

SAFETY IN HEALTHCARE INFORMATION SYSTEMS:
A SYNTHESIS OF THE LITERATURE

By Julia Weatherby

A CAPSTONE

Presented to the Department of Medical Informatics and Clinical Epidemiology
and the Oregon Health & Science University

School of Medicine

in partial fulfillment of
the requirements for the degree of

Master of Biomedical Informatics

June 2012

School of Medicine
Oregon Health & Science University

CERTIFICATE OF APPROVAL

This is to certify that the Master's Capstone Project of

Julia M. Weatherby

*"SAFETY IN HEALTHCARE INFORMATION SYSTEMS:
A SYNTHESIS OF THE LITERATURE"*

Has been approved

Capstone Advisor

TABLE OF CONTENTS

Introduction.....	1
Methods.....	2
Results.....	3
e-Iatrogenesis.....	3
Theoretical Framework: Sociotechnical Model.....	6
External Rules & Regulations.....	8
Measurement & Metrics.....	13
Internal Organization.....	17
Workflow & Communication.....	20
People.....	24
Human-Computer Interface.....	28
Clinical Content.....	30
Hardware & Software.....	33
Conclusion.....	36
References.....	38

Introduction

Healthcare professionals aim to provide the best care possible, but in the worst situations, the healthcare provided sometimes causes harm to patients. In 1999, the Institute of Medicine published a landmark report titled, “To Err is Human” which claims that between 44,000 and 98,000 people die and more than a million are injured annually from preventable medical errors. One of the many recommendations from the report is to implement healthcare information systems (HIS) to ensure safety.

Practitioners of medicine are increasingly utilizing HIS in their delivery of healthcare to patients. The benefits of using such systems include lowering costs, lowering medical errors and improving healthcare efficiency and quality (Carvalho et al., 2009; van Rosse et al., 2009). In a systematic review of Computer-based Provider Order Entry (CPOE) system usage, van Rosse et al. (2009) found that medication prescription errors were significantly reduced.

However, researchers have shown that systems can generate a new kind of error, technology-induced or technology-facilitated errors (Carvalho et al., 2009; Koppel et al., 2005; Kushniruk et al., 2005). A term has been coined to describe this effect, which is “e-iatrogenesis”. E-iatrogenesis was defined in 2007 by Weiner et al. as “patient harm caused at least in part by the application of health information technology.”

As healthcare information systems have grown in complexity, there are new opportunities for errors (Borycki and Kushniruk, 2008; Koppel et al., 2005). Palmieri et al. describe e-iatrogenesis as being the result of complex HIS innovation applied to the complex adaptive system of healthcare. In addition to generating new errors, it also can worsen

existing problems in the healthcare delivery system (Palmieri et al., 2008). Thus, experts and government have recommended healthcare organizations to be considerate of safety issues when implementing HIS (Joint Commission, 2008). There have been calls for development of new ways to detect errors before system implementation and identification of the various situations and root causes for technology-induced errors to occur (Borycki and Keay, 2010). Other recommendations include better error reporting, HIS vendor transparency, more thorough testing and certification.

Methods

We performed a literature review on the topic of safety and errors in healthcare information systems. The sources reviewed were those identified in a report to the Institute of Medicine titled “Roadmap for the Provision of Safer Healthcare Information Systems: Preventing e-Iatrogenesis” written by Ash et al. (2011). Those sources were selected in a separate literature review process. The search began with a review of the 43 literature references cited in a EHR safety literature review by Harrington et al. (2011) A reverse bibliography search was performed on the 37 relevant sources identified. From this, over 100 sources were identified as relevant to the topic of preventing e-iatrogenesis. The information in the sources was used to answer specific questions posed by the Institute of Medicine.

For this study, the literature cited in the roadmap report was reviewed and analyzed in terms of the eight dimensional sociotechnical framework discussed in the paper. The findings, recommendations and other relevant discussions were organized into a specific dimension and summarized. It is recognized that many of the discussion points are located at the intersection of multiple dimensions, the data was organized into its primary

dimension for clarity.

Results

e-Iatrogenesis

Borycki and Kushniruk list three main sources of technology-induced errors. The sources include: technology design and development, technology implementation and customization, and the interactions between technology operation and new work processes (Borycki and Kushniruk, 2008). Kushniruk et al. explain that technology-induced errors are not the programming bugs one traditionally associates with software. They are not likely to be found through traditional software testing. They are technology issues that lead to complex cognitive errors (Kushniruk et al., 2010b). The Institute of Medicine (2001) claims that healthcare is the most complex sector of our economy. Healthcare environments are noisy, clinicians are burdened with heavy workloads and perform complex tasks requiring fast decisions, multitasking and high liability for errors (Harrington et al., 2011).

Some of the difficulties in quantifying the extent and severity of e-Iatrogenesis are due to a limited number of studies, few hospital systems monitor effectively for errors, and limited systems and regulations for reporting error events. One of the systems for reporting errors is with a database called Medmarx. Medmarx is a national voluntary medication error reporting database sponsored by the United States Pharmacopeia (USP). Healthcare institutions anonymously report errors to the database, USP analyzes the reports, identifies patterns, makes recommendations on medication safety and offers the reports to participating institutions (Zhan et al., 2006). As it is a voluntary reporting

system, it is not possible to prove that hospitals with CPOE have fewer errors than those without. There is too much variability between institutions in the levels of underreporting of medication errors. However, some studies have used the data to understand the frequency and circumstances around e-iatrogenesis.

When new errors are introduced, it appears that they are generally minor in severity. In an observational review conducted at a 688-bed academic hospital, Spencer et al. (2005) determined that e-iatrogenic errors were typically mild and not serious. In a qualitative study by Ash et al. (2007) hospital staff reported more near misses than actual errors. The errors that did occur were minor.

Zhan et al. (2006) analyzed reports from Medmarx. During a 7 month period in 2003, 7029 medication CPOE-related errors were reported by 120 facilities. The majority of the errors were events in which there was a potential for error. Errors that affected patients were about 4.7%. Errors that caused temporary harm to a patient were 0.1%. There were no CPOE-related errors that caused death or serious injury.

Another study by Walsh et al. of pediatric admissions at an urban teaching hospital examined errors and found that for every 1000 patient days, there were 104 pediatric medication errors, 10 of those were computer-related pediatric errors, and 3.6 of those were serious computer-related pediatric errors. While there were few serious computer-related pediatric errors, the computer systems did introduce a new type of error. The types of errors found were 2 duplicate medication orders (serious), 9 drop down menu selection errors (4 were serious), 1 keypad entry error (serious), and 8 order set errors (0 were serious) (Walsh et al., 2006).

Reports from Medmarx data in the years 2001 and 2002 showed that use of a CPOE

system was the fifth leading cause of all medication errors and third leading cause of wrong patient errors (Thompson et al., 2005).

In a study of reports to an anonymous incident reporting system for ICUs, during a one year period, three ICUs with CPOE reported 55 CPOE-related errors. Eighty-five percent of those errors resulted in medication error. The errors were categorized as user errors (67%), software errors (20%), and computer malfunctions (13%). Insufficient training was the most common reason listed for those errors caused by users (Thompson et al., 2005).

When analyzing Medmarx data from mid 2001 to 2005, 693 facilities reported 90,001 medication errors that were related to computer entry by non-prescribers. The percentage of harm for these errors was 0.99%. The location where the majority of errors occurred by non-prescribers was in the inpatient pharmacy (Santell et al., 2009). Another Medmarx analysis of data from 2006 showed that 25% of medication errors were computer related. The leading causes for the harmful computer related errors were mislabeled barcodes on medications (5%), information management systems (2%), and unclear or confusing computer screen displays (1.5%). Other harmful errors were caused by: dispensing devices, computer software, failure to scan barcodes, computer entry other than CPOE, CPOE and overrides of barcode warnings (Joint Commission, 2008).

While the level of serious e-iatrogenic errors is low, the Institute of Medicine (1999) warns that latent errors (poor design, incorrect installation, faulty maintenance, bad management decisions, and poorly structured organizations) create an unsafe environment and pose the greatest threat to safety because end users do not always see them and they can lead to multiple active errors.

Technology-induced errors seem to occur with a higher frequency in the immediate time period after introducing new HIS. Shulman et al. (2005) studied the rate of medical errors during sampling time periods prior to and after the introduction of CPOE. The total proportion of medication errors was significantly lower with CPOE (4.8% versus 6.7%). The proportion of errors post CPOE implementation lowered with time.

As more commercially developed healthcare information systems are adopted, there is a concern that the safety risk may increase when compared to the early adopters. The earliest adopters of HIS had developers creating iterative, evolutionary software specific to their organization. These systems had a great fit between the software and organization. With more small practices and institutions implementing software previously developed, there is less of a fit with the organizational structure and the workflows and the software (Borycki and Kushniruk, 2010; Chaudhry et al., 2006). When software is originally developed for a different model organization, the vendor can unintentionally introduce errors in the design (Borycki et al., 2010).

Theoretical Framework: Sociotechnical Model

“Bad outcomes are the result of the interactions among systems components including the people, tools and technologies, physical environment, workplace culture, and the organizational, state, and federal policies which govern work. Poor HIT outcomes do not result from isolated acts of individuals, but from interactions of multiple latent and triggering factors in a field of practice.” - Karsh et al. (2010)

Borycki et al. (2010) emphasize the need for the development of holistic theories, models

and frameworks in understanding technology-based errors and the system in which they are generated. They also must include the entire lifecycle of the healthcare information system, from software design through organizational implementation and maintenance.

The theoretical framework implemented for this paper is the sociotechnical model framework outlined in “Roadmap for the Provision of Safer Healthcare Information Systems: Preventing e-Iatrogenesis” written by Ash et al. (2011).

The framework is composed of eight sociotechnical dimensions of healthcare information systems:

1. external rules and regulations that impact the organization;
2. measurement and metrics that can assess the safety of HIS;
3. internal organizational attributes such as organizational structure;
4. the workflow and communication practices of the individual organization;
5. people or stakeholders who use or deal with the system;
6. human-computer interactions and interfaces;
7. clinical content, including CDS and patient data within the system; and
8. the hardware and software itself.

Conceptual models for understanding the complexity of healthcare information systems have been evolving over the past decade. This model was adapted from the eight dimensions of health information technology framework of Sittig and Singh (2009, 2010). Sittig and Singh adapted and extended existing models, which they believed to be limited in scope, into a new framework. The basis for their framework is in four sociotechnical models. These include: the Systems Engineering Initiative for Patient Safety by Carayon et al. (2006), Vincent's framework for risk and safety, Henriksen's

model of the healthcare organization, and the Interactive Sociotechnical Analysis framework by Harrison et al.

While models for understanding error have been created in other industries, Borycki et al. (2010) explains that those models are not easily applied to healthcare due to its complexity and uniqueness. Borycki et al. says that healthcare work is “variable, dynamic, complex, emergent, involves a high degree of ambiguity, is inter-professional in nature, is highly professionalized, requires a high degree of coordination and is not easily deferred.”

The value in studying healthcare information systems in eight dimensions does not lie in simply analyzing each dimension individually. Instead, the model requires understanding the relationship between the dimensions. This is a key aspect, as many errors are located at the intersection of two or more dimensions. Likewise, many aspects of HIS can simultaneously affect multiple dimensions. The system is dynamic and dimensions are dependent upon each other, so changes in one dimension can impact another. Success in one dimension is dependent upon success in the others. Just because a dimension is successful in one system does not mean that it will be successful in a different one (Sittig and Singh, 2010). For organizational simplicity, the literature findings are summarized into their primary dimension.

External Rules & Regulations

Healthcare information system safety is affected by forces external to the institution, such as federal or state regulations, national initiatives and economic factors (Sittig and Singh, 2010). The American Recovery and Reinvestment Act of 2009 is federal legislation that

provides over \$20 billion of financial incentives for healthcare providers who implement and prove “meaningful use” of healthcare IT (Sittig and Singh, 2010). While the financial incentive requires that systems pass certification tests, the tests do little to mandate safety of the system's implementation (Hoffman and Podgurski, 2008). Due to the deadlines set by the government, there is concern that too many implementations are rushed to the detriment of patient safety (Sittig and Singh, 2009). Experts have called for rigorous safety requirements to be included in certification. (Walker et al., 2008). Hoffman and Podgurski believe vendors should have their product implementations carefully monitored for safety and be required to demonstrate low failure rates and adverse event rates as part of the certification process. They also recommend that electronic health record (EHR) certification be as rigorous as the Food and Drug Administration's approval process for drugs and medical devices (Hoffman and Podgurski, 2008).

The approach of independent safety assessments have been endorsed by international standards organizations (Karsh et al., 2010). A National Academy of Science report suggests that IT be considered “guilty until proven innocent” and that it is the responsibility of the system vendor to prove to an independent certification or regulatory organization that it is safe. Other hazardous industries require an independent hazard analysis of systems prior to being used, and the healthcare industry should do the same.

Currently, the Food and Drug Administration (FDA) considers clinical software programs to fall under their jurisdiction for regulation (Miller and Gardner, 1997). However, for the most part, the FDA has not enforced regulation on healthcare information systems, instead focusing enforcement on medical devices. The reasoning is that HIS are systems that providers can control and easily override versus devices that provide data directly to larger systems with no intervention from patients or providers. (Miller and Gardner, 1997; Karsh et al., 2010). Karsh et al. (2010) finds the reasoning that humans can catch

errors to be a fallacy. It means that we are relying on humans to catch computer-based errors, when computer systems are being introduced with the aim of reducing human errors. This assumption that humans can catch most of the errors ignores the evidence that shows that humans are greatly affected by how technology is designed, and may HIS in ways that were not intended by its designers.

The FDA is currently following a draft policy from 1989, but is evaluating future policy direction with regards to regulation of HIS. The FDA believes that some type of federal oversight should be in place to ensure patient safety (U.S. Department of Health and Human Services, 2010). Some vendors have voluntarily registered their clinical software with the FDA and vendors as well as providers and patients have reported errors and adverse events. Miller and Gardner (1997) recommend that only the highest risk clinical systems should be actively regulated by the FDA, with the remaining systems exempt from FDA enforcement. Instead, the majority of HIS should be monitored by local software oversight committees. These committees could work closely with the vendors and HIS users to better ensure system safety and monitoring. Lenzer and Brownless (2010) point to various faults of the current FDA approval and surveillance processes for medical devices.

Roughly one third of states have mandatory reporting requirements on patient safety. The Institute of Medicine (1999) calls for a nationwide public mandatory reporting system that could set the standard for the information that states would collect on adverse medical events.

Voluntarily reported data provides valuable insights and compliments mandatory reporting by focusing on less harmful errors and offering rich information (Institute of Medicine, 1999). However, data that is reported voluntarily on technology-based errors

has limitations to its value due to lack of numerators, denominators, bias and underreporting (Magrabi et al., 2010; Walsh et al., 2006; Zhan et al., 2006).

Underreporting can be influenced by leadership, resources, staffing, legal concerns and experience with the system (Zhan et al., 2006). A Medmarx database analysis found abundant variation among reporting facilities which lead to difficulty in executing a statistical comparison between CPOE and non-CPOE facilities. The Institute of Medicine (1999) suggests that healthcare providers would be more willing to participate in voluntary reporting if Congress enacted laws to protect the confidentiality of the information collected.

A different type of voluntary reporting can be done through surveys conducted by companies. For example, a consulting company called KLAS surveys hundreds of healthcare institutions in regards to specific software products. Walker et al. (2008) recommends that these surveys ask providers about their experiences specific to vendors and safety.

Some healthcare providers have found vendor contracts to contain “hold harmless” clauses in addition to requirements that they not share errors and faults of the system. These clauses have been declared unethical, as both parties should share the responsibility of patient safety and safe implementations (Goodman et al., 2011; Koppel and Kreda, 2009). While each party should not be responsible for the errors caused by the other, each party should be responsible for their part of the final system (Koppel and Kreda, 2009). The recommendation of an AMIA task force is that contracts instead mandate the sharing of defects, deficiencies and implementation practices that put patients at risk. Information on these issues should be available to a vendor's client base as well as potential clients (Goldstein et al., 2001). Current clients should be immediately informed by vendors of pertinent newly discovered errors that others have experienced

(Koppel and Kreda, 2009).

More ambitious professional organizations have taken the initiative to set policies to safeguard patient safety. Experts recommend that more organizations follow suit. Hospitals can be accredited through a voluntary organization called the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). JCAHO requires healthcare organizations to perform root cause analysis for severe adverse or “sentinel” events (Gaba, 2000). The organization reviews the analysis and resolution. Unsatisfactory resolutions may put the healthcare organization at risk of being on “accreditation watch.” Walker et al. (2008) recommends that business organizations such as the Leapfrog Group ensure organizations follow software safety practices before granting membership. HIS vendors are protective of the design of their software, and consider differences in interfaces to be a key competitive aspect of their product (McDonnell et al., 2010). An independent organization could develop standards for HIS safety and usability where vendors and healthcare organizations contribute lessons learned and receive industry best practices (McDonnell et al., 2010; Miller and Gardner, 1997).

More active monitoring and responding could be done by organizations that mirror those in the aviation industry. An agency similar to the Aviation Safety Reporting System would collect reports on errors, have experts analyze the events, send alerts to organizations that need to be aware of the hazards, and disseminate information to the healthcare community (Gaba, 2000). The Department of Veterans Affairs is creating a similar functioning system within their healthcare system. A team similar to the National Transportation Safety Board could have the authority to thoroughly investigate serious adverse events and report findings to the public (Sittig and Classen, 2010).

While providers may feel like the government heavily regulates healthcare, the reality is

that there is very little legislation on patient care activities compared to other high risk industries (Gaba, 2000). When examining oversight possibilities, consideration should be given to ensuring that innovation is not obstructed and product evolution is not stalled. A professor shared his experience with the FDA during a HIT safety hearing sharing that it took nine months to get a trivial change to software approved by the FDA (U.S. Department of Health and Human Services, 2010). No matter what the future of health safety regulation holds, it is important that across the nation, errors are studied, shared and that healthcare providers and vendors are educated and cautioned from lessons learned.

Measurement & Metrics

For optimal patient safety, healthcare information systems and the effects of HIS need to be measured continuously, both prior to implementation and post-implementation. It is a necessary step to identify HIS effectiveness in terms of patient outcomes, system availability to providers and patients, how clinicians are using the system and unintended consequences, such as e-iatrogenesis (Santell et al., 2009; Sittig and Singh, 2010). While these are vital in understanding a specific organization's HIS implementation, this measurement data should also be reported and monitored at a local, state and national level.

It is unrealistic to assume the introduction of HIS will automatically reduce overall medication errors. Therefore, the system should be evaluated in terms of its impact upon patient health. Organizations implementing HIS should be aware of the extent that the system has reduced errors and the quantity and type of new errors introduced after the implementation (Borycki and Kushniruk, 2008). Examples of other specific metrics to

track include system uptimes, recovery from failure times, response times, user load, alert override rates, percentage of providers entering orders online and practitioner efficiency (Campbell et al., 2007; Sittig and Singh, 2010).

Just as evidence-based medicine and audit are essential for quality clinical care, evaluation of HIS similarly provides evidence for medical informatics (Ammenwerth, 2005). Evaluation provides insight and new knowledge about the system which can be shared with the healthcare community and thus improve safety industry-wide.

There are some methodologies and tools available for evaluation of HIS safety. There are already proven methods used by researchers to evaluate HIS safety after implementation (Borycki and Kushniruk, 2010; Campbell et al., 2006; Carvalho et al., 2009; McDonnell et al., 2010). However, they can be costly in terms of time, resources and money. Carvalho et al. believe there is a need for additional inexpensive methods that can be used effectively by healthcare organizations to assist in making procurement decisions prior to implementation (Carvalho et al., 2009).

Heuristic evaluation is a method for analyzing the interface of a system in following best practices in human factor design (Carvalho et al., 2009). This method requires a set of heuristics, which are principles of good design. An analyst will then evaluate the system interface against each heuristic. A caveat is that the analyst needs to have a strong understanding of how the organization intends to integrate, customize and use the system. By following this methodology with multiple systems, the results can be compared against each other, and the systems with the best quality interfaces will be easy to determine. Using heuristics does not provide a complete evaluation of HIS in terms of safety, but it can be useful in the initial parts of a more comprehensive evaluation in procuring a system (Carvalho et al., 2009; Kushniruk et al., 2005). Carvalho et al. (2009)

developed a list 38 evaluation heuristics in the categories of workflow, content, safeguards and function and then analyzed a demonstration version of the Veterans Affairs Computerized Patient Record System. An example of one of the heuristics is “User has the ability to override the system during an emergency.”

Healthcare organizations can get a better idea of how a product will fit in their organization by developing clinical information processing scenarios (CLIPS) specific to their environment and testing potential healthcare information systems in their ability to handle various scenarios (Kushniruk et al., 2010a). The CLIPS scenarios should cover regular activities as well as unusual situations. Researchers have found that scenarios based on workflows are more accurate in understanding clinician’s preferences when compared to scenarios that address the system feature by feature. Clinicians can evaluate HIS during vendor demonstrations that follow the CLIPS. When vendors are given the CLIPS during the demonstration, it provides stronger evidence than when vendors know the details of the CLIPS before the demonstration. Either approach provides more evidence than a vendor demonstration not specific to the healthcare organization.

Clinical simulations are a more effective method of testing for safety in HIS before the system is deployed in a healthcare organization. The aim of a clinical simulation is to mirror the aspects of technology, social interactions, workflow and healthcare environment that will be found in the healthcare organization (Kushniruk et al., 2010b). During a clinical simulation, a clinician interacts with the system while speaking their thought processes aloud or while also attending to someone who is acting like a patient and following a script (Kushniruk et al., 2006). The clinician is in a real-world setting with actual devices and software intended for clinical use (Carvalho et al., 2009). Video and screen recordings are captured for later analysis of technology-induced errors and near misses by organization experts or researchers (Borycki and Keay, 2010). Safety

heuristics can also be used with clinical simulations. Kushniruk et al. used this process to discover usability issues with an application on a hand-held device when used for writing prescriptions (Kushniruk et al., 2006). The information learned through this process can be used to make changes to the HIS through customization, to inspire changes made to the product by the vendor, and to modify organizational workflow, policies and procedures (Borycki and Keay, 2010). An example of an issue found through this type of testing is that when a clinician accessed a patient record and was interrupted, the system potentially locked out other clinicians from the record during that time. This is a communication gap and safety issue (Kushniruk et al., 2010b).

Ethnography approaches, such as interviews, focus groups, surveys and observations can be used to study technology-based errors in the HIS once it is in use by clinicians in the healthcare environment. This approach has been used by such researchers as Ash, Koppel, Kushniruk and Borycki to understand safety issues and unintended consequences (Borycki and Keay, 2010). Ethnographic approaches are useful in finding certain types of errors, but some errors may be missed. Sometimes clinicians are not aware that errors occurred and thus do not report or describe them. Human biases can affect what is recalled by the clinicians and what is recorded and observed by the researchers. This type of evaluation can require months of time. Through ethnographic studies, researchers have been able to recommend that the government create error-reporting systems that collect details from clinicians about actual error and near-miss situations.

Case studies are used to understand the root causes of error after a system is implemented and an error has occurred. This evaluation method utilizes retrospective interviews, focus groups and observation (Borycki and Kushniruk, 2010). Through case studies, researchers identify the factors that contributed to the error. An example of a finding is physician uncertainty in handling unusual medication ordering scenarios (Borycki and

Keay, 2010).

The eight dimensional socio-technical framework can be a model for overall evaluation, especially with understanding how various dimensions of the system affect particular measurements (Sittig and Singh, 2010). Organizations can look to all dimensions to identify areas in need of improvement. Through continuous measurement, changes in one dimension can be analyzed for effectiveness in patient safety and other important areas. For example in the people dimension of the framework, the HIS skills and experience of clinicians would be an important metric for evaluation. As clinicians gain experience with a system, the computer-based error rates tend to decrease (Carvalho et al., 2009). Amount of training and level of skills may also effect error rates. Without continuous monitoring, it could be difficult to track the need for or effectiveness of training programs.

Vendors depend on post-implementation client evaluation and reporting to identify safety errors in design, coding, or implementation. It is also a source for enhancement and new feature requests. Vendors communicate with their clients through their support center, training and implementation staff, sales representatives, user communities and conferences (McDonnell et al., 2010).

Internal Organization

The internal influences of the organization's structure, culture, policies and procedures have a significant effect on the other dimensions in the framework (Sittig and Singh, 2010). Internal rules are often shaped by external regulations, and internal policies shape workflow, communication, people and software.

In a consensus statement by 13 experts on CPOE, it is advised that organizations ensure a culture that encourages feedback, quality improvement changes and continuous learning (Ash et al., 2003). Organizations should facilitate reporting of errors and other barriers to care (Sittig and Singh, 2009). UPMC has specific procedures and policies that are intended to identify risks and errors and quickly find resolutions. As technology-based errors occur, they are reviewed and interventions may be applied immediately. UPMC holds monthly reviews of all adverse events to understand trends. UPMC encourages software and design issues to be escalated to administration or safety champions when necessary. When clinicians fail to follow procedures, the events are reviewed by the manager and clinician to determine root causes and possible interventions (Santell et al., 2009). Additional examples of ways healthcare organizations facilitate error-reporting include encouraging error-reporting during system training and designing error-reporting features directly into the interface. Organizations can remind clinicians to report errors and provides contact information. Regular monitoring and evaluation of prescribing practices help to detect adverse prescribing practices (Goldstein et al., 2001).

Borycki and Kushniruk emphasize that HIS safety is directly associated with its “fit” within an organization. The internal structure, policies and culture can vary so much between two different healthcare organizations, a system that is successful and safe at one location is not necessarily going to be successful or safe at another (Hoffman and Podgurski, 2008). For example, there are significant differences in medication use processes depending on whether the organization is inpatient or outpatient, an academic or community facility, and adult and children's hospitals (Chuo and Hicks, 2008).

The policies and procedures of an organization need to be recognized in the customization and implementation of healthcare information systems. A common cause of error is failure to follow procedures and protocols (Santell et al., 2009). If the system

does not facilitate or enforce the organization's policies and procedures, then safety errors can occur with the introduction of HIS (Sittig and Singh, 2010). As workflows are modified to accommodate healthcare information systems, they need to be analyzed to ensure they still support current policy.

An unintended consequence of CPOE implementation is in the shifting of power between internal organizations and clinical roles (Ash et al., 2006). It is an important consequence to be aware of, as power influences what work gets done and how it is done. With the implementation of computer systems, more power shifts to the Information Technology department. In a pediatric hospital which saw increased adverse outcomes after CPOE implementation, the priority of medication fulfillment was determined by the pharmacy department's algorithm. Because medications were all moved to one centralized location as part of the implementation, physicians and nurses lost power in their ability to influence medication fulfillment (Han et al., 2005).

Organizational leadership influences budgets, resource allocations and procurement of healthcare information systems. The decision to buy a specific healthcare information system should be treated with care, as it is an expensive investment and usually too difficult and expensive to switch systems once the system has been implemented (Borycki et al., 2009; Hoffman and Podgurski, 2008). Potential technology-induced errors can be reduced if procurement activities are completed with safety in mind. Evaluations specific to the organization should be conducted to identify and prioritize safety issues and risks. Administrators can take actions to limit risk through interface redesign, customization, modification of workflow, customized training and performance tuning (Borycki et al., 2009). By identifying issues prior to signing a contract, there is a better chance that safety issues with software can be addressed by the vendor prior to implementation. A primary safety consideration in selecting a system that is safe is

usability. Other considerations include cost, reputation of vendor, support, standardization and interoperability (Kushniruk et al., 2010a).

A challenge in the procurement process is that software vendors often only allow limited access to their systems before purchase. Additionally, vendors typically do not share detailed information about known safety issues with their system during the procurement phase (Kushniruk et al., 2010a). Poor product selection can occur when the organization fails to thoroughly test the system, does not include clinicians in the process, does not consider the entire costs and resources, and does not follow best practices (Joint Commission, 2008). The cost of purchasing a CPOE system is estimated to be about 19% to 30% of a hospital's operating budget, and an additional annual expense of 3.4% to 14% for maintenance (Chuo and Hicks, 2008). Organizations should be cautious of blindly following vendor recommendations without the guidance of an objective third party (Joint Commission, 2008).

Workflow & Communication

The dimension on workflow and communication focuses on the steps in the process of healthcare delivery and the communication and interactions necessary between all participants. Safe and effective healthcare requires a coordinated effort within healthcare delivery teams and between departments within organizations.

The introduction of healthcare information systems can disrupt clinical workflows, both intentionally and unintentionally. Therefore, workflows in the healthcare environment should be thoroughly analyzed prior to and after implementation. Not only should the interaction between people be understood, but in more technically complex systems, the

interaction between parts of the HIS, such as devices, IV pumps and patient beds should also be analyzed (Kushniruk et al., 2006). It is also important to take note of the physical location of people, devices and systems throughout the workflow (Kushniruk et al., 2006).

It is common for healthcare information systems to not initially correspond with the workflows actually in use by clinicians. This mismatch has to be resolved through a change in the system, the workflow, or both (Sittig and Singh, 2010). Through their studies using clinical simulation, Borycki and Kushniruk have found that there can be a substantial difference between the workflow in place and the workflow necessary to accommodate the HIS. The systems require a workflow that is less flexible and more sequential (Borycki and Kushniruk, 2010). Actual clinician workflows are iterative processes more than sequential. Immediate goals change as new information is discovered, influencing decisions and priorities (Karsh et al., 2010). Kushniruk et al.'s (2010b) work found predictable errors during situations of stress and emergencies, thus recommending that healthcare information systems implement emergency override functions to allow the workflow to continue without strict sequential processing. A study of CPOE implementation by Han et al. (2005) found that in one hospital, the introduction of CPOE permanently changed the ways clinicians interacted with each other.

Allowing the vendor or healthcare information system to guide the workflow changes necessary during implementation may lead to unintended consequences. If the system only allows the patient record to be opened by a single clinician at a time, it could create delays as other clinicians are forced to wait to do their work (Han et al., 2005). During introduction of CPOE, policy changes were made at a hospital to not allow order entry until a patient was physically on site and had been completely registered in the system. This created a potential for delays in therapy and diagnostic testing (Han et al., 2005). A

healthcare information system has its own rules and concerns for the health of the patient which may not coincide with the concerns of the physician. For example, in urgent cases, long term management of hypertension is not the priority. The physician should be able to determine what the priority is and the system should facilitate the workflow of the clinical team focusing on that (Goldstein et al., 2001). Failure to allow this creates a potential source for technology-based error. Beyond the physician's priorities, goals and workflow, each role of the healthcare team has their own mental model they use in providing care. The system should let each clinician – nurse, pharmacist, specialist, etc. focus on their own priorities and responsibilities in the overall workflow rather than force clinicians to all work with the same interface and processes. If the system does not support individual roles, work may be delegated to others, causing resentment and inefficient care (Campbell et al., 2006). Even systems accommodating individual roles may shift the clinical work in unexpected ways, which could cause confusion or frustration (Joint Commission, 2008). Implementation of HIS can often put clinicians in front of computer screens when they were previously in front of patients or other clinicians. Spending more time away from patients can frustrate clinicians and create an environment where patients' immediate needs are not recognized or met. Singh et al. found that while electronic health records have a potential to improve fragmented outpatient care between practitioners, the systems themselves can also impact the level of follow-up. In the system they studied, they found a software configuration error to be the root of the problem in not alerting physicians to follow up with patients (Singh et al., 2009b).

When healthcare information systems do not meet the complex needs of healthcare providers, the providers will adapt and create a workaround (Ash et al., 2004). These workarounds are usually unintended consequences that can introduce errors (Cheng et al., 2003). It is likely that a technical solution such as a reconfiguration or simple

customization could be found to address the problem. However, it could also be that the system was not designed for the complexities of clinical work, and the clinicians will need to adapt their workflow. The existence of workarounds is another reason why organizations should be regularly monitoring how their systems are being used by clinicians.

Closely tied to the clinical workflow is the communication between clinicians, patients, administration, vendors and the technology staff. Successful healthcare delivery requires that care be coordinated through timely and meaningful communication (Horsky et al., 2005a). Communication in healthcare is greater than the transfer of information. It is a way of guiding clinicians to take specific actions, ensuring other clinicians understand the situation, and a method for building professional relationships (Ash et al., 2004). Miscommunication and other communication failures can result in missed medication or tests, diagnostic errors and adverse events (Ash et al., 2004; Singh et al., 2010).

Healthcare information system implementation can have a direct effect on communication. When clinicians communicate with each other through what they enter into the computer instead of through face-to-face communication, organizations risk reduced quality of communication (Ash et al., 2004). In a qualitative study of unintended consequences for CPOE implementations, respondents commented that there was less face-to-face communication, people relied heavily on computers in directing their work, and that some clinicians assumed if the information was in the system, it did not need to be communicated to anyone directly (Ash et al., 2007). In a qualitative study by Campbell et al. (2006), experts suggested that errors were more likely due to fewer planning and coordination discussions amongst the entire clinical team. An advantage of in person discussions is that they provide immediate feedback from other clinicians which may influence the care plan for the patient (Han et al., 2005). HIS can facilitate

better communication in some ways, as patient records can be more accessible and prescriptions are more legible. Organizations can also counteract the effect, as one ICU team did through increased verbal communication and added verification tasks (Cheng et al., 2003).

People

The people dimension represents all the people who come in contact with the system. This includes clinicians, administration, developers, testers, trainers and even patients. When implementing new systems, CPOE experts advise that the people issues should have the highest priority. Clinicians should be informed, engaged and content (Ash et al., 2003).

As adoption of healthcare information systems grows, there is a need for new skills. Healthcare professionals must learn how to incorporate technology into their daily work, and technology professionals must learn more about the healthcare industry. Healthcare organizations offer training to clinicians prior to HIS implementation. However, this training can be insufficient, with one study showing a hospital offered just 3 hours of CPOE training 3 months in advance (van Rosse et al., 2009). Insufficient training and lack of experience with systems can lead to the system being used in ways that were not intended, incorrect assumptions and technology-based errors (Horsky et al., 2005a; Santell et al., 2009). A successful HIS implementation requires adequate staff training and support, with significant attention to both in the early period of HIS use by clinicians, as this is when lack of experience contributes to more errors (Carvalho et al., 2009; Palmieri et al., 2008).

Nationally, there is a shortage of professionals with clinical informatics skills. The federal government has offered scholarships towards clinical informatics degrees, and other training options include the “10x10 Training Programs” started by the American Medical Informatics Association (Sittig and Singh, 2009).

It is important that in training, clinicians be made aware of the risks of e-iatrogenesis. In addition to training, clinicians and administrators should be alerted about the risk of technology-based errors through their vendors, professional organizations, and publications. Research articles on e-iatrogenesis should not be limited to informatics journals, but also include healthcare management and clinical journals so that clinicians and administrators are aware. Few technology-based error studies have been found in management and clinical journals (Harrington et al., 2011).

Clinicians have an understanding of how HIS works in their minds. In some cases, this differs from reality. This misunderstanding occurs when the clinicians hold incorrect assumptions about the system, and can lead to errors. Many clinicians hold beliefs that the system does more than it actually does. Some assume that electronic transmissions are immediate and guaranteed, that notifications are accurate and that processes complete when they are initiated (Campbell et al., 2006; Campbell et al., 2007). There are incorrect assumptions that data entered into the computer is useful once it is in the system, no matter what the form of the data or location of the data is (Campbell et al., 2007). There can be assumptions that the computer has features that the system is actually not designed or configured for, such as a thorough analysis of drug-drug interactions. Clinicians can place too much trust that the system will catch and remove errors, and thus fail to ensure that medication orders are correct (Shulman et al., 2005). There can also be misunderstanding in how a particular feature works. For example, when medication orders are revised, it should be clear to the ordering clinician and the pharmacist whether

an order for a smaller dose than previous means to add the smaller dose to the original, or to discontinue the first dose and start just the smaller dose. Some clinicians may assume that ordering a drug in a different amount automatically discontinues the existing order, when it does not (Spencer et al., 2005). The best ways to address false expectations is through comprehensive training and proper interface design (Goldstein et al., 2001).

An important aspect of the people dimension in healthcare is the cognitive thinking and decision-making on the part of clinicians. Healthcare information systems should be designed to facilitate cognitive thinking rather than interfere with it. Borycki and Kushniruk (2010) have found that the interface design of electronic medical record has a strong influence on a clinician's cognitive work. Instead of following a standard cognitive process taught in medical school and used throughout healthcare, clinician's thinking is instead shaped by the interface design. Poor interface design can lead to cognitive overload (Ash et al., 2004; Goldstein et al., 2001; Kushniruk et al., 2006). This happens when clinicians have to attend to tedious interface tasks rather than maintain their overall thought process. Free form writing is often part of the cognitive processing a clinician does. When using an overly structured interface, they focus on the structure of the details rather than problem-solving (Ash et al., 2004). When problem solving is changed as a result of the design of healthcare information systems, errors can occur (Goldstein et al., 2001).

Designers need to understand the context and environment in which clinicians work. Many cognitive activities are context-dependent and valuable insights can be obtained through direct observation (Horsky et al., 2005a). During stressful or time critical situations, there can be a need to bypass the standard processes, structure, alerts and other safety-based restrictions. Without it, the cognitive process is burdened with stress that is technology-induced (Kushniruk et al., 2006). Clinicians work in a context of interruptions

and multiple activities simultaneously occurring (Ash et al., 2003). Kushniruk et al. have found that patients being present at an encounter creates complex social interactions, which leads to clinicians having more problems with the system when compared to clinicians working directly with the system in isolation (Kushniruk et al., 2010b). Interruptions and context-switching are common for clinicians, so interfaces should be designed with that understanding. Screens should clearly display the logged in user, the current patient, and allow clinicians to return to where they were at a later point. For example, if a physician processing alert notifications is interrupted, one system has a feature that allows them to renew the alert so they can return to it and it is not forgotten (Singh et al., 2010).

In designing HIS interface for safety and usability, system designers must have an understanding of how clinicians think, problem solve, and make decisions. They should also be aware that the design of the interface can facilitate or negatively impact the cognitive process. The right information should be presented or requested in the most appropriate form, and at the right time (Horsky et al., 2005a). Attention should be given to the design of the ordering process, as this is time when the clinician's thoughts direct actions that directly affect patient care (Eslami et al., 2007). Horsky et al. have found through discussions with HIS developers that the cognitive aspects do not seem to be regularly considered when designing systems (Horsky et al., 2005a).

While people are often involved with errors occurring, they can also be an essential part of catching errors before they affect patients. Clinicians that know their patients and the patient's conditions well are likely to notice and question abnormal results and medication orders (McDonald, 2006). It is typical for workflows to include multiple clinicians checking orders before medication reaches the patient, so many errors are caught before the error reaches the patient (Singh et al., 2009a). However, if the

introduction of HIS reduces the number of humans who review and check the orders, errors that would have been normally caught may be missed (McDonald, 2006).

The people and context of their work is a significant consideration in the study of e-iatrogenesis. In an analysis of errors reported to Medmarx, for errors where at least one cause was identified, knowledge deficiency was the leading cause. For the errors where at least one contributing factor was identified, the leading cause was distractions, then staff inexperience and heavy workload (Zhan et al., 2006).

Human-Computer Interface

The human-computer interface includes the physical attributes of the system that interact with humans as well as the manner in which humans and computers interact with each other. Many of the challenges with using healthcare information systems are attributed to issues with the interface (Sittig and Singh, 2010).

Findings from a study of e-prescribing found that there were more errors in the process of prescribing medications than in the decision of what medications to prescribe (Donyai et al., 2007). A study of errors reported to Medmarx found a significant number of errors related to computer entry (Zhan et al., 2006). In a study of pediatric CPOE, Walsh et al. (2006) found evidence that human-computer interface issues can create a safety risk to patients. In a study of mobile devices, Borycki and Kushniruk (2010) found that all medication errors were associated with at least one usability issue.

Many of the issues with human-computer interfaces is in the design and functionality of data entry and informational screens. The examples of interfaces problems found in the

literature are numerous. When developers include too much information on a screen, critical information can be missed and errors can result (Sittig and Singh, 2009). Similarly, clinicians have reported having to view up to 20 screens just to view the entirety of a patient's medications (Koppel et al., 2005). When alerts and warnings all look the same despite severity, it is difficult for the clinician to distinguish which require the most consideration. A common error due to interface design is when clinicians select the wrong item (medication, patient, etc.) from a drop down list because they inadvertently select an item above or below the intended selection (Campbell et al., 2006; Koppel et al., 2005). When clinicians don't know exactly where a data item belongs, they will often enter it in a field that sounds the closest (Campbell et al., 2006). Many drug names look alike, and when they are listed in alphabetical order, it can be easy to select the name of a drug that is similar sounding to the drug that was intended (Santell et al., 2009). Issues with appearance, organization and navigation can make it difficult for clinicians to find the information they need (Ash et al., 2004). Inconsistencies in design within a system and between different systems lead to errors and confusion for clinicians (Horsky et al., 2005a).

Usability issues with an interface can greatly increase the time needed to complete a task for clinicians who are already quite busy (Ash et al., 2004). Interface problems can slow down users because they distract them from the overall tasks (Salvemini, 1998). In user centered design, the interface should be tested for user performance to ensure that the interface is effective. Introduction of CPOE systems have lead to increased time in completing the same task. In one example, each order took 1-2 minutes compared to previously taking a few seconds prior to implementation (Han et al., 2005). While time may be lost through initial entry, some of it can be recovered due to overall efficiency and increased safety.

Horsky et al. warns that inattention to human-computer interaction principles in the development of healthcare information systems is a serious safety issue (Horsky et al., 2005b). System interfaces should be designed and tested with usability and safety in mind, ideally from the beginning of a product's lifecycle. This practice would reduce errors, inefficiencies and frustrations related to interfaces. Designing and evaluating the interface for usability and safety requires specific expertise. While vendors do use some usability engineering practices and include end users through the process, they do not commonly use more formal and rigorous practices, such as usability testing, user-centered design, and including experts in the field of human-factors engineering and usability engineering (Bates, 2003; McDonnell et al., 2010).

There are challenges in getting vendors to design better interfaces. Vendors consider their interface to be a key competitive differentiator, and therefore do not collaborate with other vendors in terms of usability (McDonnell et al., 2010). Vendors do not share reports of errors and safety incidents relating to the design of the interface. There are not many easily accessed best practices in design, testing and monitoring for usability specific to healthcare information systems. Some vendors do use general software best practices and proprietary best practices (McDonnell et al., 2010). In discussions with vendors, many were open to the idea of an independent organization developing industry-specific best practices in usability.

Clinical Content

The clinical content includes the information about the patient, clinical decision support, rules for alerts, and vocabulary. It is the logic and data in the healthcare information system that is specific to healthcare (Sittig and Singh, 2010). The content should be

accurate, complete, based on evidence, and monitored (Sittig and Singh, 2009).

In a review of studies on the quality of data contained in a computer-based patient record, it was found that accuracy overall was “fair to good”. Data entry and transcription were considered minor causes for inaccurate data, with the most common cause for inaccurate data being the patient themselves, through offering incorrect data or medication changes (Hogan and Wagner, 1997). Monitoring data to improve accuracy seems to have a significant influence on accuracy levels. Structured forms were associated with improved completeness compared to unstructured forms. When multiple clinical systems exist within an organization but are not integrated well, the data in each can become outdated, incomplete or inconsistent (Joint Commission, 2008). There are conflicting findings on whether data accuracy is improved with direct clinician data entry. Clinicians often have their own opinions on the quality of data which may or may not align with its accuracy, and may have more to do with the source of the data. Some clinicians are highly skeptical that the data they read is correct, while others are quite trusting (Campbell et al., 2006).

Incomplete or missing information is a common issue. In a study involving primary care physicians, they reported missing clinical information in 13.6% of visits. The missing information was often located outside of the physician's system, could adversely affect the patient, and could cause duplicate services or delayed care. Physicians also spent a lot of time searching for information without finding it (Smith et al., 2005). In one study, about half of medication errors were associated with missing information about the patient and drug (Bates, 2001).

Clinical decision support includes order sets, reminders, alerts and other drug and disease information. Alerts which have been implemented poorly have been found to be less effective than intended, causing alert fatigue with clinicians. Clinicians override 49% to

96% of drug safety alerts (van der Sijs et al., 2006). Some clinicians get as many as 950 alerts per day (Singh et al., 2010). The primary causes behind alert fatigue include too many low priority alerts (Bates, 2010), irrelevance, and displayed repeatedly (van der Sijs et al., 2006). Additional reasons to override alerts include treatment requiring same drug, clinician believing other information or own knowledge, incorrect information and lack of time. Some systems do not follow human factors best practices so severity levels are difficult to distinguish and processing alerts can be tedious (Phansalkar et al., 2010).

Improving the alerts for clinicians could be addressed in a number of ways. Fewer to no low-priority alerts should be shown. Alerts should be more sensitive, with only a limited number of high importance alerts being shown (Strom et al., 2010). Alerts could have increased sensitivity if healthcare information systems support alerts that incorporated age, sex, weight, allergies, circumstances and drug serum levels and that data was available to the system (van der Sijs et al., 2006). Alerts could be adjusted to only include the more common drug-drug interactions versus those which are rare (Nebeker et al., 2005). The alerts should display brief information with a clear indicator of the severity, and present alternative actions (van der Sijs et al., 2009). Drug databases should be as current as possible. As alerts are based on evidence based clinical guidelines, they should be regularly updated to prevent errors from outdated advice (Borycki and Kushniruk, 2008). Bates calls for better evidence in understanding which drug-drug interactions are most important (2010). One approach to improve alert effectiveness is to require a response by clinicians to explain why they are overriding the alert (Strom et al., 2010). Another approach is to prevent clinician from completing the order, however, this can result in delayed orders and frustrated clinicians.

Healthcare information systems have a strong influence on how clinicians order drugs. In a study of adverse drug events in a hospital using HIS, Nebeker et al. found that 93% of

adverse drug events were dose related. Clinicians quite often rely on CPOE displays to determine dose ranges. In one study, 38% to 41% did so a few times weekly. However, not all CPOE systems were designed to provide that information. In this particular study, the CPOE displayed dosages based on the pharmacy stocking units, not clinical guidelines (Koppel et al., 2005). CPOE systems should be built to include information on effective dosing levels as well as unsafe dosing levels. Beyond clinical guidelines, systems should consider patient-specific information to customize the recommendation whenever possible (Nebeker et al., 2005).

Healthcare information systems can also influence how clinicians interpret diagnostic tests. Another example of decision support is computer interpretation of electrocardiograms (EKGs). Tsai et al. (2003) studied the relationship between resident physicians readings of EKGs and their relationship to correct or incorrect computer interpretation of EKGs. Correct computer interpretations positively influenced the accuracy in EKG interpreting. However, incorrect computer interpretations negatively influenced the accuracy in EKG interpreting. This study showed that physicians were biased towards the computer interpretation, whether it was correct or not. This has implications on many areas where the healthcare information system offers guidelines and advice. Clinicians will often rely on the data, so there is a need for it to be correct.

Hardware & Software

The hardware and software dimension of healthcare information systems consist of the entire infrastructure necessary for the system to operate: the computers, devices, network, storage, power, cooling systems, operating system, applications, backup and disaster recovery systems. The hardware and software need to be designed, developed, tested and

supported by the system vendor. The system needs to be evaluated, procured, tested, tuned, backed up, implemented, maintained and monitored by the healthcare organization (Campbell et al., 2006).

System availability is crucial to smooth operations of a healthcare organization. Many healthcare organizations have suffered unexpected and planned downtimes, some quite frequently. A manager of a CPOE system shared that the system crashed 2 to 3 times per week, often for a period of 15 minutes each (Koppel et al., 2005). When the system becomes partially or completely unavailable, organizations have backup procedures in place to continue care delivery. Despite these procedures, providers have described the downtime period as “organized chaos” and productivity plummets during this time (Ash et al., 2007). Backup processes should be well designed to not interrupt work flow, otherwise downtime will disrupt the organization's ability to function (Campbell et al., 2006). Clinicians may lose access to historical data at this time, hindering care (Campbell et al., 2007). Some backup procedures may revert to a paper-based system during downtime. Besides risking errors, downtime is costly, requiring 4.5 minutes to complete work for every 1 minute the system was down (Campbell et al., 2007).

Proper sizing, configuration, maintenance and monitoring of systems is critical (Sittig and Singh, 2009). It is natural for systems to need security and maintenance patches, upgrades, and growing capacity needs for storage, processing, and network bandwidth. When these requirements are not met, performance can be hindered, the system can malfunction or completely fail (Ash et al., 2007). As systems are upgraded and features changed, clinicians need to be trained on new features and implications of changes (Campbell et al., 2006).

Healthcare organizations should strive to have systems that interoperate with each other

as much as possible. In one instance, an increase in errors at a hospital implementing CPOE was attributed to the lack of direct connection between the CPOE and pharmacy computer system (Spencer et al., 2005). Miscommunication between CPOE and other systems can lead to errors as well (Weiner et al., 2007). Systems for demonstrations, testing and training should be as isolated as possible from production systems. Serious errors can occur if users enter test orders for test patients and the order crosses over to a production system (Campbell et al., 2006).

Even with some organizations that have implemented HIS, paper is used to fill gaps in systems, being used as backup systems for recording data, temporary data repositories and providing information to patients (Donyai et al., 2007; Dykstra et al., 2009). Such hybrid systems can increase the risk of errors as there can be multiple locations for information. This can result in confusion, inadvertent duplication or important information being lost (Koppel et al., 2005; Santell et al., 2009).

Healthcare information systems should be built with safety in mind (Walker et al., 2008). In high-hazard industries, there are strict programming standards and guidelines. Clinicians have expectations that system developers recognize the severity of risks in the healthcare industry and follow similar standards (Borycki and Kushniruk, 2008). Unfortunately many vendors have not lived up to that expectation in their design, development and testing of products. Healthcare products are unfortunately known for being unreliable. In interviews with software vendors, McDonnell et al. (2010) found few that initially claimed patient safety was a top priority. Instead, they were focused on making their product more usable.

Software requirements specification can be inadequate or otherwise poorly done. When they are not accurate and complete, there is a disconnect between the expectations of the

clinicians, the administration and the software vendor (Borycki and Kushniruk, 2008). A promising finding from discussions with EHR vendors is that they all reported involving end users throughout the design and development process (McDonnell et al., 2010). Yet, there can still be problems with the process. Due to the complexities of healthcare, it can be challenging for a clinician to describe what they need. Too much functionality for users can be just as detrimental to the success of a system as not enough functionality. Often the clinician does not know how to describe their tasks in a way that is necessary for specifications, and the way clinicians describe their work may differ from how they actually perform their work (Borycki et al., 2010). The challenges in designing excellent healthcare information systems will only be solved by collaborating with experts outside the field of medicine and computer science, such as human factors engineers, applied psychologists, medical sociologists, communication scientists, cognitive scientists and interaction designers (Karsh et al., 2010). Due to the nature of the healthcare industry, software vendors should follow thorough usability, safety and system testing before their clients use it. It is important that technology-based errors get caught earlier in the software lifecycle, rather than being discovered after implementation. As researchers develop better methodologies for safety testing, vendors should adopt them (Borycki et al., 2009). Many systems have been implemented without basic usability testing by clinicians (Kushniruk et al., 2010b). Poor programming, requirements specification, design, customization and testing can lead to errors after implementation.

Conclusion

The eight sociotechnical dimensions of healthcare information systems framework is a powerful model in analyzing potential and existing areas of e-iatrogenesis. It is a useful model for examining specific implementations as well as framing the information from

the literature on health information system safety.

Health information systems will require a significant effort on the part of vendors and healthcare organizations to be safe and effective. By reviewing the literature in terms of the framework, numerous issues and areas for improvement in safety were identified and discussed. While some of the improvements are not too difficult to implement, the greater challenge is that fundamental aspects of many healthcare information systems need to be redesigned with the complex healthcare environment in mind. In the meantime, there are many areas in which organizations can focus their efforts on increasing patient safety and improving outcomes through the use of healthcare information systems.

References

- Ammenwerth, E., and N. T. Shaw. 2005. Bad health informatics can kill - is evaluation the answer? *Methods of Information in Medicine* 44(1):1-3.
- Ash, J. S., P. Z. Stavri, and G. J. Kuperman. 2003. A consensus statement on considerations for a successful CPOE implementation. *Journal of the American Medical Informatics Association* 10(3):229-234.
- Ash, J. S., M. Berg, and E. Coiera. 2004. Some unintended consequences of information technology in health care: The nature of patient care information system-related errors. *Journal of the American Medical Informatics Association* 11(2):104-112.
- Ash, J. S., D. F. Sittig, E. Campbell, K. Guappone, and R. Dykstra. 2006. An unintended consequence of CPOE implementation: Shifts in power, control, and autonomy. *AMIA 2006 Symposium Proceedings*:11-15.
- Ash, J. S., D. F. Sittig, E. G. Poon, K. Guappone, E. Campbell, and R. H. Dykstra. 2007b. The extent and importance of unintended consequences related to computerized provider order entry. *Journal of the American Medical Informatics Association* 14(4):415-423.
- Ash, J. S., C. M. Kilo, M. Shapiro, J. Wasserman, C. McMullen, and W. Hersh. 2011. *Roadmap for Provision of Safer Healthcare Information Systems: Preventing e-Iatrogenesis*. <http://www.iom.edu/~media/Files/Report%20Files/2011/Health-IT/Commissioned-paper-Roadmap-for-Provision-of-Safer-HIS.pdf> (accessed April 10, 2012).
- Bates, D. W. 2010. CPOE and clinical decision support in hospitals: Getting the benefits. *Archives of Internal Medicine* 170(17):1583-1584.
- Bates, D. W., M. Cohen, L. L. Leape, M. Overhage, M. M. Shabot, and T. Sheridan. 2001. Reducing the frequency of errors in medicine using information technology. *Journal of the American Medical Informatics Association* 8(4):299-308.
- Bates, D. W., G. J. Kuperman, S. Wang, et al. 2003. Ten commandments for effective clinical decision support: Making the practice of evidence-based medicine a reality. *Journal of the American Medical Informatics Association* 10(6):523-30.
- Borycki, E. M., and E. Keay. 2010. Methods to assess the safety of health information systems. *Healthcare Quarterly* 13:47-52.
- Borycki, E. M., and A. W. Kushniruk. 2008. Where do technology-induced errors come from? Towards a model for conceptualizing and diagnosing errors caused by technology. In *Human, social, and organizational aspects of health information systems*, edited by A. W. Kushniruk and E. M. Borycki. Hershey, PA: Medical Information Science Reference. Pp. 148-166.

- . 2010. Towards an integrative cognitive-socio-technical approach in health informatics: Analyzing technology-induced error involving health information systems to improve patient safety. *The Open Medical Informatics Journal* 4:181-187.
- Borycki, E. M., A. W. Kushniruk, and J. Brender. 2010. Theories, models and frameworks for diagnosing technology-induced error. *Studies of Health Technology Information* 160(1):714-718.
- Borycki, E. M., A. W. Kushniruk, E. Keay, J. Nicoll, J. Anderson, and M. Anderson. 2009. Toward an integrated simulation approach for predicting and preventing technology-induced errors in healthcare: Implications for healthcare decision-makers. *Healthcare Quarterly* 12(Special):90-96.
- Campbell, E. M., D. F. Sittig, J. S. Ash, K. P. Guappone, and R. H. Dykstra. 2006. Types of unintended consequences related to computerized provider order entry. *Journal of the American Medical Informatics Association* 13(5):547-556.
- Campbell, E. M., D. F. Sittig, K. P. Guappone, H. R. Dykstra, and J. S. Ash. 2007. Overdependence on technology: An unintended adverse consequence of computerized provider order entry. *AMIA 2007 Symposium Proceedings*:94-98.
- Carayon, P., H. A. Schoofs, B.-T. Karsh, A. P. Gurses, C. J. Alvarado, M. Smith, and B. P. Flatley. 2006. Work system design for patient safety: The SEIPS model. *Quality and Safety in Health Care* 15(Suppl 1):i50-i58.
- Carvalho, C. J., E. M. Borycki, and A. W. Kushniruk. 2009. Ensuring the safety of health information systems: Using heuristics for patient safety. *Healthcare Quarterly* 12:49-54.
- Chaudhry, B., J. Wang, S. Wu, M. Maglione, W. Mojica, E. Roth, S. C. Morton, and P. G. Shekelle. 2006. Systematic review: Impact of health information technology on quality, efficiency, and costs of medical care. *Annals of Internal Medicine* 144(10):742-752.
- Cheng, C. H., M. K. Goldstein, E. Geller, and R. E. Levitt. 2003. The effects of CPOE on ICU workflow: An observational study. *AMIA 2003 Symposium Proceedings*:150-154.
- Chuo, J., and R. W. Hicks. 2008. Computer-related medication errors in neonatal intensive care units. *Clinics in Perinatology* 35:119-139.
- Donyai, P., K. O'Grady, A. Jacklin, N. Barber, and B. D. Franklin. 2007. The effects of electronic prescribing on the quality of prescribing. *British Journal of Clinical Pharmacology* 65(2):230-237.

- Dykstra, H. R., J. S. Ash, E. Campbell, D. F. Sittig, K. Guappone, J. Carpenter, J. Richardson, A. Wright, and C. McMullen. 2009. Persistent paper: The myth of "going paperless". *AMIA 2009 Symposium Proceedings*:158-162.
- Eslami, S., A. Abu-Hanna, N. F. De Keizer, and E. de Jong. 2006. Errors associated with applying decision support by suggesting default doses for aminoglycosides. *Drug Safety* 19(9):803-809.
- Goldstein, M. K., B. B. Hoffman, R. W. Coleman, S. W. Tu, R. D. Shankar, M. O'Connor, S. Martins, A. Advani, and M. A. Musen. 2002. Patient safety in guideline-based decision support for hypertension management: ATHENA DSS. *Journal of the American Medical Informatics Association* 9(6):s11-s16.
- Goodman, K. W., E. S. Berner, M. A. Dente, B. Kaplan, R. Koppel, D. Rucker, D. Z. Sands, and P. Winkelstein. 2011. Challenges in ethics, safety, best practices, and oversight regarding HIT vendors, their customers, and patients: A report of an AMIA special task force. *Journal of the American Medical Informatics Association* 18:77-81.
- Han, Y. Y., J. A. Carcillo, S. T. Venkataraman, R. S. B. Clark, R. S. Watson, T. C. Nguyen, H. Bayir, and R. A. Orr. 2005. Unexpected increased mortality after implementation of a commercially sold computerized physician order entry system. *Pediatrics* 116(6):1506-1512.
- Harrington, L., D. Kennerly, and C. Johnson. 2011. Safety issues related to the electronic medical record (EMR): Synthesis of the literature from the last decade, 2000–2009. *Journal of Healthcare Management* 56(1):31-44.
- Hoffman, S., and A. Podgurski. 2011. Meaningful use and certification of health information technology: What about safety? *Journal of Law, Medicine and Ethics* 39(Suppl. 1):77-80.
- Hogan, W. R., and M. M. Wagner. 1997. Accuracy of data in computer-based patient records. *Journal of the American Medical Informatics Association* 4(5):342-355.
- Horsky, J., G. J. Kuperman, and V. L. Patel. 2005a. Comprehensive analysis of a medication dosing error related to CPOE. *Journal of the American Medical Informatics Association* 12(4):377-382.
- Horsky, J., J. Zhang, and V. L. Patel. 2005b. To err is not completely human: Complex technology and user cognition. *Journal of Biomedical Informatics* 38:264-266.
- Institute of Medicine. 1999. *To err is human: Building a safer health system*. Washington, D.C.: National Academy Press.
- Institute of Medicine. 2001. *Crossing the quality chasm: A new health system for the 21st century*. Washington, D.C.: National Academy Press.

- Joint Commission on Accreditation of Healthcare Organizations. 2008. Safely implementing health information and converging technologies. *Sentinel Event Alert* 42:1-4.
- Karsh, B.-T., M. B. Weinger, P. A. Abbott, and R. L. Wears. 2010. Health information technology: Fallacies and sober realities. *Journal of the American Medical Informatics Association* 17:617-623.
- Koppel, R., and D. Kreda. 2009. Health care information technology vendors' —hold harmless clause: Implications for patients and clinicians. *Journal of the American Medical Association* 301(12):1276-1278.
- Koppel, R., J. P. Metlay, A. Cohen, B. Abaluck, A. R. Localio, S. E. Kimmel, and B. L. Strom. 2005. Role of computerized physician order entry systems in facilitating medication errors. *Journal of the American Medical Association* 293(10):1197-1203.
- Kushniruk, A. W., M.-C. Beuscart-Zephir, A. Grzes, E. M. Borycki, L. Watbled, and J. L. Kannry. 2010a. Increasing the safety of healthcare information systems through improved procurement: Toward a framework for selection of safe healthcare systems. *Healthcare Quarterly* 13.
- Kushniruk, A. W., E. M. Borycki, M. H. Kuo, and S. Kuwata. 2010b. Integrating technology- centric and user-centric system testing methods: Ensuring healthcare system usability and safety. *Studies of Health Technology Information* 57:181-186.
- Kushniruk, A. W., E. M. Borycki, S. Kuwata, and J. L. Kannry. 2006. Predicting changes in workflow resulting from healthcare information systems: Ensuring the safety of healthcare. *Healthcare Quarterly* 9(Special):114-118.
- Kushniruk, A. W., M. M. Triola, E. M. Borycki, B. Stein, and J. L. Kannry. 2005. Technology induced error and usability: The relationship between usability problems and prescription errors when using a handheld application. *International Journal of Medical Informatics* 74:519-526.
- Lenzer, J., and S. Brownless. 2010. Why the FDA can't protect the public. *British Medical Journal* 341:966-968.
- Magrabi, F., M.-S. Ong, W. Runciman, and E. Coiera. 2010. An analysis of computer-related patient safety incidents to inform the development of a classification. *Journal of the American Medical Informatics Association* 17(6):663-670.
- McDonald, C. J. 2006. Computerization can create safety hazards: A bar-coding near miss. *Annals of Internal Medicine* 144(7):510-516.

- McDonnell, C., K. Werner, and L. Wendel. 2010. *Electronic health record usability: Vendor practices and perspectives*. Rockville, MD: Agency for Healthcare Research and Quality.
- Miller, R. A., and R. M. Gardner. 1997. Recommendations for responsible monitoring and regulation of clinical software systems. *Journal of the American Medical Informatics Association* 4(6):442-457.
- Nebeker, J. R., J. M. Hoffman, C. R. Weir, C. L. Bennett, and J. F. Hurdle. 2005. High rates of adverse drug events in a highly computerized hospital. *Archives of Internal Medicine* 165 (10):1111-1116.
- Palmieri, P. A., L. T. Petersen, and E. W. Ford. 2008. Technological iatrogenesis: New risks force heightened management awareness. *Journal of Healthcare Risk Management* 27(4):19-24.
- Phansalkar, S., J. Edworthy, E. Hellier, D. L. Seger, A. Schedlbauer, A. J. Avery, and D. W. Bates. 2010. A review of human factors principles for the design and implementation of medication safety alerts in clinical information systems. *Journal of the American Medical Informatics Association* 17:493-501.
- Salvemini, A. V. 1998. Improving the human-computer interface: A human factors engineering approach. M.D. *Computing* 15(5):311-315.
- Santell, J. P., J. G. Kowiatek, R. J. Weber, R. W. Hicks, and C. A. Sirio. 2009. Medication errors resulting from computer entry by nonprescribers. *American Journal of Health-System Pharmacists* 66:843-853.
- Shamliyan, T. A., S. Duval, J. Du, and R. L. Kane. 2008. Just what the doctor ordered. Review of the evidence of the impact of computerized physician order entry system on medication errors. *Health Services Research* 43(1):32-53.
- Shulman, R., M. Singer, J. Goldstone, and G. Bellingan. 2005. Medication errors: A prospective cohort study of hand-written and computerised physician order entry in the intensive care unit. *Critical Care* 9(5):516-521.
- Singh, H., S. Mani, D. Espadas, N. Petersen, V. Franklin, and L. A. Petersen. 2009a. Prescription errors and outcomes related to inconsistent information transmitted through computerized order-entry: A prospective study. *Archives of Internal Medicine* 169(10):982-989.
- Singh, H., L. Wilson, L. A. Petersen, M. K. Sawhney, B. Reis, D. Espadas, and D. F. Sittig. 2009b. Improving follow-up of abnormal cancer screens using electronic health records: Trust but verify test result communication. *BMC Medical Informatics and Decision Making* 9:49.

- Singh, H., L. Wilson, B. Reis, M. K. Sawhney, D. Espadas, and D. F. Sittig. 2010. Ten strategies to improve management of abnormal test result alerts in the electronic health record. *Journal of Patient Safety* 6(2):1-3.
- Sittig, D. F., and D. C. Classen. 2010. Safe electronic health record use requires a comprehensive monitoring and evaluation framework. *Journal of the American Medical Association* 303(5):450-451.
- Sittig, D. F., and H. Singh. 2009. Eight rights of safe electronic health record use. *Journal of the American Medical Association* 302(10):1111-1113.
- . 2010. A new sociotechnical model for studying health information technology in complex adaptive healthcare systems. *Quality and Safety in Health Care* 19(Suppl. 3):i68-i74.
- Smith, P. C., R. Araya-Guerra, C. Bublitz, B. Parnes, L. M. Dickinson, R. Van Vorst, J. M. Westfall, and W. D. Pace. 2005. Missing clinical information during primary care visits. *Journal of the American Medical Association* 293(5):565-571.
- Spencer, D. D., A. Leininger, R. Daniels, R. P. Granko, and R. R. Coeytaux. 2005. Effect of a computerized prescriber-order-entry system on reported medication errors. *American Journal of Health-System Pharmacists* 62(4):416-419.
- Strom, B. L., R. Schinnar, F. Aberra, W. Bilker, S. Hennessy, C. E. Leonard, and E. Pifer. 2010. Unintended effects of a computerized physician order entry nearly hard-stop alert to prevent a drug interaction: A randomized controlled trial. *Archives of Internal Medicine* 170(17):1578-1583.
- Thompson, D. A., L. Duling, C. G. Holzmueller, T. Dorman, L. H. Lubomski, F. Dickman, M. Fahey, L. L. Morlock, A. W. Wu, and P. J. Provonost. 2005. Computerized physician order entry, a factor in medication errors: Descriptive analysis of events in the intensive care unit safety reporting system. *Journal of Clinical Outcomes Management* 12(8):407-412.
- Tsai, T. L., D. B. Fridsma, and G. Gatti. 2003. Computer decision support as a source of interpretation error: The case of electrocardiograms. *Journal of the American Medical Informatics Association* 10(5):478-483.
- U.S. Department of Health and Human Services. 2010. *HIT safety hearing*. http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_911062_0_0_18/2010-02-25_policy_ca_transcript_draft.pdf (accessed March 22, 2011).
- van der Sijs, H., J. Aarts, A. Vulto, and M. Berg. 2006. Overriding of drug safety alerts in computerized physician order entry. *Journal of the American Medical Informatics Association* 13(2):138-147.

- van der Sijs, H., L. Lammers, A. van den Tweel, J. Aarts, M. Berg, A. Vulto, and T. van Gelder. 2009. Time-dependent drug–drug interaction alerts in care provider order entry: Software may inhibit medication error reductions. *Journal of the American Medical Informatics Association* 16(6):864-868.
- van Rosse, F., B. Maat, C. M. A. Rademaker, A. J. van Vught, A. C. G. Egberts, and C. W. Bollen. 2009. The effect of computerized physician order entry on medication prescription errors and clinical outcome in pediatric and intensive care: A systematic review. *Pediatrics* 123(4):1184-1190.
- Walker, J. M., P. Carayon, N. Leveson, R. A. Paulus, J. Tooker, H. Chin, J. Albert Bother, and W. F. Stewart. 2008. EHR safety: The way forward to safe and effective systems. *Journal of the American Medical Informatics Association* 15:272-277.
- Walsh, K. E., W. G. Adams, H. Bauchner, R. J. Vinci, J. B. Chessare, M. R. Cooper, P. M. Hebert, E. G. Schainker, and C. P. Landrigan. 2006. Medication errors related to computerized order entry for children. *Pediatrics* 118(5):1872-1879.
- Weiner, J. P., T. Kfuri, K. Chan, and J. B. Fowles. 2007. "E-iatrogenesis": The most critical unintended consequence of CPOE and other HIT. *Journal of the American Medical Informatics Association* 14(3):387-388.
- Zhan, C., R. W. Hicks, C. M. Blanchette, M. A. Keyes, and D. D. Cousins. 2006. Potential benefits and problems with computerized prescriber order entry: Analysis of a voluntary medication error-reporting database. *American Journal of Health-System Pharmacists* 63:353-358.