Due to the increasing implementation of EHRs, the potential for technology-induced errors is a challenge that underscores the importance of identifying areas of vulnerability to mitigate them. This study provides a comprehensive picture of the characteristics of technology-induced errors in EHRs. Moreover, an instrument, the FIN-TIERA for controlling and preventing errors from the user perspective was developed. A more comprehensive approach to EHR safety is suggested to prevent patient harm.
THE UNDERSTANDING AND PREVENTION OF TECHNOLOGY-INDUCED ERRORS IN ELECTRONIC HEALTH RECORDS: A PATH TOWARD HEALTH INFORMATION TECHNOLOGY RESILIENCE
Sari Palojoki

THE UNDERSTANDING AND PREVENTION OF TECHNOLOGY-INDUCED ERRORS IN ELECTRONIC HEALTH RECORDS: A PATH TOWARD HEALTH INFORMATION TECHNOLOGY RESILIENCE

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ABSTRACT
Concerns regarding electronic health records (EHRs) are multidimensional and sociotechnical patient safety issues that should be considered from the viewpoint of end users, clinicians. Due to the complexity of healthcare processes and the increasing implementation of EHRs, the potential for technology-induced errors is a growing challenge that underscores the importance of identifying areas of vulnerability to mitigate them. A proactive assessment of safety risks fosters the resilience of organizations to the hazards of EHR use; the term resilience refers to how organizations monitor, adapt to and act on failures, particularly in high-risk situations. However, current EHR risk-assessment tools are underdeveloped.

The purpose of this study is to provide a comprehensive picture of the characteristics of technology-induced errors in EHRs. Specifically, the goal is to develop and validate an instrument for controlling and preventing errors from the user perspective. Two types of data provided by EHR users in specialized hospital care in Finland were collected and analyzed by applying multiple research methods, including several statistical tests. Moreover, incident reporting data on the Directive 2007/47/EC (2010–2015) from Finnish National Supervisory Authority (Valvira) were collected and analyzed.

The proportion of EHR-related safety incidents is significantly higher than previously measured, indicating that a high EHR implementation rate produces novel vulnerabilities. Severe perceived risk levels and error rates were related to many error types such as EHR unavailability. Targeted training for EHR users will enable better coping when EHR risks are encountered. Studies in this thesis have revealed challenges in the existing patient safety monitoring systems. A new FIN-TIERA tool, developed and validated for proactively detecting errors, showed initial measurement properties.

Because EHRs pose risks to patient safety, as shown in these studies, a more comprehensive approach to EHR safety is required. Refining existing safety monitoring systems is essential to ensure patient safety in the EHR environment.
ABSTRACT

Concerns regarding electronic health records (EHRs) are multidimensional and sociotechnical patient safety issues that should be considered from the viewpoint of end users, clinicians. Due to the complexity of healthcare processes and the increasing implementation of EHRs, the potential for technology-induced errors is a growing challenge that underscores the importance of identifying areas of vulnerability to mitigate them. A proactive assessment of safety risks fosters the resilience of organizations to the hazards of EHR use; the term resilience refers to how organizations monitor, adapt to, and act on failures, particularly in high-risk situations. However, current EHR risk-assessment tools are underdeveloped.

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toring systems and implementing the FIN-TIERA tool in healthcare will guide clinical EHR safety towards more resilient practice.

**Keywords:** classification, electronic health records, health information technology, patient safety, questionnaire, register study, resilience, risk management, sociotechnical


Potilastietojärjestelmien aiheuttamia virheitä esiintyy merkittävästi enemmän kuin aiemmissa kansainvälisisissä tutkimuksissa on osoitettu, mikä kuvastaa laajan käyttöönottoasteen tuottamaa uudenlaista virheprofilia. Käyttäjät arvioivat, että moniin tunnettuihin virhetyyppiin, kuten käyttökatoihin, on liittynyt omassa työympäristössä korkea riskitaso. Tutkimus osoitti, että kohdennettu käyttäjäkoulutus mahdollistaa nykyistä paremmat virhetilanteiden hallinnan. Tutkimuksessa tunnistettiin kehitystarpeita tämänhetkisissä seurantajärjestelmissä. Uusi, tässä

Palojoki, Sari
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TIIVISTELMÄ


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tutkimuksessa kehitetty ennakoivan riskienhallinnan työkalu, FIN-TIERA, osoitti validoinnin aikana alustavia mittausominaisuuksia.

Koska potilastietojärjestelmät aiheuttavat potilasturvallisuusriskejä, tilanne edellyttää tämänhetkistä laaja-alaisempaa potilastietojärjestelmien käytön turvallisuushallintaa. Sekä nykyisten seurantajärjestelmien kehittäminen että tässä tutkimuksessa kehitetyn FIN-TIERA -riskienarviointityökalun käyttöönotto osana terveydenhuollon toimintaa edesauttavat potilastietojärjestelmien käytön resilienssiä.

**Asiasanat:** luokitus, potilastietojärjestelmä, terveydenhuollon tietojärjestelmä, potilasturvallisuus, kysely, rekisteritutkimus, resilienssi, riskienhallinta, sosiotekniset

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Veikko Rouhiainen from Technical Research Centre of Finland (VTT) and Patient Safety Manager Kaisa Haatainen from Kuopio University Hospital provided valuable comments. Researcher Marika Noso from the Technical University Aalto and Senior Advisor Timo Hakala from the Government of Helsinki provided many insights and support; above all, they shared the adventure of struggling to complete their PhD at the same time. I want to thank Senior Officers Jari Knuuttila, Antti Härkönen and Head of Unit Heikki Mattlar at the National Supervisory Authority (Valvira) for their advice and flexibility during the data collection.

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Victoria, BC, Canada, 17th February 2017
Sari Palojoki
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INTRODUCTION

Research shows that medical errors are an ongoing problem in healthcare systems worldwide, resulting in high costs for both the healthcare institutions and the patient, not to mention unnecessary suffering for the patient (Landrigan et al., 2010; AHRQ, 2013, Wright et al., 2016). Estimates list unsafe medical care among the most prominent causes of human harm, as 8-15% of hospital patients in high income countries are affected by errors (Jha, Godlee and Abbasi, 2016). The accuracy of widely referenced estimates of high death rates due to medical error (IOM, 1999; James, 2013; Makary and Daniel, 2016) have now been questioned due to methodological issues (Bottle, Jarman and Aylin, 2010; Shojania and Dixon-Woods, 2016), and one evidence-based hospital mortality report from Finland shows that hospital care contributes to fewer patient deaths than previous estimates, indicating approximately 200 cases per half a million patients treated annually (HUS, 2016). Regardless of the scope, it is imperative to find effective ways to promote healthcare safety (Jha and Pronovost, 2016).

In 1999’s “To Err Is Human: Building A Safer Health System”, the Institute of Medicine argued that available approaches to preventing medical errors were not effective enough and that more inventive means were needed. At that time, health information technology (HIT) was believed to be an innovative solution that would reduce medical error rates and bring many benefits for patient care (Bates et al., 1999; Bates and Gawande, 2003; Ammenwerth et al., 2008; Black et al., 2011; Furukawa, 2011).

However, this trust in health information technology became overshadowed in the 2000s by a growing number of reports of its undesirable consequences (Battles and Keyes, 2002; Horsky, Kuperman and Patel, 2005; Chaudhry, 2006; Koppel et al., 2008; Ash et al., 2009; Black et al., 2011; Patel and Kannampallil, 2014). A 2001 Institute of Medicine report recommended the reporting of adverse events related to the use of health information technology, assuming that an increase in the implementation of information technology would introduce new vulnerabilities, potentially leading to patient safety incidents (also Battles and Keyes, 2002; Denham et al., 2013). Since the last decade, the literature has grown but is still limited, as demonstrated in a recent systematic review of eHealth technologies and their impact on the safety of healthcare (Agboola, Bates and Kvedar, 2016). The review also summarized the emerging results (Black et al., 2011; Sheikh et al., 2011; Rudin et al. 2014; Slight et al., 2015) indicating the gap between the assumed and empirically-supported benefits of health information technology (Agboola, Bates and Kvedar, 2016).

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Today, many researchers share the view that technology-induced errors arise from a number of sources in a sociotechnical environment. EHRs do not have the
capability of adapting to changes within dynamic EHR-enabled healthcare systems (Smith et al., 2014). A systems-level perspective could help to uncover the sources of errors and solutions for their prevention. Researchers exploring the causes of medical errors need to pursue theoretical diversity (Holden and Karsh, 2007; Borycki, 2010; Sittig and Ash, 2011; Singh and Sittig, 2016), as several factors impact the errors created by the use of electronic health records (EHRs) (e.g., Harrison, Koppel and Bar-Lev, 2007; Koppel, 2010; Lawler, Hedge and Pavlovic-Veselinovic, 2011; Elkin, 2012; Smith et al., 2014; Singh and Sittig, 2016).

Even if the body of research identifying errors related to health information technology is growing, the lack of HIT-related risk reporting and data describing those risks (Coiera, Aarts and Kulikowski, 2012; Borycki, 2013a and 2013b; Denham et al., 2013; Menon et al., 2014a; Agboola, Bates and Kvedar, 2016; also Jha and Provonost, 2016) is a hindrance to building and using safer information systems. A systematic analysis of EHR-related safety concerns is necessary for recognizing errors related to health information technology, but the best method for measuring or analysing these errors is ambiguous (Borycki, 2013b). As a consequence, these problems are largely left unidentified, or they are identified only after plentiful documentation accumulates. This process can take a long time, with severe consequences for patient safety (Ong, Magrabi and Coiera, 2013). One foreseeable option for analysing and extracting large amounts of data is a classification system or taxonomy to capture and differentiate types of errors (Cimino, 2011; Taib et al., 2011; Mikkelsen, Thommesen and Andersen, 2013). Unfortunately, there has not been an international consensus on a standardized format to enhance collection, analysis, and interpretation of technology-induced errors.

Moreover, as is the case with patient safety improvement efforts in general, a reactive approach alone to identifying and mitigating technology-induced errors is unlikely to be the most profitable way to prevent patient harm (JCAHO, 2008). Despite the well-known risks associated specifically with the use of health information technology, existing methods for monitoring these incidents are still scarce, and those methods rely, essentially, on voluntary reporting using generic patient safety incident reporting systems (Ong, Magrabi and Coiera, 2013). Voluntary incident reporting systems do have their benefits (Howell et al. 2016), and many other existing principles still provide a value in today’s healthcare safety efforts, such as correct prioritization and compliance (Olsen and Aase, 2010). However, the need to broaden current EHR security and safety is eminent, especially when recent evidence on meaningful progress in patient safety work has been regarded as controversial (Dixon-Woods, McNicol and Martin, 2012; Jha and Provonost, 2016).

While present EHR safety interventions focus mostly on assessing past harm, researchers should also be developing tools to aid in the monitoring of EHR safety (Singh, Ash and Sittig, 2013). Previous studies show that EHR safety depends on ongoing surveillance, specifically in relation to an ongoing assessment of
ongoing surveillance, specifically in relation to an ongoing assessment of researchers should also be developing tools to aid in the monitoring of EHR safety scarce, and those methods rely, essentially, on voluntary reporting using generic information technology, existing methods for monitoring these incidents are still been regarded as controversial (Dixon-Woods, McNicol and Martin, 2012; Jha and However, the need to broaden current EHR security and safety is eminent, efforts, such as correct prioritization and compliance (Olsen and Aase, 2010). and many other existing principles still provide a value in today’s healthcare safety Voluntary incident reporting systems do have their benefits (Howell et al. 2016), despite the well-known risks associated specifically with the use of health reactive approach alone to identifying and mitigating technology-induced errors is analysis, and interpretation of technology-induced errors. consequences for patient safety (Ong, Magrabi and Coiera, 2013). One foreseeable documentation accumulates. This process can take a long time, with severe problems are largely left unidentified, or they are identified only after plentiful or analysing these errors is ambiguous (Borycki, 2013b). As a consequence, these or taxonomy to capture and differentiate types of errors (Cimino, 2011; Taib et al., 2011; Elkin, 2012; Smith et al., 2014; Singh and Sittig, 2016). as several factors impact technology is growing, the lack of HIT-related risk reporting and data describing medical errors need to pursue theoretical diversity (Holden and Karsh, 2007; Holden and Karsh, 2007; Denham et al., 2013), which underscores the importance of the potential for health information technology to cause errors is a concern (Battles and Keyes, 2002; Denham et al., 2013), which underscores the importance of identifying areas of vulnerability and also practices to mitigate risks (Patel, Kannampallil and Shortliffe, 2015). Consequently, this summary handles relevant and actual issues, and the research area is highly significant on a practical basis. The need to consider user perspectives in technology-induced errors has become evident both in clinical work and in public discussions (e.g., McGinn et al., 2011; Papoutsi et al., 2015). In conclusion, researchers should be analyzing not only the potential advantages but also the safety risks caused by EHRs. New and more sociotechnical factors which affect the use of EHRs (Smith et al., 2014). Information technology functions are not visible to clinicians using EHR, and, without a basic HIT safety (HITS) measurement system, it is improbable that concerns related to health information technology will be detected easily. Many EHR errors are latent and involve technological features, user behaviour, and regulations, making error prevention exceptionally challenging and arduous (Singh and Sittig, 2016). It is possible that many new EHR adopters lack the essential skills and resources to cope with these shortcomings; researchers must also develop techniques to create an awareness of the risks, as well as approaches to monitoring and management. This more proactive evaluation of hazards increases the health care organizations’ resilience in the face of hazards of EHR use, but current risk assessment tools as part of organizations’ resilient practices are underdeveloped. (Sittig and Singh, 2013; Smith et al., 2014; Singh and Sittig, 2016).

The regulatory oversight system gathers data to help EHR developers and clinicians better comprehend and mitigate risks involved with the implementation and use of EHRs (EEC, 1993; Goodman et al., 2011; Sittig, Classen and Singh, 2014). Historically, regulations governing health information technology have been less strict than for medical devices (Chai et al., 2013). Today, however, both the EU and the US systems have adverse event and failure reporting models integrated into the software of a variety of medical devices, but the systems differ (Goodman et al., 2011; Myers, Jones and Sittig, 2011; Bowman, 2013; Chai et al., 2013; Sittig, Classen and Singh, 2014). The principal purpose of the EU Medical Device Vigilance System is to improve safety by reducing the likelihood of reoccurrence of the incident elsewhere (EEC, 1993). At present, researchers are unable to determine the precise number of EHR-related adverse events using the available monitoring infrastructure (Goodman et al., 2011; Smith et al., 2014). Questions have been raised regarding whether and how the regulation of EHRs could foster patient safety (Goodman et al., 2011; Sittig, Classen and Singh, 2014).

In general, EHR concerns, as a multidimensional patient safety issue, merit greater interest, because the rate of EHR systems implementation continues to grow steadily (IOM, 2001; Coiera, Aarts and Kulikowski, 2012; Wright et al., 2013; Charles, Gabriel and Searcy, 2015). Because of the intricacy of healthcare processes, the potential for health information technology to cause errors is a concern (Battles and Keyes, 2002; Denham et al., 2013), which underscores the importance of identifying areas of vulnerability and also practices to mitigate risks (Patel, Kannampallil and Shortliffe, 2015). Consequently, this summary handles relevant and actual issues, and the research area is highly significant on a practical basis. The need to consider user perspectives in technology-induced errors has become evident both in clinical work and in public discussions (e.g., McGinn et al., 2011; Papoutsi et al., 2015). In conclusion, researchers should be analyzing not only the potential advantages but also the safety risks caused by EHRs. New and more
encompassing measures than the ones of today should be taken to prevent these risks from becoming reality.

The purpose of this study is to provide a comprehensive picture of the state of electronic health records-related technology-induced errors by analyzing two types of data in the Finnish specialized hospital care setting with a 100 per cent EHR implementation rate. Additionally, the National Supervisory Authority (Valvira) user-reported data of EHR-related errors based on the Medical Devices Directive (EU, 2007) in Finland (2010-2015) is analysed in order to broaden the scope of the thesis. At the same time, the goal is to assess the adequacy of current approaches to monitor technology-induced errors, regulatory issues of medical software, and taxonomies to analyse technology-induced errors. Specifically, the goal is to develop and test an instrument for preventing and controlling technology-induced errors from clinical user’s perspective. Finally, the elements of a technology-induced error monitoring resilience practice from a user’s perspective are presented in this summary based on these four substudies.

The research domain in this work is health and human services informatics, (Saranto and Kuusisto-Niemi, 2011; 2012). It is an aggregation of several related disciplines including computer science, information science, management science, cognitive science, health and social sciences, and organizational theory and also covering several sub-domains, including clinical and biomedical informatics, telemedicine, and healthcare management informatics (Gardner et al., 2009; Mantas et al., 2010; Shortliffe, 2010; Detmer and Shortliffe, 2014; AMIA, 2016; Mantas, 2016; Shortliffe, 2016). This summary concentrates specifically on health informatics from the perspectives of patient safety and the experience of the EHR end user. Literature searches of this thesis by using MeSH and other terms on the topics of patient safety, sociotechnical research, and health information technology safety were performed in PubMed and Scopus databases and were restricted to publications in English and Finnish since 1990. The work draws from the theory of sociotechnical framework (Singh and Sittig, 2016) and applies both quantitative and qualitative research methods. It is grounded on previous studies on classification development and data on technology-induced errors. The author has held posts in the field of health informatics, especially in the national and international classification, and in eHealth and eWelfare development and leadership work, as well as National Supervisory Authority of Medicines and patient safety leadership in a university hospital.
2 PATIENT SAFETY AND TECHNOLOGY-INDUCED ERRORS

2.1 THEORETICAL FOUNDATIONS OF PATIENT SAFETY AND TECHNOLOGY-INDUCED ERRORS

2.1.1 Conceptualization of patient safety: from causality towards resilience

The past two decades have been a time of rapid expansion on patient safety initiatives and approaches. A great deal of attention has been targeted toward preventing patient harm since the Institute of Medicine's (IOM) 1999 publication of “To Err Is Human: Building a Safer Health System”. This publication helped to raise awareness of the patient safety issue in the public mind but at the same time hypothesized that patient harm reduction would be difficult. It is now known very well that medical errors and injuries have much broader consequences than the IOM report addressed and lead to harm in all health care settings (Gandhi, Berwick and Shojania, 2016). This chapter will provide the conceptual basis of patient safety and the progression of patient safety approaches that have an impact on the monitoring and managing of technology-induced errors – the core of this thesis.

The practical understanding of the concept of patient safety has been affected by an inconsistent use of language. Regarding definitions, 10 EU member states reported that they had a working definition of patient safety; four countries had a definition but did not have a consensus about it. The remaining eight countries did not have a broadly-known definition (Esmail et al., 2015). The Agency for Healthcare Research and Quality’s definition of patient safety is “freedom from accidental or preventable injuries produced by medical care” (AHRQ, 2016b), whereas, within the World Health Organization (WHO) conceptual framework of patient safety, it is defined as “the reduction of risk of unnecessary harm related to healthcare to an agreeable minimum” (Runciman et al., 2009).

Similar concepts may also have different terms, and terms may be used to absorb several concepts (Runciman et. al, 2009; Perreault, 2015); the patient safety-related key terms harm, injuries and adverse events are often used interchangeably. The Canadian Disclosure Guidelines (2008) provide the following definitions on key concepts for patient safety: harm is “an outcome that negatively affects a patient’s health and/or quality of life;” and an adverse event is “an event which results in unintended harm to the patient, and is related to the care and/or services provided to the patient, rather than to the patient’s underlying medical conditions.” The definitions of WHO and Canadian Disclosure Guidelines serve for the purpose of this study. Adverse event, defined previously, is an equivalent for the widely used term “incident” or “patient safety incident.”
Multidisciplinary approaches and models taken from human factors engineering (Gosbee and Gosbee, 2010) and safety science were used to understand how and why an incident happened in order to prevent it from recurring (Peerally et al., 2016; Wagner et al., 2016). One of the most familiar approaches, Reason’s model of organisational accidents (Reason, 1995 and 1997) was initially developed for use in complex industrial settings, and Vincent (Vincent, Taylor-Adams and Stanhope, 1998) adapted it at this time to patient safety (Carthey, 2001; Weinger, 2002; Bogner, 2007, 109-126). The “Swiss Cheese” model of Reason describes the grouping of hazards that can lead to a safety event, and differentiates between latent failures and active failures. The method’s substance is to investigate the cascade of events that leads to an adverse end result, to think over the actions of those involved, and then to look further back at the circumstances in which staff were working and at the context in which the adverse event took place (NPSA, 2010). Many valuable attempts to conceptualize patient safety and errors, mostly using Reason’s generic error modelling system, were created: cognitive taxonomy of medical errors (Zhang et al., 2004), patient safety event taxonomy (Chang, 2005) and contributing factors in hospital incident report texts (Nuckols et al., 2008) and human errors’ taxonomy (Itoh, Omata and Andersen, 2009), to name but a few. Moreover, there are a number of frameworks aiming specifically to identify latent causes of error, namely Eindhoven classification (Vuuren, Shea and van der Schaaf, 1997) and WHO International Classification for Patient Safety (Runciman et al., 2009; Sherman et al., 2009; WHO, 2009; Larizgoitia, Bouesseau and Kelley, 2013).

One of the global cornerstones in patient safety development was the first priority goal set by the World Health Organization to promote the implementation of patient safety incident reporting systems and the learning from errors (WHO, 2005a and 2005b; Runciman et al., 2009; Larizgoitia, Bouesseau and Kelley, 2013). The WHO World Alliance for Patient Safety focused on agreeing upon safety-related concepts and definitions based on theoretical fundaments since 2005 (WHO, 2005a; 2005b and 2009) resulting in a framework of definitions, concepts, and methods which were compiled into a taxonomy in 2009. The central goal of WHO International Classification for Patient Safety (ICPS) has been to clarify the conceptual confusion. The ICPS is a foundation devoted to systematic learning from the experiences of adverse events (Runciman et al., 2009; Sherman et al., 2009). The role of ICPS as a classification has been questioned, too. The framework is an information model which can be used to analyse reports of patient safety incidents by describing the core data categories to figure out what happened and why, as well as identifying the consequences (Larizgoitia, Bouesseau and Kelley, 2013). The ability of the framework to classify causal and contributing factors to patient safety incidents has still to be tested (Schulz, Karlsson and Daniel, 2009; DeFeijter et al., 2012). Despite the possible limitations, the WHO model also contains some elements of resilience, a concept which is described later in this chapter (Singh, Ash and Sittig, 2013).
As a whole, this development of the hybrid discipline “human factors” approach led to a more in-depth understanding of accidents’ causal connections, and focus shifted gradually to the factors that offer the conditions in which errors occur instead of to the individual who makes an error. These different models of human errors and organizational accidents are essential in showing failures and error types, stressing the key role of latent factors in patient safety, error recovery, and prevention mechanisms by, for example, the elimination of error cause and standardization in predictable and homogenous environments (Reason, 1997; Svedung and Rasmussen, 2002; Patterson, 2008; Cook et al., 2008; Runciman et al., 2009; Carayon et al., 2011; Longmate et al., 2011; Collins et al., 2014). The process of standardisation offers the possibility of restructuring how work is normatively performed (Patterson, 2008).

A shift towards a more proactive approach emerged in the healthcare due to a research and institutional call to detect hazards and assess patient safety risks (Hollnagel, 2008; Carayon, 2011, Carayon et al., 2011; Rasmussen, 2000; Leveson, 2012; Dixon-Woods, McNicol and Martin, 2012). Evidence on meaningful progress in patient safety work during last decade was regarded as controversial, and earlier undertakings had reached varying levels of improvement (Jha, Godlee and Abbasi, 2016). In addition, the Joint Commission on Accreditation of Healthcare Organizations started to stress regular prospective safety analyses (JCAHO, 2008). In 2000, Rasmussen described requirements for safety, one of which is the expectation that one comprehends the complexity and interdependencies between systems and their parts. Moreover, current technology has become more complex, requiring new approaches for hazard detection (Waterson et al., 2015).

Concern about the confined focus of identifying what has gone wrong, as reflected by data collected by incident reporting systems, has stimulated a novel approach in patient safety to explore aspects of resilience in the working environment (Hollnagel, 2014). The term resilience refers to how “individuals, teams and organisations monitor, adapt to, and act on failures,” particularly in high-risk situations. It is the degree to which a system constantly prevents, detects, or mitigates incidents so that health care organizations can bounce back to their original ability (Weick and Sutcliffe, 2007; Cook et al., 2008; WHO, 2009; Singh, Ash and Sittig, 2013; Hollnagel, 2014; Sittig, Ash and Singh, 2014). Resilience distances the focus from causality and simplistic reaction to error-making towards valuing an anticipatory focus on error recovery (Jeffcott, Ibrahim and Cameron, 2009; Hollnagel, 2014). In contrast to mere incident reporting, assessment of resilience in the working environment proactively samples larger sources of data and improves safety by promoting flexibility in a complex non-linear setting stressing interdependencies rather than compliance with guides and training. Resilience engineering helps an organization to cope with and recover from unexpected incidents. It aims to maintain the institution’s ability to adapt when demands go beyond an organization’s routine operating limit (Hollnagel, 2014; Cook et al., 2008;
Braithwaite, Wears and Hollnagel, 2015; Staender, 2015). Patient safety research has started to focus on system resilience to cope with healthcare-related errors (Woods, 2006; Jeffcott, Ibrahim and Cameron, 2009; Braithwaite, Wears, and Hollnagel, 2015; Staender, 2015). Some researchers believe that a focus on resilience creates the difference between organizations which inadvertently create complexity and lose signals that risks are increasing and those that can handle high-risk situations satisfactorily (Cook et al., 2008).

New models and means to understand how errors can be detected, controlled, and managed have been developed due to the reality that not all errors may be prevented (Habraken, 2010). Technologies that exist currently, like Root Cause Analysis, have been remodelled so that they would better reflect the idea of resilience (Hollnagel, Braithwaite and Wears, 2013). As an example, Hollnagel’s (2012) Functional Resonance Analysis Method (FRAM) is among more recent methods for modelling complex sociotechnical systems (Hollnagel and Hollnagel, 2012). It constitutes a basis for risk analyses and is to be utilized as accidents happen as emerging and nonlinear end results of dynamic organizational processes. The FRAM method asserts that previous causal accident models are also useful when operations are homogeneous and regular (Clay-Williams, Hounsgaard and Hollnagel, 2015).

Existing techniques to assess systems and ensure their safety before an incident occurs, such as failure modes and effects analysis (FMEA), have had less attention in healthcare. FMEA was developed by reliability engineers decades ago to foresee system reliability (Leveson, 1995). In healthcare, FMEA is used as a risk management tool to identify and control risks beyond health information technology, and it is regarded as useful for the proactive risk assessment (DeRosier, Stalhandske and Bagian, 2002; Jeffcott, Ibrahim, and Cameron, 2009; Alamry et al., 2014; VA, 2016), and it also satisfies the Joint Commission’s accreditation standards (JCAHO, 2008). The Healthcare FMEA (HFMEA) is considered to be a profound method of risk control that identifies flaws in high-risk processes, analyses different possible process failures, and prioritizes interventions for addressing threats before harm occurs (American Society for Healthcare Risk Management, 2009). Analysis starts with the identification of a high-risk process that poses a threat to patient safety. A team of topic experts is created and selected for their familiarity with the high-risk process being analysed (IHI, 2016). The advantages of the FMEA are its systematic approach, promotion of teamwork by building teams, and identification of potential problems (Leveson, 1995; Ford et al., 2009; IHI, 2016). Its cons are the resources involved in its use, and when FMEA is applied to manage adverse incidents in healthcare, it does not, for example, produce enough information about the commonness of an adverse event. Thus, healthcare organisations should not exclusively depend on their FMEA results to prioritise patient safety issues until FMEA’s validity is further researched (Leveson, 1995; Shebl, Franklin and Barber, 2012, Öhrn et al., 2015).
These previously described patient safety approaches are summarized and categorized in Figure 1.

Figure 1. Summary of patient safety approaches

In summary, the first, more causal approach builds on standardization and learning from errors which are detected and controlled by using patient safety incident reporting systems in homogenous environments by means of prevention, standardization, and elimination. The other more nonlinear approach, which stresses interdependencies, is based on flexibility and a resilience mind-set in complex environments by means of adaptation and by using various new or already existing methodologies which have been customized.

2.1.2 Defining health information technology safety

Health information technology (HIT) related medical errors are described using many concepts, and they are defined in several ways. In spite of the semantic differences between the following concepts, they share the idea of HIT errors being realized in a complex healthcare environment during the use of HIT (Borycki et al., 2011). In the literature, terms such as e-iatrogenesis (Weiner et al., 2007), HIT hazards (AHRQ, 2016b), unintended consequences (Ash, 2003; Campbell et al., 2006), and technology-induced errors (Borycki, 2013b) are used to describe HIT-related medical errors. E-iatrogenesis is defined as patient harm caused, at least in part, by the HIT system (Weiner et al., 2007). The Agency for Healthcare Research
Harrison, Koppel and Bar-Lev, 2007; Borycki, 2013b). The concept of technology—undesirable or unanticipated (Ash, 2003; Campbell et al., 2006; Wachter, 2006; Harrison, Koppel and Bar-Lev, 2007; Borycki, 2013b). The concept of technology-induced error has increasingly appeared in the literature during recent years. In terms of their origins, these errors result from ‘the design and development of technology, the implementation and customization of a technology, and the interplay between the operation of a technology and the new work processes that arise from a use of technology’ (Borycki, 2013b). The concept of ‘technology-induced error’ is referred to in this thesis as an equivalent of medical error related to HIT.

A systems level understanding achieved by using frameworks and models to capture the origins of HIT-related errors has been evolving among informatics-related literature (Holden and Karsh, 2007; Borycki et al., 2011), thus helping clinicians understand the types and reasons for incidents related to the use of HIT (Warm and Edwards, 2012; Borycki, 2013b). Moreover, it is hoped that this development will lead to more a principled and effective deployment of applications and, thereby, reduce the number of technology-induced errors that arise from use of HIT (Borycki et al., 2011).

HIT error-related frameworks and models can be divided into three categories: 1) human factors, 2) software engineering and 3) sociotechnical models and frameworks (Borycki et al., 2011). These three categories are the grounds for this chapter 2.1.2. Several frameworks and models are presented putting the main emphasis on sociotechnical models which constitute the most important theoretical starting point of this study.

Human factors research in the domain of HIT errors includes human-computer interaction and cognitive science applied to user interface design (Gosbee and Gosbee, 2010; Borycki et al., 2011). Medical errors are often induced by human errors, which occur during the healthcare process as a result of the interaction between human beings and systems. Human error is the failure of a planned series of mental or physical actions to attain the intended end result (Reason, 1995). Medical error can be regarded as a cognitive phenomenon because it is an error in human action, which is a cognitive activity. The work system must be adapted to its cognitive assets and deficiencies and must be intended to alleviate the consequences of human error in order to prevent further error (Zhang et al., 2004).

Software engineering has a settled tradition of research covering the development of frameworks that can be utilized to test software applications, devices and interactions, among these applications for their effects on worker error rates. Technology-induced errors are considered in respect to the position in the system.
development life cycle (SDLC) (Kaufman et al., 2006; Yen and Bakken, 2012) in which they occur. Work in ensuring safer HIT through processes of the SDLC has started to emerge. This type of work focuses on testing systems for their technology organization fit as part of system selection, requirements gathering, and design and testing of health information systems (Kushniruk et al., 2010; Borycki et al., 2011). Errors may arise from inadequate requirement specifications, system design, programming, customization, testing and implementation, and this stresses the need for frameworks that can be used to guide requirements during the SDLC as early as possible in the software development process (Kaufman et al., 2006; Kushniruk et al., 2006). If the error is discovered late in the SDLC, the costs are high, and this constitutes an important rationale for this approach (Kushniruk et al., 2010).

Sociotechnical theory has been the basis for the development of HIT-related model and framework development efforts (Borycki et al., 2011). Sociotechnical models and frameworks serve as a theoretical starting point for this study, too. Before showing the actual sociotechnical framework for this study, it is essential to examine the theoretical foundations of the development of sociotechnical theories (Waterson et al., 2015).

The term ‘sociotechnical’ is imprecise. However, the core concept connected to it is ‘interdependence’ (Klein, 2014). In this particular context, interdependence was originally conceptualised by scientists at the Tavistock Institute in the UK who were studying technical change in industrial systems (Trist and Bamforth, 1951; Klein, 2014). This can be seen as the actual origin of sociotechnical research (Waterson et al., 2015). In addition, the examination of Emery (1965) and Trist and Labour (1981) focused on comprehending the role of human skill and methods of working in the productiveness within industrial systems. Their hypothesis is based on the idea that organizations ‘consist of the relation between a nonhuman system and a human system’ (Trist and Labour, 1981). These theorists emphasized that the technical and social systems have to be optimized together. In the case of high uncertainty, the sociotechnical approach emphasizes the redundancy of functions over the redundancy of parts. Rather than reducing work to a set of simple tasks that employees can quickly be trained to do or that allow employers to easily replace those that perform them, it is important to train workers for several roles and empower them to be self-regulating (Emery, 1965; Trist and Labour, 1981).

The study of Hale and Hovden (1998) served as a guide for Waterson et al.’s (2015) historical review that describes the progression of working systems designed to accommodate greater sociotechnical complexity in which the need to develop empirical assessment methods that are suited for this kind of complexity have been emerging. The formation of scientific research of safety related to sociotechnical complexity is described through distinct ‘ages’ (Waterson et al., 2015):

- The period from the 19th century up until the Second World War when safety was foremost regarded as a technology-centred area.
Figure 2 illustrates the timeline of the development of sociotechnical systems, not sociotechnical systems (Klein, 2014).

New clinical workflow processes. These new workflow processes involve different areas: (a) knowledge of dynamics and interdependencies which affect risk, (b) established monitoring systems, (c) management of resources and methods, (d) anticipation of risks and (e) close review of the restrictions of the safety management process itself.

Klein (2014) provides an especially useful clarification of developments in conceptualization of the term sociotechnical. Klein states that it does not make sense to set limits between what happens on the shop floor and what happens elsewhere. As the integration of HIT with production and other work systems progresses, it is proposed that we need to conceptualise organisations as open socio-structural systems, not sociotechnical systems (Klein, 2014). Smith et al. (2014) have contributed sociotechnical research by showing in their study that practices of resilient safety are an essential component of safety in a complex sociotechnical context. The practices were classified into the following areas: (a) knowledge of dynamics and interdependencies which affect risk, (b) established monitoring systems, (c) management of resources and methods, (d) anticipation of risks and (e) close review of the restrictions of the safety management process itself.

Sittig and Singh (2010) aimed to develop a more comprehensive model for HIT in to integrate specific technological and measurement dimensions of HIT with other sociotechnical dimensions. They state that the sociotechnical intersection of patient safety and EHR is multifaceted. Firstly, this intersection describes the healthcare system as a complex, progressive, adaptive system in which safety risks arise from users’ interactions with the electronic health record (EHR) that create new clinical workflow processes. These new workflow processes involve different
Consequently, Singh and Sittig created an eight-dimensional sociotechnical model to research the safety and effectiveness of HIT in its design, development, implementation, use and evaluation phases (Meeks et al., 2014b; Singh and Sittig, 2016). Four earlier sociotechnical works were the basis of the development of this model: the model of Henriksen (Henriksen, Kaye and Morisseau, 1993); the framework for analysing risk and safety created by Vincent and colleagues (Vincent, Taylor-Adams and Stanhope, 1998; Vincent, Burnett and Carthey, 2013); Carayon et al.’s (2006) Systems Engineering Initiative of Patient Safety (SEIPS); and the sociotechnical and interactive analysis of Harrison et al. (Harrison, Koppel and Bar-Lev, 2007). Henriksen’s (Henriksen, Kaye and Morisseau, 1993) model consists of individual characteristics, complexity of work, physical working environment and human-system interaction. This model also contains contextual factors such as leadership. Vincent proposes a hierarchical model suitable for risk and safety analysis that allows a systematic approach to safety and error reduction (Vincent, Taylor-Adams and Stanhope, 1998; Vincent, Burnett and Carthey, 2013). Carayon et al.’s (2006) SEIPS consists of three parts: organizational features and resources, interpersonal and technical factors and patient behaviour or health status. The fourth model that influenced Sittig and Singh’s work is the Interactive Sociotechnical Analysis (ISTA) framework (Harrison, Koppel and Bar-Lev, 2007). The ISTA draws on previous studies of unintended consequences, together with studies in sociotechnical systems, ergonomics, technology in practice, and social constructs of technology.

The final model of Sittig and Singh was developed based on an extensive research on the safe use and implementation of HIT (Sittig and Singh, 2010 and 2011; Singh and Sittig, 2016). Also, the studies of Meeks et al. (2014a, 2014b) served as one development phase. Meeks performed an analysis of EHR-related safety reports aiming to test the face validity of two models for comprehending the sociotechnical aspects of safe EHR implementation and the multifactorial interactions of technology in a healthcare context.

The following dimensions (Singh and Sittig, 2016) illustrate the interdependent domains of an EHR-enabled healthcare system (see Figure 3): hardware and software (the computing infrastructure used to power, support and operate applications and devices); clinical content (the text, numeric data and images which form the ‘language’ of clinical applications); human-computer interface (aspects of technology that users can see, touch or hear as they interact with them); people (those interacting with technology, including, e.g., developers, users and IT personnel);
Sittig and Singh (2010) further suggested an additional three-phase model including three overlapping domains spanning the life cycle of HIT implementation and use to describe the intersection of EHR and patient safety (Meeks et al., 2014b). The first domain is concerned with the safety incidents that are unique and specific to technology (i.e., unsafe technology), which typically emerge in the early stages of implementation. The boundaries between the phases are not always explicit. The model is beneficial for goal setting and recognition of safety problems in both new and established work systems. It might also be useful to guide or prioritize such aspects to proactively identify and monitor potential safety concerns before harm occurs to the patient. Surveillance and optimisation are stressed in this domain. Phase three includes data integrity, availability and confidentiality as key issues of this domain. The second domain addresses the use of technology (i.e., unsafe technology), which typically emerge in the early stages of implementation. Data integrity, availability and confidentiality are key issues of the second domain. The third domain addresses the unsafe or inappropriate use of technology, which typically emerge in the late stages of implementation. Correct HIT use and usage safety incidents and close calls. There are major differences between these systems in the European Union (EU). Adverse incidents which should provide data on the types and the causes of adverse events are reported. Reporting remaining incidents is mandatory, but the reporting is voluntary. The focus of the reporting is on near misses. Reporting patient safety incidents suggests that EU member states should facilitate the establishment or reinforcement of non-punitive reporting and learning systems on a nationwide basis. Such systems can be utilized, for example, to improve safety in large-scale EHR implementations taking place in the future.

Figure 3. The Sociotechnical model dimensions and examples of related safety concerns or error types by a dimension. Figure adapted for this study (Singh and Sittig, 2013; Meeks et al., 2014b).

Sittig and Singh (2010) further suggested an additional three-phase model including three overlapping domains spanning the life cycle of HIT implementation and use to describe the intersection of EHR and patient safety (Meeks et al., 2014b). The first domain is concerned with the safety incidents that are unique and specific to technology (i.e., unsafe technology), which typically emerge in the early stages of im-
plmentation. Data integrity, availability and confidentiality are key issues of the first domain. The second domain addresses the unsafe or inappropriate use of technology by clinicians, staff and patients, as well as mitigating unsafe changes in the overall workflow that arise as a result of technology use. Correct HIT use and usability are key issues of this domain. The third domain addresses the use of technology to proactively identify and monitor potential safety concerns before harm occurs to the patient. Surveillance and optimisation are stressed in this domain. Phase three could be utilized, for example, to improve safety in large-scale EHR implementations taking place in the future.

The boundaries between the phases are not always explicit. The model is beneficial for goal setting and recognition of safety problems in both new and established EHR-based work systems. It might also be useful to guide or prioritize such aspects as implementation activities (Singh and Sittig, 2016; Meeks et al., 2014b).

2.2 MONITORING AND MANAGING OF TECHNOLOGY-INDUCED ERRORS

2.2.1 The regulatory framework of technology-induced errors

According to the Finnish Act on Health Care (1326/2010), all healthcare organizations are obliged to have an institutional patient safety plan and must, for example, maintain a non-punitive patient safety incident system as a part of their patient safety program (Doupi, 2009; Pietikäinen et al., 2016). Regulation of software as a medical device follows the EU legislation which is supplemented by national regulations which have requirements for EHR users’ involvement in the vigilance system. The Finnish system is described in more detail in the section 4.2.

The European Union Council Recommendation 2009/C151/012 (EU, 2009) on reporting patient safety incidents suggests that EU member states should facilitate the establishment or reinforcement of non-punitive reporting and learning systems on adverse incidents which should provide data on the types and the causes of adverse incidents and close calls. There are major differences between these systems in EU member states, and both mandatory and voluntary incident reporting systems exist. For example, in Germany and Finland, reporting systems in hospitals are mandatory, but the reporting is voluntary. The focus of the reporting is on near misses. In the Netherlands, healthcare professionals must report serious events to the healthcare authorities. Reporting remaining incidents is voluntary and recommended by professional organisations (EU, 2014). In the UK, the National Reporting and Learning System (NRLS) was developed and implemented in the early 2000s. It enables anonymous patient safety incidents to be reported by National Health Service (NHS) organizations to a nationwide database (Wallace et al., 2009; Warm and Edwards, 2012). EU Recommendation 2009/C151/012 (EU, 2009) states
that these incident reporting systems complement other safety reporting systems used to report HIT errors, such as those specified by the EU medical device directive 2007/47/EC1. A directive issued by the EU requires specific end results to be achieved in member countries, and the directive must be implemented within national regulations (EU, 2007).

Directive 2007/47/EC1 amended the definition of the term ‘medical device’ used in Directive 93/42/EEC, and stand-alone software with a medical purpose became subject to medical device directives. In 2012, the European Commission adopted a set of guidelines for medical software (EC, 2012), and in July 2016, it published a new version of its guidelines, known as MEDDEV 2.1/6 (EC, 2016), on the qualification and classification of stand-alone software when used in a healthcare setting. A medical device must have a medical purpose and it must not endanger the health or safety of a patient, user or other person. Electronic patient record systems are intended to store and transfer electronic patient records, but an electronic patient record that simply replaces a patient’s paper file does not meet the definition of a medical device (EC, 2016). If the manufacturer has specified the software product such that it can be regarded as having one or more of the purposes described in the definition of directive 93/42/EEC (EEC, 1993) on medical devices, it must be European Conformity (CE) marked under the previously mentioned medical device regulations.

In the USA, the Patient Safety and Quality Improvement Act was launched in 2005. The core aims are to help healthcare professionals to improve the safety of healthcare, to comprehend the underlying causes of risks and to share data, thereby reducing risks in patient care (AMA, 2009). In short, the legislation is intended to create an environment in which healthcare practitioners can voluntarily and anonymously report safety problems, with the idea that these reports will lead to safer care (Nash, 2011).

In the US system, the Food and Drug Administration (FDA) databases are prominent. The FDA has gathered voluntary reports of adverse incidents related to medical devices since 1984. The FDA regards health information systems as medical devices, but their regulatory requirements are not enforced. The several databases administered by the FDA are Medical Device Reporting (MDR), Manufacturer and User Facility Device Experience (MAUDE) and MedSun which is powered by an organization focused on medical device safety (Myers, Jones and Sittig, 2011). MDR is the oldest of the databases, and it includes mandatory reporting from 1984-1996 and voluntary reporting from 1993. MAUDE contains voluntary reports starting in June 1993, facility reports starting in 1991, distributor reports from 1993 and manufacturer reports since 1996. Currently, existing FDA databases for medical device errors are seldom used for reporting EHR-related events. National integration of data collection does not exist, but some patient safety organizations are working to promote a common standard for reporting EHR-related incidents (Singh, Classen and Sittig, 2011).
2.2.2 HIT classifications as the basis of the monitoring and management of technology-induced errors

William Farr, a British epidemiologist and medical statistician from the 19th century, can be regarded as the pioneer of terminology and taxonomy even though a systematic organization of medical concepts created by Hippocrates can be said to be the beginning of controlled vocabularies (Eyler, 2003). The Oxford Dictionary (2016) defines taxonomy as ‘the classification of something’ and as ‘a scheme of classification’. The terms taxonomy and classification (system) are commonly used as synonyms. Taxonomies are powerful modes of information management that have been used successfully in areas such as medicine and information technology to describe, classify, and organise items based on common features (Venkatesh et al., 2003; Cimino, 2011). By applying a classification, it is possible to capture and separate types of failures and their causal factors (Taib et al., 2011), and these actions are essential to incident reporting systems (e.g., see Blais et al., 2008; Runciman et al., 2009; WHO, 2009). Otherwise, it will be challenging to comprehend the factors and mechanisms of the problem to systematically prevent and reduce medical errors on a large scale (Zhang et al., 2004). In this chapter, various taxonomies used to classify technology-induced errors are presented.

The taxonomy of medical errors by Zhang et al. (2004) is based on cognitive factors and mechanisms at the levels of individual and individual-technology interaction. It can be used to recognize the factors, rate and severity of incidents at multiple levels of the system hierarchy (Zhang et al., 2004). The development of a usability-error ontology by Elkin et al. (2013) is underway, and it includes aggregation of the types of errors related to specific systems, e.g., computerized order entry (CPOE) and EHR. The main types used in the ontology to organize data are cognitive and non-cognitive usability errors. The ontology has a set of system types and also findings that can be used to define specific usability errors (Elkin et al., 2013).

The classification of the 25010 standard by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) (ISO/IEC, 2011) focuses on the product aspect of EHRs, and it allows EHR developers to have better traceability of the quality characteristics of their products that affect patient safety. A product quality model is composed of eight characteristics, three of which are, as an example, usability, reliability and functionality, and these are further divided into sub-characteristics that relate to static features of software and dynamic features of the computer system, for example, security as part of functionality.

Harrison, Koppel and Bar-Lev (2007) propose the Interactive Sociotechnical Analysis (ISTA) framework typeology which describes relationships among new HIT, workflows, clinicians and organizations. It shows interactions among sub-components of the sociotechnical system which act as main sources of undesired consequences. These unintended consequences are categorized by ISTA type: new
HIT changes existing social system, technical and physical infrastructures mediate HIT use, social system mediates HIT use, HIT-in-use changes social system and HIT-social system interactions engender HIT redesign.

Voluntary incident reporting relies mostly on generic patient safety adverse events reporting systems (Ong, Magrabi and Coiera, 2013). Existing classifications used to classify patient safety incident reporting data include, for example, the Finnish HaiPro (Pietikäinen et al., 2016), Australian Advanced Incident Management System (AIMS) (Magrabi et al., 2010), UK National Reporting and Learning System (NRLS) (Warm and Edwards, 2012) and the previously described International Classification of Patient Safety (Runciman et al., 2009; WHO, 2009; Sherman et al., 2009). However, these lack an HIT specific taxonomy. For example, in the Finnish HaiPro system, the incidents are sorted into several categories (foremost being ‘use of devices’ and ‘information management’) which do not apply a known theoretical framework or scientific approach of HIT. Generally, evidence of the development of investigative frameworks to help categorize and comprehend the nature of the patient safety incidents has rarely been published (Warm and Edwards, 2012).

Among the rare examples of a general HIT-orientated classification system which is not restricted to a specific HIT problem area, such as medication systems, is the classification developed by Magrabi et al. (2010). It was developed by using incidents reported in Australia and was further refined by analysing data from incident reports submitted to the US FDA MAUDE database. The classification enhances clustering of computer-related incidents and provides an objective basis for comparing patterns in incidents between settings. It can be utilized for the development and prioritization of preventive and corrective strategies. Human-computer interactions (e.g., wrong patient selected) are distinguished from machine-related problems to describe the main problem. Incidents are classified as human-computer or machine-related, and then subdivided based upon problems at the point of data entry (input), data transfer (transfer) or data retrieval (output). A ‘general technical’ category accounts for broad hardware and software issues leading to incidents that do not fit into other classes. A category of ‘contributing factors’ is included to account for sociotechnical contextual elements that contribute to computer-related incidents, such as multi-tasking during the use of a computer.

Magrabi et al.’s classification has undergone testing in the UK after preliminary development phases (Magrabi et al., 2010, 2012), and research has revealed a limitation in this classification: it was not possible to demonstrate the clinical relevance of some incidents by using the taxonomy. However, the classification is primarily intended to facilitate prioritization of preventative and corrective strategies (Warm and Edwards, 2012).
2.2.3 Technology-induced errors in patient safety incident reporting systems

A patient safety incident reporting system is regarded as one of the most fundamental mechanisms for obtaining and processing patient safety-related information for improving patient safety (WHO, 2005a; Öhrn et al., 2011; DeFeijter et al., 2012; Farley et al., 2013; Westbrook et al., 2015). The argument behind incident reporting is that with knowledge comes the power to detect problems and underlying causes and, as a result, the possibility to effect change and organizational learning to prevent the incident from occurring again (Holden and Karsh, 2007; WHO, 2005a). The aims of these systems were initially broad: monitoring levels of harm, identifying rare events and rapidly disseminating knowledge about high-risk processes of care (Howell et al., 2016). The systems form a mechanism which also includes the analysis and investigation of an incident (Benn, 2009). In healthcare, incident reporting systems provide frontline caregivers with a way to raise concerns and impact the situation (Pham, Girard and Provonost, 2013), but lack of feedback from incident reporting has been recognized to decrease the willingness of staff to report safety problems. Research predominantly done during the 2000s has identified reasons that inhibit reporting, such as fear of blame, resource constraints and a lack of clear definitions of reporting criteria (e.g., see Lawton, 2002; Edmondson, 2004; Evans et al., 2007; Wallace et al., 2009; Moeller, Rasmussen and Nielsen, 2016). These reporting systems are either mandatory or voluntary for a reporting professional, and they often contain anonymous data. It is supposed that a voluntary system is the best means to encourage reporting in a blame-free safety culture and avoid liability issues for professionals, but opposite opinions also exist (Brennan, 2000; Flink et al., 2005). Also, traditional paper-based incident reporting systems, as well as new forms of information technology, are used to enhance reporting (Haller et al., 2007; Hoffmann et al., 2008).

Analysis of incidents and their causes produces possibly useful data on patient safety problems (Howell et al., 2016). Moreover, analyses which follow the principles of the human factors approach seek to find latent causes of system failures (Reason, 1995; IOM, 1999), but a mere identification of problem areas is insufficient, and incident reports should foremost include corrective actions to improve safety (Benn, 2009). In fact, specifically in the area of HIT safety, incident reporting systems have not gathered sufficient data related to all the types of errors associated with HIT. Despite this, these data may enable those who implement systems to be aware of some of the errors that the implementation of EHRs causes (Myers, Jones and Sittig, 2011). Comprehending the limitations of incident data is essential in avoiding the misinterpretation and misuse of the data (Shojania, 2008; Shojania and Marang-van de Mheen, 2015). However, experts agree that these reporting systems should not be utilized as an epidemiological measure to monitor the rate of errors over time (Shojania and Marang-van de Mheen, 2015; Howell et al., 2016).
The earlier publications on technology-induced errors in a hospital environment in connection with incident reporting systems have been limited to specific areas of activity, such as medication problems. For example, Zhan (2006) analysed a voluntary medication error-reporting database providing valuable information on certain types of errors related to CPOE systems. Also, Cheung et al.’s (2015) large sample of medication-related incidents showed that human-computer interaction plays a crucial role in HIT incidents.

Magrabi et al. (2010) performed the first study which examined a broader scope of computer-related patient safety incidents reported by health professionals. They analysed computer-related patient safety incidents in a national AIMS database. Only 0.2% of all reports in the AIMS database were HIT-related. Machine-related problems were more common than human-computer interaction issues. However, they also found human-computer interaction errors related to the selection of patient and clinical information, as well as display errors (Magrabi et al., 2010).

Warm and Edwards (2012) studied computer-related patient safety incidents. The data reviewed included all aspects of IT within the healthcare context. Most of the reports (77%) were machine-related technical problems, such as access problems, system downtime, display issues and software errors. A further 10% of the incidents were related to human-computer interaction issues, and 13% of the incidents could not be classified using the framework. The analysis identified only rare human error events. Writers state, however, that this might have been due to the characteristics of the data. Human error-related incidents are most probably reported in other NRLS classes, which include the outcome for the patient instead of a technical incident. For example, a medication administration error may have been due to missing data, but it is reported as a medication incident rather than a data capture event.

Meeks et al. (2014a) studied EHR-related safety issues reported within a non-punitive, US-based voluntary reporting system by applying a sociotechnical conceptual model that included both technical and non-technical dimensions of safety. By applying the sociotechnical framework analysis to qualitative data, it was possible to detect recurring safety problems. Non-technical dimensions, such as workflow, policies and personnel, interacted frequently with technical dimensions, which included software/hardware, content and user interface, to produce safety concerns. A total of 94% of incidents related to unmet data display needs in the EHR, data transmission problems and ‘hidden dependencies’ related to the EHR.
2.2.4 Oversight perspective on technology-induced error monitoring

Historically, HIT has not been subject to tight regulation as medical devices (Chai et al., 2013). Today, both the EU and US systems have medical device-related software for adverse event and failure reporting models, but the systems described in Chapter 2.2.1 differ (Goodman et al., 2011; Myers, Jones and Sittig, 2011; Singh, Classen and Sittig, 2011; Magrabi et al., 2012; Chai et al., 2013; Sittig, Classen and Singh, 2014).

An incident within the EU Medical Device Vigilance System (MDVS) (EEC, 1993) context is determined as ‘any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health’. The reported events are evaluated, and, when needed, information is distributed, which could be used to prevent reoccurrence of the incident, or to mitigate the consequences of incidents. The MDVS is intended to enhance harmonised implementation of field safety corrective action (FSCA) across the member states where a medical device is in use, instead of actions taken in single countries.

In the EU, manufacturers must report medical device-related serious adverse events that might lead to or might have led to a death or serious injury to the competent authorities (CAs) in the nation where the incident occurred. There is no legal obligation in the directives for users to have an active role in the vigilance system, but this area may be reinforced by separate advice from national CAs, as is the case in Finland (Valvira, 2016). Data on suspected incidents are leveraged with the manufacturers, and, with their co-operation, the implementation of FSCAs is enhanced. However, there are differences among EU member states in EHR user involvement in the vigilance system (EU, 2007, 2016).

In the US system, there are no regulatory requirements to assess EHR system safety (Singh, Classen and Sittig, 2011). Adverse events associated with EHRs are not being systematically and consistently tracked (Bowman, 2013), which is complicated by the regulatory data storage in several databases described in Chapter 2.2.1. The core FDA requirement for manufacturers demands reporting within 30 days of awareness of an error. Key inclusion criteria are devices that (1) may have caused or contributed to a death or serious injury or (2) have malfunctioned and these devices or similar devices that are marketed would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur. In the US, EHR certification alone does not assure that EHRs will be implemented and that they will work as intended (Bowman, 2013), and experts state that how regulation of electronic health applications could strengthen patient safety should be considered (Goodman et al., 2011). As a result of this situation, it is proposed that creation of a nationwide ‘post-marketing’ surveillance system to
monitor HIT-related safety events should be facilitated (Sittig, Classen and Singh, 2014).

Only a few studies have been conducted specifically on HIT oversight data outside the EU, while study results of software as a medical device specifically from the users’ perspective do not exist. However, several expert opinion papers about software oversight have been published (Goodman et al., 2011; Singh, Classen and Sittig, 2011; Sittig, Classen and Singh, 2014).

Myers, Jones and Sittig (2011) analysed reports in the general clinical information systems of three national, adverse event medical device databases in the US. The types of adverse incidents included data displayed for the wrong patient, missing or erroneous data, confusion during downtime and system unavailability. Undesirable patient outcomes were also reported, such as delays in diagnosis or procedures, irrelevant treatments, incorrect medication administration, and patient disability and death.

Magrabi et al. (2012) studied problems in HIT reports submitted to the US FDA MAUDE database. Final analysis revealed 700 problems, of which 96% were machine-related, and 4% were problems connected to the human-computer interface. Nearly half of the events were related to unsafe circumstances, 11% caused harm for patients and four deaths were associated with IT errors.

### 2.2.5 Outcomes of studies managing technology-induced errors

Data are crucial for patient safety (James, 2013), and multiple sources of information to understand patient safety issues and identify improvement opportunities are needed (Parry, Cline and Goldmann, 2012). HIT safety data specifically on authority surveillance or vigilance systems are very scarce as stated in a chapter 2.2.4 (Myers, Jones and Sittig, 2011; Magrabi et al., 2012). Nor have voluntary incident reporting systems provided adequate research data, except in rare studies on technology-induced errors (Magrabi et al., 2010; Warm and Edwards, 2012; Meeks et al., 2014a). Several methods, such as questionnaire studies and systematic patient-initiated data collection on medical errors, are used to gain a greater understanding of patient safety (DeFeijter et al., 2012; Southwick, Cranley and Hallisy, 2015), but, in the area of technology-induced errors, the use of these methods is scarce or completely lacking.

However, there are some important outcomes of studies on technology-induced errors which need to be presented in this literature review: technology-induced errors from the standardization and software product quality characteristics view, and the identification of specific technology-induced errors and means, such as tools to manage these errors.

Virginio’s and Ricarte’s (2015) literature review concentrates on the risks that EHR systems can cause for patient safety, specifically from a standardization per-
spective. The risks presented in the paper are based on the software product quality characteristics specified in standard 25010 established by the ISO and IEC (ISO/IEC, 2011). Most of the software quality risks were connected to functional suitability and usability. Thus, the paper stresses the use of user-centred design (UCD) principles, which is an approach that involves the end users throughout the development process to ensure that the product is suitable to their needs (Kushniruk et al., 2013; Kushniruk and Borycki, 2015). In this way, UCD may help to build EHRs that are more fitted to health professionals’ needs and, at the same time, safer for patients (Horsky and Ramelson, 2016).

Lei et al. (2014) analysed HIT outage events which occurred in China by exploring news articles and incident reports. Over 50% of the events caused disruptions to healthcare administrative functions. Software errors and overcapacity problems were the principal causes of these incidents. The outpatient practices in tertiary hospitals appeared to be especially vulnerable to information technology failures, and unexpected EHR unavailability occurred more frequently with the widespread adoption of EHRs.

Referring to the focus and contents of this study, literature searches were performed on EHR-related risks and error types. Search results included foremost studies in hospital settings. Based Menon’s survey (2014a) and previous research on EHR-related patient safety, Sittig and Singh (2013) identified the following EHR-related safety concerns: incorrect patient identification; extended EHR unavailability (either planned or unplanned); failure to heed a computer-generated warning or alert; system-to-system interface errors; failure to identify, find, or use the most recent patient data; misunderstandings about time; incorrect item selection from a list of items; and open or incomplete orders (Sittig and Singh, 2013). The following results from literature searches were extracted and grouped by the specific error types created by Sittig and Singh (2013):

- Incorrect patient identification (McCoy et al., 2013; Sittig and Singh, 2013)
- Extended EHR unavailability (Sittig and Singh, 2011, 2012, 2013; Warm and Edwards, 2012; Lei et al., 2014; Meeks et al., 2014a)
- Failure to heed a computer-generated warning or alert (Bowman, 2013; Sittig and Singh, 2012, 2013; van der Sijs et al., 2006; Lapane et al., 2008)
- System-to-system interface errors (Magrabi et al., 2010, 2012; Myers, Jones and Sittig, 2011; Warm and Edwards, 2012; Sittig and Singh, 2012, 2013; Bell et al., 2009)
- Failure to identify, find, or use the most recent patient data (Khajouei, Hasman and Jaspers, 2011; Magrabi et al., 2010, 2012; Lawler, Hedge and Pavlovic-Veselinovic, 2011; Bowman, 2013; McCoy et al., 2013; Sittig and Singh, 2013; Meeks et al., 2014a)
- Misunderstandings about time (Sittig and Singh, 2013)
Incorrect item selection from a list of items (Khajouei, Hasman and Jaspers, 2011; Mangalmurti, Murtagh and Mello, 2011; Sittig and Singh, 2011; Myers, Jones and Sittig, 2011; Bowman, 2013; Weis and Levy, 2014)

- Open or incomplete orders (Magrabi et al., 2010).

Furthermore, the literature (Ong, Magrabi and Coiera, 2013; Singh, Ash and Sittig, 2013) shows that current tools to assess EHR safety are outdated. Thus, Singh, Ash and Sittig (2013) developed self-assessment guides to optimize the safety and safer use of EHRs. Also, the Safety Assurance Factors for EHR Resilience (SAFER) guides were designed to help clinicians and healthcare organizations self-assess the safety and effectiveness of their EHR implementations, recognize areas of vulnerability and develop practices to mitigate risks (Singh, Ash and Sittig, 2013; Sittig, Ash and Singh, 2014). A very recent study published in late 2016 by Gephard et al. (2016) tested the new Carrington-Gephart Unintended Consequences of EHR Questionnaire’s validity. This measure is used to describe nurses’ experiences with unintended consequences of EHRs and relate them to the professional practice environment. Sources of unintended consequences are such factors as increased workload and interruptions that shifted tasks from the computer and altered workflow (Gephard et al., 2016).

2.3 CONCEPTUAL FRAMEWORK OF THE THESIS

The literature review findings indicate that a systems level understanding gained by using frameworks and models to capture the origins of technology-induced errors has been evolving among informatics-related literature (Holden and Karsh, 2007; Borycki 2010; Sittig and Ash, 2011; Singh and Sittig, 2016), helping clinicians understand the types and reasons for incidents relating to the increasing use of HIT (Warm and Edwards, 2012; Borycki, 2013a, 2013b). Today, researchers share the view that technology-induced errors arise from a number of sources in a sociotechnical context. (Aarts and Gorman, 2007; Harrison, Koppel and Bar-Lev., 2007; Koppel, 2010; Elkin, 2012; Smith et al., 2014; Singh and Sittig, 2016).

The conceptual framework of this dissertation builds on Sittig and Singh’s eight-dimensional model based on earlier sociotechnical works and on an extensive research on the safe use and implementation of these technologies (Vincent, Taylor-Adams and Stanhope, 1998; Carayon et al., 2006; Harrison, Koppel and Bar-Lev, 2007; Koppel 2010; Vincent, Burnett and Carthey, 2013; Meeks et al., 2014b; Sittig and Singh, 2010, 2011; Singh and Sittig, 2016). The model’s dimensions represent the eight interdependent domains of an EHR-enabled healthcare system. This previous model was expanded by a three-phase model involving three overlapping domains covering the life cycle of HIT implementation and use (Sittig and Singh, 2012; Singh and Sittig, 2016).
Currently, in spite of the known risks associated with the use of HIT, prevalent methods for monitoring harm caused by these systems are minimal, essentially relying on voluntary reporting using generic patient safety incident reporting systems (Ong, Magrabi and Coiera, 2013). A rare example of an HIT-orientated classification system is one developed by Magrabi (2010), which has undergone some testing after preliminary development phases (Magrabi 2010, 2012; Warm and Edwards, 2012) but is still in need of further testing. These kinds of classifications are beneficial in understanding the fundamental factors and mechanisms of the problem to prevent them systematically on a large scale (Cimino, 2011; Taib et al., 2011; Zhang et al., 2014).

EHR errors should also be defined and monitored from the sociotechnical viewpoint of end users, but this perspective is still in its infancy (Sittig and Singh, 2011; Singh, Ash and Sittig, 2013). Tools for more proactive assessment of safety risks are especially underdeveloped (Ong, Magrabi and Coiera, 2013; Singh, Ash and Sittig, 2013, Sittig, Ash and Singh, 2014), and their potential to increase the resilience of healthcare organizations to the hazards of EHR use has been missed. Based on the previous work on technology-induced errors described in chapter 2.2.5, Sittig and Singh (2013) identified EHR-related safety concerns, and these research data are utilized in this study to suggest the means to augment the risk-assessment tools designed for EHR safety.

Patient safety research has begun to focus on system resilience to cope with healthcare-related errors. Resilience safety aims at introducing novel safety solutions by comprehending healthcare as a construct of complex and adaptive systems (Woods, 2006; Jeffcott, Ibrahim and Cameron, 2009; Braithwaite, Wears and Hollnagel, 2015; Staender, 2015). The term resilience refers to how individuals, teams and organisations monitor, adapt to and act on failures in high-risk conditions. It ranges from reactions to error making to a proactive focus on error recovery (Jeffcott, Ibrahim and Cameron, 2009). Resilient safety practices such as monitoring for threats, being proactive, awareness of risk and learning from past experiences are fundamental to resilience (Hale, Guldenmund and Goossens, 2006; Smith et al., 2014; Braithwaite, Wears and Hollnagel, 2015).
Figure 4. The conceptual framework of the study.

Figure 4 summarizes the conceptual framework of this thesis: Technology-induced errors are a growing problem which needs to be monitored and managed by applying scientific pluralism and using several theoretical elements, such as HIT-specific classifications as part of the present monitoring systems. Moreover, even if incident reporting is widely used to inform patient safety improvement, it provides limited insight into how healthcare organisations create and maintain safety. The need for broadening the scope of HIT safety perspectives has been established in this literature review, and this can be achieved by conducting studies relating to technology-induced errors from the EHR user’s point of view. These studies are needed to focus on further developing the present approaches by critical scientific reasoning and testing of classifications. In addition, user perspectives on safety measurement factors need to be fostered by offering new safety tools and methods that utilize sociotechnical approaches to achieve the goal of a more resilient way of using EHRs in complex hospital settings.
3 PURPOSE, AIMS AND RESEARCH QUESTIONS OF THE THESIS

The purpose of this study is to provide a comprehensive picture of the state of electronic health record (EHR)-related, technology-induced errors by analyzing two different types of data in the Finnish specialized hospital care setting. Additionally, reports of EHR-related errors based on the Medical Devices Directive (2007/47/EC) from National Supervisory Authority (Valvira) users are analysed to broaden the scope of the study. At the same time, the goal is to assess the adequacy of the present approaches to monitoring technology-induced errors, regulatory issues of medical software and taxonomies to analyse technology-induced errors.

The ultimate aim of this thesis is to provide research-based implications for clinicians, health care organisations, authorities and future research by using present methods and to develop a new instrument for preventing and controlling technology-induced errors from the user perspective in a paperless hospital environment to increase health information technology (HIT) resilience. The study is seeking answers to the following research questions:

1. What is the proportion of EHR-related patient safety incidents in a patient safety incident reporting database in a fully paperless, digital hospital environment? What are the most common types of computer-related patient safety incidents in a patient safety database in this environment and have actions been taken to prevent such incidents from recurring? What are the main differences between the two similar databases? (Paper I)

2. Which of the common EHR error types are associated with perceived high- and extreme-risk severity ratings among EHR users? Which variables are associated with high- and extreme-risk severity ratings? (Paper II)

3. How effective is the FIN-TIERA risk assessment tool (developed in this study) in measuring the user perceptions of EHR safety? What are the metrics of reliability in terms of internal consistency and metrics of validity in terms of face, content, external and construct validity? (Paper III)

4. What are the specific error types related to the use of HIT in the National Supervisory Authority data of 2010–2015 EHR user reports? What is the impact of supervisory authority data as part of the preventive measures in HIT safety? (Paper IV)

Papers I-IV are summarized in the Summary, which contains the ultimate research questions:

What are the characteristics and most critical areas of HIT safety and its monitoring that require attention based on the research data? What are the elements of technology-induced error monitoring and managing resilience practice from the EHR user perspective? (Summary)
4 MATERIALS AND METHODS

4.1 STUDY IN THE HEALTH AND HUMAN SERVICES INFORMATICS PARADIGM

The domain of the research in this work is health and human services informatics and it is using frameworks and concepts of patient safety literature. Health and human services informatics has been an evolving multidisciplinary scientific discipline in Finland since 2000 (Saranto and Kuusisto-Niemi, 2012). It is an aggregation of several related disciplines such as computer science, information science, management science, cognitive science, health and social sciences and organizational theory covering several sub-domains, e.g., clinical and biomedical informatics, telemedicine, and healthcare management informatics (Gardner et al., 2009; Mantas et al., 2010; Shortliffe, 2010; Detmer and Shortliffe, 2014; AMIA, 2016; Mantas, 2016; Shortliffe, 2016). Patient safety draws its approaches from several disciplines such as safety science and health care related disciplines. The epistemology, i.e., the science of the method of finding out about patient safety is considered through a risk management framework. The context of patient safety research may be considered as a subcomponent of healthcare quality, systems and services research, with technical and human behavioural elements and a variety of external and internal organisational effects (Runciman et al., 2009).

Paradigm provides the essential criteria for scientific data. This study utilizes health and human services informatics paradigm, which constitutes of four core concepts. Concepts data, action, actors and technology (Saranto and Kuusisto-Niemi, 2011, Figure 5) are applied broadly during the research process. The main concept of this research process is action where the domain of patient safety research is situated. This study focuses mainly on the use of ICT, especially on electronic health records, patient safety monitoring systems and tools which represent the concept technology. Technical and behavioral components which are essential in the patient safety research are conceptualized in this study by applying the sociotechnical framework (Singh and Sittig, 2016). Two of the substudies concentrate essentially on the classifications and draw from the challenges of present data structures and classifications.

EHR clinical users are study’s main actors in the context of health care (Figure 5). This study is limited into health care and mainly into hospital environment and thus not covering the aspect of social care. The context of the study is described in detail in the chapter 4.2.
The domain of the research in this work is health and human services informatics and it is using frameworks and concepts of patient safety literature. Health and human services informatics has been an evolving multidisciplinary scientific discipline in Finland since 2000 (Saranto and Kuusisto-Niemi, 2012). It is an aggregation of several related disciplines such as computer science, information science, management science, cognitive science, health and social sciences and organizational theory covering several sub-domains, e.g., clinical and biomedical informatics, telemedicine, and healthcare management informatics (Gardner et al., 2009; Mantas et al., 2010; Shortliffe, 2010; Detmer and Shortliffe, 2014; AMIA, 2016; Mantas, 2016; Shortliffe, 2016). Patient safety draws its approaches from several disciplines such as safety science and healthcare related disciplines. The epistemology, i.e., the science of the method of finding out about patient safety is considered through a risk management framework. The context of patient safety research may be considered as a subcomponent of healthcare quality, systems and services research, with technical and human behavioral elements and a variety of external and internal organizational effects (Runciman et al., 2009). Paradigm provides the essential criteria for scientific data. This study utilizes health and human services informatics paradigm, which constitutes of four core concepts. Concepts data, action, actors and technology (Saranto and Kuusisto-Niemi, 2011, Figure 5) are applied broadly during the research process. The main concept of this research process is action where the domain of patient safety research is situated. This study focuses mainly on the use of ICT, especially on electronic health records, patient safety monitoring systems and tools which represent the concept technology. Technical and behavioral components which are essential in the patient safety research are conceptualized in this study by applying the sociotechnical framework (Singh and Sittig, 2016). Two of the substudies concentrate essentially on the classifications and draw from the challenges of present data structures and classifications.

EHR clinical users are study’s main actors in the context of healthcare (Figure 5). This study is limited into healthcare and mainly into hospital environment and thus not covering the aspect of social care. The context of the study is described in detail in the chapter 4.2.

Patient safety research has produced a prominent body of scientific knowledge over the last 10 years. The focus on patient safety research has been on fostering safety controls, standardising health care processes, and minimizing the possibility of error through safer procedures in micro-system rather than the wider care system. However, more recent contribution considers how safety is formed by the interdependencies of actors and function in a complex environment (Lamont and Waring, 2014). In this study patient safety problems in the use of electronic health records (EHRs) are conceptualized by applying mainly a more recent approach. One of the key concepts, electronic health record (EHR) in this study represents the concept Technology in the paradigm. International antonyms for the EHR varies: electronic patient record (EPR), electronic medical records (EMR), computerized patient records, and digital medical record (Kruse et al., 2014). A qualification of software as medical device, European Commission MEDDEV 2.1./6 (EC, 2016) uses the term Electronic Patient Record (EPR) Systems and this term is used in this study when describing specifically medical software. The defining difference by the Institute of Medicine, focuses on the interoperable nature of the electronic patient record (IOM, 2012).

Current EHRs which have been mostly implemented over the past decade, are a first step in the health care digitization process (Celi et al., 2015; Evans et al., 2016). The Figure 6 describes studies of this thesis in relation to the EHR lifecycle in Sittig and Singh’s three-phase model involving three overlapping domains of health IT implementation and use (Sittig and Singh, 2012).
An interoperable electronic health record (EHR) is determined as a secure and private electronic record of individual’s lifetime health history and care in the health system. The record is available electronically to authorized professionals and the individual anywhere, anytime and it often contains data such as prevalent health conditions, physician visits, hospitalizations, test results, and prescribed medications (Canada Health Infoway and Health Council of Canada, 2006). In hospitals EHRs are often software applications that contain or interact with other applications. They cover applications for computerized provider order entry, clinical decision support, test results repository and medication administration systems. These software applications need networked hardware and clinical data structures to operate. (Smith et al., 2014; Celi et al., 2015; Evans et al., 2016). In this summary term EHR is used principally to cover terms EMR and EPR.

Both quantitative and qualitative approaches are presented to reach the multifaceted picture of the phenomenon which has been studied only in a limited scale. A multi-method approach was chosen to reach a comprehensive picture of the technology-induced errors from a user’s perspective and to abstract the elements of health information technology resilience practice. To understand the broad phenomena of patient safety and specifically technology-induced errors one research method is unlikely to reveal the characteristics of these errors (Brown et al., 2008; Runciman et al., 2008; Runciman et al., 2009; Lenz, 2016). The tool development and testing followed the design described in the literature (e.g., Presser, Rothgeb and Couper, 2004; Kline, 2010). By analysing two types of register data and results of questionnaire study, this dissertation seeks to describe characteristics and most critical areas of HIT safety and its monitoring that require

Figure 6. Studies of the thesis in relation to Health information technology (HIT) Safety Domains
attention. Selected elements of technology-induced error monitoring and managing resilience practice from a EHR user perspective are shown based on these studies.

4.2 STUDY CONTEXT

A decentralized administration and multiple funding sources are the main characteristics of the Finnish health care system. Primary health care and specialized care is financed by municipalities which provide primary health care in municipal health centers, but have also increasingly contracted out their services to the private enterprises. The hospital districts are responsible for specialized care (Tynkkynen et al., 2016). The qualifications of health care professionals in Finland, as in other member states of the European Union (EU), are in accordance with the EU directive on professional qualifications 2005/36/EC (EU, 2005). This directive applies to doctors, specialist doctors, nurses, specialist nurses, and midwives.

Patient safety became a topic of discussion in Finland 2008, due to an incident reporting system that had started to make safety problems in hospitals apparent. The Finnish patient safety incident reporting model and instrument, HaiPro, was developed by the National Agency for Medicines (now Fimea) and the Technical Research Center of Finland, in collaboration with Helsinki University Hospital, the Medical Center of Tampere and the Heart Center of the Tampere University Hospital (Doupi, 2009; Pietikäinen et al., 2016). The patient safety development emphasis in Finland was on modifying the actions of individual professionals and their immediate preconditions of work. The Ministry of Social Affairs and Health had launched a strategy that described national objectives for a culture change and obligated organizations to be active in patient safety work (Pietikäinen et al., 2016). Finally, Finnish Act on Health Care from 2011 (1326/2010) obliged all healthcare organisations to maintain a patient safety incident system as a part of their patient safety program.

Finnish EHR systems cover 100 per cent of specialized and primary healthcare organizations since many years. Health information technology systems are mostly locally developed. Currently, two large vendors dominate EHR market in Finnish healthcare (Hyppönen et al. 2009; Kushniruk et al., 2013) but Finland is now underway towards shared client and patient information system, e.g, Epic Information System (Apotti, 2016).

The studies I-III were conducted in the Hospital District of Helsinki and Uusimaa (HUS), and included 23 hospitals covering a population of 1.6 million Finns; 34% of the Finnish population. HUS treats half a million patients annually. HUS runs the largest academic teaching hospital (Helsinki University Hospital) in Finland, which covers all medical specialties and emergency services in its different facilities. The entire hospital district has approximately 22,300 employees (HUS, 2015).
By 2011, a voluntary HaiPro incident reporting approach incorporating a system model features (Doupi, 2009; Pietikäinen et al., 2016) had included all clinical units in 23 hospitals of HUS, the setting of the studies I-III. The incident reports in HaiPro describe the background details of the incident (e.g., incident unit, time of the incident, reporter’s profession, incident, contributing factors, consequences). Events are classified into 13 incident types using HaiPro’s national classification. Among the most frequently used incident categories are ‘Medication and Transfusions’, ‘Information Flow’ and ‘Information Management’ categories as well as ‘Laboratory’, ‘Imaging’ and ‘Other Patient Treatment Procedures’ categories. All the HaiPro main categories include detailed subcategories. A report can contain multiple event descriptions. HUS offers on-going training as well as an e-learning programme to train its staff to report and other responsible persons to handle the reports. Every unit has appointed a medical and nursing manager to classify the reports according to national guidelines, which include classification rules. Duplicate reports must be deleted. The quality managers, the hospital district’s chief patient safety officer and a group of the hospital’s HaiPro classification development experts seeks to ensure the consistency and compliance with the classification principles. The HUS patient safety committee monitors the incident data on a regular basis. The reports are obliged to be shared with staff, and the person reporting an event receives feedback on the investigation through the system. HaiPro is not an integrated component of the EHRs, but an Internet-based interface (HUS, 2016).

Finnish hospitals in the studies I-III have used the same EHRs for several years. The hospital district has a computerized physician order entry with clinical decision support and major ancillary systems, a picture archiving and communication system, as well as a clinical data repository for reviewing results. The closed loop medication system is not part of the EHRs. As the questionnaire study took place a new version of the EHR program was implemented in order to incorporate the system into the Finnish national health care archive KanTa (Hyppönen et al., 2009).

The study IV was conducted due to data security reasons in the premises of National Supervisory Authority of Welfare and Health (Valvira) which is a national agency operating under the Ministry of Social Affairs and Health, responsible for the supervision of the social and health care (Valvira, 2016).

The Finnish Medical Device Act 629/2010 (2010) defines a medical device according to the EU Directives described in Chapter 2.2.1. National regulations on reporting serious adverse incidents are in force from 15 September 2010, after which the data collection period in this study started. Professional user of medical device is defined in the 5 § of the Medical Device Act 629/2010 (2010). The duty to report applies to manufacturers and professional users of medical devices in Finland. Medical device serious adverse incidents must be reported to Valvira within ten days of the user or manufacturer first becoming aware of the incident. The cases of a near incident should be reported within thirty days. Failure to report
is a punishable offence. Valvira notifies relevant parties of measures to be taken in the case of a serious adverse incident (Valvira, 2016).

### 4.3 RESEARCH PROCESS

This thesis consists of four studies (Papers I-IV) which are published in international, peer-reviewed scientific journals, and Summary. Table 1 presents the design of the research process and shows the four substudies in detail. The chapters 4.4 and 4.5 describe the data collection and analyses in a more profound way.

Table 1. Study objectives, data collection, context, type of the study, methods and data analyses of Papers I-IV and Summary

<table>
<thead>
<tr>
<th>Objective</th>
<th>Data collection and context</th>
<th>Type of the study</th>
<th>Methods and data analyses</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>To analyse EHR related patient safety incident reports in hospital environment with 100% EHR implementation rate. To compare the data with previous research results after the procedure of taxonomy mapping.</td>
<td>Voluntary patient safety incident reporting data (N=23 023) in 23 hospitals of a university hospital district in Finland. Data consist of years 2011-2013, were collected and analysed in 2014.</td>
<td>Retrospective register study</td>
</tr>
<tr>
<td>II</td>
<td>To explore EHR users’ perceptions on the EHR related high and extreme risk error types in hospital environment with 100% EHR implementation rate</td>
<td>All health care professionals (N=17 336) possibly using EHR in 23 hospitals of a university hospital district in Finland. Study was conducted and analysed in 2015.</td>
<td>Quantitative, non-experimental, cross-sectional questionnaire study</td>
</tr>
<tr>
<td>III</td>
<td>To test the questionnaire’s (risk assessment tool) reliability and validity.</td>
<td>Questionnaire developed during August-November 2014. Study sample of 2864 answers was received in the beginning of 2015. Data were analysed 2015-2016.</td>
<td>Development and validation of a questionnaire</td>
</tr>
<tr>
<td>IV</td>
<td>To analyse EHR related medical software users’ reports in the nationwide supervisory (competent authority) database.</td>
<td>National Authority register data of medical software from 2010-2015. Data were collected in September-December 2015. 138 reports were included in the final content analysis and coding in 2016.</td>
<td>Retrospective qualitative register study</td>
</tr>
<tr>
<td>Summary</td>
<td>To summarize the substudies I-IV by answering the ultimate research questions.</td>
<td>Literature and studies I-IV. Conducted in September-November 2016.</td>
<td>Descriptive study</td>
</tr>
</tbody>
</table>
Results are described in the chapter 5. Conclusions and recommendations are shown based on a descriptive synthesis of the critical conclusions, mainly based on the sociotechnical theory of health information technology.

4.4 ETHICAL CONSIDERATIONS

The organization’s research review process approved the study protocol in 2014 (Permission number HUS §40/2014). Since patients were not the subject of this study, Finnish Medical Research Act 488/1999 did not require the approval of the Institutional Review Process for the study. The study sample of the questionnaire study was expanded from the original study protocol in September 2014. An amendment of the study protocol was submitted to the research director for an assessment. An approval for the amended protocol was received 8.11.2015, and it is archived in the TIETU research register. National Supervisory Authority of Welfare and Health granted a study permission (Number 2849/06.01.03.01/2015) for the register study in June 2015.

Analysis of the voluntary incident reporting database (Paper I) is a register study where data is collected from hospital district’s register database. No connection to patients nor professionals exists due to the nature of the anonymized information which does not contain any identification details.

All participants in the questionnaire study (papers II-III) were given a covering letter including the contact details of the researcher, details of the respondent selection, the aims of the study and use of the data as well as the voluntary nature of the participation. All respondents will remain anonymous; the analysis of the data does not contain any identification details. The study involved no financial incentives.

The National Supervisory Authority register data (Paper IV) were collected under premises of the institution because of data security reasons. The data were collected in a confidential manner and any details of the reporting organization, professional or patients were included in the research register. When analyzing the data only general definitions were used securing the anonymity of the reports’ contents.

All possibly personalized data have been destroyed. Fully anonymized research data are stored (Medical Research Act 488/1999) in an electronical format to ensure the possibility to repeat the research. The storage is secured by appropriate electronical data protection tools and restricted access to data is ensured.
4.5 DATA COLLECTION

4.5.1 Voluntary incident reporting data (Paper I)

All patient safety incidents reported through the hospital district’s HaiPro system between December 2011 and November 2013 were collected for the study phase I. The study involved searching the HaiPro incident reporting system and identifying incidents according to the current HaiPro classification of incidents. Search conditions were ‘reports by the category “Information Flow” or “Information Management,” “reports by the subcategory “Patient Information Management (Documentation)”’ and ‘reports by the category “Devices and Use of Devices.”’ Free-text searches and used keywords are described in the Paper I.

The query of structured data generated a total of 2379 incident reports, while the total number of incident reports in the entire database during this period was 23,023. Of HaiPro’s 13 event types, the final analysis focused on the ‘Information Flow’ and ‘Information Management’ subcategory ‘Patient Information Management (Documentation)’, with its detailed subcategories, as well as the category ‘Devices and Use of Devices’. (Paper I)

4.5.2 Questionnaire study and tool validation (Papers II-III)

Based on instrument development standards, the protocol for this mixed-methods study included four steps: (1) eliciting error types and risk indicators from the available literature (see Chapter 2.2.5); (2) translating, back-translating and developing the draft questionnaire; (3) piloting the draft questionnaire using expert panel methods; and (4) running test-rounds of the draft questionnaires. Panel members were selected through purposeful sampling to ensure that membership covered in-depth knowledge of the area from various perspectives. A panel of 12 members from Finnish hospitals and research institutions was created during the first round. The second round took place in health informatics research group including five panel members. Factors modified after the second round were included in the third round, which involved clinicians who had been using EHR. The final questionnaire was pilot-tested by asking a focus group of six experts from the sample population to complete the online questionnaire and to assess whether they had difficulty answering it.

The questionnaire used in the studies II and III consisted of eight error types (shown in the Chapter 2.2.5 and in the Paper II) to be assessed on a qualitative risk matrix scale used in the organization since many years (HUS, 2016). The structure of the matrix contains categories of probability and categories of severity for possible hazardous events. Each intersecting cell of the matrix is pre-assigned an insignificant, low, medium, high or extreme risk. The questionnaire scale consisted of
the following values: insignificant corresponded to the value 1, and extreme, to 5 (Krimsky and Golding, 1992, ISO 2009a, ISO 2009b).

The questionnaire with online platform was sent with detailed information for answering, as well as an explanation of the risk matrix, to all potential EHR users (N=17,336) at the same time early 2015. Because identifying exactly which individuals use EHR was impossible questionnaires were sent to all professionals in these groups. The participants were advised to rate all error types and risk factors on the questionnaire in their own working environment during the last 12 months.

Previous data on personnel absenteeism of the 17,336 total staff members indicated that at least 10% of them would be on different kinds of leave and thus ineligible to participate in the survey. Of the 15,602 eligible respondents, 2868 completed the survey, yielding an overall response rate of 18.4%. Of the all respondents 4 were eliminated due to missing data on all but a few questions, leaving a final dataset of 2864 respondents.

4.5.3 National Supervisory Authority register data (Paper IV)

A retrospective study of EHR users’ incident reports was conducted for cases submitted to the competent authority (CA) database (Valvira) during the period September 2010, through September 2015.

The data collection started as the researcher received a list of report IDs which had been classified with an electronic patient record (EHR) tag related by the authority and thus belonging to the research focus. The list in an Microsoft Excel format contained a total of 365 EHR-related reports during this period, including not only incident reports by EHR users, but also national competent authority reports (NCAR), field safety corrective action documents (FSCA) and other manufacturer reports. The study focused on EHR user reports only, with the exclusion of all other types of documentation.

Additionally, in order to verify the list of report IDs containing all relevant user cases, all Medical Device reports in paper format in the authority archive during the study period were selected for the preliminary analysis: every report was checked to confirm whether it was EHR related and it was compared to the list of report IDs. It was noticed that three user incident reports went missing from the original report list as a result of the authority’s efforts to transition towards e-archiving; these were added to the list.

The analysis continued by selecting all relevant user reports for a subsequent in-depth content analysis. Cases that failed to meet the EU reporting criteria were removed from the research database. These cases included reports concerning software not classified as a medical device, but rather for medication logistics, and one report classified as user feedback. The authority was consulted in borderline cases where the reporting criteria were unclear.
It is especially noteworthy that the authority database also includes EHR user incident reports of health information system downtime. Downtime does not fall under the reporting criteria of the directive but is instead a borderline issue that may seriously affect patient safety in institutions with a 100 per cent EHR implementation rate. A decision to include these cases in the analysis was made due to their importance for patient safety.

4.6 DATA ANALYSIS

4.6.1 Voluntary incident reporting data (Paper I)

A taxonomy mapping which is a research method for testing the reliability and validity of standardised taxonomies (Burkhart et al., 2005, Kim, Hardiker and Coenen, 2014, Salvador-Carulla et al., 2013) was performed between the HaiPro classification and the HIT-specific taxonomy described in the Chapter 2.2.2 (Magrabi et al., 2010).

The analysis by applying Magrabi’s taxonomy is performed by categorizing incidents using in the beginning a binomial classification of human or machine-related categories, and then a range of one or several sub-categories including input; transfer; out-put; general technical; and contributing factors. The rationale of using this kind of approach was to guarantee a consistent approach to reviewing incidents. Problems involving human factors are related to human interaction with information technology.

The HaiPro classification subcategory ‘Patient Information Management (Documentation)’ as well as the category for incidents related to a ‘Device or Use of Devices’ were cross-mapped with Magrabi’s taxonomy because these HaiPro categories include HIT-related content. The main categories of the two classifications appear in the Chapter 5.1.1, Figure 7.

The researchers placed appropriate HaiPro classifications into the categories created by Magrabi et al. (2010) and performed an inter-rater reliability analysis to ensure consistency between the researchers. After the first coding, the researchers discussed the rules and coherence of the mapping. At this stage any results were compared. The researchers then recoded and compared the chosen categories before compiling the data. Selecting the same category created a match. Choosing a different alternative or failing to recognize the category at all was considered a non-match. In one situation, one researcher understood the definition of the category differently than the other. In total, no complex situations developed during the analysis.
4.6.2 Questionnaire study and tool validation (Papers II-III)

The dependent variables were based on the eight multi-item scales, each having between three and six individual question items. The reliability of the summative scales was tested with Cronbach’s alpha. Sum variable means and reliability estimates are shown in the table of Paper II.

For the statistical analyses, each of the multi-item scales was regrouped into binary variables. After the preliminary analyses, a decision to define the outcome variable as responses of “Pose a high risk” (value 4 on a scale from 1 to 5) or “Pose an extreme risk” (value 5 on a scale from 1 to 5) to any of the items on the subscale was made. This cut-off point was chosen because reporting a severe risk related to patient care was considered an important indicator of patient safety.

Logistic regression served to assess the association of the independent variables to each of the eight risk factors. After initial univariate models the following information about a respondent figured in the final multivariate models: profession, type of clinical unit, professional experience, EHR training mode and self-reported EHR skills. In the models, we included variables at $P<.10$ level of significance, and a 95% confidence level was used to calculate CIs.

When testing the questionnaire’s psychometric properties confirmatory factor analysis (CFA) instead of exploratory factor analysis (EFA) served to assess the construct validity of the instrument, since the constructs and question sets were defined a priori and were based on theory and rigorous expert assessment. CFA is driven largely by theory and evaluates a priori hypotheses. CFA analyses require the researcher to hypothesize and specify beforehand the number of factors, regardless of whether these factors correlated or which items load onto and reflect which other factors (Kline, 2010; Lenz, 2016).

Kline (2010) recommends reporting the root mean square error of approximation (RMSEA), the goodness of fit index (GFI), the SRMR and the Chi-squared test results. Discriminant validity was assessed by testing whether the AVE estimates for two factors are greater than the square of the correlation between them in order to provide evidence of discriminant validity.

4.6.3 National Supervisory Authority register data (Paper IV)

At the beginning of the coding process the researcher pilot-tested the coding scheme with 30 reports. Relevant factors in each report were identified based on a complete review of the national authority report file including summaries and the original reports and supplementary material. The authors who were all familiar with the coding themes and contents discussed the coding rules several times. It was decided that a class “other” is added on the coding framework and discuss the development needs of the classification later.
The first author then completed the coding independently. In the end coding principles were discussed with the co-authors once more and the decisions made by the researcher were deemed acceptable and following the rules of the coding framework. The co-author, professor in health informatics, coded the data independently, and the results were discussed in detail. Kappa coefficients for computing inter-rater reliability were therefore deemed unnecessary because they were in perfect agreement (Cohen, 1960; Landis and Koch, 1977, 159-174).

After discussing the coding results, the data underwent additional analysis. Adding a dimension to the three-fold taxonomy of the AHRQ Common format 1.2 (AHRQ, 2016a) facilitated the identification of characteristics of certain content related to error type, thereby separating the adverse events resulting from medical devices into three classes: 1) Device defect or failure, including HIT; 2) Error in use, and 3) Combination or interaction of device defect or failure and error in use. The authority’s remarks about the root cause of the incident were used in this analysis.
5 RESULTS: EHR SAFETY AND OPPORTUNITIES FOR SAFER EHRS

In this chapter the main study results are described. The results are described in a detailed way in four research papers listed in the end of this thesis.

The analysis includes two themes: At first the phenomenon of EHR related technology-induced errors is described by using three different data: Voluntary incident reporting data, EHR user perceptions and National Supervisory Authority Data. Secondly, a development and a preliminary validation of an EHR risk assessment tool to anticipate and prevent technology-induced errors will be presented.

5.1 PERSPECTIVES ON TECHNOLOGY-INDUCED ERRORS IN EHRS

5.1.1 An analysis of electronic health record–related patient safety incidents

The results in this study regarding voluntarily reported patient safety incidents are shown by using the taxonomy developed by Magrabi (Magrabi et al., 2010) described in the chapter 4.3.1. Study results are at first shown using binominal classes 1) machine-related problems versus 2) problems related to human–computer interaction. After that principal results are shown by using the main categories of Magrabi’s classification (Figure 7).

In the Finnish HaiPro system, 8.45 per cent (n = 211) of the reports involved machine-related problems. The original HaiPro category ‘Devices or Use of Devices’ contained only 12 (0.5%) machine-related reports, whereas the category ‘Patient Information Management (Documentation)’ included 199 machine related reports (8.4%).

On the contrary, a total of 73 per cent (n = 1755) of the HaiPro reports involved problems related to human–computer interaction. These were classified originally in the HaiPro system category ‘Patient Information Management (Documentation)’. Only three reports (0.13%) in the category ‘Devices or Use of Devices’ were human-related. These cases were related to Magrabi’s categories ‘Data Input’ and ‘Data Retrieval Error’. The remaining HaiPro cases were either not classified or the category was unknown, so the framework could not serve to classify the incidents.

The main category ‘information input problems’, clearly the largest category in the data, accounted for 59.5 per cent (n = 1415) of the incidents. 8.8 per cent (n = 210) of the reports involved information transfer problems and were classified in the original HaiPro category ‘Information Retrieval or Input in the EHR Hindered’ (n = 199,
8.4%), the category’s only machine-related condition. A total of 14.4 per cent (342) of the reports were in the category ‘output problems’. These were coded in the original HaiPro category ‘Patient Information Not Retrieved or Put Out in the EHR’.

Machine-related problems in HaiPro partly overlapped with Magrabi’s category ‘Information Transfer Problems’. The original HaiPro categories used for this problem were ‘Device Dysfunction’ and ‘Device not Working, Unavailable, being Serviced (in Repair)’, which accounted for the same five reports (0.2%) as did the category ‘Information Transfer Problems’.

In HaiPro, the class ‘Other’ in the ‘Devices or Use of Devices’ category was equivalent to Magrabi’s ‘General Technical’ category, which accounted for four reports (0.17%). In addition, the HaiPro category ‘Unknown’ was mapped as ‘General Technical’, despite having no cases.

The main categories of the classifications and HaiPro data on different problem types is shown in the Figure 7.
Of the 2379 HaiPro reports, 2119 (89.1%) contained a completed risk assessment. A majority (89.2%) of the incidents involved low-risk cases, and only a minority (0.8%) involved high-risk incidents.

HaiPro contains information on the ways to prevent incidents recurring. 8 per cent of the cases led to no actions. The most common (82.6%) way to prevent incidents recurring was to inform the staff of the incident and share the data with other parties; 4.9 per cent of the incidents were transferred to the leaders of the hospital due to the seriousness and recurrence of the case or because support of the need for support to manage the incident. A concrete development intervention took place in 4.3 per cent of the incidents.

### 5.1.2 Health care professionals’ perceptions of common EHR concerns

The final dataset of the Finnish questionnaire study on EHR users’ perceptions of EHR-related error types consisted of 2864 eligible respondents. The highest proportion, nearly half of the respondents in both gender groups (49%), reported a high-risk level related to extended EHR unavailability. A high perceived risk was reportedly related to incorrect patient identification, system-to-system interface errors, failure to find or use the most recent data, EHR time measurement errors, and open/incomplete or missing orders. The lowest overall risk level was associated with selecting an incorrect item from a list of items (27% of females and 33% of males).

Physicians reported higher risk levels on all of the eight factors, especially those relating to extended EHR unavailability and failures to find the most recent patient data. Registered nursing professionals reported the second highest overall risk scoring, and the highest values were related to extended EHR unavailability and open/incomplete or missing orders. Emergency departments (ED), operating rooms (OR), and procedure units were associated with higher perceived risk levels, whereas clinical laboratory and radiology units were related to lower risk scoring. Professionals working on general wards reported high-risk scoring on extended EHR unavailability.

The distribution of the study’s background variables and the percentage of respondents reporting a high- or extreme-risk rating per error type appears in Table 2.

Table 2. The distribution of the study’s background variables and the percentage of respondents reporting a high- or extreme-risk rating per error type (unpublished material)

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
<th>%</th>
<th>Percent of all respondents reporting a high risk level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Incorrect patient identification.</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

58
errors, failure to find or use the most recent data, EHR time measurement errors, respondents reporting a high- or extreme-risk rating per error type appears in Table 2. The distribution of the study’s background variables and the percentage of respondents reporting a high-risk level related to extended EHR unavailability. A high perceived risk was reportedly related to incorrect patient identification, system-to-system interface failures, and open/incomplete orders. The lowest overall risk level was associated with patient identification errors.

A majority (89.2%) of the incidents involved low-risk cases, and only a minority (0.8%) involved high-risk incidents. Of the 2379 HaiPro reports, 2119 (89.1%) contained a completed risk assessment. A concrete development intervention took place in several cases due to the seriousness and recurrence of the case or because support of the need for action was lacking.

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The final dataset of the Finnish questionnaire study on EHR users’ perceptions of EHR-related error types consisted of 2864 eligible respondents. The highest percentage (47.9%) reported high-risk incidents when they were working on general wards, whereas clinical laboratory and radiology units were related to lower risk scoring. Emergency departments (ED), operating rooms (OR), and procedure units were associated with higher perceived risk levels, and the highest values were related to extended EHR unavailability and failures to find the most recent patient data. Registered nursing professionals reported the second highest overall risk level related to extended EHR unavailability. A high perceived risk was reportedly related to incorrect patient identification, system-to-system interface failures, and open/incomplete orders. The lowest overall risk level was associated with patient identification errors.

A majority (89.2%) of the incidents involved low-risk cases, and only a minority (0.8%) involved high-risk incidents. Of the 2379 HaiPro reports, 2119 (89.1%) contained a completed risk assessment. A concrete development intervention took place in several cases due to the seriousness and recurrence of the case or because support of the need for action was lacking.

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<td>0-5 years</td>
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<td>36.8</td>
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<td>6-15 years</td>
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<td>44.0</td>
<td>38.0</td>
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<td>16-25 years</td>
<td>659</td>
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<td>40.8</td>
<td>28.3</td>
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<tr>
<td>25+ years</td>
<td>617</td>
<td>21.5</td>
<td>44.2</td>
<td>36.2</td>
<td>30.9</td>
<td>37.6</td>
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</tbody>
</table>
The univariate analyses found profession and clinical unit to be the strongest predictors for perceived high- and extreme-risk ratings. Physicians reported a higher perceived risk on all risk dimensions (odds ratios between 1.21 and 2.55). The associations remained statistically significant in the multivariate analyses, even after adjusting for education, work experience, type of EHR training received, and self-reported EHR skills for all of the risk factors, except the one related to incorrect patient identification (odds ratios between 1.30 and 2.51). Health care professionals working in EDs, ORs, and procedure units reported higher perceived risk ratings on all error types. Professionals working at an intensive care unit (ICU)/critical care unit (CCU) reported higher perceived risk ratings on extended EHR unavailability, system-to-system interface errors and open, incomplete or missing orders, but in the multivariate models the association remained significant only for interface errors. Lower perceived risk levels were associated with working in a clinical laboratory or in radiology, providing less acute patient care, and working in outpatient units, although to a somewhat lesser degree.

Prior participation in eLearning courses on EHR-use was associated with lower risk ratings on some of the risk factors (extended EHR unavailability, P=.03; EHR warning dismissed, P=.015; failure to find or use the most recent patient data, P=.018). Poor self-reported EHR-use skills were associated with higher risk ratings, and the effect remained significant even after controlling for other factors.

An Association of background variables with perceived EHR risk rating (Odds ratios [OR], 95% CIs, and P-values from logistic regression analyses) as well as more detailed study results are shown in the tables and figures of Paper II.

| Frequency of EHR Use | Several times per shift | Less often | | | |
|----------------------|-------------------------|------------|----|----| |
|                      | 2640                    | 92,2       | 43,0| 36,7| 27,7 | 40,7 |
| EHR Training Mode    |                         |            |    |    |    |
| Classroom            | 610                     | 21,3       | 43,4| 37,7| 25,3 | 39,3 |
| eLearning            | 880                     | 30,7       | 38,3| 33,8| 25,4 | 38,2 |
| General training     | 803                     | 28,0       | 43,7| 37,7| 29,9 | 44,8 |
| IT Support           | 304                     | 10,6       | 46,0| 35,9| 28,4 | 38,1 |
| Other/no training    | 267                     | 9,3        | 48,4| 41,0| 35,0 | 43,7 |
| EHR Skills Level     |                         |            |    |    |    |
| Good                 | 793                     | 27,7       | 39,0| 36,5| 25,6 | 43,7 |
| Fair                 | 1590                    | 55,5       | 42,9| 34,8| 27,6 | 38,1 |
| Poor                 | 481                     | 16,8       | 48,1| 43,0| 31,6 | 44,2 |
| Total                | 2864                    | 100        | 42,6| 36,6| 27,7 | 40,6 |
5.1.3 National Supervisory Authority reports on EHR errors

A total of 138 users’ incident reports were analysed. In all, 6 of 8 previously presented error types (Chapter 2.2.5) and class ‘Other’ were identified among the reports. The most common error types were (n = 37, respective) downtime in 26.8% of the reports and System-to-system interface errors in 26.8% of the reports. The error type Open, incomplete or missing orders accounted for 23.9% (n=33) of incidents and Incorrect patient identification 10.1% (n=14). The error types EHR time measurement translational challenges (2.2%/ n=3) and Incorrect item selected from a list of items (0.7%/ n=1) were among the rarely reported incidents.

The error type Other included 13 reports accounting for 9.4% of incidents. The cases in this class did not fit in to any other categories. These reports included 5 reports related to the data security and licensed clinicians’ professional rights Professionals who should not have access to the the data could see it. 3 cases were where the software module specifically related to the medication administration was locked hindering the clinician see or handle data. 4 reports were medical software’s dictation module problems where the application was adding patient information which the physician did not provide. One of the cases described several error types but didn’t include enough detailed information to select major error type in a reliable way.

Error types Failure to heed a computer-generated warning or alert and Failure to find or use the most recent patient data were not represented in the sample. Errors in total of 31 reports (22.46%) were related to the software used in ePrescription modules for national ePrescribing system. Figure 8 provides a summary of the descriptive statistics of error types.

![Figure 8. Descriptive statistics (%/ n) on error types in EHR users’ reports](image)

23.2% (n=32) of the reports were labeled as serious incidents. 31 of these were rated by the competent authority and one by the researcher who used supplementary
information from the manufacturer’s report which could be linked with the users’ report. Serious cases were typically related to a prolonged EHR downtime and medication related software errors. One serious case was related to an incident where a physician had stopped patient’s medication but the software continued the medication with a higher dose as previously. The only report in the error category Incorrect item selected from a list of items was serious: the software enhanced selecting a wrong medication from the list which led to serious consequences for the patient.

Primary care organisations such as health care centers and community elderly homes accounted for 38.5% the cases (n=53). Specialized care organizations e.g, university hospital districts accounted for 58% of the reports (n=80). Two of the user reports were created by a private care organization such as private doctor company. In three cases, the information available was insufficient to determine the organization type.

The results of the analysis by taxonomy of the AHRQ Common format are only directional due to the type of data (i.e., register data that did not allow a full investigation of the root cause in all cases). These data include a total of 111 reports out of 138 reports in the class ‘Device defect or failure, including HIT’ diagnosed by the competent authority. The authority labelled most of downtime-related reports, as well as system-to-system interface errors, as device defects or failures. An additional 14 downtime and interface reports that lacked root cause analysis by the authority as a ‘Device defect or failure’ were analysed. In summary, a total of 126 reports (91.3%) involved device defects or failures. The detailed results are shown in the paper IV.

5.1.4 State of technology-induced errors in Finland 2010-2015

During this study, a large number of technology-induced errors’ data were analysed using two types of registers: EHR related reports in a voluntary patient safety incident reporting database and EHR professional users’ incident reports in the National Supervisory Authority (Valvira) database. EHR users’ perceptions were studied during a large questionnaire study. Due to the differences in the nature of these data a direct comparison is not plausible but some common features may be presented.

In this dataset, the proportion of EHR related incidents was high accounting for approximately 10% of all patient safety incidents (N=23,023) in these hospitals. Problems involving human factors are related to human interaction with information technology. This study shows that problems related to human–computer interaction were clearly the largest category accounting for over 70 per cent of the reports. 8.5 per cent were machine-related problems. A majority, around 90 per cent of the incidents involved low-risk cases.
HIT problems emphasising human-computer interaction and use of EHR confirmed the need to study the phenomenon by applying sociotechnical framework suitable for detecting problems in complex healthcare settings (see Chapter 2.1.2). Consequently, the next substudies were performed by using the sociotechnological framework by refining the results of previous studies related to known error types (Chapters 2.2.2 and 2.2.5). The Table 3 contains the description of the risks in EHRs in three data.

Table 3. The description of the risks in EHRs in three data (unpublished).

<table>
<thead>
<tr>
<th>Paper I</th>
<th>Paper II</th>
<th>Paper IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>The EHR related incident rate is high, approximately 10 per cent of all incidents reported. 8.5 per cent of the reports involved machine-related problems and 73 per cent involved problems related to human-computer interaction.</td>
<td>Use of EHRs involves risks. Almost half of the respondents reported a high level of risk in their own working environment related to the error type Extended EHR unavailability. In multivariate analyses, profession and clinical unit proved to be the strongest predictors for high perceived risk in multiple error types.</td>
<td>The amount of reports is low: 138 national users’ reports during 5-year period. Cases were most typically Information system downtime, System-to-system interface errors and Open, incomplete or missing orders. Total of 23% of cases involved severe harm.</td>
</tr>
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</table>

The main results of the final multivariate models in the questionnaire study (Paper II) are in summary: Results showed profession and type of unit to be the strongest predictors for perceived high- and extreme-risk ratings. Physicians reported a higher perceived risk on all risk dimensions. Health care professionals working in EDs, ORs, and procedure units reported higher perceived risk ratings on all error types. Professionals working at an intensive care unit intensive and critical care unit reported higher perceived risk ratings on extended EHR unavailability, system-to-system interface errors and open, incomplete or missing orders. Lower perceived risk levels were associated with working in a clinical laboratory or in radiology, providing less acute patient care. In the oversight study (Paper IV) adverse events associated with EHR vulnerabilities clustered around certain error types: The most common error types in the reports were ‘Downtime’ (26.8%) and ‘System-to-system interface errors’ (26.8%). These error types caused serious harm and occurred in all types of health care settings.
5.2 THE FIN-TIERA TOOL TO ENABLE RESILIENCE IN THE USE OF EHRS

The Paper III describes the development process of a Finnish Technology Induced Errors’ Risk Assessment Tool (FIN-TIERA) in detail. The tool, based on the socio-technical theory and Sittig and Singh’s study findings (Chapter 2.2.5), was constructed for this study through a multi-stage process, and expert panels evaluated it.

The psychometric test results are in short: All eight multi-item scales showed high internal consistency (Cronbach alpha range $\alpha > 0.798$-0.932). Composite Reliability (CR) values (CR 0.845-0.983) provided support for reliability and internal consistency. CR indices were greater than 0.7 for all the latent variables indicating good reliability. The results of the detailed risk factor statistics and Cronbach alpha values as well as the alpha values even for deleted items were reported. The results appear in the Paper III.

The average variance extracted (AVE) served to assess the confirmatory factor analysis (CFA). The results of the model fit with AGFI = .86, CFI = .898, RMSEA = .052, SRMR = .048. were deemed acceptable. For all factors, AVE yielded values $> 0.5$, which indicates adequate convergence and supports convergent validity. Discriminant validity was established for five out of a total of eight latent variables. Discriminant validity was adequate for factors 1, 2, 3, 6 and 7 (AVE is greater than ASV or MSV). However, factors 4, 5 and 8 showed ASV and MSV values greater than AVE indicating poor discriminant validity. Convergent and discriminant validity assessment are shown in the Table 4.

Table 4. Convergent and discriminant validity assessment (modified from Paper III)

| Factor 1: Incorrect patient identification | CR 0.910 | MSV 0.543 | ASV 0.501 | AVE 0.678 |
| Factor 2: Extended EHR unavailability | CR 0.929 | MSV 0.589 | ASV 0.512 | AVE 0.639 |
| Factor 3: Computer-generated warning or alert | CR 0.919 | MSV 0.631 | ASV 0.543 | AVE 0.599 |
| Factor 4: Interface errors | CR 0.983 | MSV 0.645 | ASV 0.537 | AVE 0.524 |
| Factor 5: Failure to find or use the patient data | CR 0.916 | MSV 0.830 | ASV 0.635 | AVE 0.593 |
| Factor 6: EHR time measurements errors | CR 0.926 | MSV 0.745 | ASV 0.618 | AVE 0.648 |
| Factor 7: Incorrect item | CR 0.931 | MSV 0.830 | ASV 0.617 | AVE 0.677 |
| Factor 8: Open, incomplete or missing orders | CR 0.845 | MSV 0.745 | ASV 0.626 | AVE 0.566 |

The Cronbach’s alpha of measured or deleted items as well as CFA serve as the basis of decisions to modify the instrument. Tests showed higher alpha values for only one question set if Item 6 on Factor 4 (Question: “The organization has no procedure for sending or receiving referrals or test results through a direct interface to the EHR.”) is deleted (0.89 compared to 0.87). Dropping any other question items
would not improve the risk factor reliability estimates. In the future, modification of the FIN-TIERA should consider rewording or dropping this item. However, the improvement in the alpha value is quite modest.

CFA showed partly satisfactory results but discriminant validity for three of the eight factors was less than satisfactory, requiring further elaboration of the factor structure. Various models with slightly different factor structures yielded slight improvements in the original factor construction. However, any post hoc modifications to models based on modification indices should occur only when the modifications are theoretically and practically relevant.

The final questionnaire consists of eight error types to be assessed on a qualitative risk matrix scale. The questionnaire is shown in Paper III. The Figure 9 describes how the FIN-TIERA tool is localized in the conceptual framework of the study.

Figure 9. The study results in relation to the conceptual framework of the study

Finally, the FIN-TIERA is a new multi-dimensional instrument which may be a useful tool for assessing risk in EHRs. The testing shows its potential for use in-hospital settings: the involvement of EHR users demonstrated initial reliability and validity. However, further research is needed to assess the instrument’s psychometric properties. The tool is to benefit not only HIT resilience in hospital settings but also informatics research.
6 DISCUSSION

6.1 RELEVANCE OF THE STUDY

Health information technology (HIT) safety has become an important issue. Data about technology-induced errors has grown during the past decade, but there is relatively little information about these errors (Coiera, Aarts and Kulikowski, 2012; Borycki, 2013a, 2013b; Denham et al. 2013; Agboola, Bates and Kvedar, 2016). The studies in this thesis are specialized care facilities with 100 per cent EHR implementation rate and lots of experience with EHR use. Such facilities are rare. The three related perspectives and initial validation of a tool for technology-induced error detection are meant to increase knowledge about the domain. Thus, this thesis provides unique content in the area of health informatics and patient safety to benefit patient care and the domain of health informatics research (Gardner et al. 2009; Mantas et al., 2010; Detmer and Shortliffe, 2014; AMIA, 2016; Mantas, 2016).

Similar EHR clinical user perspectives on technology-induced errors in a specialized hospital environment are rarely published in health informatics literature. A questionnaire study with nearly 3,000 multiprofessional EHR users is unusual, even though it lacks a possibility to generalize the findings in a broader context. The findings of a paperless hospital environment have merit because only rare examinations have been introduced in a context with extensive experience in implementation of EHR.

The results of this thesis indicate that voluntary patient safety incident reporting systems need to be refined to include use of commonly established theoretical approaches for managing technology-induced errors. The work described provides guidance for structuring patient safety incident reporting. The applicability of the HIT-specific classification (Magrabi et al., 2010; Warm and Edwards, 2012) has not yet been explored extensively within the context of patient safety reporting systems. This study comprised one test phase of the framework for future purposes.

Outside the EU, only a few researchers have specifically studied HIT supervisory data (Myers, Jones and Sittig, 2011; Magrabi et al., 2012); the EU lacks this type of study from users’ perspectives. In the study (Paper IV), the goal was to determine the impact and current obstacles of oversight reporting as part of preventive measures in HIT safety. The study also sought to add information on specific types of EHR–related problems by using a novel structure developed in this study.

This thesis deals with fundamental issues, and the area of interest is significant on a practical basis. The need to consider user perspectives of technology-induced errors exists both in clinical work and public discussions (e.g., McGinn et al., 2013; Papoutsi et al., 2015). At present, as hospitals prepare to implement new information systems (Apotti, 2016), organisational and clinical challenges require a novel
method to monitor EHR-associated risks. This thesis includes a review of the current essential means in EHR safety monitoring, especially from EHR users’ perspectives, suggestions for refining these systems, including implications for oversight functions, and the use of an initially validated EHR safety assessment tool. Implementing EHR risk assessments involving EHR users around operational processes provides the opportunity to identify threats in an effective way and thus benefit patient care and, subsequently, cost for healthcare organisations.

6.2 LIMITATIONS, RELIABILITY AND VALIDITY OF THE STUDIES

Voluntary incident reporting data

Even though voluntary incident reporting is an important and widely used means for identifying patient safety problems, these systems have major limitations. The major problem is that incident reporting systems generate numerators without denominators (Sari et al., 2007; Shojania, 2008; Shojania and Marang-van de Mheen, 2015; Howell et al., 2016).

In spite of incident reporting systems’ limitations and the fact that their purpose has been under debate (Shojania, 2008; Pham, Girard and Provonost, 2013; Shojania and Marang-van de Mheen, 2015), the data provide a sample of hazards for identifying risks (Pham, Girard and Provonost, 2013; Howell et al., 2016). Characteristic profiles may be identified when collecting and analysing a large number of incidents. The data are robust, but are the kind of data to utilize in detecting EHR failures before they impact patient safety (Adelman et al., 2013; Howell et al., 2016). Consequently, when looking at the limitations of this study, it is noteworthy to consider that these data do not seek to provide exact error rates but rather a descriptive analysis of typical EHR-related safety problem types and their comparison with similar data, applying the same classification.

Among the studies’ substantial limitations is the fact that the incidents in this study were related to the use of the same EHRs within a single, albeit large, hospital district (Lakes, 2013). These findings may not represent all types of EHR-related safety concerns and might not be generalizable to other institutions with different levels of EHR implementation and patient safety reporting procedures.

To ensure consistency between the researchers, two coders performed the taxonomy mapping independently (Burkhart et al., 2005; Kim, Hardiker and Coenen, 2014; Salvador-Carulla et al., 2013). The researchers have years of experience working in health informatics. Both have developed classifications at national and international levels, such as the WHO Collaborating Classification Centre. This study used suitable reliability measurements (Cohen, 1960; Landis and Koch, 1977, 159-174).
In this dataset, structured responsibilities, surveillance of the quality of data, and a training programme for those classifying the reports ensured the appropriate use of classifications (HUS, 2016). However, without a full content analysis (e.g., Lenz, 2016, 321-332) of the reports, one cannot be 100 per cent sure of the correct use of classifications. The risk of invalid data, however, is presumably low. Additionally, free text searches that focused on all general incident classes ensured the validity of the use of target classifications.

Questionnaire study and tool validation

In this type of research, the most important issues to take into account are weaknesses in the questionnaire’s validity and reliability. This study demanded considerable resources of expertise to ensure the processes of translation and adaptation. The methodology of the content validity assessment was similar to that of previous literature. The multi-phased iterative questionnaire development process aimed to ensure semantic equivalence of the translated terms and acceptable content validity (Presser, Rothgeb and Couper, 2004; Arat et al., 2016; Lenz, 2016). It is worth noting that some risk factors found in the literature were omitted because they were not relevant to the Finnish environment. Moreover, some questions required modification because they were difficult to interpret. No additional dimensions were added during the testing. In general, complicated syntax was avoided, and examples were provided when difficult concepts were used. However, during the next test-phase, it is important to pay attention to questions’ clarity and length because ambiguous terms are the most common problems in the response process (Podsakoff et al., 2003).

Due to the cross-sectional nature of this study, caution in interpreting study results is suggested. There are factors, e.g., profession and unit that were associated with high risk ratings. These results are discussed in detail in Paper II. Results may vary in other settings, particularly those with differing healthcare systems, such as the US. Recruiting participants from a single hospital district causes a lack of diversity in terms of geography and types of hospitals. Thus, these results may only be applicable to a specific hospital context.

The response rate was relatively low, as is typical of many questionnaire studies. However, the representativeness of the study is crucial. Comparing respondents’ background characteristics with personnel department data on all staff members revealed only a few demographic differences between participating and non-participating employees. Data on the respondents’ sex, age, profession, and education distributions were collected from the human resources systems, and χ² tests were used to compare the corresponding sample distributions. The sex, age, and education distributions did not differ in a statistically significant manner from the
staff records (Hernán, Hernández-Diaz and Robins, 2004; Lakes, 2013; Aerny-Perreton et al., 2015; Horevoorts et al., 2015).

It is important to identify how different aspects of method biases influence the response process (Hartling et al., 2009). The fact that participants systematically received training in the utilization of the risk matrix as part of the safety program (HUS, 2016) markedly improved the reliability of this study. Moreover, bias was reduced by providing verbal labels for the points of scales (Podsakoff et al., 2003). However, due to the importance of validity issues, validity testing of the scale is one of the suggestions for future research (Streiner, Norman and Cairney, 2014). Procedures to reduce method biases, such as allowing respondents’ answers to be anonymous, were applied (Podsakoff et al., 2003).

Like all questionnaire studies, this study was subject to potential problems associated with response bias (Cull et al., 2005). Some responders may have had a greater interest in problems with EHRs than did non-responders, and these data may overestimate the actual risk level of EHRs. On the other hand, participants were well aware of EHR risk factors, because nearly all respondents used EHRs several times per shift.

Instrument design by implementing both procedural and statistical methods of control will be a focal point of further research. Some specific features of the psychometric tests require attention. Taking into consideration the initial test stage, confirmatory factor analysis (CFA) yielded decent fit statistics and composite reliability (CR) indices, which indicated good reliability (see Chapter 5.2). Discriminant validity is essential for this kind of study. Subscales must correlate enough to be considered part of the same overarching construct without being redundant. Discriminant validity was adequate for a total of five factors, but three factors showed ASV and MSV values greater than AVE, indicating poor discriminant validity. Thus, further elaboration of the factor structure is needed. Also, previous valid factors should be possible to recreate empirically using item-level structural analyses (Clark and Watson, 1995).

The main limitation of this study is that its cross-sectional design did not permit evaluation of the questionnaire’s predictive validity and test-retest reliability. Future studies and statistical tests are needed, preferably test-retest reliability testing by applying Pearson’s correlation coefficient in the same institution (Hair, 2010).

**National Supervisory Authority register data**

In this study (Paper IV), two independent coders assigned reports in the data structure by examining the descriptions after creating common rules for classification work. Inter-rater reliability analysis was performed to determine consistency between coders.
Some limitations necessitate discussion. The first is that these results represent only EHR users’ aspects of technology-induced errors in the Authority register. The second limitation is the relatively small number of reports (138 cases during 2010-2015) for analysis. The data collection period started from the point Valvira launched national regulation of software as medical devices (Valvira, 2016). The fact that vendors completed the process of European conformity (CE) application in 2010 and 2011 affected the selection criteria of this study. Moreover, not all EHR users were fully aware of the regulation at first.

In summary, there is a need for additional scientific evidence in this multifaceted, challenging, and continuously changing domain. For effective reporting systems and monitoring health information technology safety, other factors may be relevant for study in the future to serve the needs of clinicians and the healthcare system at large. Also, different methods can be applied to reduce technology-induced errors. New challenges, e.g., error types shown in this study, and needs of organizations must be assessed as systems with new features are implemented.

6.3 STUDY RESULTS’ COMPARISON WITH PREVIOUS LITERATURE

Characteristics and the most critical areas of health information technology safety

Voluntary patient safety incident reporting systems can be used to recognize EHR-related safety concerns when taking the limitations into account (Shojania, 2008; Shekelle et al., 2009; Shojania 2010, IOM, 2012). This study of a Finnish incident reporting system shows that the proportion of computer-related safety incidents is much higher than previous international publications suggest (Staggers et al. 2008; Magrabi et al. 2010; IOM, 2012).

The Finnish data and the proportion of incidents (Paper I) are primarily discussed with regard to study findings, which are based on similar data and the same taxonomy that focuses on the use of HIT (Magrabi et al., 2010; Warm and Edwards, 2012). In the reference study (Magrabi et al., 2010), a search of around 40,000 patient safety incidents during a two-year period yielded only 123 computer-related incidents. This may be because recent research has started to provide evidence on what IOM already assumed (IOM, 2001): new technology increases technology-related vulnerabilities (Myers, Jones and Sittig, 2011; Sittig, Ash and Singh, 2014). The Finnish rate of EHR implementation is 100 per cent, and no paper health records exist, whereas the reference study was performed in a setting with partial EHR implementation. Thus, this study result (Paper I) is worth noticing not only locally but also in a broader context. These types of data in this context are still rare, and this result can be used foremost in organisations increasing EHR implementation.
Also, the questionnaire study (Paper II) evidences the significant presence of technology-induced errors in the same study context. EHR users rated their perceptions of risk levels, indicating that some error types occur frequently. Previous studies of the EU medical software directive (EC, 2016) from a user’s perspective do not exist. However, nationwide data (Paper IV) confirm that adverse incidents related to use of EHRs exist. The issue of low reporting rate in an authority system raises other questions that will be argued later in this chapter.

The study results (Paper I) are supported by research which indicates that technology-induced errors result from the complex interaction between EHRs and clinicians (e.g., Koppel, 2010; Harrison, Koppel and Bar-Lev, 2007; Sittig and Singh, 2010, 2011; Elkin et al., 2012; Meeks et al., 2014; Smith et al., 2014; Singh and Sittig, 2016). As such, the results emphasise the need to consider these errors from a sociotechnical view. A key finding (Paper I) is that human–computer interaction problems were reported more frequently in the Finnish study than in the reference study (Magrabi et al., 2010). Only 8.5 per cent of incidents were machine-related problems; 73 per cent were problems of human–computer interaction. Of all reference reports, 55 per cent included machine-related problems, and 45 per cent of problems were human–computer interaction. Thus, as a result of analyzing the data, the following substudies were performed by utilising the sociotechnical framework (e.g., Sittig, Ash and Singh, 2011; Singh and Sittig, 2016) and previous research results (see Chapters 2.1.2 and 2.1.5).

The risk profiles of the two same kinds of voluntary incident reporting databases clearly differed. In the reference data, 70 per cent of cases received a medium-risk score (Magrabi et al., 2010), whereas in the Finnish system, the corresponding figure was only 10 per cent. This disparity may partly stem from the wide coverage of Finnish incident reporting, which stresses reporting minor incidents and close calls (Doupi, 2009; Pietikäinen et al., 2016). On the other hand, in the oversight study (Paper IV), errors were associated with possible severe harm and death. Previous study on a US regulatory database found 11 per cent related to patient harm, and nearly one per cent of deaths were linked to HIT problems (Magrabi et al., 2012), indicating the Finnish system contained predominantly severe cases. In this study (Paper IV), severe cases represented more than 20 per cent, even though a minority of these led to death. This result further indicates the importance of fostering EHR safety monitoring and mitigation procedures. Still, the most important explanatory factor in analyzing the severity of the cases between databases (Paper I and Paper IV) is the nature and purpose of databases, which differ. The oversight study (Paper IV) especially indicates that EHRs pose severe risks to patient safety, and active steps are needed to promote EHR safety. It is important to consider that these results are related to EHRs used at real-world sites, not in a simulation environment (e.g., March et al., 2013). Thereby, errors directly affect patient care.

The highest proportion participants in the questionnaire study (Paper II) reported a severe perceived risk level related to extended EHR unavailability, which was
seen as a particularly high-risk area in EDs and critical care units. Also in the oversight study (Paper IV), downtime was among the most common error types. Research has found this error type as a high priority practice in all areas of EHR safety and, as such, a critical safety issue. Loss of continuous access to patient information risks leading to harm (Nelson, 2007). Moreover, a very recent study showed that even a short downtime affects patient care (Wang et al., 2016).

The finding of severe perceived risk related to EHR downtime can also be seen in hospitals with high EHR adoption rates; paper records are no longer in use, and contingency plans have been only partially implemented. This area is important because unexpected downtime is fairly common (Sittig et al., 2014b) and occurred in this study. Moreover, adoption of EHR systems continues to grow (Wright et al., 2013; Charles, Gabriel and Searcy, 2015), and concerns about future EHR use are related to prolonged downtime, even if this seldom occurred in the past five years (Menon et al., 2014a). Downtime failure has become a cause for concern following adoption of large-scale EHR systems to handle many operations within the broader healthcare system (Blumenthal et al., 2010; Sittig and Singh, 2012; Wright et al., 2013; Lei et al., 2014). The study in Paper IV reinforces that potential risks related to EHR downtimes are known to occur long after implementation (Sittig and Singh, 2012). Even if system downtime is not predominantly regulated by the EU directive, downtime does have a major impact on HIT safety and thus requires oversight measures. These results (Paper II, IV) stress the priority of structured organisational processes to continue operating and minimize patient risk in case of downtime (Myers, Jones and Sittig, 2011; Singh, Ash and Sittig, 2013; Sittig et al., 2014; HealthIT.gov, 2014).

Error type Failure to find recent data did not exist in the oversight study (Paper IV). The reason is probably because the error type is closely tied to the use of EHR. Therefore, clinicians may not consider this error type as a technical problem that meets the Authority reporting criteria (EU, 2016) but rather an issue of poor usability (ISO/IEC, 2009; Greenhalgh et al., 2010). This disparity between the two data (Paper II, IV) stresses the need to clarify the reporting criteria of EHR-related adverse events in the Health Supervisory Authority systems. Previous studies have shown that most clinicians do not know what incidents should be reported (Smith et al., 2014; Sittig et al., 2015).

Time measurement errors in the oversight data (Paper IV) led to serious harm, indicating a severe latent vulnerability in EHRs that was not detected during the EHR development process. This unique result clearly fosters the finding that surveillance of EHR vendors’ development processes does not reveal all EHR-related problems or what happens after implementation (Sittig and Singh, 2013; Singh and Sittig 2016). The need for adequate EHR testing before implementation, well-coordinated mitigation processes, and rapid communication of safety flaws is crucial (Walker et. al., 2008). Other findings of the error types are discussed in Paper II.
The oversight study (Paper IV) confirms that technology-induced errors can occur in any healthcare or clinical setting (Menon et al., 2014b; Tanner et al., 2015). Risks in ambulatory care settings are due to, e.g., information exchange across multiple settings (Hammons et al., 2003; Bell et al., 2009; Sokol and Neerukonda, 2013). The questionnaire study (Paper II), focused on more detailed unit information; these results are discussed in the publication (Paper II). In EDs, ORs, and ICUs, risk factors were relatively high for all professional groups. Use of EHRs strongly impacts ICU physician workflow by, e.g., clinical review becoming the focal point of many tasks (Carayon et al., 2015). The unique and challenging characteristics of EDs, including rapid turnover, constant interruptions, and unfamiliar patients, make the ED context particularly prone to errors. Thus, those implementing and maintaining EHRs in this context should carefully consider these issues (Farley et al., 2013). A newly published study (Han et al., 2016) shows a decrease in the number of severe medication errors following implementation of EHRs in critical care. Based on these diverse results and restricted focus of this study (Paper II), there is a need for research that focuses on the type of software applications, such as closed loop medication management systems, in specific contexts like intensive care units by applying different research methods.

**Characteristics and the most critical areas of monitoring systems**

Although the voluntary reporting data suggest that interventions can reduce risks, these systems have not led to the expected risk reduction (Landrigan et al., 2010; Pham, Girard and Provonost, 2013; Rafter et al., 2015). Measuring the successful use of an incident system is challenging but may be estimated by rating the number of changes made because of the system. In the data (Paper I), only eight per cent of HIT incidents were left without measures, which, if still below the target level, can be considered reasonable progress in the optimal use of the system. Still, this raises a question about the appropriate implementation and use of such systems. Management support for patient safety is among the substantial challenges in this area (Aase et al., 2008). Combinations of human, technical and organizational aspects and interactions affecting the outcome of an implementation process need to be considered (Høyland and Aase, 2008). There is a lack of front-line staff involvement of in the learning process and a limited evaluation of the implemented interventions (Wallace et al., 2009; Moeller et al., 2016). Efforts to maximise learning from incidents is still a challenge. To conclude, the aspect of learning from previous incidents is a key area of incident reporting systems and research.

The study (Paper I) also revealed an existing obstacle in the use of these data. Using the Finnish HaiPro classification would not have enhanced comparisons with previous international study results. Without taxonomy-mapping (Burkhart et al., 2005; Kim, Hardiker and Coenen, 2014; Salvador-Carulla et al., 2013), adding value
to scientific data would have proved difficult (see also Howell et al., 2016). Even if
the use of standard classifications facilitates data use across countries, there has
only been a little evidence of the development of frameworks to help categorize and
comprehend the data (Warm and Edwards, 2012). Also, this study (Paper I) con-
formed the result which stresses the need for HIT-specific classification when re-
porting and analysing these incidents. A very recent international study supports
this important finding (Howell et al., 2016).

Cross-mapping (Burkhart et al., 2005; Kim, Hardiker and Coenen, 2014; Salva-
dor-Carulla et al., 2013) revealed weaknesses in both structures (Paper I). These
classifications do not include elements to describe user interface defects,
inadequacy of semantic elements, or incorrectness of data structures. This gap
should be considered when further developing these classifications (Cimino, 2011).
Magrabi et al.’s (2010) taxonomy is a possible starting point for international inci-
dent classification of machine-related incidents. Because healthcare is increasingly
regarded as a complex sociotechnical environment, the human-computer interaction
aspect of classification is not strong enough and, thus an area to be considered
for future development.

Current EU directives governing medical software indicate a gradual move to-
wards stricter software regulation. Currently, the EU is expected to propose new
rules on medical devices (EU, 2016) that will most probably lead to tighter surveil-
lance. This is a reasonable expectation, since more serious EHR-related safety
events are likely to occur as the implementation of comprehensive EHRs grows
(Battles and Keyes, 2002; Denham et al., 2013). This study (Papers I, II, IV) also pro-
vided examples of risks stemming from the development or use of EHRs in envi-
ronments with high implementation rates.

Tighter regulation, however, is seldom so straightforward. Closer regulation
raises issues of balance; previous experiences with barriers to the commercialisation
of, for example, advanced medicinal therapies, including the complex interfaces of
the pharmaceutical regulatory system and the intellectual property system’s bur-
densome procedure for marketing authorization (Plagnol et al., 2009). Developing
effective regulatory solutions that do not hinder innovation is among the greatest
challenges of smart regulation.

Moreover, the problem of underreporting (Paper IV) raises questions about the
adequacy of the present supervisory system. This phenomenon is similar to the US
system, which maintains only a small number of incidents (Sittig and Singh, 2015).
An important question is whether the vigilance system in the EU fulfills its prin-
cipal purpose of improving patient and user health and safety protection by reducing
the likelihood that incidents would recur elsewhere (EEC, 1993). Studies (Paper I-II)
in a specialised care setting show that, if the supervisory system worked effectively,
the number of reports in this nationwide study would be significantly higher (Pa-
per IV).
Application requirements of the medical software directive are relatively unfamiliar for, e.g., EHR users and leaders, but the new MEDDEV guidance (EC, 2016) is assumed to improve the situation. Still, not all standalone medical software qualifies as a medical device. This complexity of criteria highlights the fact that resources are needed to strengthen clinicians’ knowledge of reportable EHR issues and consequently contribute by reporting incidents to improve the effectiveness of the regulatory system. Furthermore, when clinicians must use multiple reporting channels, the amount and quality of reporting inevitably come into question. The purpose and processes of multiple EHR safety reporting systems must be clarified, and overlapping systems should be coordinated to make them more effective.

To enhance learning, organisations must share lessons learnt from events (Paper IV) and data on implemented risk controls (Sittig and Singh, 2015; Peerally et Carr, 2016). Every case (Paper IV) highlights an EHR vulnerability that institutions should know about. Establishing a regulatory database for sharing experiences of medical software errors with the goal of developing prevention strategies is recommended (see Goodman et al., 2011). A classification system that distinguishes error types is also necessary for this purpose, (Cimino, 2011; Taib et al., 2011; Warm and Edwards, 2012).

**Technology-induced error monitoring and managing resilience practice elements from a user’s perspective**

Health information technology safety requires something more than retrospective analyses (e.g., Rasmussen, 2000; Woods 2006; Cook et al., 2008; Hollnagel 2008; Carayon et al., 2009; Leveson, 2012, Braithwaite, Wears and Hollnagel, 2015; Hollnagel, 2015). In the following, selected elements of technology-induced error monitoring and resilience practice management from a user’s perspective, as well as views fostering resilience extracted from the results of the studies of this summary, are discussed.

Hollnagel’s statement in an article by Wilson, et al. (Wilson et al., 2009) about industrial safety is suited for current patient safety and technology-induced errors:

> The main problem in [industrial] safety today is that most safety management and risk assessment methods are from 20 to 40 years old. These may have been adequate for the systems that existed at the time they were developed, but are inadequate for present day systems (Wilson et al., 2009).

Despite this, existing principles still provide value in today’s healthcare safety efforts. Olsen and Aase (2010) describe components of preventive industrial risk management systems developed several decades ago, such as correct prioritisation, compliance, and open dialogue (Olsen and Aase, 2010). These elements are closely
related to a strong safety culture (Jones et al., 2008), which can be regarded as a prerequisite for HIT resilience (Shirali et al., 2012).

The participation of sharp-end practitioners in safety management facilitates resilience. Not only tools, but processes to support collaboration between IT system administrators and clinicians are part of resilient practices (Smith et al., 2014). The Finnish Tool for Assessing Technology Induced Errors (FIN-TIERA) for EHR users based on research on recognized error types (see Chapter 2.2.5) and the studies of this thesis was developed. The FIN-TIERA is recommended for use e.g., in the Healthcare Failure Mode and Effect Analysis (HFMEA) process (DeRosier, Stalhandske and Bagian, 2002; VA, 2016). The HFMEA process uses multidisciplinary professionals (Smith et al., 2014) in this context, e.g., technical knowledge of the hardware and software systems and extensive expertise of clinical work processes, to identify and evaluate vulnerabilities. Vulnerabilities are judged by using the risk-matrix (ISO, 2009a; ISO, 2009b) (Papers II-III) but this approach could be easily adjusted when needed. The FIN-TIERA is meant to be used as a prognostic method for stratifying risk in routine clinical practice. At the same time, the FIN-TIERA tool will presumably also support clinicians’ risk awareness by providing an easy-to-use categorization of recognized error types. Awareness of risks has been identified as a critical requirement for HIT resilience (Smith et al., 2014).

An important part of the proposed resilience practice, the FIN-TIERA tool, is still being validated even though it has undergone many test phases. The oversight study findings (Paper IV) promote the development of the FIN-TIERA: a new error type of patient data privacy supported by the literature (e.g., ISO/IEC, 2011; Malin et al., 2011; Elrefaey, Borycki and Kushniruk, 2015; Papoutsi et al., 2015) was detected in the study. The risk of patient privacy violations has been an increasing concern for patients and the public and requires establishing security mechanisms for electronic data exchange (Wright et al., 2010; Boxwala et al., 2011; Papoutsi et al., 2015; Agboola, Bates and Kvedar, 2016). The error type of data privacy violation with its subcategories will be developed and added into the FIN-TIERA tool.

In addition to new tools, interventions to support resilient behaviours are imperative. The possibility of an EHR use error as a cause for incidents was detected (Paper IV). It is known that safe use of EHR requires significant training (Goodman et al., 2011). Participation in eLearning courses on EHR use was associated with lower risk (Paper II). Research indicates that low computer literacy and inadequate EHR training are major factors that limit clinicians’ adoption of EHRs. The consensus of research suggests a need for ongoing training to optimize efficient use of EHRs, but these studies are few (Ventres, 2006; Holden and Karsh, 2011; Sheikh et al, 2011; Dastagir et al., 2012). Moreover, to achieve safe care when using EHRs, the broader educational perspective of informatics should be considered. Informatics, an essential component of organizations’ skills and HITS, should be integrated into educational programmes (Shortliffe 2010; Sanchez-Mendiola et al., 2013). Consequently, EHR training and skills supporting EHR use seem to affect how EHR safe-
ty issues are controlled, enhancing a more resilient way of encountering these errors. Thus, training is one essential solution for meeting safety concerns resulting from failure to use EHRs appropriately, or misuse of EHRs.

This study summarizes selected practical elements of EHR resilience from a user’s perspective needed to step toward more holistic management and anticipation of vulnerabilities created using EHRs. The practical elements of EHR resilience based on this study are, in short: involvement of sharp-end practitioners in safety management by implementing the FIN-TIERA tool in clinical practice, increasing awareness of risks by using the FIN-TIERA tool, and promoting interventions which support clinicians’ resilient behaviours. Moreover, present monitoring systems can be improved based on this thesis to achieve resilience in EHR-enabled health care system. Reflecting on limitations of the safety management process itself is an important part of resilient safety practices (Smith et al., 2014).

6.4 IMPLICATIONS

The implications focus on healthcare organisations, clinicians, and Healthcare Supervisory Authority. They are presented by using Sittig and Singh’s (2012) three-phase model (Chapter 2.1.2).

Implications for safety events that are unique and specific to technology:

EHR downtime: Institutions must implement EHR contingency plans. Downtime is proposed to be regulated in a detailed way to enhance wide-scale preparedness.

Critical care: Implementing and maintaining EHRs in Emergency Departments, Operating Rooms and Intensive Care Units must consider EHR error types presented in this thesis. These units should have detailed, risk-based implementation and follow-up plans.

Implications for addressing unsafe or inappropriate use of technology by clinicians, staff, and patients as well as mitigating unsafe changes in overall workflow that emerge due to technology use:

Proactive safety management to enhance resilience: Implementation of the FIN-TIERA tool for clinicians and multiprofessional teams for identifying areas at high risk.

Use of EHRs: Interventions for resilient behaviors to focus on how end-users utilize EHRs. Part of this is compulsory and structured training for those using EHRs.

Classifications: Implement standard classifications for technology-induced errors to facilitate monitoring and use of voluntary incident and oversight data to promote resilience.
Monitoring processes: Clarify and harmonise the purpose and processes of multiple EHR safety reporting systems and overlapping issues to enable more effective safety control.

Sharing data: Establish a publicly available regulatory database on experiences with medical software errors for creating prevention strategies.

**Implications which proactively address the use of technology to identify and monitor potential safety concerns before harm occurs:**

Implement new tools for clinicians to facilitate risk identification as an integral part of new comprehensive information systems. These systems enable more effective, proactive, and up-to-date monitoring of potential safety concerns.

### 6.5 SUGGESTIONS FOR FUTURE RESEARCH

There are plenty of aspects for future research in the health information technology safety. Following selected aspects based on the study results in this thesis are proposed for further exploration.

The psychometric properties of the FIN-TIERA instrument are suggested to be evaluated at the same institution. Further elaboration of the factor structure is needed. Also previous valid factors should be able to be recreated empirically using item-level structural analyses. New items of the tool recognized in this study, such as privacy violations are to be assessed by involving expert panels. After the retest and following modifications the research in other clinical settings including international context is suggested.

The initial elements of resilience theoretization are suggested to be expanded. These study data concentrated in an EHR user perspective in health care organizations, and other perspectives such as vendors and organizations’ IT department view could be added on the practice.

A future study to test health information technology specific standardized classification which is suitable specifically for voluntary incident reporting purposes is among the study needs.

This thesis showed statistically significant evidence among others on the impact of training on EHR safety. Studies on this topic are proposed to steer the development of clinicians’ EHR training program. Both the type of EHR training, contents and e.g., frequency are research topics. Additionally, more specific research concentrating on type of software applications specific contexts such as intensive care units applying different research methods is among research needs.
7 CONCLUSIONS

In conclusion, EHRs bring many benefits for patient care but at the same time high EHR implementation rate produces novel vulnerabilities in the use of EHRs. This multidimensional patient safety issue needs a more comprehensive system of EHR safety than today. The refinement of the already existing safety monitoring systems and the new elements developed and suggested in this summary will guide clinical EHR safety towards a more resilient practice.

The proportion of EHR-related safety incidents is significantly higher in this study than in previous international studies. A severe perceived risk was related to several error types, among which EHR downtime stresses the need for organizations’ preparedness to guarantee safe care. Structured and targeted training for EHR users will enable better coping with EHR risks in clinical work.

The existing voluntary and authority patient safety monitoring systems to report technology-induced errors need focused development efforts. A pivotal part of the theoretical challenge is the common format to aggregate and analyse technology-induced errors in both systems. This issue is discussed by means of taxonomy testing and further implications based on the testing. Specifically, the FIN-TIERA tool developed and validated in this study for recognizing technology-induced errors more proactively may be used as part of the safety management processes to achieve better resilience in the use of EHRs.
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ARTICLE I
AN ANALYSIS OF ELECTRONIC HEALTH RECORD-RELATED PATIENT SAFETY INCIDENTS
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Abstract
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Keywords
electronic health records, health information technology, hospital incident reporting, patient safety, sociotechnical

Background
Electronic health records (EHRs) are promoted due to their capacity to reduce clinicians' work-loads, costs and errors. Health information technology (HIT) is also expected to improve the co-ordination of care, thereby allowing for improved follow-up. However, new technology may...
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Background
Electronic health records (EHRs) are promoted due to their capacity to reduce clinicians’ workloads, costs and errors.1–4 Health information technology (HIT) is also expected to improve the co-ordination of care, thereby allowing for improved follow-up.5 However, new technology may
also pose novel risks to patient safety by disrupting established, traditional working norms and creating new risks in practices related to HIT design, implementation and use.6–10 Despite this, current evidence concerning HIT safety is relatively limited,11,12 and the few studies on the subject suggest that HIT contributes to less than 1 per cent of total errors in healthcare systems.2,13

The establishment of a voluntary patient safety incident reporting system is a core method for receiving and processing patient safety-related information and creating a more accurate understanding of patient safety risks. The data on patient safety incident reporting presented in this study provide a sample of hazards well-suited for identifying risks.14 Characteristic profiles may be identified when collecting and analysing large numbers of incidents.15 Magrabi et al.16 searched and analysed computer-related patient safety incidents in a state-wide Australian Advanced Incident Management System (AIMS) database. Only 0.2 per cent of all reports in the AIMS database were HIT related. Machine-related problems were more common than human–computer interaction issues. The framework described by Magrabi et al.16 has been used in more recent studies related to incident reporting data in the United Kingdom,17,18 and the results stress the significance of machine-related errors. Controversial evidence about HIT safety shows that HIT-related errors have complex sociotechnical origins.19–22

More information regarding EHR-related patient safety concerns is needed. Different patient safety data sources that complement each other are useful in identifying hazards and providing a more comprehensive view of the risks in a particular system.23,24 Adverse events occurring in one institution are known to recur in other institutions, often with the same causes and contributing factors.25 By identifying the nature of patient safety incidents, initiatives for improvement can be developed and prioritised.26 The lessons learned from incident reporting data can also be used to prevent the same incidents from occurring in other organisations on an international level. Currently, these systems do not include specific interventions to reduce risk, which requires consideration.14,26

Methods

Objective

The first aim of this study was to analyse EHR-related patient safety incidents in a patient safety incident reporting database in a fully paperless, digital hospital environment and, consequently, to contribute evidence about HIT safety. Our second aim was to compare these data to a similar international database in public hospitals and discuss the data content. In particular, we aimed to answer the following research questions:

What is the proportion of EHR-related patient safety incidents in a patient safety incident reporting database in a fully paperless, digital hospital environment? Which are the most common types of computer-related patient safety incidents in a patient safety database in a fully digital hospital environment and have actions been taken to prevent such incidents from recurring? And finally, what are the main differences between the two similar databases?

Setting

According to the Finnish Act on Health Care from 2011,27 all healthcare organisations must maintain a patient safety incident system as a part of their patient safety system. The Finnish patient safety incident reporting model and instrument, HaiPro, was developed mainly during 2006 and is anonymous.28

The incident reports in HaiPro consist of structured and free-text fields and describe the background details of the incident (e.g. incident unit, time of the incident, reporter’s profession, incident, contributing factors, consequences for the patient and the organisation, quantification of harm on a
5-point scale/risk matrix and corrective measures). Events are classified into 13 incident types using HaiPro’s national classification. The most frequently used incident categories are ‘Medication and Transfusions’, ‘Information Flow’ and ‘Information Management’ categories as well as ‘Laboratory’, ‘Imaging’ and ‘Other Patient Treatment Procedures’ categories. All the HaiPro main categories include more detailed subcategories. An incident report can contain multiple event descriptions.

The hospital district of Helsinki and Uusimaa with over 21,000 employees and some 500,000 patients annually is the largest hospital district in Finland and includes tertiary university hospital functions. By 2011, its reporting system had included all clinical units in its 23 hospitals. The hospital district devotes resources to reporting and analysing the events. The hospital district offers on-going classroom training as well as an e-learning programme to train its staff to report and other responsible persons to handle the reports. Every unit has two medical and nursing managers to classify the incident reports according to uniform national guidelines, which include classification rules. Duplicate reports must be deleted from the database. The quality managers, the hospital district’s chief patient safety officer and a group of the hospital’s HaiPro classification development experts ensure the consistency and compliance with the classification principles. The hospital’s patient safety committee monitors the incident data on a regular basis. Managers are obligated to share reports with staff, and the person reporting an event receives feedback on the investigation through the system.

Since 2007, the entire hospital district has been using a fully paperless, comprehensive EHR system. The hospitals in this study used the same EHR system. HaiPro is not an integrated component of the EHR system, but an Internet-based user-friendly interface.

**Data collection**

Our analysis included all safety incidents reported through the HaiPro system between December 2011 and November 2013. The study involved searching the HaiPro incident reporting system and identifying incidents according to the current HaiPro classification of incidents. The following search conditions were ‘reports by the category “Information Flow” or “Information Management”,’ ‘reports by the subcategory “Patient Information Management (Documentation)”’ and ‘reports by the category “Devices and Use of Devices.”’ Free-text searches used the keywords ‘EHR’, ‘HIT’, ‘computer’, ‘documentation’, ‘incorrect information’, ‘referral’, ‘missing test result’, ‘identification’, ‘contact details’, ‘EHR downtime’, ‘hardware devices’, ‘device dysfunction’, ‘screen’, ‘mouse’, ‘output’, ‘print’, ‘printout’, ‘interface’ and the most common EHR proprietary names to avoid misclassification of the intended reports into categories other than those used in this study.

The query of structured data generated a total of 2379 incident reports, while the total number of incident reports in the entire database was 23,023. Of HaiPro’s 13 event types, the analysis included the ‘Information Flow’ and ‘Information Management’ subcategory ‘Patient Information Management (Documentation)’, with its detailed subcategories, as well as the category ‘Devices and Use of Devices’. The free-text search using keywords and analysis of this sample reflected the use of appropriate classifications, and the reports included the subcategory ‘Patient Information’, ‘Device and Use of Devices’ or ‘Unknown’. The frequencies of HaiPro incident reports, according to the HaiPro classification, appear in Figure 1.

**Taxonomy mapping**

Mapping, or the process of linking terms that share the same meaning, is a research method for testing the reliability and validity of standardised taxonomies. We performed taxonomy mapping between the HaiPro classification and the HIT-specific taxonomy developed by Magrabi
et al. because Magrabi’s taxonomy is more widely used and was developed specifically to classify HIT-related incidents. This enables comparisons to international research results.

We first categorised problems into those principally involving human factors or technical problems, and then assigned them to one or more subclasses. Problems involving human factors are related to human interaction with information technology.

We cross-mapped the HaiPro classification subcategory ‘Patient Information Management (Documentation)’ as well as the category for incidents related to a ‘Device or Use of Devices’ with Magrabi’s taxonomy because these categories include HIT-related content. The main categories of the two classifications appear in Figure 2.

To measure intercoder reliability, two researchers performed the taxonomy mapping independently in September 2014 on the basis of available definitions and examples according to HaiPro national guidance and the literature. The researchers placed appropriate HaiPro classifications into the categories created by Magrabi et al. and performed an inter-rater reliability analysis to ensure consistency between the researchers. One of the researchers is a chief patient safety officer and the other is a senior medical officer; both are experienced in informatics.
Health Informatics Journal et al.16 because Magrabi’s taxonomy is more widely used and was developed specifically to classify HIT-related incidents.16,34,35 This enables comparisons to international research results.

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After the first coding, the researchers discussed the rules and coherence of the mapping, which neither yielded nor compared any results. The researchers then recoded and compared the chosen categories before compiling the data. Selecting the same category created a match. Choosing a different alternative or failing to recognise the category at all was considered a non-match. In one situation, one researcher understood the definition of the category differently than the other. In another case, the researcher interpreted the content of the class according to his previous understanding rather than the research context. In these cases, discussion made choosing the certain match obvious, and no complex situations developed.

The researchers used percent agreement and Cohen’s kappa coefficient to perform the inter-coder reliability measurements. Small corrections and a brief discussion yielded 100 per cent (i.e. perfect) agreement (Table 1).37–39

The analysis indicated that most of the HaiPro Documentation classes were related to Magrabi’s ‘Input’ category, and the HaiPro ‘Device or Use of Devices’ category was related to all Magrabi’s main categories. If the mapping procedure for the two classifications showed that one HaiPro class was equivalent to several of Magrabi’s categories, the HaiPro classification recognised all Magrabi’s classes and identified the primary class.16 Responsible persons at the organisations did not classify some of the HaiPro reports (18.5%) or the class was unknown. Cases containing too little descriptive information to classify them in detail fell into the HaiPro main category, with no indication of the exact class (e.g. ‘Missing Referral’ or ‘Wrong/Outdated Information’). Consequently, the tested framework could not classify these incidents exactly.

HaiPro features a separate category ‘Circumstances and Contributing Factors’, which represents an important part of the data on incident reporting. These HaiPro category classes are not interpreted unambiguously as a direct cause of an incident, as is the case in Magrabi’s framework. In HaiPro, ‘Circumstances and Contributing Factors’ may play an important role in the origin of an incident, but the class is still incomparable to Magrabi’s Contributing Factor. Thus, although the
researchers in this study decided not to cross-map contributing factors in order to avoid research validity issues, they did identify similarities.

Results

Machine- and human-related problems

In the Finnish HaiPro system, only 8.45 per cent (n = 211) of the reports involved machine-related problems. The category ‘Devices or Use of Devices’ contained only 12 (0.5%) machine-related reports, whereas the category ‘Patient Information Management (Documentation)’ included 199 reports (8.4%). A total of 73 per cent (n = 1755) of the reports involved problems related to human–computer interaction and were classified originally in the HaiPro system category ‘Patient Information Management (Documentation)’. Only three reports (0.13%) in the category ‘Devices or Use of Devices’ were human-related. These cases were related to Magrabi’s categories ‘Data Input’ and ‘Data Retrieval Error’; the remaining HaiPro cases were either not classified or the category was unknown, so the framework could not serve to classify the incidents.

Both machine- and human-related problems in the HaiPro system led to rework (e.g. additional tests or treatments) in 49.5 per cent of cases.

Risk assessment

Of the 2379 HaiPro reports, 2119 (89.1%) contained a completed risk assessment. A majority (89.2%) of the incidents involved low-risk cases, and only a minority (0.8%) involved high-risk incidents.

Information input problems

The information input problems, clearly the largest category in the HaiPro data, accounted for 59.5 per cent (n = 1415) of the incidents, and incorrect identification or contact details accounted for 5.8 per cent (n = 139) of the computer-related incidents. In total, 2.8 per cent (n = 67) of the incidents were related to a case involving assignment of a referral or test result to the wrong patient, and 7.1 per cent (n = 170) of the cases were missing the referral or contained insufficient or wrong referral information. In 30.7 per cent (n = 731) of the incidents, insufficient, lacking or unclear patient information triggered incident reporting. In 4.6 per cent (n = 109) of incidents, patient information had been documented in the wrong place in EHR. Wrong or outdated patient information accounted for 8.2 per cent (n = 196) of the reports. Three reports (0.13%) in the HaiPro ‘Devices or Use of Devices’ category were related to data input.

Information transfer problems

In the HaiPro, data 8.8 per cent (n = 210) of the reports involved information transfer problems and were classified in the category ‘Information Retrieval or Input in the EHR Hindered’ (n = 199, 8.4%), the category’s only machine-related condition. Six reports (0.25%) involved network errors
in the HaiPro ‘Devices or Use of Devices’ category, and a total of five reports (0.2%) in the HaiPro ‘Devices or Use of Devices’ category were classified as information transfer problems. The HaiPro categories used in this problem were ‘Device Dysfunction’ and ‘Device not Working, Unavailable, being Serviced (in Repair)’.

**Information output problems**

In HaiPro, 14.4 per cent (342) of the reports involved human–computer interaction problems coded in the category ‘Patient Information Not Retrieved or Put Out in the EHR’. Moreover, the previously mentioned HaiPro category ‘Insufficient, Lacking or Unclear Patient Information’ is equivalent to this category and accounted for 30.7 per cent (731) of the incidents, although these incidents are primarily regarded as information input problems.

Machine-related problems partly overlapped with Magrabi’s category ‘Information Transfer Problems’. The HaiPro categories used for this problem were ‘Device Dysfunction’ and ‘Device not Working, Unavailable, being Serviced (in Repair)’, which accounted for the same five reports (0.2%) as did the category ‘Information Transfer Problems’.

**General technical**

In HaiPro, the class ‘Other’ in the ‘Devices or Use of Devices’ category was equivalent to Magrabi’s ‘General Technical’ category, which accounted for four reports (0.17%). In addition, the HaiPro category ‘Unknown’ was mapped as ‘General Technical’, despite having no cases.

The classification of problems in the HaiPro and AIMS databases appears in Table 2.

**Contributing factors**

The HaiPro category ‘Circumstances and Contributing Factors’ fails to indicate the specific reason for an incident even if these factors play a major role in the origin of the incident. The researchers decided not to perform a full cross-mapping procedure with regard to contributing factors in order to avoid problems with research validity. We analysed HaiPro’s contributing factors and recognised similarities. Of all HaiPro incidents, 69.3 per cent identified the contributing factor. One of the most common contributing factors in this dataset is communication in general. Reports show that the available information is used only partially and that both oral and written communication contribute to the event.

Some of the HaiPro subcategories were equivalent to Magrabi’s categories. Magrabi’s ‘Staffing and Training’ category corresponded to the HaiPro category ‘Education and Training’, which includes the categories ‘Knowledge and Skills’, ‘Competence and Qualification’ and ‘Availability and Sufficiency of Education and Guidance’. These categories accounted for 8 per cent of the HaiPro incidents.
The HaiPro category ‘Procedures’ included methods, instructions and the availability or use of written material, whereas ‘Clarity of the Task’ is equivalent to Magrabi’s ‘Staffing and Training’ and ‘Interruption and Multitasking’. The HaiPro category ‘Circumstances, Tools and Resources’, which includes the category ‘Problems in the EHR or Other HIT Systems and Problems Using Them’, was considered to be linked to all Magrabi’s categories. Of the HaiPro incident reports, 8.7 per cent identified this as the contributing factor.

Learning from incidents

HaiPro contains information on ways to prevent incidents recurring. A team comprising a responsible physician and a head nurse in the unit suggest the measures; 8 per cent of the cases led to no actions. The most common (82.6%) way to prevent incidents recurring was to inform the staff of the incident and share the data with other parties; 4.9 per cent of the incidents were transferred to the leaders of the hospital due to the seriousness and recurrence of the case or because support of the need for support to manage the incident. A concrete development intervention took place in 4.3 per cent of the incidents. The action taken was related to EHR downtime, which caused serious problems in a surgery department. The administrators decided to develop structured communication procedures with the information and technology (IT) department and to provide paper copies of patients’ records available depending on the likelihood of EHR downtime. The types of development interventions appear in Table 3.

Table 3. Development interventions in the HaiPro system.

<table>
<thead>
<tr>
<th>Development intervention type</th>
<th>Frequency n = 124 (%) in HaiPro database</th>
</tr>
</thead>
<tbody>
<tr>
<td>Processes, procedures and methods</td>
<td>50 (40.3)</td>
</tr>
<tr>
<td>Health information systems and devices</td>
<td>27 (21.8)</td>
</tr>
<tr>
<td>Information flow and communication procedures</td>
<td>32 (25.8)</td>
</tr>
<tr>
<td>Training</td>
<td>8 (6.5)</td>
</tr>
<tr>
<td>Leadership</td>
<td>4 (3.2)</td>
</tr>
<tr>
<td>Other development work</td>
<td>3 (2.4)</td>
</tr>
</tbody>
</table>

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Discussion

The data with respect to the literature

Our study shows that computer-related safety incidents are far more common than previous studies suggest.2,13,16 Our data are primarily discussed with regard to Magrabi et al.’s16 study findings, which are based on similar data. In Magrabi’s study, a search of 42,616 patient safety incidents during a 2-year period yielded only 123 computer-related incidents. The Australian data describe 99 computer-related patient safety incidents, which had been analysed by examining free-text descriptions.16 Our research data contain over 20,000 reports classified by a trained physician and head nurse. Our finding is based on a large, structured dataset of quality reports.

The following facts may account for the number of computer-related incidents in the Finnish data compared to Magrabi et al.’s16 data. First, the coverage of EHR in Finland is 100 per cent, and Finnish hospitals are fully digital. Previous research shows that new technology increases the number of technology-related errors.6–10,40 Second, hospital districts in Finland devote institutional resources to incident reporting procedures, obtain feedback and share reports. Consequently, the staff are also encouraged to report HIT incidents, because managers consider them as important as
clinical bedside events. Our results show that HIT-related problems pose a noteworthy safety risk in fully digital hospitals.

The risk profiles of the two databases clearly differed. In the AIMS data,16 69 per cent of the cases received a medium-risk score, whereas in HaiPro the corresponding figure was only 10 per cent. This disparity may partly stem from the wide coverage of HaiPro incident reporting, which especially stresses the importance of reporting both minor incidents and near misses. The Finnish Act on Health Care and the National Patient Safety Program27,28 have emphasised the importance of anticipating potential problems.41

A key finding of our study is that human–computer interaction problems were reported far more often in our study than in Magrabi’s studies,16,18 whereas machine-related problems were reported more rarely. A total of only 8.5 per cent of the incidents were machine-related problems, and 73 per cent were problems of human–computer interaction. Of all Australian AIMS reports, 55 per cent (n = 64) included machine-related problems, and 45 per cent (n = 53) problems of human–computer interaction.16 In Magrabi’s more recent study,18 the majority of IT events consisted of notifications about hazardous circumstances related to technical problems.

In the AIMS database, ‘Information Input Problems’ was the largest category, accounting for 31 per cent (n = 36) of the incidents. Most incidents, such as incorrect entry of patient name, diagnosis, discharge hospital or typographical errors, were associated with ‘Incorrect Human Data Entry’ (17%, n = 20). This category was also the largest in the Finnish data, accounting for 60 per cent of incidents. ‘Problems in the Transfer of Information’ accounted for 20 per cent of all AIMS incidents and for 9 per cent of Finnish incidents. ‘Information Output Problems’ did not differ markedly between databases.

Our results support a growing body of research which shows that adverse events result from the complex interaction between Health Information System (HIS) and clinicians.22,42–44 The Finnish data clearly show that the interaction of technology with non-technological factors requires more in-depth research from different perspectives. Users’ interactions with EHR are linked to complex processes which should be better understood. According to a recent study, problems involving human factors were four times more likely to result in harm to patients than technical problems, further stressing the importance of sociotechnical aspects.18 Moreover, research confirms the importance of a sociotechnical perspective in system design.45

Incident reporting systems provide a mechanism for identifying safety risks. Although the data suggest that interventions can reduce risks, these systems have not led to expected improvements and interventions to reduce risk.14,46 This raises a question about the appropriate implementation and use of such systems. Measuring the successful use of an incident system is challenging, but can be accomplished by counting the number of system changes made as a result of the system.14 In the Finnish data, only 8 per cent of the IT-related incidents were left without measures, which can be considered reasonable progress in the optimal use of an incident reporting system, if still below the target level. The aspect of learning from previous incidents must inevitably be the future focus of incident reporting systems and research. Furthermore, studies show that technology-based solutions alone will only partially mitigate concerns. Interventions for EHR-related safety improvement must concentrate on how end-users actually use EHR.19

The use of standard classifications, including clear category descriptions, makes data more valid and data use across countries possible. At the moment, single organisations are the main users of this valuable data source. Mapping the on-site reporting taxonomy with international standards is feasible.47,48 and Magrabi et al.51,16 taxonomy constitutes a basis for patient safety incident reporting recommended for use as a starting point for international incident reporting classifications of machine-related incidents. Research shows that pre-defined reporting categories are well-suited to voluntary reporting needs and could also provide solutions for international quality reports.47
Limitations

In this Finnish dataset, structured responsibilities, manifold surveillance of the quality of data and an on-going training programme all ensure the appropriate use of classifications. However, without content analysis of the incident reports, one cannot be 100 per cent sure of the correct use of classifications. The risk of invalid data, however, is presumably relatively low.

Voluntary incident reporting is an important tool for recognising patient safety issues in healthcare settings. However, these systems have their limitations;\textsuperscript{49,50} reports do not provide exact frequencies of incidents. Consequently, our data provide not exact error rates but rather a descriptive analysis of typical EHR-related safety problem types in fully digital, paperless hospitals. Large collections of incidents may serve to identify characteristic profiles, thereby enabling the aggregation and analysis of incidents.\textsuperscript{15}

The cross-mapping procedure clearly showed that the strength of Magrabi’s classification is its ability to identify technical problems. The human–computer perspective in the classification is weaker than it could be, given the complexity of a healthcare organisation. The sociotechnical perspective could be combined into this classification, because it contains multiple dimensions of HIT use.\textsuperscript{9,20,44,51}

Conclusion

The Finnish safety data analysed in this study show that human–computer interaction associated with most HIT-related incidents. Detecting these safety concerns is challenging because they result from complex interactions among heterogeneous triggering factors. Consequently, healthcare information systems require an infrastructure for proactive risk assessment, specifically for EHR-related patient safety concerns. Developing techniques to support user awareness of EHR-related risks and their monitoring and management is therefore necessary.

Declaration of conflicting interests

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ARTICLE II
ELECTRONIC HEALTH RECORD RELATED SAFETY CONCERNS: A CROSS-SECTIONAL SURVEY OF ELECTRONIC HEALTH RECORD USERS
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Electronic Health Record-Related Safety Concerns: A Cross-Sectional Survey of Electronic Health Record Users

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Abstract

Background: The rapid expansion in the use of electronic health records (EHR) has increased the number of medical errors originating in health information systems (HIS). The sociotechnical approach helps in understanding risks in the development, implementation, and use of EHR and health information technology (HIT) while accounting for complex interactions of technology within the health care system.

Objective: This study addresses two important questions: (1) “which of the common EHR error types are associated with perceived high- and extreme-risk severity ratings among EHR users?”, and (2) “which variables are associated with high- and extreme-risk severity ratings?”

Methods: This study was a quantitative, non-experimental, descriptive study of EHR users. We conducted a cross-sectional web-based questionnaire study at the largest hospital district in Finland. Statistical tests included the reliability of the summative scales tested with Cronbach's alpha. Logistic regression served to assess the association of the independent variables to each of the eight risk factors examined.

Results: A total of 2864 eligible respondents provided the final data. Almost half of the respondents reported a high level of risk related to the error type “extended EHR unavailability”. The lowest overall risk level was associated with “selecting incorrectly from a list of items”. In multivariate analyses, profession and clinical unit proved to be the strongest predictors for high perceived risk. Physicians perceived risk levels to be the highest (P < .001 in six of eight error types), while emergency departments, operating rooms, and procedure units were associated with higher perceived risk levels (P < .001 in four of eight error types). Previous participation in eLearning courses on EHR-use was associated with lower risk for some of the risk factors.

Conclusions: Based on a large number of Finnish EHR users in hospitals, this study indicates that HIT safety hazards should be taken very seriously, particularly in operating rooms, procedure units, emergency departments, and intensive care units/critical care units. Health care organizations should use proactive and systematic assessments of EHR risks before harmful events occur. An EHR training program should be compulsory for all EHR users in order to address EHR safety concerns resulting from the failure to use HIT appropriately.

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KEYWORDS
Electronic Health Records; Health Information Technology; Patient Safety; Risk Assessment; Questionnaire
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Abstract

Background: The rapid expansion in the use of electronic health records (EHR) has increased the number of medical errors originating in health information systems (HIS). The sociotechnical approach helps in understanding risks in the development, implementation, and use of EHR and health information technology (HIT) while accounting for complex interactions of technology within the health care system.

Objective: This study addresses two important questions: (1) “which of the common EHR error types are associated with perceived high- and extreme-risk severity ratings among EHR users?”, and (2) “which variables are associated with high- and extreme-risk severity ratings?”

Methods: This study was a quantitative, non-experimental, descriptive study of EHR users. We conducted a cross-sectional web-based questionnaire study at the largest hospital district in Finland. Statistical tests included the reliability of the summative scales tested with Cronbach’s alpha. Logistic regression served to assess the association of the independent variables to each of the eight risk factors examined.

Results: A total of 2864 eligible respondents provided the final data. Almost half of the respondents reported a high level of risk related to the error type “extended EHR unavailability”. The lowest overall risk level was associated with “selecting incorrectly from a list of items”. In multivariate analyses, profession and clinical unit proved to be the strongest predictors for high perceived risk. Physicians perceived risk levels to be the highest ($P<.001$ in six of eight error types), while emergency departments, operating rooms, and procedure units were associated with higher perceived risk levels ($P<.001$ in four of eight error types). Previous participation in eLearning courses on EHR-use was associated with lower risk for some of the risk factors.

Conclusions: Based on a large number of Finnish EHR users in hospitals, this study indicates that HIT safety hazards should be taken very seriously, particularly in operating rooms, procedure units, emergency departments, and intensive care units/critical care units. Health care organizations should use proactive and systematic assessments of EHR risks before harmful events occur. An EHR training program should be compulsory for all EHR users in order to address EHR safety concerns resulting from the failure to use HIT appropriately.

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KEYWORDS

Electronic Health Records; Health Information Technology; Patient Safety; Risk Assessment; Questionnaire
Introduction

Previous success in the adoption and use of health information technology (HIT) has been darkened by the growing number of reports of its unintended consequences and potential for errors [1]. Risks associated with electronic health records (EHR) have been identified as related to technologies themselves, their applications, and their use [2]. The systematic analysis of EHR-related safety concerns is clearly a prerequisite for recognizing safety threats [3-4]. The sociotechnical approach facilitates understanding of the risks in the development, implementation, and use of EHR and HIT while accounting for complex interactions of technology within the health care system [5-12].

Sittig and Singh have provided extensive work and a foundation for understanding EHR safety. These researchers define the HIT work system as the combination of the hardware and software required to implement HIT, as well as the social environment in which it is implemented [6-8]. According to Sittig and Singh’s research, HIT errors may involve failures of either structures or processes. These errors can occur in the design and development, implementation and use, or evaluation and optimization phases of the HIT lifecycle [9]. HIT-related errors occur anytime the HIT system is unavailable for use, malfunctions during use, is used incorrectly, or interacts with another system component which incorrectly results in data loss or incorrect entry, display, or transmission. The dimensions are not independent, sequential, or hierarchical, but rather interdependent and interrelated concepts similar to the compositions of other complex adaptive systems [6-8]. This approach is consistent with the currently recommended approaches to systems and human factors used to identify and minimize error [9]. HIT errors should be defined from the socio-technical viewpoint of end users [6-8].

Risk assessment is the process through which organizations develop an understanding of the risks they face [13]. This process is supported by various tools and techniques. Risk analysis consists of determining the consequences and their probabilities for identified risk events. The consequences and their probabilities are then combined to determine a level of risk [14]. Use of a risk assessment matrix is a growing practice. The simplicity and ease of use of this approach contributes to widespread adoption, including a generic international standard for risk assessment techniques to support risk management [13]. Organizations can reduce the number and severity of EHR-related safety events by anticipating the risk factors [15].

The results of a recent study suggest that EHR safety depends on persistent testing and monitoring, especially in terms of the ongoing appraisal of sociotechnical factors that affect the use and maintenance of EHRs. Because the new EHR adopters lack relevant skills and resources, it is more critical to develop techniques to support awareness of the risks, as well as their monitoring and management [16]. One method to support awareness of risks is to identify risk indicators that are easily detectable. Sittig and Singh present a red-flag-based approach that can serve to identify potential EHR safety concerns. Common EHR-related safety concerns have been identified based on Sittig and Singh’s work in EHR-related patient safety, and a survey focusing on the frequency of serious EHR-related safety events, variables affecting serious EHR-related safety events, and the tracking of EHR-related safety measurements [15,16].

The research data in this study has been refined to explore users’ perceptions of high- and extreme-risk severity ratings in the use of EHR. We were interested in assessing EHR users’ perceptions of EHR safety issues because no previous study has explored this problem area in a specialized hospital context. Consequently, we used a mixed-methods approach in several phases to develop and validate a questionnaire based on Sittig and Singh’s research and findings [15,16]. The final Finnish questionnaire consisted of eight error types, each with three to six related questions. Future research will focus on developing a tool to mitigate EHR-related safety concerns.

Methods

Research Questions

Our goal was to study health care professionals’ perceptions of common EHR concerns. The specific objective was to concentrate on severe-risk error types and risk factors.

This study aimed to answer the following questions:

1. Which of the common EHR error types are associated with perceived high- and extreme-risk severity ratings among EHR users?
2. Which variables are associated with high- and extreme-risk severity ratings?

Recruitment

This study was a quantitative, non-experimental descriptive study of Finnish EHR users. A cross-sectional web-based questionnaire study took place over a four-week time period in the beginning of 2015. The study was conducted in the Hospital District of Helsinki and Uusimaa, and included 23 hospitals (covering a population of 1.6 million Finns; 34% of the Finnish population) that treat half a million patients annually. The hospital district runs the largest academic teaching hospital (Helsinki University Hospital) in Finland, which covers all medical specialties and emergency services in its different facilities. Furthermore, the district runs four regional hospitals that support local primary care outside the Helsinki metropolitan area. The entire hospital district has approximately 22,300 employees [17].

All nurses, nursing aids, physicians, clinical secretaries, and academic hospital workers (eg psychologists, pharmacists and clinical nutritionists) working, and potentially using the EHR, throughout the hospital district comprised the target population. The qualifications of health care professionals in Finland, as in other member states of the European Union (EU), are in accordance with the EU directive on professional qualifications (2005/36/EC) [18]. This directive applies to doctors, specialist doctors, nurses, specialist nurses, and midwives. There are no set entry requirements for clinical secretaries, but they do require proficient information technology (IT) skills to use and process EHRs.
These hospitals have used the same EHRs for several years. The hospital district has a computerized physician order entry with clinical decision support and major ancillary systems (ie, laboratory), a picture archiving and communication system, as well as a clinical data repository for reviewing results. The closed loop medication system is not part of the EHRs. These hospitals have the same risk-assessment approach and systematic education for all clinicians as part of their patient safety programs.

The questionnaire took place in early 2015. At the same time, a new version of the EHR program was implemented in order to incorporate the system into the Finnish national health care archive, known as KanTa. Although the overall availability of EHR in 2014 was as high as 99.9%, the system’s total unplanned widespread unavailability for 12.4 hours during 2014 threatened the continuity of operations in these hospitals.

A commercial online platform (Webpropol) served to conduct the survey. We sent the questionnaire, with detailed information for answering, as well as an explanation of the risk matrix, to all potential EHR users (N=17,336) at the same time. Identifying exactly which individuals use EHR was impossible, so questionnaires were sent to all professionals in these groups. We also advised the participants to rate all error types and risk factors on the questionnaire in their own working environment during the last 12 months. We sent two reminder e-mails to all individuals who had not completed the questionnaire.

The organization’s research review process approved the study protocol. Since patients were not the subject of this study, Finnish national legislation (488/199) did not require the approval of the Institutional Review Process for the study [19]. All respondents will remain anonymous, and the study involved no financial incentives.

**Questionnaire Items and Assessment Scale**

The questionnaire consisted of eight error types based on Sittig and Singh’s previous research [7,15,16]. Each of the error types included three to six EHR-related safety issues or risk factors based on commonly identified EHR safety concerns.

The error type *incorrect patient identification* includes questions related to key patient-identifying information. These errors include information missing from the EHR screens or printouts, the absence of documented processes and procedures for verifying patient identification at crucial stages of patient visits, and incorrect site information or incorrect patient surgery/procedure information originated from an order that was entered for the wrong patient. One commonly recognized safety issue, in which nurses use copies of one or more patient barcode identification bands taped to their clipboard as a workaround when performing barcoded medication administration, was omitted during questionnaire development because this practice does not exist in these hospitals’ EHRs.

The error type *extended EHR unavailability* means that some portion or, more likely, all of the patient’s medical records are unavailable for review. This error results from total or partial failure of the EHR system, or planned downtime.

**Statistical Analyses**

We sent the questionnaire to every potential EHR user, encompassing all staff members in the hospital district’s 23...
Respondents’ Characteristics and Perceived Risk Level

The final dataset consisted of 2864 eligible respondents, 85.16% (2439/2864) of whom were women and 77.72% (2226/2864) of whom were aged 34 years or older. The participants were primarily nursing professionals (71.37%, 2044/2864) and held a university of applied sciences or equivalent degree (56.81%, 1627/2864); 15.12% (433/2864) were physicians. As expected, the largest proportion of participants (57.19%, 1638/2864) worked in a ward or outpatient clinic.

Of the respondents, 92.18% (2640/2864) used EHRs several times per shift. An additional 3.00% (86/2864) of the respondents said they consulted the EHR system once or twice per shift, while 1.01% (29/2864) of the respondents did not use the EHR themselves, but acted as the superior of other EHR users and consequently were aware of EHR risk factors.

A total of 30.73% (880/2864) of the respondents had participated in EHR eTraining; 28.04% (803/2864) attended a general lecture about EHR, and 21.30% (610/2864) received classroom training; 10.61% (304/2864) received personal guidance or training from an IT support person.

The distribution of background variables and the percentage of respondents reporting a high- or extreme-risk rating per error type (defined as reporting a high or extreme risk level on at least one subscale item) appears in Multimedia Appendix 2.

The highest proportion, nearly half of the respondents in both gender groups (48.99%, 1403/2864), reported a high-risk level related to extended EHR unavailability. A high perceived risk was reportedly related to incorrect patient identification, system-to-system interface errors, failure to find or use the most recent data, EHR time measurement errors, and open/incomplete orders. The lowest overall risk level was associated with selecting an incorrect item from a list of items (27.02% [659/2439] of females and 32.94% [140/425] of males). Men reported higher levels of perceived risk scores than did women. Older respondents tended to report higher risk levels, but the association was inconsistent across all error types.

Physicians reported higher risk levels on all of the eight factors, especially those relating to extended EHR unavailability and failures to find the most recent patient data. Registered nursing professionals reported the second highest overall risk scoring, and the highest values were related to extended EHR unavailability and open/incomplete or missing orders. Clinical clerks and academic specialists reported lower risk levels than did other professionals. Clinical clerks’ highest perceived scoring was related to extended EHR unavailability, whereas academic specialists’ highest values were related to failure to find or use the most recent patient data and system-to-system interface errors.

Emergency departments (ED), operating rooms (OR), and procedure units were associated with higher perceived risk levels, whereas clinical laboratory and radiology units were related to lower risk scoring. Professionals working on general wards reported high-risk scoring on extended EHR...
Having received no EHR training was associated with higher perceived risk levels, and classroom and eLearning correlated with lower risk levels. However, we found no differences in the error type relating to system-to-system interface errors. Poor self-reported EHR skills were related to high perceived risk.

Factors Associated with Perceived Risk Ratings in Multivariate Logistic Regression Analyses

The initial univariate analyses (results not shown) found profession and clinical unit to be the strongest predictors for perceived high- and extreme-risk ratings. Physicians reported a higher perceived risk on all risk dimensions (odds ratios between 1.21 and 2.55). The associations remained statistically significant in the multivariate analyses, even after adjusting for education, work experience, type of EHR training received, and self-reported EHR skills for all of the risk factors, except the one related to incorrect patient identification (odds ratios between 1.30 and 2.51). Academic specialists reported lower levels of perceived risk, and the association remained significant in multivariate models of four of the eight risk levels measured.

Healthcare professionals working in EDs, ORs, and procedure units reported higher perceived risk ratings on all error types. The association remained robust for most dependent variables, even after adjusting for profession and other background variables. Professionals working at an intensive care unit (ICU)/critical care unit (CCU) reported higher perceived risk ratings on extended EHR unavailability, system-to-system interface errors and open, incomplete or missing orders, but in the multivariate models the association remained significant only for interface errors. Lower perceived risk levels were associated with working in a clinical laboratory or in radiology, providing less acute patient care, and working in outpatient units, although to a somewhat lesser degree.

Prior participation in eLearning courses on EHR-use was associated with lower risk ratings on some of the risk factors (extended EHR unavailability, \( P=.03 \); EHR warning dismissed, \( P=.015 \); failure to find or use the most recent patient data, \( P=.018 \)). General lecture training was associated with greater risk, although the association did not remain significant in most of the multivariate models. As expected, poor self-reported EHR-use skills were associated with higher risk ratings, and the effect remained significant even after controlling for other factors. However, controlling for the level of EHR-use skills in multivariate models failed to explain the association of the other factors with the risk dimensions. The association of background variables with perceived EHR risk rating appears in Multimedia Appendix 3.

We also tested the interaction between professional qualification and working unit. The interaction terms did not remain significant in the multivariate analyses, in large part due to small sample sizes in some of the subgroups. To analyze the joint association between profession and clinical unit, we combined academic specialists and clinical clerks into one group and assigned labor wards to the other units group (see Figure 1 and Multimedia Appendix 4 for margins of error and 95% CIs).

In EDs and ORs we detected a general tendency towards relatively high-risk factors in all professional groups, except for system interface errors and failures to find most recent patient information, for which physicians reported higher risk levels than did nurses. Physicians generally tended to report higher risk for outpatient wards and general wards. Figures 1-4 show the proportion of high-risk assessments according to respondents’ professions and clinical units.

Figure 1. Proportion of high risk according to respondents’ professions and clinical unit (+95% CIs) in incorrect patient identification.
Figure 2. Proportion of high risk according to respondents’ professions and clinical unit (+95% CIs) in extended EHR unavailability.

Figure 3. Proportion of high risk according to respondents’ professions and clinical unit (+95% CIs) in system-to-system interface errors.

Figure 4. Proportion of high risk according to respondents’ professions and clinical unit (+95% CIs) in failure to find or use the most recent patient data.

Discussion

Principal Results and Comparison with Prior Work

Research interest in EHR safety has been growing recently [25,26], but data specifically relating to EHR risk levels and severe-risk problem areas remain scarce, and to date no studies have explored this kind of specialized hospital context. One previous survey of risk managers and health care system lawyers provided valuable data about EHR-related serious events, but lacked EHR users’ perceptions. This previous survey also notes that additional data are needed to identify the extent of EHR-related safety concerns. To date, serious EHR-related events appear to be underreported and understudied [27].
Our study findings are based on a large number of EHR users in hospitals with a 100% degree of EHR implementation; approximately 92% of respondents used the EHR system several times per shift. Consequently, respondents were well aware of existing EHR safety concerns in their working environment. Despite the lack of similar studies, our results can be compared with previous study results.

Almost half of the respondents reported a severe perceived risk level related to **extended EHR unavailability**, which was perceived to be an especially high-risk area in EDs and CCUs. Although previous studies have not found this result, it can be explained by the fact that the literature has recognized **error type** as a high priority practice in all areas of EHR safety and, as such, a critical safety issue. Loss of continuous access to patient information risks leading to patient injuries [28]. Our finding of severe perceived risk can also be explained by hospitals with 100% EHR adoption rates, where paper records are no longer in use and comprehensive contingency plans have seen only partial implementation. Our results stress the importance of contingency planning, which includes processes and preparations that should be available when an incident occurs. The organizations’ activities, structured processes, and tasks are core requirements to continue operating and to minimize patient risk [29-32]. This area is important, especially because unexpected downtimes related to EHRs are fairly common in US-based health care organizations [33], and also occurred in this study. Moreover, this EHR concern merits greater interest, as the adoption of EHR systems has grown in recent years and continues to grow steadily [34]. A recent study in the United States shows that concerns about future EHR-use are related to the prolonged downtime of EHR systems, even if such incidents have seldom occurred in the past five years [27]. The potential consequences of an EHR downtime failure have become a cause for increasing concern as hospitals and health care organizations adopt large-scale EHR systems to handle many operations within the broader health care system. This also means that downtime can quickly affect not just a single ward or department, but an entire community [2,34,35]. We seek to emphasize how potential risks related to EHR downtimes are known to occur long after implementation [2]. Our study reinforces this previous result.

Previous studies have also shown that most (94%) safety concerns are related to either unmet data-display needs in the EHR, software upgrades or modifications, data transmission between components of the EHR, or hidden dependencies within the EHR [28]. In our study, approximately 40% of severe perceived risk was related to **system-to-system interface errors**, failure to find or use the most recent data, **EHR time measurement errors**, and **open or incomplete orders**. Unlike previously published studies, the lowest overall risk level in this study was associated with **selecting an incorrect item from a list of items**. **Selecting an incorrect item from a list of items** is partly a user interface issue, and previous studies have shown that usability is a key attribute of EHR system quality among users [32,36]. Studies have also reported that clinicians’ safety concerns often stem from EHR design and usability which fail to meet user requirements [37]. Our result for this specific error type may result from regulations [38] related to the safety and performance of medical devices in the EU. Products that fall within this scope (eg medical software) must meet all applicable essential safety requirements and must bear an EC conformity mark to indicate that they comply with all relevant EU directives. Manufacturers may only put medical devices into service that do not compromise the safety and health of patients, users and others. Therefore, the most obvious issues in the program (eg overly narrow columns in the drop-down menus) have been corrected.

In this study, profession proved to be a strong predictor for severe perceived risk, alongside clinical unit. Physicians reported a higher perceived risk with all EHR problem areas and factors. Large questionnaire studies in Finland have explored physicians’ views about EHR development and confirmed that physicians were critical of their IT systems [39]. High satisfaction among physicians associated strongly with perceived benefits [40]. In Finland, the previous survey results [39] showed that the EHR tools that physicians used daily can lead to a waste of operational resources and hinder physicians’ work. This result may also partly explain the physicians’ perceptions in this study, but this question requires further research. In EDs, ORs, and to a somewhat lesser degree ICUs, the risk factors tended to be relatively high for all professional groups, except for **system interface errors** and **failures to locate the most recent patient information**, for which physicians reported higher risk levels than did nurses. A recent study indicates that the use of EHR technology strongly impacts ICU physician work (eg more time spent on clinical review and documentation) and workflow (eg clinical review and documentation becoming the focal point of many other tasks) [41]. Studies in the literature have examined the unintended consequences of information systems in EDs. The unique and particularly challenging characteristics of EDs, including rapid turnover, frequent transitions in care, constant interruptions, variation in patient volumes, and unfamiliar patients, make the ED environment particularly prone to errors. Thus, those implementing and maintaining HIT in such environments must give these factors careful consideration [42].

Participation in eLearning courses on EHR-use was associated with lower risk for some of the risk factors. Conversely, self-reported poor EHR-use skills were associated with higher risk scoring. This result can be viewed in the light of previous research. One of the major factors limiting clinicians’ adoption of an EHR system is low computer literacy and inadequate EHR training. A general consensus suggests a need for on-going support and additional systems training to optimize the efficient use of EHRs, but studies in this area are few. One study often identified learning as a necessary and inevitable condition for the efficient use of EHR [43,44]. Training supports EHR adoption and use, and according Ventres, high-quality training improves physicians’ proficiency in using an EHR system [45]. Consistent with these results, inadequate and poor-quality training was associated with poor utilization of EHR and participants failed to benefit from the full potential of the EHR system [46]. Additionally, one should take into account the broader educational perspective of informatics when striving to achieve safe care; informatics is an essential component of health care organizations’ skills and HIT safety, and should be
integrated into educational programs [47,48]. Consequently, EHR training and skills supporting more efficient use seem to affect how EHR safety issues are controlled. Thus, EHR training is one core solution for meeting EHR safety concerns resulting from the failure to use HIT appropriately, or the misuse of HIT.

Finally, because comprehensive data on IT-related safety events are lacking, alternative approaches are needed to assess and respond appropriately to the HIT-related safety risks. The health information technology safety (HITS) framework described in a recent paper suggests that organizations will change their existing patient safety structures and processes to incorporate the unique set of skills needed for comprehensive HITS measurement. Organizations are encouraged to use clinicians trained in clinical informatics, and utilize a multidisciplinary oversight committee to help identify and prioritize risks [49]. The questionnaire developed for this study is one potential tool for this kind of approach.

Limitations

Readers should take into account certain limitations of our study. Like all questionnaire studies, ours was subject to potential problems associated with response bias [50,51]. Some employees who responded to our survey may have had a greater interest in problems with EHRs than did non-responders. Thus, although our data may overestimate the actual risk level of electronic health records, it still provides valuable new information, especially about the variables associated with the most critical problem areas.

Possible validity and reliability weaknesses of the questionnaire are the most significant issues to be taken into account in this type of research. Considerable resources served to ensure a process of translation and adaptation in this study. The multi-phased questionnaire development process aimed to ensure semantic equivalence of the translated terms, thereby rendering good final face validity.

Some limitations in the study design limit one’s capacity to generalize the findings to a wider context. The response rate was relatively low, as is typical of many questionnaire studies [51,52]. Time constraints are reportedly a major barrier to studying health care professionals’ perceptions in this hospital setting. Consideration of the length of the questionnaire is thus relevant. Our questionnaire is designed to address the most important EHR problem areas at this time, and shortening it would have proved difficult. In the future, however, these problem areas may be revised as needed.

The use of qualitative assessment scales is subjective, and raters tend to vary. The fact that the personnel at responding hospitals systematically received training in the use of the risk matrix as part of the patient safety program significantly increased the reliability of this study.

Conclusions

In conclusion, HIT safety hazards should be taken very seriously. Health care organizations should systematically assess EHR risks before harmful events occur. On the basis of this questionnaire study of 2864 respondents, our study indicates that the error type extended EHR unavailability is perceived as the most serious safety concern. The perceived risk ratings were relatively high for all professional groups in EDs and ORs. Consequently, implementing and maintaining EHRs in these areas will require consideration and follow-up.

Previous participation in eLearning courses on EHR-use was associated with lower risk for some of the risk factors. EHR training programs and preferably well-designed eTraining courses should be compulsory for all EHR users. EHR training is an important solution in meeting EHR safety concerns resulting from the failure to use HIT appropriately.

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Conflicts of Interest

None declared. This work benefited from the support of Finnish governmental research funding (study grant TYH2014224).

Multimedia Appendix 1

Sum variable means and reliability estimates (N=2678).

[PDF File (Adobe PDF File), 31KB - medinform_v4i2e13_app1.pdf]

Multimedia Appendix 2

Distribution of background variables and proportion of respondents reporting a high- or extreme-risk severity rating, including margins of error and 95 % CIs for the proportions (N=2864).

[PDF File (Adobe PDF File), 383KB - medinform_v4i2e13_app2.pdf]
The questionnaire developed for this study is one potential tool to assess information technology safety (HITS) framework described in the context of health IT (HIT) safety. However, there are limitations in existing patient safety structures and processes to incorporate the error type resulting from the failure to use HIT appropriately, or the misuse of HIT. Time constraints are reportedly a major barrier to EHR risks before harmful events occur. On the basis of this multi-phased questionnaire development process aimed to ensure semantic equivalence of the translated terms, thereby rendering reliability of this study. Consequently, implementing and maintaining EHRs in these contexts become critical issues of this study.


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Possible validity and reliability weaknesses of the questionnaire may have had a greater impact on the results. For instance, employees who responded to our survey may have had a greater awareness of the EHR-related safety risks before harmful events occur. It is likely that the personnel at responding hospitals would have a greater awareness of the EHR-related safety risks before harmful events occur. Consequently, implementing and maintaining EHRs in these contexts become critical issues of this study.


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32. HealthIT.gov: The Office of the National Coordinator of Health Information Technology Safety assurance factors for EHR resilience (SAFER) guides URL: https://www.healthit.gov/safer/ [accessed 2015-10-11] [WebCite Cache ID 6cVh1sFu]


Abbreviations

CCU: critical care unit
ED: emergency department
EHR: electronic health record
EU: European Union
HFMEA: health care failure mode and effects analysis
HIS: health information system
HIT: health information technology
HITS: health information technology safety
HR: human resources
ICU: intensive care unit
IT: information technology
OR: operating room

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Appendix 1: Table A1. Sum variable means and reliability estimates (N=2,678)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean of sum variable</th>
<th>SE(^b) of sum variable</th>
<th>Cronbach's alpha</th>
<th>[95% CI(^c)]</th>
<th>Complete cases(^d)</th>
<th>% Complete cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect patient identification</td>
<td>2.38</td>
<td>1.05</td>
<td>.858</td>
<td>[0.847 - 0.868]</td>
<td>1225</td>
<td>42.7</td>
</tr>
<tr>
<td>Extended EHR unavailability</td>
<td>2.82</td>
<td>1.04</td>
<td>.864</td>
<td>[0.856 - 0.873]</td>
<td>996</td>
<td>34.7</td>
</tr>
<tr>
<td>Failure to heed a computer-generated warning or alert</td>
<td>2.28</td>
<td>0.92</td>
<td>.866</td>
<td>[0.856 - 0.875]</td>
<td>983</td>
<td>34.3</td>
</tr>
<tr>
<td>System-to-system interface errors</td>
<td>2.59</td>
<td>1.08</td>
<td>.880</td>
<td>[0.872 - 0.888]</td>
<td>983</td>
<td>34.3</td>
</tr>
<tr>
<td>Failure to find or use the most recent patient data</td>
<td>2.58</td>
<td>0.95</td>
<td>.868</td>
<td>[0.859 - 0.877]</td>
<td>1546</td>
<td>53.9</td>
</tr>
<tr>
<td>EHR time measurement translational challenges</td>
<td>2.58</td>
<td>1.03</td>
<td>.870</td>
<td>[0.860 - 0.879]</td>
<td>877</td>
<td>30.6</td>
</tr>
<tr>
<td>Incorrect item selected from a list of items</td>
<td>2.36</td>
<td>0.99</td>
<td>.888</td>
<td>[0.879 - 0.896]</td>
<td>1218</td>
<td>42.5</td>
</tr>
<tr>
<td>Open, incomplete or missing orders</td>
<td>2.74</td>
<td>1.02</td>
<td>.789</td>
<td>[0.773 - 0.803]</td>
<td>1389</td>
<td>48.4</td>
</tr>
</tbody>
</table>

\(^a\) Question items were measured on a scale of 1 to 5  
\(^b\) SE=Standard Error  
\(^c\) CI=Confidence Interval  
\(^d\) Respondents who answered every single item in the multi-item scale (between 3 to 6 items/scale)
Appendix 2: Table A2. Distribution of background variables and proportion of respondents reporting a high or extreme risk severity rating including margin of errors and 95% confidence intervals for the proportions (N=2,864).

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<th>%</th>
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## Percent of all respondents reporting a high risk level (in %)

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### Percent of all respondents reporting a high risk level (in %)

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<td>29.0-32.4</td>
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Appendix Table A3. Proportion of high risk according to respondents’ professions and clinical unit (+95% confidence intervals) by risk type including margin of errors and 95% confidence intervals for the proportions (N=2,864).
<table>
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<tr>
<th>Clinical Unit</th>
<th>Professional Qualification</th>
<th>N</th>
<th>%</th>
<th>Margin of Error</th>
<th>95 % CI</th>
<th>%</th>
<th>Margin of Error</th>
<th>95 % CI</th>
<th>%</th>
<th>Margin of Error</th>
<th>95 % CI</th>
<th>%</th>
<th>Margin of Error</th>
<th>95 % CI</th>
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<tbody>
<tr>
<td>Clinical Lab /Radiology</td>
<td>Registered Nurses</td>
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<td>39.7</td>
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<td>33.7-45.7</td>
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<td>23.7-34.9</td>
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<td>8.96</td>
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<td>9.01</td>
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<td>39.6</td>
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<td>4.41</td>
<td>28.3-37.2</td>
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<td>3.81</td>
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**ARTICLE III**

FIN-TIERA: A TOOL FOR ASSESSING TECHNOLOGY INDUCED ERRORS

Palojoki S, Pajunen T, Lehtonen L, Saranto K.

Due to the increasing implementation of EHRs, the potential for technology-induced errors is a challenge that underscores the importance of identifying areas of vulnerability to mitigate them. This study provides a comprehensive picture of the characteristics of technology-induced errors in EHRs. Moreover, an instrument, the FIN-TIERA for controlling and preventing errors from the user perspective was developed. A more comprehensive approach to EHR safety is suggested to prevent patient harm.