is Human* published by the Institute of Medicine (National Research Council, 2000). When HIT is developed and utilized appropriately within a health care organization, it has the potential

to increase patient safety (Salyer, 2014), yet when there are system design flaws and there is a lack of fit between a technology and health professionals work, technology-induced errors may arise (Borycki & Kushniruk, 2008).

1.3 Design and Development

During the design and development of HIT, most errors are associated with either the requirements specification, design or programming stages of the systems development lifecycle process. Inadequate requirements specification has been shown to contribute to the most amount of errors. It is often the result of a difference between the expectations of users and organizations and the overall functionality of the technology in a real clinical setting. This can lead to a technology that does not satisfy the user's needs, either by providing too little or too much functionality. Another potential source of technology-induced errors is inadequate design. This could result from developers not adequately planning for how the system components are integrated (Borycki & Kushniruk, 2008). For example, in a study conducted by Spencer, Leininger, Daniels, Granko and Coeytaux (2005), there was a dramatic increase in errors that involved pharmacy order processing after a computerized prescriber-order-entry (CPOE) system was introduced. There was no direct electronic communication between the CPOE and pharmacy system which required the pharmacists to enter medication orders in the CPOE system manually after having already entered the orders in the pharmacy system (Spencer et al., 2005). Had the CPOE been linked to the pharmacy's system, there would likely not have been an increase in errors in pharmacy order processing. The final source of technology-induced error that can occur during design and development is a programming error. Inadequate testing that would reveal potential programming errors

can lead to the occurrence of technology-induced errors with varying levels of severity (Borycki & Kushniruk, 2008).

1.4 Implementation and Customization

There are two sources of technology-induced error that can occur during the implementation process. They are related to inadequate beta testing and customization. Beta testing occurs when HIT is first being tested at its intended organization. This is completed in order to determine if any changes need to be made after the testing is conducted while observing the system operating in a real clinical setting. However, the organization where the beta testing is conducted may not be representative of a variety of settings where the new technology could be implemented or used. Attempting to implement a health information system that does not integrate well with an organizations' already established processes may result in technology-induced errors. The second source of technology-induced error during this phase is customization. An organization may alter the health system for it to become more aligned with their workflows. Dramatic changes in the system or the user's workflows can lead to an increased likelihood of technology-induced errors (Borycki & Kushniruk, 2008).

1.5 Interaction in Processes from Actual Use

The operation of a new HIT can also lead to technology-induced errors. Although the technology can be altered through customization to better fit an organization, the new processes resulting from the introduction of a new system can influence the future use of the system and can lead health professionals' to use workarounds in an effort to improve efficiency (Borycki & Kushniruk, 2008). In a study conducted by Patterson, Cook and Render (2002), a bar code medication administration technology was implemented and

examined for potential errors. It was found that many nurses would type in patient identification numbers rather than scan barcodes as was originally intended. Since the barcodes did not always scan reliably, the nurses found manually entering a patients' identification number to be more efficient (Patterson et al., 2002). Workarounds such as this can increase the likelihood of the occurrence of technology-induced errors.

1.6 Statement of the Problem

The report published by the Institute of Medicine entitled *To Err is Human* (National Research Council, 2000) began the drive to introduce HIT in healthcare in an effort to improve patient safety by reducing the instance of medical errors (Salyer, 2014). However, it is also known that HIT has the potential to introduce new types of medical errors. It has been shown that there are many aspects of patient care that have been significantly improved by the introduction of HIT. However, the overall impact on patient safety is an aspect that still requires more research (Salyer, 2014). The purpose of this thesis is to examine the different types of technology-induced errors across HIT vendors and how these vendors address and resolve technology-induced errors. The specific objectives of this research are to:

- Identify what types of technology-induced errors are present with the key health information technology vendors in the United States
- Determine if there are any similarities and differences in technology-induced errors present among the key health information technology vendors in the United States

- Determine what methods are utilized, if any, by the key vendors of health information technologies to address and/or resolve reported technology-induced errors

1.7 Research Questions

1. What types of technology-induced errors are common among the manufacturers of health information technologies in the United States?
2. Are there any similarities or differences in reported technology-induced errors among the health information technology manufacturers in the United States?
3. How are health information technology manufacturers or vendors in the United States addressing technology-induced errors and what are they reporting as solutions?

1.8 Summary

This research will aim to answer these questions by examining reported technology-induced errors in an American adverse event database. Research surrounding technology-induced errors is very limited, and at present there is no research that examines technology-induced errors as they relate to different HIT vendors. This research will be valuable towards closing the gaps present in technology-induced error research as it relates to technology-induced error reporting. In order to increase the safety of HIT by decreasing the amount of technology-induced errors that occur, it is important to thoroughly examine adverse event reports as they provide valuable insight into the contributing factors and implications for patient safety that are present with technology-induced errors (Magrabi et al., 2012).

Chapter 2: HIT and Technology-Induced Errors

2.1 Technology-Induced Errors

In the Institute of Medicine's report *To Err is Human*, it was estimated that the cost of preventable adverse events in the United States was between $17 and $29 billion and studies have estimated that the annual number of deaths caused by medical errors is between 44,000 and 98,000 (National Research Council, 2000). A more recent article written by Makary and Daniel (2016) suggests that in the United States, medical error is the third leading cause of death and accounts for approximately 250,000 deaths every year. The number of deaths resulting from medical errors totals more than that resulting from motor vehicle accidents, breast cancer and AIDS (National Research Council, 2000). HIT is seen as one of the most important tools for improving patient safety (Chadwick, Fallon, van der Putten & Kirrane, 2012), but there needs to be additional consideration for patient safety when HIT is used (Singh & Sittig, 2015). Research involving HIT has been largely focused on the benefits and successes of HIT implementation and its potential for reducing errors has been well documented (Chadwick et al., 2012). However, the use of HIT can introduce new types of errors that can significantly affect patient safety (Singh & Sittig, 2015) resulting from problems such as disruptions in regular workflow, issues with usability and potentially dangerous workarounds (Meeks et al., 2013). Although there has historically been numerous studies conducted related to patient safety, the study of technology-induced errors has not been widely established until very recently. It was only in the mid-2000s that awareness of these new types of errors began to emerge (Borycki, 2013). However, since then there has been numerous studies demonstrating the importance of researching these errors in

order to discover new strategies for preventing them. Researchers are now developing models and frameworks aimed at determining when and how technology-induced errors are most likely to occur with HIT in order to prevent their occurrence and thereby increase patient safety (Borycki, 2013).

It is often difficult to anticipate the types of errors than can occur since HIT can be integrated with almost every aspect of care delivery. The errors associated with HIT can also be difficult to identify as they can be influenced by both technical and non-technical factors. As a result, HIT is often not included as part of patient safety monitoring (Singh & Sittig, 2015). For many industries, it would be unthinkable that a new product or system would first be tested after its implementation in the real world. However, many HITs are being implemented very quickly with inadequate testing. This creates a situation where it is impossible to fully understand all of the risks associated with implementing the HIT (Graham et al., 2008). Technology-induced errors are often not discovered until after an HIT has been implemented as errors are more difficult to detect prior to implementation with HIT than with other information technologies (Borycki et al., 2016). Technology-induced errors are often not simply software errors, but can arise from interactions of the technology with the processes that arise once the technology has been implemented in a real-world setting (Borycki et al., 2016). As health technologies advance and become pervasive in their use, so does the potential for the occurrence of new errors (Samaranayake, Cheung, Chui & Cheung, 2012). Research on technology-induced errors is becoming increasingly important as the vendors that manufacture HIT begin to expand their products globally. There has been research suggesting that the rates and effects of technology-induced errors vary across different

countries and regions. As a result, studies evaluating the safety of HIT will need to take into account the differences in health care delivery across countries (Borycki, 2013). The study of technology-induced errors is essential in order to identify factors related to HIT that can lead to errors. This will not only benefit organizations that currently use that HIT, but also future organizations who have not yet adopted HIT (Samaranayake et al., 2012).

2.2 Identifying Technology-Induced Errors

The complex nature of HIT has made it difficult to make use of traditionally used software testing methods for detecting errors prior to implementation (Borycki & Kushniruk, 2008). Past research has been focused on the development of methodologies to identify technology-induced errors after the implementation of an HIT (Carvalho, Borycki & Kushniruk, 2009). However, it is becoming increasingly important to conduct adequate testing on new HIT prior to implementation in order to prevent the occurrence of errors. Although it is clear that testing in advance of implementation reduces the likelihood of errors, additional research needs to done to determine what methods are most appropriate for identifying these errors (Borycki & Kushniruk, 2008). The early diagnosis of technology-induced errors is essential to ensure that the occurrence of these errors is reduced. In addition, the cost of fixing a software issue increases dramatically if the issue is discovered in the operations and maintenance phases of the software development lifecycle. The cost of addressing errors prior to a systems' release is also substantially lower than the cost associated with treating patients who were harmed as the result of a technology-induced error (Borycki, 2013). If a potential error is identified through testing, it is possible to alter the technology to eliminate that error (Borycki &

Kushniruk, 2008). Some examples of methods that can be utilized to identify possible technology-induced errors prior to system release are: heuristic evaluation, the eSafety checklist, usability testing and clinical simulations. Methods that are typically used to identify potential errors prior to a technology's implementation can also be used after an error has occurred. Clinical simulation and usability testing are two such methods that can be used in an attempt to reproduce the error in order to gain insight into the events that led to the error (Borycki, 2013).

There are also methods that can be utilized during the design phase of HIT development. Technology-induced errors are often not detected until after implementation and are difficult to detect through traditional software testing methods as they often appear as though they are related to HIT design and do not emerge until the technology is used in a real-world setting. An important step towards reducing the number of technology-induced errors is to employ safe HIT design methods. There is evidence indicating that many technology-induced errors could originate from poor HIT design and insufficient testing prior to its implementation. There is also current research describing how certain HIT design methods can reduce the potential for technology-induced errors. These methods are: user-centered design, participatory design and composable design (Borycki et al., 2016).

2.3 Design and Technology-Induced Errors

The following section will describe three methods of design, user-centered design, participatory design and composable design, and how they can be utilized to reduce the occurrence of technology-induced errors.

2.3.1 User-Centered Design

User-centered design is defined as "(1) an early and continual focus on end users, (2) the empirical evaluation of systems, and (3) application of iterative design processes." This method of design when combined with usability engineering techniques, has been shown to help identify technology-induced errors prior to the systems release. It is a process that recognizes the importance of user involvement throughout the development process and allows the users to influence the design which leads to an overall increase in the usability of the system (De Vito Dabbs et al., 2009). This application of usability testing involves observing users that have been selected as having characteristics similar to real-world users. They will then complete tasks that would be typical of the representative user. This process ensures that the focus is kept on meeting the needs of the users (De Vito Dabbs et al., 2009). The utilization of this method of systems design is much less costly than it would be to discover potential technology-induced errors and rectify them post-release. However, this method can also be used after a system is released in combination with error reporting systems to help gain a better understanding of why the technology-induced errors are occurring and what can be done to prevent them in the future. Current research has shown that there is a strong connection between usability issues and technology-induced errors. When usability engineering methods are used in combination with a user-centered design approach, the occurrence of technology-induced errors can be greatly reduced (Borycki et al., 2016).

2.3.2 Participatory Design

Participatory design is another method that involves users in the design process. Similar to user-centered design, the participatory design process is an iterative process

that involves the user during every stage of design (Clemensen, Larsen, Kyng & Kirkevold, 2007). Participatory design focuses on the involvement of users and key stakeholders so that they are actively participating in design activities. Users participate actively and fully engage in every step of the design process. Mutual learning between the users and developers allows for an increased understanding of the design process for all participants. The users are able to provide the developers with an increased understanding of their specific practices and the developers are able to educate the users on considerations from the technological side of the design process (Robertson & Simonsen, 2012). There are many techniques that can be utilized to achieve participatory design including: interviews, workshops, questionnaires, and simulations. This high level of user involvement can help to ensure that the systems can fully integrate into the current environment of the users. Projects that utilize participatory design achieve much more accuracy in their user requirements (Borycki et al., 2016).

2.3.3 Composable Design

Another approach to ensure systems are designed with users in mind is composable design. In this approach, systems can be re-designed by individuals with no programming experience. In a situation where the occurrence of a technology-induced error is discovered, this approach allows changes to be made very rapidly, reducing the potential for future technology-induced errors. The users may have the ability to customize their experience with the systems including changing the interface so that it is more supportive to their current workflow (Borycki, Kushniruk, Bellwood & Brender, 2012).

2.3.4 Summary

User-centered design, participatory design, and composable design are three methods that heavily involve users and can be utilized to help prevent technology-induced errors that arise from disruptions in a users' workflow. Research has shown that there are greater levels of acceptance among users when they are actively involved in the design process as they will gain an increased understanding of the system being designed which can lead to more effective use of the system by users (Kujala, 2003).

2.4 Methods to Identify Technology-Induced Errors

The following section will provide an overview of current methods to identify technology-induced errors. Methods to identify potential errors before they occur include heuristic evaluation, the eSafety checklist, usability testing and the use of clinical simulations. Two additional methods also discussed in this section, case study and root cause analysis, can be used to evaluate the events leading up to the error and be used to reduce the likelihood of future errors.

2.4.1 Heuristic Evaluation

Heuristic evaluation is a method that involves one or more analysts recording violations of certain principles that are related to human factors by comparing the systems design against a set of heuristics while completing certain tasks (Kushniruk, Borycki, Kuwata, & Ho, 2008). There is very limited research that provides examples of how heuristics can be used to evaluate HIT for potential technology-induced errors (Carvalho et al., 2009). In a study conducted by Carvalho et al. (2009), a set of heuristics that are specific to health information systems were developed and used to evaluate a patient record system. It was found that heuristic evaluation was a valuable method for

identifying the potential for errors during the procurement process (Carvalho et al., 2009).

2.4.2 eSafety Checklist

An eSafety checklist was developed by Dhillon-Chattha, McCorkle and Borycki (2018) in order to assist information technology and clinical informatics professionals with implementing evidence-based safety practices during EHR configuration or optimization. This checklist was developed in response to a gap that was identified in the availability of a centralized resource for eSafety best practices. Following an initial literature search to consolidate current research on eSafety practices, the checklist was created and underwent multiple rounds of end user testing in order to ensure that the tool was user-friendly. The checklist was also reviewed by an expert panel. The final tool is one that has consolidated best practices in eSafety in an easy to use format that can be used to ensure safe configuration of EHR user interfaces (Dhillon-Chattha et al., 2018).

2.4.3 Usability Testing

Usability testing is a method that uses a detailed analysis of a user's interaction with the application (Kushniruk et al., 2008). It involves users completing tasks that are representative of actual use in order to assess usability (Borycki, 2013). The user is typically video recorded and is asked to "think aloud" while completing the tasks allowing for a more detailed analysis of the event. In a study completed by Kushniruk, Triola, Borycki, Stein & Kannry (2005), the researchers utilized a usability testing approach to identify 11 usability problems that added up to 27 total errors. This approach allowed the researchers to determine the most frequently occurring usability problems and to identify what types of errors were able to be detected by the users and which errors

went undetected (Kushniruk et al., 2005). Conducting this type of testing early on can ensure that potential errors are discovered when it is much easier and less costly to correct. This type of testing can also be applied after an HIT has been implemented by investigating error reports. Usability testing can help identify specific details about why an error is occurring and in what situations the error is most likely to arise (Borycki et al., 2016). This feedback is essential for ensuring that these errors do not occur again.

2.4.4 Clinical Simulations

Clinical simulations are related to usability testing but involve users completing representative tasks in simulated realistic environments (Borycki, 2013). They can be conducted in simulation labs as well as in the actual environments where the system will be used (Borycki et al., 2016). They often involve audio and video recordings, as well as screen recordings to monitor how the user completes the tasks. Simulations can be used to identify potential errors prior to the implementation of a new technology as well as assess the potential impact on the user's workflow (Borycki et al., 2009). If a significant change in user workflow results from a new HIT, the technology can be modified so it is more aligned with the users' current workflow or more user training can be planned so that users are aware of the potential impacts which will reduce the potential for technology-induced errors (Borycki et al., 2016).

2.4.5 Case Study

After a technology-induced error has occurred, there are additional methods that can be utilized to determine what may have led to the occurrence of an error and how future errors can be prevented (Borycki, 2013). A case study is one of those methods. Case studies can use a variety of approaches to analyze errors including review of

computer logs, expert reviews of software, and interviews with all individuals who were involved in the event (Borycki, 2013). In a study completed by Horsky, Kuperman and Patel (2005), a case study approach was used to describe the events leading to a medication dosing error. Using this method, the evaluators were able to establish a timeline that detailed the series of events that occurred over three days leading to this error. They used a combination of results from computer order entry logs, cognitive evaluations of ordering screens, and semistructured interviews of clinicians to construct this detailed timeline. From this, they were able to identify possible cognitive errors in medication ordering processes and make specific recommendations to reduce the future likelihood of similar errors (Horsky et al., 2005).

2.4.6 Root Cause Analysis

Root cause analysis (RCA) is another method used to increase the understanding of how a technology-induced error has occurred. Using this method, there is a focus on understanding the entire series of events leading to the error and involves the individual, the HIT and any system level influences that may have contributed to the error. The results of this type of analysis will produce a list of causes and contributing factors that are grouped into categories to allow for the development of strategies to reduce the risk of these errors reoccurring (Borycki et al., 2016).

2.4.7 Summary

Increasingly complex information systems require comprehensive evaluations of technology-induced errors to fully understand the events that led to the error (Horsky et al., 2005). Heuristic evaluation, the eSafety checklist, usability testing, clinical

simulations, case study and root cause analysis are all effective methods to evaluate and understand technology-induced errors and prevent their future occurrence.

2.5 Reporting Technology-Induced Errors

In addition to completing testing to identify technology-induced errors prior to implementation of HIT, it is also important to monitor the occurrence of errors on a larger scale after they have occurred. One way to do this is to utilize adverse event reporting databases. However, there are major obstacles in researching the occurrence of these types of errors as there are low numbers of reported events involving HIT within adverse event databases (Chai, Anthony, Coiera & Magrabi, 2013). For example, in the U.S. Food and Drug Administration's (FDA) Manufacturer and User Facility Device Experience (MAUDE) database only 0.1% of reported medical device incidents were related to HIT (Magrabi et al., 2012). However, as awareness of technology-induced errors increases and when rates of HIT implementation are higher, the rate that HIT-related errors are being reported will also increase. Samaranayake et al. (2012) found that 17.1% of all medication-related incidents reported were related to the use of HIT. Across these studies, it was noted that areas with higher rates of HIT adoption have higher incidents of HIT-related adverse events (Palojoki, Makela, Lehtonen & Saranto, 2016). It is possible that as the use of HIT increases, so will the amount of adverse event reports that are related to technology-induced errors (Borycki, 2013).

2.6 Adverse Event Reporting

Reporting medical errors is an essential process in order to continually improve patient safety. Research has shown that increasing the reporting rates of these errors is an essential step in reducing medical errors (Stow, 2006). Reports that contain information

related to patient safety incidents are very useful as they have the potential to help discover emerging errors and can be used to monitor trends (Magrabi et al., 2012). These reports could also be used to inform healthcare organizations about errors that have been detected in certain products so these organizations can be warned about possible errors in their HIT (Borycki, 2013). Additional research surrounding the error reports at a national level could lead to an increased level of accountability for errors and improve upon the processes for addressing technology-induced errors (Borycki, 2013).

2.6.1 Reporting Limitations

A major limitation to the use of adverse event databases for monitoring and research is the underreporting of medical errors and the quality of reporting (Barg-Walkow, Walsh & Rogers, 2012). As a result of the level of underreporting, adverse event reporting systems cannot be used to examine the frequency of adverse events. However, these systems can provide valuable insight into causes, contributing factors and the consequences associated with not addressing these errors (Magrabi et al., 2012). Another limitation is that voluntary reporting of HIT-related errors often does not include collection of near-misses that could identify significant patient safety issues (Singh & Sittig, 2015). Users may not have an understanding of how technology-induced errors should be identified and classified when completing a report (Barg-Walkow et al., 2012) and may not have an understanding of what qualifies as a technology-induced error (Borycki, 2013). Many healthcare workers often believe that HIT is completely safe and could not lead to patient harm, which may also influence whether a report is made (Borycki, 2013). Reporting systems depend on the quality of submitted reports in order to be effective. Reports should be submitted in a timely manner so reporters can

accurately recall and describe the incident (Hoffmann, Beyer, Rohe, Gensichen & Gerlach, 2008). The subjective nature of incident reports is another limitation to the use of these databases. Potential causes and any factors contributing to the event are reported according to the judgement of the individual submitting the report. There will need to be more focus on encouraging improvement to the overall quality of reports (Hoffmann et al., 2008). One way to do this is to introduce more education aimed at healthcare workers that are using a new technology in order to increase the overall awareness of technology-induced errors and instruct these workers on how, when, and where to report these technology-induced errors (Borycki, 2013). This type of program will be beneficial to increasing the overall safety of HIT.

There also may be nondisclosure clauses included in software license agreements for HIT that discourage users from reporting technology-induced errors. Additionally, hold-harmless clauses, which are also included in many vendor contracts, may lead the users to believe that they are solely liable for errors related to the use of HIT. If the release of information about events involving technology-induced errors are restricted by vendors, then it will not be possible to fully understand how patient safety is affected by these systems. It is not clear whether these types of clauses have been previously used to prevent the reporting of technology-induced errors; however, the fear of subsequent legal actions may be a contributing factor to the underreporting of technology-induced errors (National Research Council, 2012). The opinion of the Institute of Medicine (2012) is that limitations on the release of HIT-related patient safety events do not allow for enough transparency and are contributing to the current gaps in knowledge related to technology-induced errors.

Technology-induced errors are currently being reported in adverse event reporting systems that also contain information about other patient safety incidents not related to HIT. There is currently no standardized approach to collecting data about technology-induced errors from these reporting systems (Borycki et al., 2016). This lack of standardization makes it difficult to study technology-induced errors across reporting systems. There are different classification systems for technology-induced errors and categorizations of these errors also varies greatly. There needs to be more standardization in these categories so that the reports more accurately reflect the incidents (Borycki et al, 2016).

2.6.2 Adverse Event Reporting Systems

There are many adverse event reporting systems being implemented in order to encourage the reporting of medical errors. The main purpose of these systems is to gain an understanding as to why these errors occur and how the health care system can be improved upon in order to prevent further errors from occurring. The prevention of medical errors requires a much deeper understanding as to why they occur. To get this information, there needs to be error reporting that is both honest and accurate. This will not only provide useful information for improving the safety of health care, but will also provide a baseline measurement of the current state of medical errors for which to compare the effectiveness of future processes (Stow, 2006).

The need for increased reporting of adverse events was identified in the Institute of Medicine's (2000) report *To Err is Human*. In a study conducted by de Vries, Ramrattan, Smorenburg, Gouma & Boermeester (2008), it was calculated that the median number of patients who had experienced an adverse event in-hospital was 9.2% and

almost half of all adverse events were considered preventable. It was also found that 7% of these adverse events had a lethal outcome which emphasizes the importance of ensuring the safety of HIT (de Vries et al., 2008). External reporting systems are one method that can help facilitate an increased understanding of how and why errors occur. A mandatory reporting system can introduce more accountability to organizations when it comes to errors. This type of system would ensure a timely response to errors that involved injury or serious illness. Reporting systems can also help to identify potential areas of improvement before serious harm occurs. The goal of an error reporting system is to identify strategies to prevent future errors from occurring (National Research Council, 2000). A voluntary adverse event reporting system is another method for collecting and analyzing medical errors. The perception surrounding adverse events has recently altered from a person approach to a systems approach (de Vries et al., 2008). Instead of placing blame on individuals for their involvement in the event, the systems approach takes human error into account and assumes that systems should act as a safeguard against these potential mistakes (de Vries et al, 2008). Although many events do not result in harm to a patient, it is still very important that they be reported. When these types of events are included, a reporting system could identify particular situations that may be error-prone and allow organizations to study these situations to prevent future errors. These types of errors may never occur with a high enough frequency to be noticed and addressed at an individual organization. An additional benefit with reporting systems is that they can encourage the adoption of standardized definitions related to errors (Terezakis et al., 2013).

An example of an adverse event reporting system was described in a recent study conducted by Palojoki, Makela, Lehtonen and Saranto (2016). Finnish hospitals are all required to maintain a patient safety incident system according to the Finnish Act on Health Care introduced in 2011. The current system for incident reporting contains a combination of structured and free-text fields and allows users to submit reports anonymously. Hospital districts offer training on how to effectively use the tool and hospital units devote resources to ensuring that adverse events are classified according to national guidelines. The data submitted to this system is monitored regularly and reports are frequently shared with hospital staff. In addition, the staff who submit the events receive feedback directly through the incident reporting system (Palojoki et al., 2016). This is a good example of how an adverse event reporting system could be implemented to encourage the reporting of adverse events and support ongoing monitoring and research.

Adverse event reporting systems are a powerful tool in identifying potential risks and improving the quality of patient care. There are multiple ways in which reporting systems can help to prevent these errors. First, individuals can potentially be alerted to newly emerging risks after only a few reports (Leape, 2002). Second, information about new methods to prevent certain errors can be distributed to other organizations. Third, analyses of reported events can lead to a discovery of trends in errors. These analyses can lead to best-practice recommendations that will help all organizations increase overall patient safety. In order to be most effective, reporting systems should be "safe, simple and worthwhile" (Leape, 2002). Reporters should not receive any disciplinary action, reports should be easy to complete and submit and feedback regarding the event

should be provided in a timely manner in a way that is useful for preventing future errors (Leape, 2002).

2.7 HIT Safety Governance

Another consideration when making decisions about improving patient safety is the governance of these improvements. Governance is defined as "the interaction of processes, institutions and traditions that determine how decisions are made on issues of public concern" (Balka et al., 2007). Healthcare is influenced by a variety of organizations including those at the government, institution and consumer levels and their degree of involvement can have a direct impact on each other. For example, if a government were to implement a policy that requires the reporting of all adverse events related to HIT, then this could lead to private organizations developing software to support this policy and lead to institutions changing their practices with regards to error reporting. There are many different influences in the healthcare sector and their involvement and effectiveness with regards to HIT is not fully understood (Balka et al., 2007).

There are a variety of stakeholders involved in the development of HIT such as the manufacturers, vendors, users, public and governments and they all hold some degree of responsibility when it comes to patient safety. Vendors are responsible for making sure that all their products are in compliance with any regulatory requirements. They should also be providing services after the sale of a product by providing training and support to their customers and participating in post-market surveillance which is an important part of ensuring the safety of medical devices. The users of HIT are often the first that become aware of any problems and so the responsibility of reporting those

errors falls on them. However, since there are a variety of stakeholders involved in the implementation of HIT, this should be a shared responsibility (Balka et al., 2007).

2.8 Technology-Induced Error Classification Systems

Magrabi et al. (2012) have created a classification system to categorize technology-induced errors. Errors are first categorized as being either human- or machine-related, then further categorized based on problems at information 'input', 'transfer' or 'output'. For errors that do not fit into those three categories, there are two additional classifications at this level, 'general technical' for general hardware and software issues and 'contributing factors'. In this classification system, more than one category can be chosen if there was more than one problem.

Alemzadeh, Iyer, Kalbarczyk and Raman (2013) conducted a study using the data from the MAUDE database to investigate the causes of computer-related failures in medical devices. The failures were categorized based on: fault class (the defective components that led to device failure), failure mode (the impact of failures on the devices safe functioning), recovery action category (the type of actions the manufacturer took to address the recall), number of recalled devices (the quantity of recalled devices distributed in the market), and device category (the categories and types of recalled devices). They used these five categories to classify actions taken by the manufacturer. The categories are: safety notification, safety instructions, software update, repair, and replace or remove (Alemzadeh et al., 2013).

Myers, Jones and Sittig (2011) have defined a set of sociotechnical dimensions in order to classify HIT-related errors. The eight dimensions are: hardware and software, clinical content, human-computer interface, people, workflow and communication,

organizational policies and procedures, external rules, regulations, and pressures, and systems measurement and monitoring.

The Finnish Technology Induced Error Risk Assessment Tool (FIN-TIERA) classifications for technology-induced error include eight error types, each with three to six associated risk factors (Palojoki et al., 2017). The first error type, 'Incorrect Patient Identification', covers instances where patient identification is missing from EHR screens or printouts or there is a lack of proper documentation outlining the processes or procedures for identifying a patient or verifying their identity. The second error type, 'Extended EHR Unavailability', occurs when some or all of the patient's electronic health records becomes unavailable. The third error type, 'Failure to Heed a Computer-Generated Warning or Alert', occurs when critical information is overlooked because of an overload of other information. The fourth error type, 'System-to-System Interface Errors', is caused by communication failures between different software applications. The fifth error type, 'Failure to Find or Use the Most Recent Patient Data', arises from difficulties in navigating, noticing, understanding or interacting with user interfaces. The sixth error type, 'Translational Challenges in EHR Time Measurement', is the result of computers not translating time measurements in the same way as the users. The seventh error type, 'Incorrect Item Selected from a List of Items', occurs when a user incorrectly selects an item from a dropdown menu that is directly adjacent to the item they meant to select. The eighth and final error type, 'Open, Incomplete or Missing Orders', results from the inability to complete the order process, which includes the ability to sign and submit (Palojoki et al., 2017).

Kushniruk et al. (2005) created a coding scheme to classify issues related to usability in health information systems. This coding scheme consisted of two categories of usability problems: issues related to interface design and issues related to the content of information in a health information system. The interface category includes eight specific problems: data entry, display visibility, navigation, locating, procedure, printing, speed and attention. The content category includes three problems: database, default and training manual.

There are a number of classification systems that have been created specifically for classifying technology-induced errors and there are similarities in codes that exist between these systems. For example, a code for an interfacing error is present in all the previously described classification systems. However, there is currently no standardized method for classifying technology-induced errors which makes it difficult to study these errors (Borycki et al, 2016).

2.9 Summary

One of the recommendations put forth by the Institute of Medicine (2012) is to increase the collection and analysis of adverse events related to health information technology and increase reporting. The analysis of adverse events will provide useful information that could help improve these systems, leading to increased patient safety and a decrease in future adverse events. In other healthcare areas, there is regular reporting of adverse events and routine analyses that are conducted to ensure patient safety. However, adverse event reports and analyses related to HIT are currently very limited. There are reporting systems currently in place, but many are voluntary and/or confidential. Since these reports are often voluntary, it is likely that many adverse events

are not being reported (Myers et al., 2011). In order to make health information systems safer, there needs to be increased reporting of adverse events.

The report published by the Institute of Medicine entitled *To Err is Human* (National Research Council, 2000) began the drive to introduce HIT in healthcare in an effort to improve patient safety by reducing the instance of medical errors (Salyer, 2014). Technology-induced errors are often difficult to detect as they will often only occur within a complex, realistic clinical setting (Borycki, 2013). Research has shown that there are methods of testing HIT prior to their implementation in order to reduce or eliminate the occurrence of technology-induced errors. It has also been shown that there are many aspects of patient care that have been significantly improved by the introduction of HIT. However, it is also known that HIT has the potential to introduce new types of medical errors. Studies investigating the potential sources of technology-induced errors began only recently in the early 2000s (Borycki, 2013), so the overall impact on patient safety is an aspect that still requires more investigation (Salyer, 2014). Research will need to continue in order to refine methods of testing for potential technology-induced errors as well as encourage increased error reporting in order to ensure the safety of HIT.

Chapter 3: Methods

In this study, data extracted from the FDA's MAUDE database was quantitatively and qualitatively analyzed to attempt to: a) identify what types of technology-induced errors are present with the key health information technology vendors in the United States, b) determine if there are any similarities and differences in technology-induced errors present among the key health information technology vendors in the United States, and c) determine what methods are utilized, if any, by the key vendors of health information technologies to address and/or resolve reported technology-induced errors. The following section outlines the methods used to answer the research questions.

3.1 FDA Regulations

Since the mid-1980s, manufacturers have been required to report serious adverse events to the Food and Drug Administration (FDA). In 1990, the Safe Medical Devices Act was passed which requires user facilities to also submit reports related to adverse events that involved a death or serious injury. The FDA defines a user facility as "a hospital, an ambulatory surgical facility, a nursing home, an outpatient treatment facility or an outpatient diagnostic facility" (FDA, 2017). This definition excludes physicians' offices. User facilities are required to submit adverse event reports to the FDA and manufacturer within 10 business days of the event if a death has occurred, and only to the manufacturer if a serious injury has occurred. In this case, a report is only submitted to the FDA if the manufacturer is not known. Requirements for user facilities are only related to the reporting of an adverse event. There is no regulation indicating that a user facility is required to investigate an adverse event to obtain information other than what is

already reasonably known. User facilities are also encouraged, but not required to submit reports on adverse events that did not involve death or serious injury (FDA, 2017).

3.2 FDA Classifications

In the United States, medical devices are classified into 16 groups of medical specialties and into 3 regulatory classes based on their risk level (Balka et al., 2007). Class 1 devices have the lowest level of risk (non-invasive devices), class 2 devices are medium risk (equipment used for diagnostic and treatment purposes) and class 3 devices are high risk (implantable devices and those used for life support) (Balka et al., 2007). What class a device is assigned to will determine its regulatory requirements, which may include special labelling instructions, performance standards and mandatory post-market surveillance (Balka et al., 2007). HIT-related devices are categorized as class 1 devices and have minimal regulatory requirements.

The FDA Center for Devices and Radiological Health (CDRH) created a set of Event Problem Codes in 1996 that were used to classify device problems that were associated with medical devices until July 2009. In 2009, the FDA CDRH updated the Event Problem Codes so that there are more meaningful categories and definitions to reduce ambiguity in coding the problems. There is now a hierarchical structure to the Event Problem Codes (Reed & Kaufman-Rivi, 2010). These problem codes are assigned by the submitter and are required to be included in every adverse event report that is submitted to the MAUDE database. There are files available for download from the MAUDE website that list all of the old problem codes and contain a description of the change that was made to that code. The FDA CDRH has also mapped all the old codes to

the improved product codes within these files. The detailed descriptions of all problem codes and their hierarchies are available for download from the MAUDE website.

3.3 Data

In this study, the MAUDE Database, which is governed by the FDA, was used. This database is publicly available and is currently the most comprehensive source for extracting adverse events in the United States (Yao, Kang, Wang, Zhou & Gong, 2018). The MAUDE database, which contains data related to adverse events occurring in the United States, was chosen due to the lack of availability of Canadian data. The FDA defines a medical device as "any item that is used for the diagnosis, treatment, or prevention of a disease, injury or other condition and is not a drug or biologic" (FDA, 2017). The mandatory and voluntary adverse event reports related to medical devices are stored in the Manufacturer and User Facility Device Experience (MAUDE) database. The data elements that are included in submitted adverse event reports are: patient information (if applicable), a description of the adverse event or product problem, information on the suspect medical device, information about the initial reporter and information about the user facility (FDA, 2017). Although patient specific information is sometimes included in submitted reports, the FDA does not release any identifiable patient information to the public.

3.4 Inclusion Criteria

Adverse event records from MAUDE database were included if they met the following criteria:

- HIT vendor is one of the top eight based on the 2016 U.S. market share

- Adverse event reports involve the interaction between users and health information technology
- Events occurred between January 1, 2012 and December 31, 2016

The 2016 U.S. market share report included eight vendors, which individually represented greater than 1.6% of the market share and combined represented 91.5% of the overall market share. Only reports that were associated with these eight vendors were included. Additionally, only adverse event reports that involved the interaction between a user and health information technology were included to limit the reports to only those that involved a technology-induced error. A technology-induced error is defined as an error that can 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 the new technology and the new work processes that arise from a technology's use" (Borycki & Kushniruk, 2008) and d) the transfer of data from one system to another (Kushniruk et al., 2012).

The reports from the MAUDE database were filtered to only include events up to December 31, 2016 in order to include the most recent full calendar year at the time the data was extracted. A total of 5 years to include, beginning January 1, 2012, were chosen since this represents a period of significant growth in terms of EHR adoption rates. A report released by The Office of the National Coordinator for Health Information Technology (2016) indicated that the rate of basic EHR adoption, which are those that include basic EHR functions such as storage of clinic information, medication ordering and the ability to view diagnostic imaging and test results, increased from 15.6% in 2010 to 83.8% in 2015.

3.5 Exclusion Criteria

Adverse event records from MAUDE database were excluded if they met the following criteria:

- HIT vendor was outside of the top 8 based on the 2016 U.S. market share
- Adverse event did not involve the interaction between a user and health information technology

There was an additional category in the 2016 market share ("Other") which included an additional 15 vendors. Each of these vendors represented less than 1.6% of the market share. As they are not well represented in the U.S. market for EHR vendors, they were not included in this study. There are some HIT vendors which also produce non-HIT medical devices. These adverse events did not involve the interaction between a user and health information technology, so they were excluded from the data.

3.6 Data Extraction and Cleaning

There have been a number of studies completed using data from the MAUDE database. Myers et al. (2011) analyzed adverse events reports within the MAUDE database related to clinical information systems. In order to identify reports related to these systems, they utilized the Certification Commission for Health Information Technology (CCHIT) list and a list of vendors that have been evaluated by KLAS to produce a list of vendors and keywords related to those vendors to search the MAUDE database for reports. They downloaded master lists from the MAUDE website and manually searched through the unique list of manufacturer names to identify variations in vendor names. The vendor names were then used to identify generic product names that could be used to search for adverse event reports. They used these keywords and

performed a search using wildcards to ensure nothing was unintentionally excluded. The resulting list of reports was then manually searched to ensure they were all relevant. The process of searching was iterative in this study, as new potential keywords were discovered at each step. This process was repeated until no new search terms were discovered (Myers et al., 2011). Magrabi et al. (2012) used a similar method to identify HIT-related incidents. The free-text field in addition to the 'Brand Name', 'Generic Name' and 'Manufacturer' fields within the MAUDE master record files were searched using keywords related to HIT. In a more recent study, Yao et al. (2018) compared the results between searching for HIT-related events in the MAUDE database by using the 'Brand Name', 'Generic Name' and 'Manufacturer' fields and using the 'Classification Product Codes' field. These product codes used by the FDA are intended to classify all medical devices. The purpose of this study was to examine how HIT events can be identified through the MAUDE database. It was found that neither strategy was ideal for identifying HIT events and the authors have recommended standardization in the fields for generic name, manufacturer and product code in order for researchers to be able to fully utilize this database (Yao et al., 2018). However, it is believed that utilizing the 'Generic Name' and 'Manufacturer Name' fields results in the identification of more HIT-related events that the use of other fields (Kang, Wang, Yao, Zhou & Gong, 2018). Methods from these studies were utilized to extract the relevant data from the MAUDE database in this study, as described below.

The data used for this study was extracted from the MAUDE database website, which is publically available (FDA, 2017). The Master Event Data was the first dataset downloaded. This file contains a distinct master record of every submitted adverse event.

Within this file, there may be multiple records for a single adverse event if more than one source submitted a report. For example, if the user of HIT and the HIT vendor both submitted a report, then there would be two records for this event. These records can be linked using a field called "EVENT KEY", which links multiple sources to a single event. This Master Event Data text file was downloaded on November 22, 2017 and at the time, contained data up to December 31, 2016. At the same time, two additional text files were also downloaded from the same website. The Text Data file contains textual information related to adverse events. This file contains the narrative descriptions of the adverse events and was required to code specific technology-induced errors and recovery actions. The Device Data file is the final file that was downloaded. This file contains information about the specific medical device that was involved in the adverse event. It was required to filter records based on vendor names. All of the downloaded files contained a field, "MDR REPORT KEY", that allowed the records from all three files to be linked.

The Master Event Data file was first filtered to only include adverse events that occurred between January 1, 2012 and December 21, 2016 by using the 'Date of Event' field. This file was then further filtered to only include adverse events relating to specific vendors. A list of keywords related to these vendors was created and the fields 'Distributor Name', 'Manufacturer Name', 'Brand Name, 'Generic Name', and 'Text' were searched to locate these keywords and restrict included adverse events to only those related to the top eight vendors based on the 2016 U.S. market share. After producing a dataset that only contained the desired vendors, the narrative descriptions of each adverse event were read to ensure that the event involved the interaction between user and an

HIT. Many of the included vendors also produce non-HIT medical devices, so this step was necessary to exclude these unwanted events.

3.7 Classification Schemes

3.7.1 Technology-Induced Errors

Although the MAUDE database has its own classification system for errors, this system cannot be used to for technology-induced errors as it does not contain codes specific to HIT. Therefore, the data was coded using the coding scheme defined by Kushniruk et al. (2005) which includes 11 specific usability-related problems categorized by being either interface-related or content-related. The definitions of these codes are listed in Table 1.

Classification	Description	Reference
Interface		
Data entry	User experiences difficulties in entering data.	(Kushniruk et al., 2005)
Display visibility	Inability to see all the required information easily (without searching or scrolling).	(Kushniruk et al., 2005)
Navigation	User has difficulties navigating through the system or interface.	(Kushniruk et al., 2005)
Locating	Inability to locate all of the desired information.	(Kushniruk et al., 2005)
Procedure	An established or official way of doing something, a series of actions conducted in a certain order or manner.	(Procedure, n.d.)
Printing	User experiences printing errors or printed information is incomplete.	(Magrabi, Ong, Runciman & Coiera, 2010)
Speed	System is slow or there are issues in response time.	(Kushniruk et al., 2005)
Attention	Notice taken of something; the regarding of something as interesting or important.	(Attention, n.d.)
Content		
Database	The content of the database does not include the desired selection.	(Kushniruk et al., 2005)
Defaults	Inappropriate system defaults appear automatically.	(Kushniruk et al., 2005)
Training manual	Lack of a training manual or documentation with instructions related to using the system.	(Kushniruk et al., 2005)

Table 1. Descriptions of Technology-Induced Error Classifications

3.7.2 Recovery Actions

Many adverse events in the MAUDE database include a record of a response from the vendor. These responses were coded in addition to the error descriptions in order to understand how these errors are being addressed and what vendors are presenting as solutions. A coding scheme developed by Alemzadeh et al. (2013) was used to classify these responses. This coding scheme includes five different recovery actions taken by vendors: (1) safety notification, (2) safety instructions, (3), software update, (4) repair and (5) replace or remove. The definitions for the recovery actions are listed in Table 2.

Recovery Action	Description	Reference
Safety notification	A notification was sent out by the vendor informing the organization of the error.	(Alemzadeh et al., 2013)
Safety instructions	Instructions for alternative workflows/workarounds to avoid the error were provided by the vendor.	(Alemzadeh et al., 2013)
Software update	A software update was performed by the vendor.	(Alemzadeh et al., 2013)
Repair	A hardware repair was performed by the vendor.	(Alemzadeh et al., 2013)
Replace or remove	The hardware was replaced or removed by the vendor.	(Alemzadeh et al., 2013)

Table 2. Descriptions of Recovery Action Classifications

3.8 Qualitative Data Analysis

The narrative descriptions of adverse events were qualitatively coded to identify technology-induced errors and recovery actions using the classification schemes described in Table 1 and Table 2. These adverse events were analyzed by reading the narratives written by the submitter and highlighting the portion of the narrative that matched the definition for the associated classification scheme. Additional codes were added when the description did not fit into any of the predetermined classifications.

3.9 Quantitative Data Analysis

Frequencies of technology-induced errors and recovery actions by vendor were calculated and used to examine the current differences in reporting across vendors. The overall number of adverse events were determined and the total number of technology-induced errors and recovery actions were calculated and presented as a percentage of the total across vendors. These percentages were compared across vendors to understand what types of technology-induced error are being reported in the MAUDE database for the included vendors and if there are any similarities or differences in type of technology-induced error across these vendors. Recovery actions were presented in a similar way to understand how technology-induced errors are being addressed by vendors.

3.10 Ethics

Ethics approval exemption was obtained from the University of Victoria's Research Ethics Board on April 22, 2016 as the data source for this study is publicly available. A copy of the ethics exemption letter can be found in Appendix A.

Chapter 4: Results

This section provides an overview of the findings related to the coded adverse events from the MAUDE database and includes frequencies of technology-induced errors and recovery actions taken by vendors.

4.1 Number of Adverse Events

There were 204 total adverse events extracted from the MAUDE database between January 1, 2012 and December 31, 2016 that met the inclusion criteria.

4.2 Qualitatively Coded Technology-Induced Errors

Adverse events (n=204) were coded for technology-induced errors and recovery actions. These included 11 technology-induced errors plus an additional 4 that were added for a total of 15 technology-induced errors that are grouped into three categories. The additional codes that were added to this scheme are: (1) alert not displayed, (2), system to system interface error, (3) decision support system rule and (4) decision support system. Table 3 provides the final list of all the technology-induced error classifications and includes their corresponding definitions.

Classification	Description	Reference
Interface		
Data entry	User experiences difficulties in entering data.	(Kushniruk et al., 2005)
Display visibility	Inability to see all the required information easily (without searching or scrolling).	(Kushniruk et al., 2005)
Navigation	User has difficulties navigating through the system or interface.	(Kushniruk et al., 2005)
Locating	Inability to locate all of the desired information.	(Kushniruk et al., 2005)
Procedure	An established or official way of doing something, a series of actions conducted in a certain order or manner.	(Procedure, n.d.)
Printing	User experiences printing errors or printed information is incomplete.	(Magrabi et al., 2010)
Speed	System is slow or there are issues in response time.	(Kushniruk et al., 2005)
Attention	Notice taken of something; the regarding of something as interesting or important.	(Attention, n.d.)
Content		
Database	The content of the database does not include the desired selection.	(Kushniruk et al., 2005)
Defaults	Inappropriate system defaults appear automatically.	(Kushniruk et al., 2005)
Training manual	Lack of a training manual or documentation with instructions related to using the system.	(Kushniruk et al., 2005)
Additional Classifications		
Alert not displayed	Drug or allergy rules were not triggered as expected.	(Myers et al., 2011)
System to system interface error	Communication failure occurred between software applications.	(Palojoki et al., 2017)
Decision support system	A system feature was assumed to be present by users, but was not present, or the system behaved in an unexpected manner.	(Myers et al., 2011)
Decision support system rule	Rule-based logic is either incomplete or incorrect.	(Myers et al., 2011)

Table 3. Descriptions of Expanded Technology-Induced Error Classifications

4.2.1 Data Entry

Data entry can be defined as those events where the user experiences difficulties in entering data. Such events can result in the user entering incorrect information or the

user being unable to enter all the desired information (Kushniruk et al., 2005). Some of the vendors did not have events related to data entry (e.g. Vendor 3 and Vendor 5) while other vendors did have this issue. This error is associated with 12% (n=24) of all adverse events across vendors. Vendor 2 had the highest percentage of adverse events related to data entry (21%, n=3), followed by Vendor 4 (14%, n=10), Vendor 6 (12%, n=3) and Vendor 1 (11%, n=8). The following are examples of issues experienced by submitters to the database with data entry:

> The issue occurs in [order entry system] when the user adds and signs more than one electronic prescription orderable item and one of the orderable items contains an invalid character outside of … characters in the special instructions. This will result in those special instructions to be applied to all orderable items. This issue could result in a patient taking prescribed medications in a manner other than what the prescriber intended and could lead to negative patient reactions.

This report describes an issue with entering special instructions for orders. If the instructions contain an invalid character and more than one order is being placed, then the information is unintentionally entered into every order.

In another example (see below) we see that the reporter describes a situation where a user was unable to enter information because a different user had accessed the patient's chart on another workstation. As a result of this issue, orders could not be entered, delaying the availability of radiology and laboratory results.

> During resuscitation, unable to enter orders for fluids, medications, lab work, x-rays in the tachycardic because the chart is open … in clinic workstation. Called clinic but call went to voice mail. Called IT help desk who said call clinic, then said there was nothing they could do. Would not even go to clinic to shut down workstation because number provided did not correspond to their ids. Asked our department administrator to take on problem as we were busy with direct care. After about an hour, problem eventually went away.

Issues with data entry, as shown in the above examples, can have extensive impacts on the delivery of patient care. These impacts can include incorrect information being documented in a patients' chart or being provided to the patient upon discharge, and can result in the delay of necessary interventions.

4.2.2 Display Visibility

Display visibility refers to the inability to see all of the desired information easily without the need for searching or scrolling (Kushniruk et al., 2005). Display visibility was coded for 18% (n=37) of all adverse events. Every vendor had technology-induced errors that involved this issue. Vendor 5 had the highest percentage (100%), although there was only 1 adverse event identified over 5 years. Vendor 6 had the second highest percentage (42%, n=11), followed by Vendor 2 (29%, n=4), Vendor 4 (18%, n=13), Vendor 1 (9%, n=7) and Vendor 3 (7%, n=1). Below is an example of an excerpt in the database where display visibility is identified as a concern:

> For the specific patient in question, a large number of procedures had already been performed at multiple facilities, and the total list of studies exceeded the available space in the display window. A scroll bar was provided on the display window to view the list of studies that exceeded the available space in the display window. The user did not scroll the list down to see the complete list of studies for that particular patient, which included a CT Angio head/neck imaging procedure that had already been performed at another location. As a result, a second CT Angio head/neck imaging procedure was inadvertently scheduled and performed on the patient.

In this first example, the user is unable to see all of the procedures that had previously been performed without scrolling down. The user did not see all procedure records, which lead to a second unnecessary CT procedure being performed on a patient resulting in additional health care costs and exposure to radiation.

In another example (see below), a display visibility event describes an issue with the EHR that requires users to search for certain results. In this case, critical information on vital signs were not visible unless the user searched for them which resulted in inappropriate medication administration.

> With the work flow controlled by the electronic care record system, vital sign data is out of sight, tucked away is a silo that requires multiple clicks and time to access. Consequently, the key data of vital signs is out of sight, and thus, out of mind. No one

> knows the patient data, yet medications are administered resulting in complications because of the inappropriate (for the vital signs) administration of therapies. In this particular case, the patient was hypotensive and received additional blood pressure lowering medication resulting in a critical condition.

The display of vital information in a way that is easily viewed and accessible to health care workers is essential to support healthcare delivery. As demonstrated in the previous examples, not having all relevant information can cause patient harm and increase health care costs from having to perform unnecessary procedures.

4.2.3 Navigation

The technology-induced error navigation refers to when users experience difficulties navigating through a system or interface (Kushniruk & Borycki, 2015). Navigation was coded for 4% (n=8) of all adverse events. There were some vendors that did not have any adverse events associated with this technology-induced error (e.g. Vendor 3 and Vendor 5). Vendor 6 had the highest percentage of events with this error at 8% (n=2), followed by Vendor 2 (7%, n=1), Vendor 4 (6%, n=4) and Vendor 1 (1%, n=1). Below are two examples of events where the submitters were unable to navigate through their system or interface effectively.

> Order was intended to be 20ml/hr for 6 hours for a total of 120ml. It was a 1000 ml bag so first they put 20ml/hr which would have defaulted the infusion over time to 50 hrs. They tried to change the infusion over to 6 hours which then changes the ml/hr rate to 167 ml/hr. They did not notice this had changed. They did not

> realize that they needed to go into details tab to show the time frame so the patient got 167ml/hr instead of 20ml/hr for 6 hours. Order was verified by pharmacy and administered at that rate via peripheral IV.

In this example, a physician was attempting to alter the default infusion rate for a medication order, but was not able to navigate to the appropriate screen to do so as it was not clear that this was the correct method to change infusion rates. As a workaround, the ordering physician changed a different part of the order on the screen that they were able to access which resulted in the administration of a medication at an inappropriate infusion rate.

The next example (see below) describes a situation where if a user alters defaults related to the display, then they may have difficulties in navigating information for multiple patients. This is a situation where the user altered the default view to more closely align with their workflow and the result is that it became more difficult for providers to navigate the interface.

> The issue may occur when the user has set their default tab to a tab other than document viewing in the [EHR]. When a patient's chart is displayed and the user then navigates to another patient's chart then returns to the original patient chart, a list of notes for a patient other than the patient displayed in the demographics bar may be displayed in the document viewing tab, and you may create notes for a patient other than the patient displayed in the demographics bar in that tab.

Navigation-related events impact the ability of users to access pertinent information about their patients. If the user cannot navigate the system effectively, it can lead to medication errors, as in the first example, or increase the time required for documentation to occur, which reduces the amount of time health professionals spend providing direct patient care.

4.2.4 Locating

Locating was coded for events where users were unable to locate all of the desired information they needed to complete their current task, such as documentation or medication ordering (Kushniruk et al., 2005). This technology-induced error was present in 5% (n=11) of all the identified adverse events. There was only one vendor (e.g. Vendor 5) that did not have any events related to locating; however, this vendor was also the only vendor to have had one adverse event identified over 5 years. Vendor 6 had the highest percentage of events with this error at 8% (n=2), followed by Vendor 4 (n=5), Vendor 2 (n=1) and Vendor 3 (n=1) all having 7% of events coded for this error and finally Vendor 1 with 3% (n=2). The following are two examples of submissions that involved errors with locating information:

> When trying to investigate if floranex could have been the cause of the allergic reaction, the provider/pharmacist went to [order entry system] which does not have this listed as a warning, precaution or contraindication (as it does with other food/drug allergies such as propofol with egg/soy). It is only listed under dosage forms which is not the first place the provider or pharmacist who typically search for this information.

In this example, the submitter was attempting to locate information on the ingredients of a specific drug after it was suspected that a patient's recent allergic reaction was due to there being dairy in the recently prescribed medication. The submitter was unable to locate this information initially because it was located in a form in the database where allergy-related contraindications are not normally found.

In the second example (see below), a user was attempting to locate notes related to a specific medication order in order to understand the reasoning behind why the order was placed. They found multiple lines of text on the interface and were not able to determine which text matched with each order.

> It is difficult to determine which lines of text apply to which lines of order. This is a systemic problem with all [order entry system] order sets. I noticed a new order set for vitamin K reversal of an elevated INR and could not easily determine what text went with what order. I asked our head pharmacist and lead hospitalist, and neither could readily navigate the information on this screen.

In these two examples, clinicians were attempting to locate very specific information related to medication orders to support a diagnosis or treatment and were unable to get the required information from the order entry systems. Delays in medication administration can have a substantial impact on a patient's health and result in increased health care costs due to an increase in hospital length of stay (Hunt, Harding, Taylor & Curtain, 2018).

4.2.5 Procedure

Procedure is a technology-induced error that refers to when an error is the result of a system disrupting a user's pre-established workflows or procedures (Procedure, n.d.). Procedure was coded for a total of 3% (n=6) of adverse events. There were two vendors that did not have any events associated with this error (e.g. Vendor 2 and Vendor 3). Vendor 5 had the highest percentage (100%, n=1) of events with this error, although there was only 1 event involving this vendor over 5 years. Vendor 1 (n=3) and Vendor 6 (n=1) had the second highest percentages at 4%, followed by Vendor 4 with 1% (n=1). The following are examples where a system did not support a users' previously established workflows or procedures.

> The user defined workflow allows for the authorization of non-radiologist physicians to create diagnostic reports in [medical imaging system] for some studies that would lead a subsequent reading radiologist to delay interpretation of those studies because they incorrectly believe that another radiologist is already interpreting those studies.

In the example above, the organization has a pre-defined workflow that allows non-radiologist physicians to create reports. The medical imaging system used does not allow for this workflow and in doing so will result in it appearing as though the imaging study has already been interpreted. This can lead to delay of results or missed imaging interpretations from imaging studies which will impact timely patient care.

The second example (see below) describes a situation where an order was placed with the intention of it being completed prior to an operation. However, due to the

differences in the way information is communicated with the use of this new system, no one saw the order and the test was not completed.

> Stat arterial blood gas ordered pre-op. No one on the operating team saw the order such that it would be done prior to the anesthesia (not the anesthesiologist, surgeon, nurse, no one.) The recipient was not in receipt of the order, operating room, the recipient did not timely see it. Communication has been disrupted with the deployment of these care controlling devices.

Both examples describe how events that disrupt current workflows and procedure can cause delays in patient care. The examples both demonstrate the importance of designing systems that will support a users' already established workflows and procedures.

4.2.6 Printing

Printing refers to when the user experiences printing errors or the printed information is not complete (Magrabi et al., 2010). A total of 2% (n=4) of all adverse events were coded for this error. Many vendors did not have any adverse events that were assigned this technology-induced error (e.g. Vendor 1, Vendor 3, Vendor 5 and Vendor 6). Vendor 2 had the highest percentage with this error at 7% (n=1) and Vendor 4 had the second highest at 4% (n=3). The following two examples describe events where the submitter has experienced difficulties in printing information:

> The issue occurs when the nursing documentation downtime medication administration report (MAR) is used to administer medications to patients when the [EHR] is unavailable. In the [EHR], when the user prints the downtime MAR report,

> suspended medications are included on the report but do not include a note of the "suspended" status.

In this example, when a user attempts to print a MAR during downtime, medications that have been “suspended” will appear as though they are still active. Downtime printing with this system does not produce all relevant information, which could result in patient harm if a patient were to receive incorrect medications.

The next example (see below) describes a situation where the EHR is not able to print documents properly when they contain a table with multiple lines of text within a single cell. A clinician may not be aware of the information loss, which could lead them to make decisions regarding patient care with incomplete information.

> The issue occurs when a [order entry system] document includes a table that contains multiple lines of text within a cell. When these documents are rendered in the [EHR], the documentation captured in the affected cells may not be printed in its entirety.

This technology-induced error has the potential to cause harm to patients, as the loss of information may lead to decision-making that is not in the best interest of the patient.

4.2.7 Speed

The classification speed was coded for 8% (n=17) of all adverse events. This error refers to when a system is too slow or there are issues related to response time (Kushniruk & Borycki, 2015). There were multiple vendors that did not have any adverse events coded for this error (e.g. Vendor 2, Vendor 3 and Vendor 5). Vendor 1 had the highest percentage of events that were coded for this error with 18% (n=14),

followed by Vendor 6 (8%, n=2) and Vendor 4 (1%, n=1). The following are examples where the submitters experienced difficulties with system response time.

> The reporting facility contacted [vendor] to request assistance with an investigation into slow transfer of images from modalities connected to [radiology system]. The reporting facility alleged a trauma patient was transferred to another facility, due to a delay in availability of a study for the patient.

This first example described a specific event where the transfer of information between systems was very slow. In this case, the information was required before continuing with the patient's treatment. As a result of this delay, the patient had to be transferred to another facility which caused a significant delay in receiving necessary care.

The second example (see below) describes a similar situation where specific information was required to complete a surgery. This information was unavailable for approximately 20 minutes which delayed the surgery causing the patient to be anesthetized for longer than expected.

> The site reported that an archived prior study was unavailable for an anesthetized patient during surgery. It was alleged that the surgery was delayed for approximately 20 minutes as a result.

The information contained within these systems is often required to be immediately accessible to continue with care delivery. Issues with the speed of a system can negatively impact the hospital workflow overall, as a delay with one patient can also affect subsequent patients.

4.2.8 Attention

Attention refers to situations where the user does not notice important information (Attention, n.d.). This technology-induced error was coded for 6% (n=13) of the included adverse events. There were some vendors that did not have any events related to this error (e.g. Vendor 2 and Vendor 3). The vendor with the highest percentage was Vendor 5 with 100% (n=1) of events being coded for attention, although there was only 1 adverse event associated with Vendor 5 over 5 years. The second highest was Vendor 6 (15%, n=4), followed by Vendor 4 (6%, n=4) and Vendor 1 (5%, n=4). The following examples describe events where submitters did not take notice of important information within their EHR:

> Post operative patient was being infused normal saline at a rate of 125 per hour. Serum sodium result was sent electronically to the EHR but there was no warning or notice that the result was there. A hemoglobin level was less than 7 which also was sent to the EHR repository, but no one knew that there was a new result there. This resulted in a delay of treatment with potential life threatening consequences.

This example involves a submitter who did not notice that an important result was available, which was necessary for the continuation of treatment. The results of the ordered test were abnormal and required attention from clinicians. However, the result was silently delivered within the EHR and no one was made aware of its availability.

The second example (see below) describes a similar situation where a crucial test result was made available, but the neurologist responsible for this patient did not notice

that it was complete. In this case, the patient continued to receive treatment which included medication that was unrelated to their diagnosis as described below:

> The patient was admitted to the hospital with a wobbly gait, ataxia. A vitamin B12 level was ordered by the neurology consultant, in addition to other tests. It takes several days for the result to appear, which ultimately gets sent to the EHR and stored as of the date the sample was obtained. The level was abnormal, low, and consistent with the gait problem; but no one saw the result, including the neurologist. The neurologist treated the patient for Parkinson's disease instead, erroneously.

Both examples describe situations where important results were made available in the EHR silently, so no one took notice of their availability. The implications are that diagnosis will be delayed, and in the second example, a patient continued to receive treatment for a condition that they did not have.

4.2.9 Database

The technology-induced error code database refers to when a systems database does not contain the user's desired selection (Kushniruk et al., 2005). This technology-induced error was coded for 26% (n=53) of all adverse events. Just over one quarter of all the adverse events were coded for database. Each vendor was assigned this code for multiple adverse events, with the exception of Vendor 5. This vendor had only had 1 adverse event over the included date range. Vendor 2 had the highest percentage coded as having a database-related problem with 36% (n=5), followed by Vendor 1 (28%, n=21), Vendor 4 (28%, n=20), Vendor 3 (20%, n=3) and Vendor 6 (15%, n=4). The

following are two examples of situations where a database did not include the user's desired selection:

> Patient with permanent atrial fibrillation and labile rate was on a negative chronotropic medication called digoxin that was titrated as an outpatient in the clinic to a dose of .125 mg on Monday, Wednesday, and Friday to keep the heart rate between 60 and 85 beats per minute. The patient was admitted to the hospital for a medical condition. The [CPOE] has a drop-down menu to order dosing intervals, without a manual over ride. The drop-down menu and over 50 options for dosing intervals, but none were for Monday, Wednesday, and Friday, or three days per week. As a result, the patient was either overdosed or underdosed, which is significant in view of his age and the narrow therapeutic ratio of digoxin.

In this example, a patient arrived at the hospital with a very specific order for a medication. They were previously instructed to take a specific dose three days a week on Monday, Wednesday and Friday. Upon admission when the patients pre-existing orders were being entered, the submitter noted that this option did not exist. In addition, there was no option to manually input a dosing interval. The order was entered with a different interval, causing this patient to receive a dose other than what was initially prescribed.

In the next example (see below), a user has indicated that their database contains a pre-built drug order that does not allow for the selection of specific doses, only dosages based on weight.

> Inappropriate choices for medications ordering. [COPE] using [vendor] database. I have reported to [vendor] and they say it's an issue with [database]. Digoxin oral ordering suggests only weight based dosing. Even further down the list it does even not offer digoxin 0.125 mg or digoxin 0.25 mg.

If a database does not contain a desired selection for drug orders, then it's possible that a patient could be receiving an incorrect dosage. The patient in the first example was admitted for a completely separate condition, but the constraints with dosage interval selection made it impossible for them to receive the correct dosage.

4.2.10 Defaults

Defaults refers to events where the system includes inappropriate default values that appear automatically (Kushniruk et al., 2005). This technology-induced error appears in 16% (n=33) of all included adverse events. There was only one vendor that did not have any events that were coded for defaults (e.g. Vendor 5). This error was most common with Vendor 2 (43%, n=6), followed by Vendor 4 (19%, n=14), Vendor 3 (13%, n=2), Vendor 6 (12%, n=3) and Vendor 1 (11%, n=8). The following two examples are events in which a system contains an automatic default value that is not appropriate for the situation.

> Orders for medication show up in the medication administration charting (MAR) section in an erroneous, and, I believe, confusing and possible dangerous manner. The MAR, and the label that issues from the printer in [EHR], confuses product strength with dose. For example, a 3 mg daily dose of sirolimus appears as

> "sirolimus tablet 3 mg; dose 3 mg oral daily. Sirolimus is not marketed in a 3 mg tablet. Similarly, any dose of a product that does not exactly match the tablet strength appears in the same confusing pattern: e.g., a dose of mesalamine capsules 1600 mg appears as "mesalamine capsule 1600 mg dose 1600 mg etc." mesalamine is not marketed as a 1600 mg capsule. The above should read, correctly, in the mar (and on labels) as: sirolimus tablet (or tablets) 1 mg, dose 3 mg, and mesalamine capsule (or capsules) 400 mg, dose 1600 mg, etc.

In this situation, the default for an order is to list the product strength and dose as the same value. The drugs that are listed by the submitter do not exist in the same strength as the dose as the default, which is inaccurate and misleading.

The next example describes a system where the notation for a certain order is opposite to what is conventionally used. This had led to a number of near-misses and one confirmed medication error.

> A prescription was written for norco 325/10mg tablet, but what was dispensed was hydrocodone 5/325. The way the drug is noted in the prescriber's software lists the ingredients in a manner which is backwards from the conventional listing where the hydrocodone dose is listed before the acetaminophen dose. For example, [order entry system] denotes the different hydrocodone products as: norco 325/5mg; norco 325/7.5mg; and norco 325/10mg. We have had several instances where we nearly made

> an error, and now one confirmed error. In reading the prescription, it is easy to recognize the 325mg and easily overlook the other number, or to expect to see the dose we usually use.

The impact of having inappropriate system defaults can be that orders are entered incorrectly, as described in the second example. This greatly increases the potential for medication errors as users may not notice that a default has appeared automatically.

4.2.11 Training Manual

The least common technology-induced error was training manual, which refers to a lack of a training manual or documentation related to using the system (Kushniruk et al., 2005). Training manual was coded for only 0.5% (n=1) of events. Vendor 1 (1%, n=1) is the only vendor with an adverse event that was coded for this technology-induced error. The following is the only example of an event involving this classification:

> [EHR] has identified that the need for performing annual maintenance testing is not reiterated in the [EHR] instructions for use with versions 12.2 and earlier, although each unit has an attached sticker indicating the due date of the next maintenance test required, and as communicated to the customers as part of the user administrator training. To date, there have no reports of an adverse event, injury or illness as a result of the labeling deficiency described in this report.

The submitter in this example has indicated that the instructions for EHR use do not include specific instructions related to the need for annual maintenance. It is mentioned

that there is a sticker on the device indicating the next due date for maintenance. However, this information should also be listed in the official EHR instructions.

There was only one event that was coded for training manual, and this event did not result in any direct impacts to patient care. However, proper documentation is essential to ensuring that a system is being used as intended and can help reduce the likelihood of an adverse event occurring.

4.2.12 Alert not Displayed

The alert not displayed code refers to when a rule related to drugs or allergies was not triggered as expected (Myers et al., 2011). This technology-induced error was described in 17% (n=34) of all adverse events. There were two vendors that did not have any events coded for this error (e.g. Vendor 2 and Vendor 5). The highest number of events involving alert not displayed errors are those related to Vendor 6 (38%, n=10), followed by Vendor 4 (28%, n=20), Vendor 3 (7%, n=1) and Vendor 1 (4%, n=3). The following are examples of events where alerts did not trigger as expected:

> The clinical decision support failed to warn of an allergy listed under the name of a combination drug, "lotrel". The patient was allergic to enalapril (and all ACE inhibitors). The next day after receiving the amlodipine component of lotrel, the pharmacist alertly notified the health care team of the allergy listed as "lotrel", but the allergy was to the ACE inhibitor component of lotrel. It appears that the computerized provider order entry (CPOE) and clinical decision support (CDS) devices of this EHR (and perhaps the pharmacy allergy checker) are defective in their

> failure to recognize the individual components of the combination drugs listed on the allergy banner, and thus, the patient may get a drug to which he/she is allergic.

In the example above, the pharmacy allergy checker did not recognize the different components of medications and could not alert users to allergies for combination drugs. The patient in this example had an allergy to ACE inhibitors, which was a component of the drug that they received. The pharmacist had to list their allergy as "lotrel" which does not cover all ACE inhibitors. As a result, it's possible that this patient may receive another drug with an ACE inhibitor component, and again experience an allergic reaction.

The next example (see below) describes an issue where a drug allergy alert is not triggering. In this example, the cause is unknown and the issue is described as sporadic. This is an example where further testing is required to identify the cause and prevent patients from receiving drugs that they have an allergy to.

> A sporadic issue in the [EHR] where drug allergy interaction checking does not occur as expected when a medication order is placed for which a patient has a known allergy noted on their order profile. This issue happens sporadically and is difficult to recreate.

The two examples described above involve alerts generated from allergy checking. The impact of this issue could be very severe depending on the type of allergy a patient has to a drug and can lead to an increased hospital length of stay (Légat et al, 2018).

4.2.13 System to System Interface Error

The system to system interface error refers to a communication failure between two systems (Palojoki et al., 2017). This is the second most common technology-induced error, with just over one quarter of all the included adverse events being coded for this error. In total, there were 26% (n=54) of adverse events coded for this error. Vendor 3 had the highest percentage of events involving a system to system interface error with 40% (n=6), followed by Vendor 4 (31%, n=22), Vendor 2 (29%, n=4), Vendor 1 (24%, n=18) and Vendor 6 (15%, n=4). Vendor 5 had only 1 adverse event and it did not involve a system to system interface error. The following examples illustrate the impact of an interface failure between two systems:

> When patients were registered in a third party registration system, an "m" or an "f" was placed in the social security number (SSN) field instead of an SSN. When this information was transferred to [EHR] through the system integration - foreign system interface, a match was triggered with all the other patients in the database that also had an "m" or an "f" documented as a social security number. This led to multiple patients' information being combined incorrectly on unrelated records.

The submitter has described in the above example an issue that occurred between a third party registration system and an EHR. Occasionally, a letter is entered in the SSN field instead of the SSN. When this occurs, patient records are being combined upon transfer of information between the systems. These records are being matched on this field erroneously, which has caused unrelated patient records to be combined.

The next example (see below) involves communication between a medication management system used by a pharmacy and a patient portal. When a pharmacist alters either the strength, dosage or frequency of a medication, these changes are displayed in the patient portal. However, the portal also displays the unchanged instructions from the original prescription. This could result in a patient following incorrect instructions related to their prescriptions, as illustrated in the report below:

> The issue occurs when the prescription is filled by a pharmacy using [medication management system], and the pharmacy changes the strength, dose or frequency of the ordered medication and adds signature line instructions to describe these changes. The updated signature line instructions are displayed in the portal, conflicting with the dose and frequency of the original prescription which remain unchanged in the portal. Patient care could be adversely affected in the event the patient mistakenly uses the portal as a source of dosage instructions, as the instructions displayed are not for the strength, dose and/or frequency displayed in the portal.

A system to system interface error can lead to lost or incorrect information. If users do not realize that information has been lost or altered, then it could result in treatment decisions being made based on incomplete information or cause a delay in treatment if extra time is required to resolve the issue.

4.2.14 Decision Support System

Decision support system is the code that was associated with the highest number of adverse events. This technology-induced error refers to events where a system behaved in an expected manner or was missing features that were assumed to be present by the user (Myers et al., 2011). Almost half of all adverse events related to HIT involved this error with 99 (49%) events being coded for decision support system. Every vendor had adverse events where a decision support system was involved. Vendor 1 had the highest percentage of adverse events with this error (100%, n=1), although this vendor had only 1 reported adverse event over 5 years. Vendor 3 had the second highest with 60% (n=9) of adverse events involving a decision support system, followed by Vendor 4 (50%, n=36), Vendor 6 (50%, n=13), Vendor 1 (46%, n=35) and Vendor 2 (36%, n=5). The following events occurred when systems behaved in an unexpected manner, as illustrated in the report below:

> When susceptibility results that contain footnotes (comments) have been written to the patient chart, additional updates to any of the antibiotics on that panel (for example, correcting an existing result, suppressing or unsuppressing an existing result, or posting new results) result in an error; not allowing susceptibilities to be charted. Therefore, the results would not be clinician-viewable but would be available in the laboratory view.

This example is one where if the user charts in a certain way, other information is not able to be documented. The submitter has indicated that when results are posted with footnotes, attempts to chart additional updates will result in an error. If a change was

made to this result, it would not be viewable by a clinician. It is possible that decisions surrounding treatments could be made based on information that is not the most up to date.

The second example (see below) involves a system that has intermittent downtime. There are consistent issues with connecting workstations in the operating room, which involves increasing the amount of time that a patient is under anesthesia, as described in the report below:

> The reported facility contacted [vendor] to request assistance with an investigation into intermittent downtime of the [medical imaging system] for a specific workstation at the site. The site reported that a patient was kept under anesthesia 30 minutes longer than planned prior to the start of a surgical procedure. The workstation from the operating room was not able to connect to the [medical imaging system] leading to images for the patient being unavailable. Someone from the radiology department retrieved the images on film from the radiology department.

Issues with decision support systems can have a variety of impacts on patient care, including delaying the delivery of care and causing information loss (Ash et al., 2004).

4.2.15 Decision Support System Rule

Decision support system rule is coded when a systems rule-based logic is either not complete or not correct (Myers et al., 2011). This classification is present in 9% (n=18) of the included adverse events. Only Vendor 5, which only had 1 adverse event, did not have this code assigned. Vendor 3 had the highest percentage of events related to

decision support system rules (20%, n=3), followed by Vendor 4 (15%, n=11), Vendor 2 (14%, n=2), Vendor 6 (4%, n=1) and Vendor 1 (1%, n=1). The following examples are of situations where there was an event related to incorrect or incomplete rule-based logic:

> When a multiple-ingredient medication is dispensed, it will not check all of the ingredients against a patient's medication history for possible duplicate therapies. Therefore, an alert is not displayed when the patient has an active prescription for a medication containing an ingredient that is also in the multiple-ingredient medication. This could result in a patient taking more of a medication than was prescribed.

In this example, users would expect a drug interaction checking functionality to check against each medication ingredient for each medication in a patient's history. The submitter of this event has indicated that this functionality is not present with multiple ingredient drugs, which could result in the patient receiving a much higher dosage than intended of a certain ingredient. Depending on the medication, this could have serious negative effects on a patient's health.

The second example (see below) is of an event where a dose range checker does not function correctly in certain situations. When content from the submitter's drug database is provided, the dose will not automatically be compared to the pre-established safe range. This error could result in a patient taking a dose that is higher than recommended, as illustrated below:

> This issue affects the dose range checking functionality in [order entry system]. DRC is an automated method to compare a

> medication order dose against a pre-established safe range to assist the clinician in providing the correct dosage to a patient. The issue occurs when a medication order is entered in [order entry system] where [medication database] content is used; a dose range checking alert may not be displayed.

Decision support system rules are present to detect potential problems that might otherwise go unnoticed. If these functions are not operating as expected, there is a strong potential for adverse events to occur that result in patient harm, as demonstrated through the two previous examples.

4.3 Qualitatively Coded Recovery Actions

There were 197 total recovery actions coded. Out of the 204 total adverse events included, 99 (48.5%) adverse events included a vendor response. Descriptions of each of the recovery action classifications are listed in Table 4.

Recovery Action	Description	Reference
Safety notification	A notification was sent out by the vendor informing the organization of the error.	(Alemzadeh et al., 2013)
Safety instructions	Instructions for alternative workflows/workarounds to avoid the error were provided by the vendor.	(Alemzadeh et al., 2013)
Software update	A software update was performed by the vendor.	(Alemzadeh et al., 2013)
Repair	A hardware repair was performed by the vendor.	(Alemzadeh et al., 2013)
Replace or remove	The hardware was replaced or removed by the vendor.	(Alemzadeh et al., 2013)

Table 4. Descriptions of Recovery Action Classifications

4.3.1 Safety Notification

Safety notification was coded for events where the vendor response indicated that a notification was sent to an affected organization informing them of the potential error (Alemzadeh et al., 2013). This classification had the second highest number of responses

by vendor with 68 events having notifications (68% of events with a vendor solution, 33% of events overall). Vendor 4 had the highest number of responses for this classification as well as the highest percentage of events resulting in a notification (69%, n=50). Vendor 3 had the second highest (66%, n=10) and Vendor 1 had the lowest (11%, n=8). The following are two examples of safety notifications from vendors:

> This issue is a result of a change in data handling in SQL server 2012. [Vendor] is advising customers of the issue, and will provide mitigation through software updates.

In the above example, the vendor has informed the submitter through a response that they will be notifying other sites that could potentially be affected. The notification also includes their intent to develop a software solution to resolve the issue.

The example below is a response described in a very similar way. Both responses also contained a short description of the original event.

> [Vendor] distributed a priority review flash notification on Feb 8, 2013 to all potentially impacted client sites. The software notification includes a description of the issue and a software modification to address the issue for all sites that could be potentially impacted.

Vendor responses that include notifications will often also include a short description of how they will be resolving the errors. Many of the notifications indicate that they are being sent to organizations other than the one who originally submitted the issue to ensure that everyone who could potentially be affected is aware of the problem.

4.3.2 Safety Instructions

Safety instructions are responses given by vendors for alternative workflows or workarounds to avoid the error reoccurring (Alemzadeh et al., 2013). This is the third highest reported solution category with 47 events (representing 47% of events with a vendor response and 23% of all adverse events). Vendor 4 had the highest number and highest percentage of events that resulted in instructions being given with 36 (50%) of their adverse events being coded for safety instructions. Vendor 3 is the second highest with 33% (n=5) of adverse events receiving safety instructions, and Vendor 1 had the lowest percentage (8%, n=6). The following are examples of responses that contain safety instructions:

> The software notification includes a description of the issue, an alternative to prevent the issue from occurring, and notification that a software modification has been developed and is available to address the issue for all sites that could be potentially impacted.

In the example above, the specific instructions are not given in the vendor response. However, the vendor has indicated that they will be sending specific instructions to all sites that would potentially be affected by the same issue.

The second example is one from a vendor who has included the specific instructions in the response, as well as the method that they intend to distribute the instructions.

> The following workaround has also been provided: re-activating the procedure prompt causes the results to be visible again on all

> affected specimens, in microbiology and the EMR. Notification and distribution: beginning on 01/17/2014, [vendor] distributed a notification to customers who have magic or client server microbiology software product in either test or live for the releases noted above. This notification was made via -emailed task updates that can be printed by the customer. Task updates sent via e-mail are immediately transmitted to the customer.

The information included in these types of responses varies greatly. Some vendors include the specific instructions in their response, while other vendors simply state that instructions are going to be provided.

4.3.3 Software Update

Software update is the most frequent vendor solution. This was coded for responses that contained an indication that the vendor has completed, or intends to develop a software update to address the issue (Alemzadeh et al., 2013). There were 77 events that were coded for receiving a software update (78% of events with vendor solutions, 38% of all adverse events). Of the 77 events that resulted in a software update, 44 were posted by Vendor 4, 23 by Vendor 1 and 10 by Vendor 3. Vendor 3 had the highest overall percentage of their own events receiving a software update at 67%, followed by Vendor 4 (61%) and Vendor 1 (30%). The following are two examples of responses from vendors that include mention of software updates:

> Due to the software defect the preference setting was not saved resulting in not automatically assigning selected studies and alerting the emergency department physicians for further review.

> This could potentially cause a delay in care for patient requiring further treatment. A software update has been provided to the reporting facility to resolve the issue.

In this example, a short description of the original issue was included and the vendor indicated that the update has already been provided.

The next example (see below) is one where the vendor has developed the software update to resolve the issue, but has not yet implemented it. They have included in their response that the update will be sent to all potentially affected sites.

> When archiving a task is stopped and then started quickly, a software defect in [vendor] will create a non-unique 'job id.' in this case, that defect caused 2 studies to be given the same job-id. The incorrect study was presented to the radiologist and the requested study was deleted without being archived. [Vendor] has determined that the identified software defect is the root cause for this problem. [Vendor] has developed a software solution which will be provided to potentially affected users to reduce the risk of future recurrences.

Similar to the other types of vendor responses, there is a lot of variation in the amount of detail included in the response for software updates.

4.3.4 Repair

Repair is the solution with the lowest number of vendor responses. Events were coded for repair when a hardware repair was performed (Alemzadeh et al., 2013). Only Vendor 4 had events coded for repair. There were 2 total repair events for this vendor.

This represents 3% of all adverse events involving that vendor, 2% of the events with a reported solution and 1% of all adverse events. The following are two examples of events where there was a hardware repair:

> [Vendor] has made changes to the barcode reader to narrow the scanner beam and realign the scanner to the proper angle.
>
> [Vendor] is implementing a further hardware modification to disallow the barcode reader to be out of alignment.

In this example, a barcode reader was malfunctioning and out of alignment. The vendor responded to this event indicating that they would be performing a hardware modification in order to resolve the issue.

The second example (see below) also involved a malfunction with a barcode reader. The comment from the vendor includes a short description of the problem and indicates that they intend to recalibrate the scanners to resolve the issue.

> The blood bank encountered an unanticipated problem with scanning expiration dates and unit numbers after implementation of a [vendor] upgrade resulting in truncated or scrambled numbers. The bar-code scanners were recalibrated to read slower.

There were very few responses from vendors describing systems requiring a repair to hardware components. There were only 2 events and they both involved barcode scanning technology.

4.3.5 Replace or Remove

Replace or remove is the classification for recovery actions with the second lowest number of events. Events with this classification are ones where a hardware

component was either replaced or removed by the vendor (Alemzadeh et al., 2013). Only Vendor 1 had events that were coded for repair or remove. There were 3 total events with this solution reported, representing 4% of the adverse events involving Vendor 1, 3% of all events with a reported solution and 1% of adverse events overall.

> The [vendor] software application detected that no data was being received from the front-end monitoring hardware components. When the [vendor] application detected that data was not being received from the front-end components, it automatically attempted to restore the connection, as designed. All hardware items and cables from the monitor to the patient interface cables were replaced at the site.

The vendor response for this event included a very brief description of the error and indicated the recovery action as replacing hardware.

The next example (see below) describes a similar situation where there was a failure with disk drives. In this situation, the result was that the drives needed to be replaced.

> [Vendor] reviewed the system's logs and determined that predictive drive failure messages were sent from both disk drives prior to their failure but the customer did not act on the messages and arranged to replace the hard drives. As a result, the drives failed and images are lost.

There was only 1 vendor that was coded for replace or remove. All of these responses also included a short description of original error.

4.4 Quantitative Analysis

4.4.1 Frequency of Technology-Induced Errors

The coded events involved 6 different vendors; however, the majority of events were associated with just 2 vendors. The adverse events involving these 2 vendors represent 72% (n=148) of the total number of adverse events. Although Vendor 5 is one of the top 5 vendors based on the 2016 U.S. market share, there was only 1 adverse event associated with Vendor 5 reported in the MAUDE database. Table 5 provides a summary of the number of adverse events broken down by vendor.

There were 412 total coded technology-induced errors within 204 adverse events that occurred between January 1, 2012 and December 31, 2016. Vendor 4 had the highest number of coded technology-induced errors with 164, representing 40% of the total number of technology-induced errors. Vendor 1 has the second highest number of errors (31%, n=126), followed by Vendor 6 (15%, n=60), Vendor 2 (8%, n=32), Vendor 3 (6%, n=26) and Vendor 5 (1%, n=4). The ordering is very similar when comparing the total number of adverse events across vendors. Vendor 1 had the higher number of adverse events (37%, n=76), followed by Vendor 4 (35%, n=72), Vendor 6 (13%, n=26), Vendor 3 (7%, n=15), Vendor 2 (7%, n=14) and finally Vendor 5 (0.5%, n=1). Vendor 1 had 4 more adverse events (n=76) than Vendor 4 (n=72), but had 25 more coded technology-induced errors when compared to Vendor 4. A complete summary of the number of adverse events by vendor can be found in Table 5 and the number of technology-induced errors by vendor in Table 6.

Vendor	Frequency
Vendor 1	76 (37%)
Vendor 2	14 (7%)
Vendor 3	15 (7%)
Vendor 4	72 (35%)
Vendor 5	1 (1%)
Vendor 6	26 (13%)

Table 5. Total Number of Adverse Events by Vendor

TIE Classification	Vendor 1	Vendor 2	Vendor 3	Vendor 4	Vendor 5	Vendor 6
Interface						
Data entry	8	3	0	10	0	3
Display visibility	7	4	1	13	1	11
Navigation	1	1	0	4	0	2
Locating	2	1	1	5	0	2
Procedure	3	0	0	1	1	1
Printing	0	1	0	3	0	0
Speed	14	0	0	1	0	2
Attention	4	0	0	4	1	4
Content						
Database	21	5	3	20	0	4
Defaults	8	6	2	14	0	3
Training Manual	1	0	0	0	0	0
Additional Classifications						
Decision support system rule	1	2	3	11	0	1
Decision support system	35	5	9	36	1	13
Alert not displayed	3	0	1	20	0	10
System to system interface error	18	4	6	22	0	4

Table 6. Frequency of Technology-Induced Errors by Vendor

4.4.2 Frequency of Recovery Actions

Not all of the adverse events included a response from the vendor. Of the 204 total adverse events, 105 (51%) did not include a vendor response. Vendor 4 had the most recovery actions (n=132), followed by Vendor 1 (n=40) and Vendor 3 (n=25). Over half (52%, n=52) of the total number of responses (n=99) to adverse events were posted by Vendor 4. Vendor 3 had the highest response rate to adverse events. Of the 15 adverse events associated Vendor 3, 12 (80%) included a response from the vendor.

Vendor 4 had the second highest response rate with 52 (72%) of their 72 adverse events having a response, and Vendor 1 had the lowest response rate with 35 (46%) events having a posted response. Vendor 2, Vendor 5 and Vendor 6 did not respond to any of the reported adverse events in the MAUDE database during the specified time period. A summary of the number of recovery actions taken by vendors is listed in Table 7.

Recovery Action	Vendor 1	Vendor 2	Vendor 3	Vendor 4	Vendor 5	Vendor 6
Repair	0	0	0	2	0	0
Replace or remove	3	0	0	0	0	0
Safety notification	8	0	10	50	0	0
Safety instructions	6	0	5	36	0	0
Software update	23	0	10	44	0	0

Table 7. Frequency of Recovery Actions by Vendor

Chapter 5: Discussion and Conclusion

5.1 Introduction

The purpose of this chapter is to discuss the findings from this thesis along with the current research and to answer the following research questions:

1. What types of technology-induced errors are common among the manufacturers of health information technologies in the United States?
2. Are there any similarities or differences in reported technology-induced errors among the health information technology manufacturers in the United States?
3. How are health information technology manufacturers or vendors in the United States addressing technology-induced errors and what are they reporting as solutions?

5.2 Common Errors among HIT Vendors

The most common technology-induced error found among HIT vendors is a 'decision support system' error. This type of error is used to identify a system that has behaved in an unexpected manner or was missing features that were assumed to be present by the user. 'Decision support system' errors make up nearly one quarter (24%, n=99) of all the identified technology-induced errors, which represent almost half (49%) of all adverse events. The second most common technology-induced error identified is 'system to system interface error' which was assigned when there was a communication or interfacing error between two systems. This represents 13% (n=54) of all coded technology-induced errors, while 26% of all adverse events were assigned this type of error. The two most common errors are related in that they involve a system that is behaving unexpectedly, either through the use of that system or communication with

another system. Every included vendor had adverse events that were coded as 'decision support system' and every vendor with the exception of vendor 5 had adverse events that involved a 'system to system interface error'. The percentage of adverse events that involved a 'decision support system' by a vendor ranged from 36% (Vendor 2) to 60% (Vendor 3), and the percentage of events involving a 'system to system interface error' ranged from 15% (Vendor 6) to 40% (Vendor 3). These ranges do not include Vendor 5 as this vendor only had 1 adverse event identified over 5 years.

5.3 Similarities and Differences between Vendors

There were many similarities found in the types of technology-induced errors across vendors. The technology-induced error associated with the most events, 'decision support system', was the same for five out of the six vendors. Vendor 2 is the only one where 'decision support system' is not the error associated with the most events. For this vendor, that technology-induced error is second highest. Vendor 1 and Vendor 4 have the most similarities both in number of errors and types of error. Vendor 1 was associated with the most number of adverse events (n=76) which was followed closely by Vendor 4 (n=72).

There was a large difference in the number of reported events across vendors. Just three vendors represented 85% of the identified adverse events. The top eight vendors by market share were included in this study which represents approximately 91.5% of the total 2016 U.S. market share. However, the prevalence of adverse event reports varied greatly among the vendors with the highest market shares. The vendors that followed up on submitted adverse events also were the vendors that had the most adverse events submitted. Occasionally, these vendors would also submit their own

ticket when an adverse event was reported directly to the vendor by a facility. The vendors with the highest number of adverse events in the MAUDE database are all self-reporting some of their adverse events. However, only three out of the six vendors were reporting follow-ups to adverse events. Vendors 2, 5 and 6 did not post responses to any adverse events.

5.4 Responses to Reported Errors

There were 99 total adverse events that also included a response from a vendor. This is almost half of all adverse events that were included (49%). The most common recovery action by a vendor was performing a 'software update' in response to the event. Out of the 99 adverse events that had a vendor follow-up, 77 (78%) of them involved a 'software update'. A 'safety notification' was often accompanied by a 'software update' when it was associated with Vendor 4. Out of the 44 software updates performed by Vendor 4, 41 events also resulted in a notification to affected facilities and 31 events also had instructions on alternate workflows to avoid the error. Vendor 4 is the only vendor where most of the events involving software updates also came with instructions or notifications related to the error. There were 6 (6%) events where the only response was a 'safety notification'. These are events where there was a vendor response acknowledging the error, but no instructions provided for a workaround or workflow change or any software update to eliminate the error. The least common recovery actions by a vendor were 'replace or remove' and 'repair'. Both of these actions are related to hardware issues which were much less common than a software issue. There were only 5 (5%) adverse events with vendor responses that involved either of these actions.

5.5 Contributions to Current Research

There has been previous research completed that focused on adverse events related to HIT in the MAUDE database. However, there has not been any previous research completed examining technology-induced errors across HIT vendors. This study highlights the current differences in the types of technology-induced errors prevalent across vendors, the differences in the reporting of these errors, and the solutions created in response to these errors. The findings from this study will be compared to previous research in the field by examining the overall frequencies and classifications of identified technology-induced errors in the MAUDE database.

The classification used in the study completed by Magrabi et al. in 2012 categorized reports by being either human- or machine-related and then subdivided these reports into one of five primary classifications: information input problems, information transfer problems, information output problems, general technical or contributing factors. There were many differences identified between the data collected for this study and the study completed by Magrabi et al. (2012). The highest percentage of technology-induced errors were found to be in the general technical classification with 60% of adverse events being related to either hardware or software issues. Software issues specifically were associated with 41% of the reported adverse events. This is related to the decision support system classification used in this study, which was assigned for 49% of events. Output/display errors accounted for 28% of the identified errors which include issues with the display of information, consistency of data across applications and issues with alert displays. The data that has been collected for this study related to these classifications (e.g. ‘display visibility’, ‘defaults’ and ‘alert not displayed’) indicate a

much higher percentage. There were 104 adverse events that involved one or more of these classifications which totals 51% of all adverse events. There were also large differences in the number of events identified that are related to computer speed. 8% (n=17) of adverse events were related to a system being too slow. However, Magrabi et al. (2012) found that 16% of adverse events were related to this issue which is double what was found in this study. There were also differences in the number of events related to data entry problems. Magrabi et al. (2012) found only 3%, whereas this study identified 12% of events related to this classification. Magrabi et al. (2012) did not find any adverse events within the contributing factors classification. This classification includes the subcategories: staffing/training, cognitive load, and fail to carry out duty. This result is similar to what was identified in this study. Only 1 adverse event was found within this classification and it was related to training. The classifications used are very different and not every classification has an equivalent which makes it difficult to compare results. However, it does appear as though there were very limited similarities in the number of adverse events. This may be attributed to the differences in HIT adoption and number of adverse events in the MAUDE database from 2010 and 2016.

Myers et al. completed a study in 2011 using data from the MAUDE database and found that just three vendors were represented in over half of all adverse events that were identified. This is consistent with the adverse events identified in this study, although the percentage was found to be higher. Just 3 vendors were represented in 85% of the identified adverse events. Myers et al. (2011) found that the most common error was related to user interface. It was determined that 52.5% of their included adverse events were related to a problem with the user interface. This was similar to what was identified

in this study (59%). The slightly higher percentage may be due to the increased awareness of the importance of usability testing during HIT design and the emergence of new research since the Myers et al. study was published in 2011. Adverse events from the MAUDE database were included in that study up to March 31, 2010. It was also found that 17.5% of reported errors were related to 'integration' which is an adverse event caused by data exchange between products. This is a much lower number than was identified in this study where it was found that 26% of all adverse events were related to a 'system to system interface error'. There have been many changes in the HIT landscape since this research was published in 2011. The number of organizations that have adopted HIT has increased dramatically which may account for the increase in potential for technology-induced errors (Borycki et al., 2012).

The study completed by Palojoki et al. (2016) utilized the Magrabi et al. (2012) classification scheme to examine adverse event reports submitted to a Finnish incident reporting system. The largest differences found are related to the 'system to system interface error' classification used in this study. This error accounted for 26% of adverse events, but it does not have an equivalent to the classifications used in the Palojoki et al. (2016) study. The information transfer problems identified by the Palojoki et al. (2016) study are not related to communication or interfacing issues between systems. This is likely related to the differences in EHRs between the United States and Finland. The hospitals in Finland are all fully digitized and every hospital included in that study used the same EHR. There was also large difference in the number of events identified as being related to data entry. Palojoki et al. (2016) found just 3 events (0.13%) whereas this study identified 24 events (12%). Another major difference is that all but 8% of the

incidents in the database identified by Palojoki et al. (2016) contained descriptions of follow-up actions and only 49% of the adverse events in the MAUDE database had a vendor response.

Kang et al. (2018) completed a study to attempt to develop a method for standardizing the process of identifying HIT-related adverse events from the MAUDE database with the goal of extracting these events into a separate HIT-specific database. They estimated that the adverse events in the MAUDE database represent 0.46% to 0.69% of all reported adverse events. This is a higher percentage than has been previously reported. In a previous study conducted by Magrabi et al., in 2012, it was found that only 0.1% of extracted adverse events from the MAUDE database were related to HIT. Another study completed by Myers et al. (2011) also found that only 0.1% of adverse events in the MAUDE database were related to HIT. However, both of these previous studies used data up to 2010 from the MAUDE database. There has since been substantial growth in the adoption rates for hospitals in the United States. Between 2010 and 2015, the adoption rate of EHRs increased by almost 70% from 19.1% in 2010 to 88.3% in 2015 (Henry, Pylypchuk, Searcy & Patel, 2016). In addition, the number of events that have been submitted to the MAUDE database over the same time frame increased by 186% from 338,830 reports submitted in 2010 to 969,966 submitted in 2015 (FDA, 2017). The increased amount of adverse events in the MAUDE database identified through the study completed by Kang et al. (2018) may be attributed to the increase in EHR adoption as this study includes MAUDE data up to 2016.

In this study, the adverse events were only selected if they indicated that they involved a vendor that is in the top U.S. market share for 2016. Even so, only 0.005% of

all adverse events in the MAUDE database contained reports related to those vendors. This study has shown that there are substantial differences in the number of adverse event reports being submitted even among the top vendors by market share. It's possible that the HIT reports identified in other research involved vendors that are outside of the top eight by market share, but place more of a focus on submitting adverse events involving their technology to the MAUDE database. Improving the reporting of adverse events in the MAUDE database by vendor will lead to increased accountability and transparency in the prevalence of technology-induced errors within their technologies.

In a study completed by Alemzadeh et al. (2013), the MAUDE database and a second database that contains reports on medical device recalls were used to identify computer-related recalls due to failures in medical devices. In addition to classifying type of failure and impact of the failure, they classified recovery actions to understand the actions that were taken by the vendor to address the recall. The classification scheme for recovery actions used in their research was also used to classify the responses submitted by vendors in response to technology-induced errors in this study. The study completed by Alemzadeh et al. (2013) did not focus specifically on HIT, rather they examined events that involved recalls and were computer-related. There is no previous research of this type of analysis being completed using HIT-related events in the MAUDE database. Previous research has not examined how vendors are responding to reported adverse events within the MAUDE database.

The qualitative analysis of the adverse events in the MAUDE database revealed the need for additional technology-induced error classifications beyond the original coding scheme. These four additional classifications (alert not displayed, system to

system interface error, decision support system rule and decision support system) have not been found together in previously used classification schemes. In order to build a comprehensive list of codes, four studies were used (Kushniruk et al., 2005; Magrabi et al., 2010; Myers et al., 2011; Palojoki et al., 2017) to produce a final list of fifteen codes used to classify technology-induced errors. These findings demonstrate the need for a standardized classification system for reporting technology-induced errors.

5.6 Changes in Practice

There has been considerable debate on the regulation of HIT as a medical device. Adverse event reports related to HIT are currently only submitted on a voluntary basis to the FDAs MAUDE database which has led to the underreporting of technology-induced errors (Myers et al., 2011). There is limited research completed on the prevalence of technology-induced errors by utilizing the MAUDE database. In addition, it is difficult to discern whether an event is HIT-related from the fields that are required in the MAUDE database upon submission since there is no identifying field to separate these events. Users must search the free text fields for keywords related to HIT. MAUDE has the potential to be a useful resource in monitoring and researching technology-induced errors, but for it to be fully utilized there needs to be an increase in the rate of reporting these errors. This database is currently the only publicly available adverse event database in the United States (Kang et al., 2018) so there should be a focus on improving the quality and frequency of reporting HIT-related adverse events. This can be achieved by both increasing the overall awareness of technology-induced errors and increasing awareness of the availability of the MAUDE database.

5.7 Contributions to Health Informatics Education

The most important information that could be brought into education is on the emergence of technology-induced errors. Current health education does not always include this type of medical error, although there is a focus on other types of medical error. The importance of reporting all types of medical error would be a valuable contribution to current education as it has been shown that often adverse events are not reported if they involve HIT as many users do not believe that this qualifies as medical error (Borycki, 2013). Methods to identify technology-induced errors, as discussed in Chapter 2, would also be a valuable contribution to current education. There has been emergence of research completed in the last decade on how to identify, address and prevent technology-induced errors (Borycki, 2013). Incorporating this into all types of health education would support the goal of reducing the occurrence of technology-induced errors and increasing the overall safety of HIT. Allowing students to interact with and learn about HIT in a classroom setting prior to using these systems in a real-world setting would allow them to understand how the technology could be used and the limitations that exist in an environment where there is no direct impact to patient care (Borycki, Joe, Armstrong, Bellwood & Campbell, 2011). Increased awareness of technology-induced errors could also lead to an increased rate of reporting these issues. Currently, adverse events related to HIT are extremely under-reported. Having a publicly available database that contains more comprehensive data on the types and frequencies of technology-induced errors in HIT would lead to an increased understanding of these types of error and support initiatives aimed as decreasing the incidence of technology-induced errors.

5.8 Future Research

There are many limitations to the use of the MAUDE database for the reporting of technology-induced errors. Future research should be focused on how best to improve on these limitations to increase awareness of technology-induced errors and increase reporting rates of these errors. There have been a number of studies published utilizing this database and they have all highlighted the importance of improving the reporting of technology-induced errors. Greater transparency with HIT-related adverse events will be beneficial in highlighting current issues and increased reporting rates will help establish a baseline for future improvement. Additional research should also be completed on methods to extract and report data from the MAUDE database. It is very difficult to identify an HIT-related event and studies are all using different methods to extract these events. They are also using multiple systems for classifying the technology-induced errors. An increased availability of data will lead to a greater understanding of the different types of technology-induced errors and how they can occur, which is a crucial step in reducing the overall occurrence of technology-induced errors.

5.9 Limitations

There were a number of limitations identified from this study. Firstly, there are very few events being reported that relate to technology-induced errors. This may be due to a continued lack of understanding as to what type of events may be considered a technology-induced error (Borycki, 2013). These individuals may also not be aware of the existence of a database that they can submit these events to. Another possible cause would be that adverse event reporting for HIT is currently not mandatory and not monitored. Reporters may feel as though submitting an adverse event of this nature

would offer no benefit since there is no regulation and data extraction from the database is difficult. One method to address this limitations that has been suggested by Myers et al. (2011) is to include instructions within the HIT on how and when to submit an adverse event report. In addition to instructions, vendors could include a link within the technology to direct users to the MAUDE submission website and potentially auto-populate many of the required fields making it easier for the user to make a submission which would encourage reporting of errors. However, it would also be beneficial for the FDA to provide clearer regulations on the use and reporting of HIT as medical devices. The voluntary nature of HIT adverse event reporting is a major barrier and contributes to the under-reporting of technology-induced errors.

The FDA does not enforce its reporting requirements as heavily with HIT as it does with other medical devices and there is much debate about how involved the FDA should be in its regulation. According to the Federal Food, Drug and Cosmetic Act, HIT is considered to be a medical device. Although there is not a lot of enforcement, manufacturers and healthcare facilities still submit voluntary adverse event reports relating to HIT to the MAUDE database (Magrabi et al., 2012). The MAUDE database has been used previously to examine safety related to a variety of medical devices. However, the MAUDE database has not been fully utilized to examine the safety of HIT. Since it has been reported that the United States produces approximately 37% of all medical devices (Balka et al., 2007), it will be beneficial to all countries to adequately utilize the data contained within the MAUDE database. In order for it to become more feasible to use the MAUDE database to continuously monitor HIT incidents, there needs to be some changes made to the database so it can become easier to distinguish HIT

incidents from those involving other medical devices (Chai et al., 2013). There are more than 2 million incident reports available within the MAUDE database making manual review of the incidents almost impossible (Chai et al., 2013). The most commonly used approach used for extracting HIT-related incidents is to download the yearly master event files, filter out reports by using pre-defined keywords and perform a manual review of a much smaller subset of reports (Chai et al., 2013).

Another limitation of the MAUDE database is that it only contains reports of adverse events related to commercial systems. Any HIT that is developed by an organization for internal use only is not going to be included in the MAUDE database (Myers et al., 2011). It is a difficult process to extract reports from the MAUDE database. It is even more difficult with HIT as the categories and problems associated with these systems vary greatly. It has been recommended that the FDA MAUDE database employ strategies to more accurately capture adverse events occurring with HIT. The current list of Product Problems does not include specific categories for capturing these types of medical devices (Alemzadeh et al., 2013). There are also no clear guidelines on what types or severity of errors should be reported. A study conducted by Kramer et al. (2012) found that between 2009 and 2011 there were 142 instances of malware infections that affected medical devices; however, none of these instances were reported to the MAUDE database. Since the submission of reports is voluntary, the lack of clarity in guidelines for submitting HIT-related incidents could make users less likely to submit reports (Myers et al., 2011).

5.10 Conclusion

This study aimed to identify what types of technology-induced errors are present with the key health information technology vendors in the United States, determine if there are any similarities and differences in technology-induced errors present among the key health information technology vendors in the United States, and determine what methods are utilized, if any, by the key vendors of health information technologies to address and/or resolve reported technology-induced errors. It was found that the most common reported technology-induced errors involved systems behaving unexpectedly, either through the direct use of that system or through the communication between systems. The largest difference between vendors was in the number of reported events. Just three out of the included vendors represented 85% of all the identified adverse events. These vendors have also been responding to reported errors and describing how they would resolve the error and prevent future occurrences.

Electronic health records are being implemented with the goal of increasing efficiency and safety in health care. However, inadequate testing has led to a limited understanding of the new types of medical error that can arise from EHR implementation and use. In addition, there is a lack of oversight on the implementation of EHRs and in the United States, no monitoring of these systems post-implementation. There is also limited regulation and no mandatory reporting of adverse events involving HIT. Improvements to the way technology-induced errors are reported will help ensure that HIT is designed and implemented effectively, increasing the overall safety of healthcare.

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Appendix A: Ethics Exemption

Eugenie Lam <hrethics@uvic.ca> Fri, Apr 22, 2016, 7:04 PM

to me

Dear Victoria Pequegnat,

The Chair of the UVic Research Ethics Board and I reviewed the information you provided via email.

Based on UVic policies and the *Tri-Council Policy Statement on the Ethical Conduct of Research Involving Humans* (TCPS2 2014) the proposed study is exempt from human research ethics review as the identified source is publicly available.

In the event the proposed study changes and the inclusion of human participants and/or non-public/protected documents is contemplated, please contact us as research ethics clearance may be required. Please retain a copy of this email for your records. We will do the same.

Feel free to contact us at any time.

Thanks,

Eugenie

Eugenie Lam, M.A.

Research Ethics Coordinator | Office of Research Services, University of Victoria | PO Box 1700 STN CSC Victoria, BC. V8W 2Y2 Canada hrethics@uvic.ca Phone: 250- 472-5202

http://www.uvic.ca/research/conduct/home/regapproval/humanethics/index.php

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