Using Theoretical Frameworks to Tailor Error Prevention Strategies to the Type of Task Being Performed

Abstract
Numerous studies of errors in health care identify medication-related errors as at or near the top of the list of concerns, both in terms of frequency and severity of impact. Despite the development of automated technologies, such as smart infusion pumps, medication errors are still prevalent and typically occur in more than half of all intravenous (IV) infusions. Incorrect setup, programming, and management of IV systems, particularly complex secondary and multi-line infusions, are often caused by knowledge and performance deficits. These deficits are influenced by several factors, one of which is a lack of clinician training on fundamental infusion principles. Thus, to improve patient safety related to administering IV infusions, there is a great need for (a) infusion system design that optimizes capability and ease of use, and (b) an effective means of educating clinicians on the system fundamentals necessary to support critical thinking and decision making when operating IV medication systems.

We have undertaken a case study in which we have applied various theoretical frameworks/approaches, to determine the underlying cause of IV medication administration-related errors, and to compare types of errors that were best mitigated through improved device design to those that benefited most from improved user training. Theoretical frameworks/approaches used in our case study include an AcciMap analysis taken from Rasmussen’s Risk Management Framework [1], and Rasmussen’s Skill-Rule-Knowledge conceptual framework for human performance [2].

Methods used in our studies included literature reviews, mining of incident databases, ethnographic observations in clinical environments, and laboratory-
based simulations designed to uncover performance limitations, and to test proposed benefits of improved technology designs and clinician training.

Results showed that applying theoretically informed safety-based improvements to known shortcomings in technology design for IV infusions were beneficial in reducing, and even eliminating, errors of omission. Conversely, training-based interventions aimed at teaching fundamental principles of infusion systems were beneficial in reducing errors where actions required higher-level clinical decision-making.

This case study highlights the benefits of applying a combination of theoretical frameworks/approaches when identifying and developing error mitigation strategies that include both technological solutions that can achieve higher accuracy and reliability than human processes, as well as user-centric based training solutions that enhance clinicians’ understanding of the systems they are controlling and thus their problem solving skills.

**Author Keywords**
complex medical devices, AcciMap, Skill-Rule-Knowledge conceptual framework, technology design, user training, patient safety.

**Introduction**
Adverse events and medical errors pose a serious problem to health care systems [3]. In 1999, the Institute of Medicine (IOM) report, “To Err is Human: Building a Safer Healthcare System” [4], concluded that medication errors account for 7,000 deaths annually, while total preventable medical errors cause between 44,000 and 98,000 annual deaths in the United States alone. Even when considering the lower estimate, deaths in hospitals due to preventable adverse events exceed the deaths attributable to motor vehicle accidents, breast cancer, and AIDS combined [4]. The IOM estimated that the annual cost associated with preventable medical errors is as much as $29 billion US annually. Similarly, research on incidence rates of adverse events in Canadian hospitals indicated that approximately 185,000 admissions per year are linked to an adverse event, and that nearly 70,000 of these may be avoidable [5]. Medication errors are the most frequent cause of medical injuries, representing 19.4% of all adverse events [6]. Furthermore, a subsequent report by the IOM on medication errors [7] estimates that a minimum of 1.5 million people are harmed yearly due to preventable adverse drug events, suggesting that every hospital patient may be subjected to as much as one medication error per day. As a result of these landmark reports, there has been an increased awareness of patient safety issues over the past decade, particularly in the context of medication safety.

Clinicians’ user errors and improper use of medical devices have been linked to multiple patient injuries [8]. Adverse events involving medical devices have led to serious problems, including incorrect or delayed diagnosis and treatment or patient injuries and deaths. ECRI Institute [9] estimates that approximately 75 percent of the reported problems they receive are related to user error. Specifically, the majority of reported problems concern users who do not fully understand the devices and systems they are being asked to use. Recent statistics from the FDA show that that between Jan. 1, 2005 and Dec. 31, 2009, there were 56,000 adverse events associated with the use of infusion devices in the United States.
in 710 deaths [10]. When errors involving medical devices occur, people typically blame the users rather than investigate broader systems factors that are likely contributing, such as a poorly designed interface between the medical device and the user, or inadequate user training. The Medicines and Healthcare product Regulatory Agency (MHRA) has identified inadequate staff training as a primary cause of incidents with medical devices [11]. There is a need to understand how to better ensure that (a) medical devices are designed for optimum capability and ease of use, and (b) clinician training is thorough and effective.

In health care, the objective of human factors is to improve human performance with medical devices and systems, and to reduce the likelihood of error or injury, thereby improving patient and workplace safety [12].

**Objectives**

In the present paper, we present a case study and discuss how we used complementary theoretical frameworks/approaches to determine the underlying cause of intravenous (IV) medication-related errors, and identify the types of errors that were best mitigated through improved device design, and those that benefited most from improved user training.

**Background**

The case study discussed in this paper focused on the safe delivery of IV medication therapies, as these procedures have become more complex over the years due to the introduction of technologies such as smart large volumetric infusion pumps. That is, to address the high incidence of infusion errors, manufacturers have developed pumps that have dose error reduction systems (DERS), which include hospital-defined drug libraries with dosing limits and clinical advisories (i.e., smart pumps). While traditional general-purpose infusion pumps have a wide range of acceptable programming settings/parameters, smart pumps are designed with drug-specific safety software to help nurses avoid programming errors. Smart pumps provide either a “soft” limit warning (allows nurse to override the limit and continue infusing) or “hard” limit warning (requires nurse to reprogram the pump within acceptable parameters). Although the purported benefits of these technologies are that medications can be given accurately and reliably at all times, clinicians often encounter difficulties using the devices, which can increase the risk of patient injury.

Secondary (also referred to as “piggyback”) infusion is a convenient set-up that allows clinicians to administer two medications intermittently to patients through a single channel in the infusion pump. Our own past experimental data demonstrated that the error rates for nurses to complete all secondary infusion task scenarios were as high as 50% [13]. Moreover, we identified that many secondary infusion issues, such as misalignment of infusion bags, errors in tubing setup, and the failure to open the roller clamp on secondary IV tubing, cannot be detected or intercepted by the commercially available smart infusion technologies that are commonly used in the clinical setting.

The lack of effectiveness of smart infusion technologies is attributed to the fact that these solutions don’t fully support clinical reasoning and problem solving [14]. Research has shown that medication infusion errors are not solely attributable to poor system design or lack of system integration [15]. A major factor in the failure to
reduce IV infusion errors is that abstract thinking tasks are essential to the final medication administration process, and current technologies do not support abstract clinical thought [14]. Although automating lower cognitive functions (e.g., perception, categorization) is effective in reducing workload by performing mechanistic tasks that would otherwise be performed by humans, it is not as effective at supporting higher order cognitive functions such as those required during critical thinking tasks [16]. Automated technical systems, such as smart pumps, are limited in that they are designed to deal with the foreseen. That is, technological solutions are based on tasks, actions, or procedures that can be anticipated and therefore built into the design [17]. The reality of health care environments, however, is that they are complex, dynamic, and often unpredictable [18]. Consequently, clinicians must be adaptive problem solvers. Therefore, complementary approaches are needed to benefit from the strengths of technological solutions that can achieve higher accuracy and reliability than human processes, while compensating for their weaknesses through novel solutions that enhance clinicians’ higher cognitive functions (e.g., reasoning, problem solving).

**Application of Theoretical Frameworks**

In response to the known issues associated with administering IV infusions, we conducted a study using multiple methods to (1) determine the comprehensive set of issues leading to IV infusion administration errors, and (2) identify potential solutions. To support the first objective, we used Rasmussen’s Risk Management Framework [1] to analyze the data collected through a literature review, incident database review, and ethnographic observations in clinical environments. Factors across the entire system were considered and the data were analyzed according to the cause-consequence relationships between factors at each level of the system. To support the second objective, Rasmussen’s Skill-Rule-Knowledge framework for human performance [2] was applied to determine whether each human performance issue represented a failure to apply the appropriate skills, rules or knowledge. Human performance issues associated with the failure to apply appropriate skills and rules were identified as issues where automation or infusion device design changes could potentially be most effective. Human performance issues associated with the failure to apply appropriate knowledge were identified as issues where improving the users’ mental model of the system could potentially be more effective. Laboratory-based simulations were conducted to uncover performance limitations and to test proposed benefits of improved technology designs and clinical training. In the following sections we describe the theoretical frameworks used in this case study.

**A. Rasmussen’s (1997) Risk Management Framework**

Several theories and analysis techniques exist to understand and model adverse events, such as Leveson’s systems-theoretic accident model and processes (STAMP) model [19], Reason’s model of organizational accidents [20], and Rasmussen’s AcciMap approach within his Risk Management Framework [1]. We opted for Rasmussen’s approach for several reasons. First, it is intended for modeling accident behaviour in complex socio-technical systems (such as healthcare). Second, because it supports looking across all levels of the system and at the
dynamic changes that occur over time that eventually lead to an incident. Third, because it compiles the multiple potential contributing factors to an adverse event in a single causal diagram that illustrates how factors interconnect. Consequently, the AcciMap diagram depicts the context in which an adverse event could occur and the potential contributing factors. The AcciMap enabled us to identify the complex interactions between factors that can contribute to IV infusion errors. These results then led us to the next phase of our study, which was to categorize these factors according to three basic task/error types: skill-based, rule-based and knowledge-based.

The AcciMap generated in this case study is too large to include in this paper. It contains over 100 data elements, spread across six levels of the system. However, Figure 1 illustrates a general approach to an AcciMap.

B. Skill-Rule-Knowledge Framework

Rasmussen’s conceptual framework for human performance structures tasks/errors into three basic types: skill-based (e.g., an execution failure), rule-based (error in applying a rule) and knowledge-based (errors due to a bias or mindset that dictates inappropriate solution for the given situation) [22]. Based on this framework, expectation of errors may relate to the familiarity and complexity of the task. Mechanistic tasks, which compare two tangible sources of information and require minimal stored knowledge, may be prone to skill- and rule-based errors. Abstract tasks requiring integration of knowledge from multiple sources and analytical thought processes for interpretation and evaluation of situations, relate to the knowledge-based level of error.

The skill-based level of human performance involves little thought and is generally related to preprogrammed instructions [22]. In the context of our case study (i.e., IV medication administration), a nurse neglecting to start an IV infusion due to a distraction is an example of an execution failure. Mistakes, either rule-based or knowledge-based, are associated with slightly more complex tasks. Rule-based mistakes relate to problems that occur despite training or experience due to an error in applying a rule. This may involve the misclassification of a situation or incorrect recall of a procedure (e.g., forgetting to lower the primary bag when delivering a piggyback infusion). Knowledge-based mistakes generally occur in novel situations of limited familiarity and rely on conscious, analytical processes and abstract knowledge. Failure to recognize an inappropriately prescribed dosage during
medication administration is an example of a knowledge-based mistake.

At the end of Phase 2, we concluded that current smart infusion pump systems solely address certain mechanistic tasks prone to skill-based and rule-based errors, and identified the need for clinical training that will also address abstract tasks prone to knowledge-based errors. Specifically, we identified that the unique focus of the training should be the elucidation of the mechanisms of higher order cognitive functions, under various conditions (e.g., routine vs. unexpected situations).

We identified existing technological solutions that could address skill and rule based tasks/errors, and developed a novel training tool aimed at addressing knowledge-based problem solving. Our unique focus was to develop error prevention strategies that are tailored to the type of task being performed (e.g., mechanistic vs. abstract) to better manage the various error types (i.e., skill vs. rule vs. knowledge). That is, we identified technology-based interventions that could help prevent skill and rule-based errors (e.g., automatic clamp detector that alarms users when a roller clamp is closed at the start of a secondary infusion) and developed a training-based intervention to reduce knowledge-based errors (e.g., incorrect bag height differential established due to lack of understanding of fluid mechanics).

Our training-based intervention consisted of an online educational module to reduce knowledge-based errors. This educational module incorporated a combination of audio narration, on-screen text, graphics, and animations. We empirically compared the effectiveness of our newly developed training-based intervention to the technology-based interventions on nurses’ ability to safely administer IV infusions. Results showed that safety-based improvements to known shortcomings in technology design for intravenous infusions were beneficial in reducing errors of omission (e.g., user knows that s/he must open the secondary clamp but forgets to perform the action). Conversely, training-based interventions (e.g., education module that addresses information on basic infusion principles and known failure modes) were beneficial in reducing errors where actions required higher-level clinical decision-making (e.g., managing flow of multiple concurrent infusions combined in a single IV line).

In sum, our research findings suggest that IV infusion errors are attributable to both; (1) the way the technology to deliver infusions is designed, and (2) clinicians’ knowledge of key infusion principles.

**Conclusion**

It has been well established that technological systems can achieve a much higher accuracy and reliability than any human processes [14]. Consequently, considerable attention has been directed towards automating these mechanistic tasks of the IV infusion process through design of smart pumps (e.g., bar code readers). Less attention, however, has been paid to other (non-mechanistic) components of the IV infusion system. Although automated technological innovations are effective at assisting in the performance of mechanistic tasks, they are not as effective at assisting in the performing of tasks requiring critical thought.

Automated technical systems are limited in that they are designed to deal with the unforeseen. That is,
technological solutions are based on tasks, actions, or procedures that can be anticipated and therefore built into the design. The reality of health care environments, however, is that they are complex, dynamic, and often unpredictable. Consequently, clinicians must be adaptive problem solvers. Thus, mitigation strategies aimed at reducing medication administration errors must include both technological solutions that can achieve higher accuracy and reliability than human processes as well as user-centric training solutions that enhance clinicians’ problem solving skills. Through our case study, we have shown how Rasmussen’s Accimap enables the identification of causal chains to patient harm, and his SRK framework allows for an understanding of the behavioural or psychological processes involved in the identified errors.

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References
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