

# Understanding the Context of Patient Safety Through The Lenses of Three IMIA Working Groups

Craig E. KUZIEMSKY<sup>a,1</sup>, Christian NØHR<sup>b</sup>, Elizabeth M. BORYCKI<sup>c</sup>, Andre W. KUSHNIRUK<sup>c</sup>, Yalini SENATHIRAJAH<sup>d</sup>

<sup>a</sup>*Telfer School of Management, University of Ottawa, Ottawa, ON, Canada*

<sup>b</sup>*Department of Development and Planning, Aalborg University, Denmark*

<sup>c</sup>*School of Health Information Science, University of Victoria, Victoria, BC, Canada*

<sup>d</sup>*SUNY Downstate Medical Center, Brooklyn NY, USA*

**Abstract.** Delivering safe patient centered care remains an important yet elusive goal across healthcare systems worldwide. The complexity of healthcare delivery and the unique contexts where it is delivered necessitates patient safety solutions that go beyond individual perspectives. This paper articulates the current state of patient safety research and HIT from the perspective of three International Medical Informatics Association (IMIA) working groups. Each WG will describe patient safety issues within their domain. We then integrate the three WG perspectives into an integrated model to support research, education and policy development for patient safety where HIT is concerned.

**Keywords.** Sociotechnical, human factors, patient safety, technology induced errors, context, health information technology

## Introduction

Delivering safe, patient centered care remains an important goal across healthcare systems worldwide. Despite the attention to medical errors and patient safety raised by reports such as ‘To Error is Human’ [1], it is still suggested that medical errors are a significant cause of patient death [2]. More significant is that many of the health information technologies (HIT) we design to improve care delivery such as electronic medical/health record systems or computer physician order entry may actually lead to new types of errors (i.e., technology induced errors) [3,4]. Today, the health informatics industry has recognized that HIT exist on a continuum, from safe to unsafe systems, with some HIT having features and functions that may improve while others detract from patient safety. With this awareness there has emerged an impetus towards designing HIT that prevent traditional medical errors and are considered safe technologies [5].

To address these patient safety issues academics, HIT industry leaders, and governments at all levels have called for studies that look at the multiple dimensions that contribute to medical errors including technical, human factors, organizational, and cognitive dimensions [6-9]. However, while research has looked at these issues it has

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<sup>1</sup> Corresponding Author: Craig Kuziemsky, Email: Kuziemsky@telfer.uottawa.ca

tended to do so in an isolated manner (i.e. considering the HIT independently from its context of use). HIT is used within a healthcare ecosystem that is influenced by all of the above dimensions depending on the specific context of use [10]. While sociotechnical frameworks have been developed to provide insight on HIT elements and patient safety, a shortcoming of these frameworks is that they often look at the various components as isolated entities, rather than as a set of integrated components.

Information about occurred errors are usually recorded in a database. For example, in Denmark errors are reported by health professionals but since 2010 patients and their relatives have also been able to report experienced errors. Approximately 50.000 errors are reported annually from hospitals. While the largest category are medication errors (23% in 2014), other categories - communication and other administrative procedures referrals, admission/discharge etc. - exceeds the number of medication errors. These type of errors happens in transitions between sectors, departments, staff groups, and between patients and professionals. These categories of errors usually involves the use of HIT, but the technology involved in the error is only occasionally mentioned in the reports. A content analysis of 17, 000 reports from the capital region of Denmark found 448 reports explicitly mentioning a specific HIT system. However, very few usability errors were reported – the staff tended to blame themselves for not using the system correctly [26]. Every system breakdown was reported and many errors were reported when systems were replaced or upgraded to newer versions.

Self-reporting systems are meant to improve patient safety by establishing a closed loop learning cycle. However, self-reporting systems have shown to be inadequate as they are difficult to code for data entry – the reports are mainly free text. They are incomplete as they contain sparse information to identify IT induced errors, and they are also found ineffective as the reporting culture is changing over time [11].

A more viable alternative to register errors that has happened will be to prevent them by applying a multi perspective on technology induced errors. We need to look beyond any one perspective to devise multi-perspective, context sensitive solutions. This paper addresses that need by developing a multi-dimensional perspective on patient safety from the perspectives of three International Medical Informatics Association (IMIA) Working Groups: Organizational and Social Issues (OSI), Health Informatics for Patient Safety and Human Factors Engineering for Health Informatics.

## **1. A Multi-Perspective Panel on Patient Safety**

Each of the authors represents an IMIA working group. In the sections below patient safety is discussed from the perspective of three working groups followed by the development of an integrated model of patient safety. We also discuss the implications of the model on the design and evaluation of HIT.

### *1.1. Organizational and Social Issues*

We cannot manage safety per se but rather we need to manage the clinical behaviors that lead to patient safety issues. From an Organizational and Social Issues (OSI) perspective, one of the challenges is that while patient safety initiatives start at the macro level, they are integrated at the micro level. And at times there are gaps between the two levels that may lead to patient safety issues. One such gap is at the system design level. In a study of a perioperative information system [12], an anesthetist commented

about the security feature that automatically logs out a user after 5 minutes of inactivity. It was designed for security reasons to prevent people from walking away from the system and someone else gaining inappropriate access to data. However, surgeries are typically longer than 5 minutes and have periods without data entry but where the anesthetist will have the system contextually configured for the next data entry point. If they are logged out they will have to reconfigure the setup and may miss something. One anesthetist commented ‘I realize it [automatic logout] is a security feature but it creates a patient safety issue’.

Collaborative rules of engagement are another issue. While HIT may be designed to facilitate integration across areas as a building block of patient safety, practice variations of individual users can limit the effectiveness of these safety initiatives, or even create new unsafe practices. In the perioperative study there were instances where an anesthetist would put a memo in the HIT to guide patient care. For example, when a patient transfers from the operating room to post-anesthesia care unit a memo might be created saying the patient’s blood pressure is prone to spikes or their O<sub>2</sub> de-saturates quickly. However, because there was no organizational protocol on memos, nurses in PACU may not know where to look for it and therefore may not see it [12].

How people interact with HIT at the micro level can also create unsafe conditions. One OSI perspective is how people actually use HIT in context compared to how it was designed. One such theory is prospect theory that attempts to predict how people will make decisions during uncertainty [13]. It also states that people who perceive something as a loss will be enticed to engage in more risky behavior to accommodate for their loss [13]. Implications of HIT implementation such as paper persistence or workarounds can be seen as people taking risks to accommodate perceived losses from HIT. Both anesthetists and nurses commented that while the benefits of the electronic system were well conveyed pre-implementation, the benefits they would lose from the paper system were not communicated nearly as well and were only truly understood once the HIT had been implemented. At an OSI level, people often perceive HIT as a loss, or at least an obstacle to doing day-to-day tasks, and as a result may create shortcuts or workarounds to minimize their perceived losses. However, these workarounds may create unsafe situations. If we can position HIT from the perspective of gains, by openly discussing trade-offs between paper and electronic systems and how clinical routines will be impacted by HIT, it may help people understand the changes from HIT implementation and how to accommodate such changes.

### *1.2. Health Informatics for Patient Safety: Improving the Quality and Safety of HIT*

HIT safety should be everyone’s concern in the healthcare industry. Around the world governments, vendors, healthcare organizations and health professionals have identified the presence of technology-induced errors and they have a desire to address this growing issue. This represents a significant shift from 11 years ago when the first publications emerged identifying technology-induced errors as an important safety issue [6, 14]. Today, we have governments, healthcare organizations and researchers who are monitoring for technology-induced errors and discovering new ones [15, 16, 23] – as new technologies are introduced so are new types of technology-induced errors [4, 5]. Organizations are innovating and exchanging ideas about how best to improve the safety of HIT by improving its quality [17].

Health informatics researchers have developed and proven the usefulness of several methodologies in identifying and addressing these types of errors before systems are

implemented (e.g. heuristic evaluation, usability testing, clinical simulations, rapid and traditional ethnographic approaches and case studies) [3, 6, 8,14,18,20,21]. In addition to this, we have models (i.e. human factors, sociotechnical, organizational behavior and software engineering models) [17, 19] that can be used to understand and develop strategies that allow for technology-induced errors to perpetuate and propagate over health care systems and across organizations (i.e. differing vendor and healthcare organizations) [19] and across health care contexts (e.g. physician offices, regional health authorities, home care agencies) [4,6,8,10].

To date we have also seen professional organizations and governments step forward with new regulations for software testing such as the work by Health Canada [15], new policies and programs (see the work of the Office of the National Coordinator in the United States and Canada's Health Informatics Association [24,25], a new culture of HIT safety [25], and organizational strategies for moving towards great utilization and improvement of HIT safety attributes [17,24,25]. This is exemplified by the report published by the Institute of Medicine on Health Information Technology Safety [22].

Even so, there is much work that continues to need to be done to improve the safety of HIT as many safety issues still exist. There is a need to continue to extend human factors, socio-technical and HIT safety research [3,6,12,17,19,23]. To date we have seen a significant shift from documenting the value of HIT to reducing errors and moving towards improving the overall quality and safety of HIT [3,5,22,17]. In a span of 11 years technology safety has moved to the forefront of health informatics research and professional practice.

### *1.3. Human Factors Approaches to Improving Healthcare Safety*

Over the past decade methods from usability engineering and human factors have been used proactively to identify and mitigate technology-induced errors in healthcare IT. This work ranges from usability testing to use of clinical simulations conducted in situ in real settings where health information technology will be deployed. The IMIA human factors working group has identified an approach to ensuring system safety that argues for an initial phase of usability inspection and usability testing for detecting surface level usability errors that might lead to technology-induced error (e.g. screen layouts that are confusing, inability for users to navigate to patient allergy information etc.) [3]. In addition, the working group has recommended that such evaluation lead to iterative cycles of system and user interface refinement to ensure system safety at the level of surface level usability. After detection and correction of such usability problems, a system safety approach to IT testing goes on to recommend application of clinical simulations to test the system/user interface under close to real conditions that can be artificially controlled (in order to explore certain aspects of interest of the user-system interaction in depth). Feedback from this stage of evaluation can again be input into system refinement and redesign [3]. Finally, the working group has identified a final layer of evaluation involving testing of systems in-situ under near-live and then live conditions. It is argued that such testing is also required to identify issues and problems related to impact of systems on workflow and problems that would occur during use of the system in real clinical practice [3].

In summary, the human factors working group recommends a layered approach to testing and evaluating systems that ranges from the individual interacting with the system in isolation (the level of user-computer interaction) to testing of systems under

realistic technical and social conditions. Finally, no matter how much testing is done prior to system release, a small scale pilot release with continuation of data collection (using unobtrusive data collection methods) is recommended prior to widespread release to identify and mitigate the potential negative impact of technology-induced error and lead to increased system safety.

2. An Integrated Model of Patient Safety

Fig.1 shows our integrated model of patient safety. The integrated model is intended to guide how patient safety and HIT are studied from multi-disciplinary perspective. The figure illustrates how each of the three WGs study patient safety from the perspective of HIT-provider interactions and the ‘undesirable’ adverse events (AEs) and ‘desirable’ care outcomes that emerge from the interactions. Fig. 1 highlights that while the focus of study for the three dimensions is different, that patient safety cannot be studied in isolation, but rather it requires an integrated effort to identify adverse events as well as the people and HIT issues that lead to them. The model emphasizes that it is the behavior and interactions between people, processes and technology that we need to be most interested in.

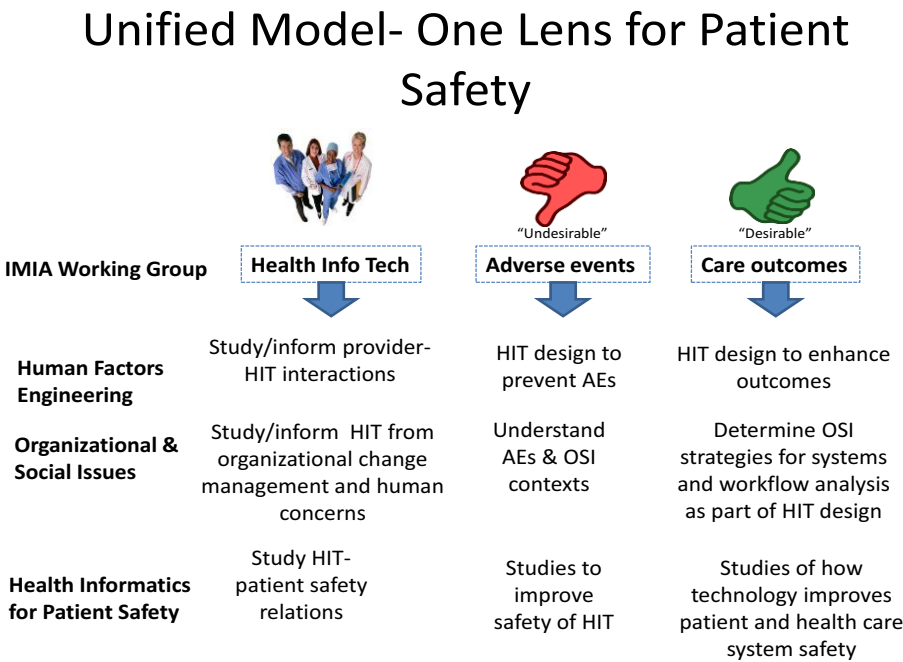


Figure 1. Integrated model of patient safety

As shown in Fig.1, while adverse events are undesired outcomes of how users and HIT interact, understanding the errors requires us to understand contexts of how people and HIT interact (OSI WG). Once we have understood the relationship between AEs

and contexts we can then identify AEs (Patient Safety WG) and inform HIT design to prevent AEs (Human Factors WG).

For example, in section 1.3 we described how usability testing needs to be used in all phases of HIT design including testing that incorporates social and technical contexts. The OSI working group complements that work by identifying contexts such as the rules of engagement for how collaboration works to enable usability testing to incorporate those contexts. Simulation is another method used by the human factors WG as it allows us to test context. However, the specific contexts that we need to consider may not be defined and the identification and understanding of different contexts is a large part of the work of the OSI WG.

### 3. Discussion

In this paper we discussed patient safety from the perspective of three IMIA WGs and provided an integrated model of patient safety and HIT. Our overarching message is that patient safety cannot be studied in isolation but rather it requires collaboration across WGs such as the three described in this paper. The integrated model of patient safety presented in this paper is meant to provide the starting point for studying, and understanding medical errors and adverse events as part of the design and evaluation of HIT to prevent errors. Our quest to identify patient safety issues and then to develop human factors strategies to prevent the issues will need to be shaped by the organizational and social contexts where healthcare delivery is provided. Complementary methods to study patient safety issues are also needed. One such example being Activity Theory to identify contextual factors related to activities which can then be used to inform clinical simulation studies. Overall, we need to move away from studies that simply describe unsafe practices or adverse events and conduct more research that explains *why* these unsafe situations occur. Research that provides explanations would enable us to better predict patient safety issues to allow us to then inform HIT design and evaluation to prevent them.

Understanding and managing patient safety is an ongoing task. While HIT has helped reduce ‘classic’ errors it has also created a new category of technology induced errors. It stands to reason that as we solve those errors new ones will arise. Our quest to reduce patient safety issues needs to be viewed as an ongoing journey and not a destination.

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