Safety in Hospital Medication Administration Applying STAMP Processes

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Abstract

Repeated application of root cause analysis techniques has not led to significant hospital medication administration safety improvements. The healthcare industry has begun to draw on scientific approaches to safety from outside traditional medical fields, including human factors engineering and systems design. This thesis lays the foundation to advance quality hospital healthcare for patients and providers by reducing hospital medication errors and enhancing hospital safety practices using STAMP techniques.

A CAST analysis is performed for a frequently occurring hospital medication administration error to demonstrate the power of avoiding future losses through causal analysis based on systems theory compared to root cause analysis techniques. An STPA hazard analysis for hospital medication administration is also performed. The current hospital safety management system is analyzed, highlighting gaps where applying STAMP analysis to the hospital organization structure would enhance the safety within the hospital organization at large. Potential future directions in healthcare safety engineering are discussed.

Thesis Supervisor: Nancy G. Leveson, Ph.D.
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Contents

List of Figures

List of Tables

Chapter 1: Introduction

Beginning with the Institute of Medicine's [1] seminal work (*To Err is Human)*, several investigations into patient safety in the United States have found that patients are frequently injured due to the care they receive. The exact number of deaths resulting from patient care has been debated at some length [2]–[5]. However, experts posit that the number is likely in the hundreds of thousands annually, with many more patients injured unnecessarily [6].

Studies point out that the reported numbers likely underestimate the medical errors for two reasons: 1) the studies rely solely on errors that can be extracted from documented health records, which many medical errors cannot be and 2) the studies include only in-patient deaths, not those deaths that occur after the patient has been discharged that result from in-hospital errors [3], [4]. Additionally, serious harm to patients is estimated to be ten times to twenty times more common than lethal harm. Such an estimate brings the number of overall hospital harm cases to 2.5-5 million cases a year in the United States alone, in addition to medical errors leading to patient deaths [3].

Putting these patient safety numbers in perspective, medical error is the third leading cause of death in the United States, after heart disease and cancer, compared to Center for Disease Control and Prevention (CDC) rankings of causes of death [7], the equivalent of 865 Boeing 787-9 Dreamliners crashing each year and killing all onboard. How quickly would the aviation industry be grounded if 5 of these Dreamliners crashed every 2 days, killing everyone onboard? Yet, in spite of industry's efforts, medical error rates remain high with significant patient disability and death and contribute substantially to increased healthcare costs [8].

Much of the focus of safety efforts have been focused within hospitals. Several areas of hospital care have been found to be lacking in sufficient safety focus. Many different sources of medical error occur within the hospital setting. These include adverse drug events; catheter-associated urinary tract infection; central line-associated bloodstream infection; injury from falls and immobility; obstetrical adverse events; pressure ulcers; surgical site infections; blood clots; ventilator-associated pneumonia; wrong site/wrong procedure surgery; and misdiagnosed conditions related to cancer, neurology, cardiology, urology, and surgery complications, during surgery and post-operatively [9]. Growing reliance on medication therapy as the primary intervention for most illnesses intensifies the focus on medication errors.

Specifically, hospital accidents resulting from incorrect medication administration have been identified as a common cause of patient harm, both in the US [10], [11] and globally [12]. While many of the accidents do not result in long-term patient harm, the reality of severe harm and death remains a pressing concern to patients, healthcare practitioners, and hospital administrators alike. Studies have reported that preventable, hospital in-patient medication adverse events (ADE) that result in severe harm range in error rates from 2.8% [10] to 10.49% [13].

Beyond the human suffering that results, hospital medication errors and harm have an equally devastating financial impact. Using a healthcare financial impact analysis method from Andel et al. [14] and quality-adjusted life-years (QALYs), each hospital medication death is estimated to cost ten years of lost life. Valuing a life-year at $75,000 to $100,000 USD, the total financial impact of hospital medication deaths ranges from $220 million to $300 million per year. More broadly including all medication-related harm, the Institute of Medicine [15] in "Preventing Medication Errors" reported 400,000 harmful medication-related events occur annually, costing hospitals an estimated $3.5 billion annually in 2007 dollars. This most recently published data's age, over 15 years old, points to the very limited understanding the healthcare industry has of the costs of medication errors. What is clear is that quality care is ultimately less expensive care – better, more efficient, and less wasteful.

Healthcare professionals and administrators are aware that the social actors, the healthcare practitioners and patients, have as much impact on hospital system safety as the technical systems, along with the context of the care being given, including the policies, procedures, training, hospital culture, staffing, workloads, and workplace climate [16]–[19]. In investigating medication errors in hospitals, it has become clear that these socio-technical factors are at the core of the losses suffered [20], [21].

Yet, the repeated application of root cause analysis techniques has not led to significant improvements in the safety of in-patient medication. The systemic factors involved in these medication administration errors remain ever-present, and accidents continue to happen. Safety reporting and compliance are not enough to ensure safety for healthcare practitioners and patients. We need a better approach to safety analysis in healthcare, specifically in hospitals, an approach that is comprehensive and cost-conscious.

The healthcare system has begun to draw on scientific approaches to safety from outside traditional medical fields, including human factors engineering and systems design. This thesis aims to apply a systems approach called STAMP (systems-theoretic accident model and processes) for the safe administration of medication in US hospitals. A CAST analysis [22], [23] is shown for a frequently occurring hospital medication administration error. The goal is to demonstrate the power of learning how to avoid future losses through causal analysis based on systems theory in comparison to the standard root cause analysis techniques.

In addition to a retrospective analysis of safety in this environment, a proactive analysis of hospital medication administration is shown using STPA, System Theoretic Process Analysis [24]. STPA uses the same theoretical model of causality as CAST. Yet, this hazard analysis technique can identify all potential scenarios that may lead to losses, not just the scenario that led to a particular, specific loss. The power of STPA is that systems designers and engineers can identify a larger set of potential scenarios that may lead to losses than can be identified using other methods applied in hospitals.

CAST analysis results and STPA analysis provide potent tools for reengineering established hospital medication administration systems to ensure higher levels of safety systemically rather than taking an ad-hoc, reactionary approach to addressing safety lapses. The ability to consider safety and environmental concerns using STAMP processes is particularly important for both humans and the technology in the hospital setting, addressing workplace safety concerns and patient safety concerns simultaneously, inclusive of process factors, human factors, and system factors.

By turning away from root cause analysis techniques and moving to STAMP processes, the hospital can improve system safety by designing the system to allow the healthcare practitioners to be flexible and resilient and to handle unexpected events without the specter of blame hanging overhead should a loss occur [25]–[27]. This thesis lays the foundation to advance quality hospital healthcare for patients and providers by focusing on reducing hospital medication errors and enhancing hospital safety practices.

The structure of the remainder of this thesis is as follows. Chapter 2 consists of the literature review, which presents in more detail differing philosophies of safety in healthcare by looking at the accident causality models, accident analysis tools, and hazard analysis tools currently in use in the field. Chapter 3 details the methodology used for this work, with Chapters 4 and 5 presenting a hospital medication administration CAST analysis and STPA analysis, respectively. Chapter 6 presents a safety management system analysis of US hospital organizations and insight on future directions in healthcare safety engineering. Future work and conclusions are presented in Chapter 7.

Chapter 2: Literature Review

Healthcare System Safety in Hospital Medication Administration

Medication administration error is clearly prioritized as a class of medical adverse events to focus on mitigating and eliminating. The Joint Commission on National Patient Safety Goals [28] report includes two goals specifically targeting medication error mitigation/elimination out of its four key national patient safety goals. The first goal to eliminate preventable adverse drug events (ADEs) is to use medications correctly and safely, double-checking labeling and correctly passing on patient medicines to the next provider. The second goal is to label all medications, even those in a syringe, done in the area where the medications are prepared [29].

Other non-profit organizations (e.g. ECRI & the Institute of Safe Medication Practices (ISMP), and the Institute for Healthcare Improvement (IHI)) and US government entities (e.g., the Department of Health and Human Services (DHHS) Agency for Healthcare Research and Quality (AHRQ)) primarily focus on reducing medication errors. The ECRI & ISMP patient safety organization has this medication administration error reduction focus exclusively. Pediatric hospitals have formed the Solutions for Patient Safety (SPS) network where each member hospital shares its safety data to learn from each other working toward zero patient harm. Among their hospital members, adverse drug event rates have decreased 65.1% overall from 2011 to 2021, to 0.019 adverse drug events per 1,000 patient days [30].

Medical Error Reporting

Medical error reporting, including ADE reporting, is an essential part of any hospital safety culture [31], [32]. Reporting is required by the Joint Commission for sentinel events of death, permanent harm, and severe temporary harm requiring intervention to sustain life. With 90% of these sentinel events happening in acute care hospitals, there is already a sufficient reporting infrastructure in hospitals to support accurate and timely reporting [8].

In spite of high prioritization, high quality quantitative data on adverse drug events in hospital has proved exceptionally difficult to capture [33]. This lack of quality data makes insightful, effective safety analysis difficult. The most significant barriers to error reporting were: 1) hospital culture where staff disagree about definition of reportable errors; (2) fear of the response of hospital management, administrators, and peers to a reported error; and (3) the amount of time-effort involved in documenting and reporting an error [16]. Adverse events that are not required to be reported, such as near misses and no-harm incidents, are often not reported, often due to the time pressure on hospital providers [34].

In addition, not all medication errors are detected. Thus, the healthcare industry only has weak knowledge of the actual incidence of errors. To uncover recurrent errors or discover leading indicators for hospital medication administration errors, there must be a reporting culture of mishaps, incidents, near misses, and lessons learned detailing the events for further analysis [35].

The trend of adding technology tools into the hospital safety system to reduce medication error has been shown to increase medication administration safety [36], [37]. Introducing electronic health records (EHR) and computerized physician order entry systems (CPOE) have allowed for greater oversight of medication ordering and administration in hospitals and reduced errors [38]. Automated pharmaceutical dispensing systems and barcode verification technology have also reduced medication errors and enabled efficient medication distribution [39], [40].

At the same time, technology to reduce medication errors often introduces new hazards that did not exist prior to the technology implementation [41], [42]. Reliance on technology alone to address medication administration safety is insufficient. The past decade has seen a false sense of

increased safety from healthcare information technology systems. Facilities found that digital processes introduced new and additional types of errors that did not exist prior to the introduction of this healthcare information technology while implementing electronic health care systems at several different points of hospital medication administration.

Research conducted on the impact of EHRs and CPOEs on error rates in medication administration demonstrated that overall adverse drug events declined but could not draw conclusions about what the best interventions might be to reduce these new and remaining errors [43]–[45]. With humans and technology interrelatedly involved in the complex medication administration system, the knowledge base to inform interventions to improve safety is weak [16].

Accident and Hazard Analysis Tools in Healthcare

The healthcare field began its engineered approach to hospital safety applying accident investigation techniques based on the "Swiss cheese" model proposed by Reason [46]. This model emphasizes human error, called "unsafe acts" or "active failures." These actions lead to an accident when they occur within a set of "latent conditions." These latent conditions may reside harmlessly within the system for a long time before combining with an active failure to create an accident opportunity. Latent conditions can translate into error-producing conditions within the system when those latent conditions experienced by humans (time pressure, understaffing, fatigue) lead to an accident. The model shows that "holes" in the safety defenses for a system are those latent conditions and active failures that align to cause an accident. Reason [47] considers this approach to accident investigation a systems approach to error management to tackle latent conditions to lessen the impact of active failures.

It is important to note that while Reason's model is referred to as a systems approach to error management, the model is not based on systems theory but instead the traditional linear chain of events accident causality model that has existed for at least 200 years. This chain of events model persists as the basis of the most widely applied accident analysis techniques in healthcare, root cause analysis (RCA) and Failure Mode Effects Analysis (FMEA). The use of these techniques persists despite calls to apply the systems theory of accident causation to healthcare as early as the mid-1990s [48].

Root Cause Analysis

Most hospitals use the root cause analysis process in the United States [49], [50]. The process's widespread adoption primarily results from the RCA process being mandated by the Joint Commission in 1997 to report sentinel events in hospitals. RCA methods have been used to analyze high-risk medications that commonly result in adverse medication errors [8], [51].

However, there is a significant body of literature that indicates that RCA analyses are not effective in preventing future accidents, even with their requirement by the Joint Commission [52]. One study presented results challenging RCA effectiveness by studying state-reportable adverse medical events with RCAs performed over eight years within a hospital center. Multiple adverse event types were observed to be repeated during this study period, despite repeated RCAs on the same type of adverse events [53]. This repetition of accidents post-analysis demonstrated RCA methods' weakness in preventing accidents from recurring in the future. Therefore, even with the intent to use RCA methods to evaluate system-level problems, studies have shown that RCAs in healthcare often focus on attempts to fix individual human actors rather than effect system improvements. In contrast, safety engineering fields show that system-level interventions are more effective [54], [55].

Failure Mode Effects Analysis (FMEA)

Healthcare practitioners and administrators focus heavily on being able to avoid accidents before they occur. The most widely used hazard analysis technique in healthcare settings is FMEA, an approach borrowed from reliability engineering and based on the same traditional linear chain of events model as RCA [8], [56]. The goal of FMEA is "to establish the overall probability that the product will operate a certain length of time between failures" [57, p. 269]. The widespread adoption of FMEA as a hazard analysis technique comes from the Joint Commission's requirement that hospitals perform one prospective hazard study annually for accreditation, with FMEA analyses being most frequently submitted.

FMEA has been used to lower medication dispensing errors in a hospital, primarily through its application to evaluating risk assessment in the medication administration process [58]. The effectiveness of FMEA in decreasing medication errors has been challenging to achieve beyond a certain threshold of error, shown as FMEA has been more broadly investigated as a technique in the hospital medication administration domain. Anjalee et al. [59] showed that FMEA had been successfully applied in high-risk areas of medication administration but was a challenging process to use.

The significant investment of resources needed to train several hospital team members to implement FMEA and the subjectivity of the resulting risk analysis makes it impossible to generalize and reproduce results across different hospital settings. As an example, Shebl et al. [60] conducted a study where the reliability of FMEA was questioned. The two groups conducting the FMEA on the hospital process identified similar steps in the process of care but different potential failures with very different risk priority rankings. Such discrepancies make it impossible to reliably identify those failures that should be prioritized. Additionally, it is impractical to look at all possible scenarios for the operation of a complex system and determine if any of these scenarios then lead to a hazard, as FMEA attempts to do. This comprehensive scenario generation is virtually impossible to complete in an extensive, complex system such as a hospital [26].

Healthcare has continued to refine the FMEA hazard analysis process despite these drawbacks by introducing extensions of FMEA specific to healthcare processes. Healthcare FMEA (HFMEA) was developed in 2001 by the Department of Veterans Affairs to evaluate healthcare processes proactively. Other healthcare safety entities, including the Institute for Safe Medication Practices, have developed their own FMEA frameworks. van Tilburg et al. [61] used HFMEA to analyze medication administration in a pediatric oncology ward and found the technique to reduce these high-risk medication administration errors.

However, HFMEA does not sufficiently consider human factors to extend healthcare systems safety more effectively to integrate humans and technology in healthcare processes. Faiella et al. [62] proposed a hybrid HFMEA that took into account human factors and preventative controls by adding two additional processes to HFMEA: SHERPA (Systematic Human Error Reduction and Prediction Approach) and STAMP-STPA. Poulsen et al. [63] used this hybrid HFMEA hazard analysis technique to analyze the risks related to drug shortages in hospitals. This proposed technique is a fundamental misapplication of STAMP-STPA to the hazard analysis process. It is interesting that healthcare is trying to adopt a very old technique like FMEA, which was developed in the 1940's for reliability of electronic system components when most of the world of safety engineering is abandoning as ineffective for complex systems.

A Systems Approach to Safety (STAMP)

The systems approach to safety treats safety as a control problem. Accidents viewed with the STAMP lens are a dynamic control problem, where designed controls did not prevent the accident from happening. Hazards result from the lack of enforcement of safety constraints in system design and operations. Controls are created to prevent hazards. STAMP allows for a more sophisticated analysis of accidents and hazards, by identifying interactions between humans, components, software, organizational culture, regulatory constraints, etc. as factors that are involved in system safety.

STAMP is a substantive change in focus from what is done by other tools, specifically RCA and FMEA. These two tools treat safety as a reliability problem, rather than a dynamic control problem. This focus on reliability leads to accident investigations examining failures and assigning responsibility. These approaches promote looking for something that broke or went wrong in the proximal sequence of events prior to the accident. Ultimately, RCA and FMEA cannot address all of the other factors involved in system safety beyond component failure, rendering both tools incapable of effectively analyzing modern, highly complex, systems involving humans, hardware, and software.

Causal Analysis based on Systems Theory (CAST)

CAST is an accident analysis method based on the STAMP model of accident causality. Its approach to accident investigation is to learn as much from every accident as possible through identifying the questions that need to be asked during an accident investigation and determine why the events occurred. CAST avoids assigning blame for an accident to a human operator and instead looks for why the systems and structures to prevent the events were unsuccessful. The recommendations generated at the end of a CAST analysis focus on strengthening these prevention (control) structures based on knowledge uncovered in the accident investigation. CAST has been applied in analyzing hospital adverse events [64], [65]. These studies demonstrate the increased safety effectiveness of this systems-based analysis approach when compared to the results of linear chain of events-based approaches. Applying CAST analysis to hospital adverse events answers a call to action by Harms-Ringdahl [66] for improved accident investigation methods in healthcare. The results of his study where healthcare accident investigations were evaluated comparing in-depth approaches and root cause methodologies indicate a clear need for improvement in healthcare event accident investigations.

System Theoretic Process Analysis (STPA)

STPA is a hazard analysis technique based on the STAMP accident causality model. This technique assumes that accidents are caused by unsafe interactions of system components in addition to component failures [24]. The causal scenarios generated by STPA are far greater in depth and breadth than those developed using more traditional hazard analysis techniques. STPA identifies scenarios that involve inadequate control over the system as a whole, in addition to those generated by the older techniques [57]. STPA has begun to be used increasingly over the past decade in the hospital healthcare domain, including radiation therapy [67]. The hybrid HFMEA that Faiella et al. [62] propose is unnecessary to perform in order to conduct a comprehensive hazard analysis. Conducting an STPA hazard analysis would uncover the same causal scenarios as the hybrid HFMEA because the STPA part of the hybrid HFMEA is identical. To conduct the HFMEA and SHERPA analyses in addition to the STPA adds unnecessary work for the analysis team by including information that STPA would already generate in its approach. Further application of STPA to hospital medication administration processes would provide hospital

practitioners and administrators insights that would be valuable in proactively avoiding adverse medication events.

Chapter 3: Methodology

A comprehensive safety engineering approach looks to past events to avoid repeating prior losses and looks to the future to prevent losses. This research focuses on applying STAMP processes, i.e., CAST and STPA, to medication administration in US hospitals. Examples are provided to compare the results of the standard approach to those of the STAMP processes.

CAST analysis illustrates the systems approach to investigating accidents compared to the widely used root cause analysis (chain of events) approach. This comparative analysis provides hospitals with guidance on how to institute more effective measures to avoid losses in the medication administration process. The findings from a CAST analysis of a commonly occurring medication administration accident is compared with the findings of the chains of events analysis provided in the published accident report.

A proactive approach to hospital medication administration safety based on systems theory provides a compelling framework to improve the underlying complex sociotechnical system designed for hospital patient care. STPA is being used in most other industries and has been applied to radiation therapy devices but is beginning to be more widely adopted in the healthcare domain. Applying STPA to the hospital medication administration process creates a systemic view of the interactions among healthcare workers, their patients, the enabling cyber-physical information systems, and legal and commercial industry operations that contribute to medication errors. The results of the STPA analysis can be used to create more effective safety interventions, higher patient quality of care metrics, and ultimately lead to fewer resources spent by hospitals for safety compliance audits, legal actions, and accident investigations.

A safety management system analysis is also conducted for a hospital organization to provide additional insight into how the organization can develop an effective safety management system as a part of the STPA analysis. Current hospital safety management system structures are presented and contrasted with what the structures would be if the hospital took a systems approach to safety. This analysis provides some understanding as to how medication administration error rates within hospitals remain significant and are not lowered beyond a certain point even with substantive accident investigations and investments in safety throughout the organization.

Chapter 4: Applying CAST to Hospital Medication Accidents: A Case Study

ERCI, one of the preeminent healthcare quality and safety entities worldwide, identified data input errors associated with similar looking and sounding drugs as number 2 on its list of Top Ten Health Technology Hazards for 2021 [68]. This CAST analysis investigates an accident that involved hospital medication administration processes resulting in non-lethal harm to the patient.

The accident report used as the basis of analysis is taken from the Patient Safety Network (PSNet), part of the Agency for Healthcare Research and Quality (AHRQ) in the US Department of Health and Human Services. The title of the report is "40 of K" [69]. This accident report is published as a case study for those who are developing hospital policies and procedures to minimize medication administration errors and is illustrative of the safety challenges that are routinely present in hospital medication administration. This accident shows that typically low-risk patient care activities can create the opportunity for serious errors to occur.

Root cause analysis based on a chain of events was used in the accident report to identify the cause of the accident. The report concludes that there were several contributing causes that put together brought about the accident. These causes include a breakdown in communication during the ordering of the medication, where the verbal order for the medication was misinterpreted, communicated to the dispensing party incorrectly, and thus, administered inappropriately. In the case report blame was ascribed to improper care taken by those healthcare providers to ensure that the medication order was transcribed properly, with the root cause identified as a communication failure among two different nurses and the ordering physician in the ordering process for the medication. The conclusion that the cause was a chain of failure events, focusing on the human parts of the process, is not surprising as this is the underlying model of causality in RCA and FMEA. But is this the only and best way to conceive of the cause of this accident? This chapter contains a CAST analysis of this case study accident and compares the results found by RCA.

CAST Analysis of Case Study

Incident Description

The event occurred in a hospital setting. The boundary of analysis is the hospital entity itself. The system analyzed included the hospital administration, the medication ordering physician, the hospital pharmacist, the unit nurse, the procedure area nurse, the evening shift nurse, the patient, the pharmaceutical automated dispensing system, the electronic health record information system (holding the patient treatment record), and the medication administered to the patient. The adverse event (loss) was that the patient was administered the incorrect medication, leading to potential negative clinical consequences. The hazard is not administering medication to the patient as ordered by the medication-ordering physician (Safety Hazard 1).

The system-level safety constraints that are required to prevent this safety hazard are:

- Patient must be administered his/her medication as ordered with the correct dosage.
- Patient must be administered his/her medication as ordered with the correct timing of dosages.
- Measures must be taken to reduce harm if incorrect medication administration occurs.

The events leading up to the adverse medication administration event are listed in Table 1, along with questions raised about the timeline of events.

Table 1. Events Leading up to the Adverse Medication Administration Event

ID	Event	Example Questions Raised
1	An 81-year-old female patient maintained on warfarin for a history of chronic atrial fibrillation and mitral valve replacement developed asymptomatic runs of ventricular tachycardia while hospitalized.	*What was the medical reason for her hospital admission initially? What was the history of the success of her warfarin treatment? What medications was she already on? Had a medication reconciliation been done for the patient? Was this patient's medication information documented in the EHR? Was the patient capable of discussing medication history and treatments with care providers? Was a friend/family member advocate available to do so?*
2	The unit nurse contacted the physician for the patient's treatment instructions.	*Was this nurse a staff nurse or contract? Did s/he work with cardiac patients often? What time did this event happen? What were the shift conditions for the nurse (overtime, mid-shift)?*
3	The physician was engaged in a sterile procedure in the cardiac catheterization laboratory.	*Why was this particular physician needed for this patient's treatment? Was there another physician who could have been consulted for medication ordering? Are there procedures for nurses when physicians are performing other duties to be able to contact a different/alternate physician for treatment instructions? If there was a procedure, was it followed? If not, why not?*
4	The physician gave a verbal order for the patient's medication administration to the procedure area nurse in the catheterization lab.	*Were verbal orders common in the hospital? Were there procedures for verbal orders in this hospital? Did the procedure area nurse relay this information in accordance with the procedure? (Was this verbal order relay a "workaround" for a hospital procedure or not?) Did the procedure area nurse verify this order with the physician after he gave the verbal order? Did she verify it with another nurse or physician in the catheterization lab as a double-check?*
5	The procedure area nurse verbally relayed the order to the unit nurse for medication administration.	*What was the physical environment when this order was relayed verbally? Was the environment noisy/loud? Was there significant activity happening that would cause a lack of concentration? Was the order verbally relayed during a procedure, or during a break between procedures? How long did this process take?*
6	The verbal order was given for "40 of K."	*What was the understanding/mental note of the procedure area nurse about what medication was being ordered? Did s/he give any instruction to the unit nurse regarding medication order verification? Was there a procedure for this? Was it followed? Was this a typical medication ordered for a patient with this type of medical condition?*
7	The unit nurse wrote the order as "Give 40mg Vitamin K IV now." (40 milligrams of Vitamin K intravenously)	*Did s/he have another nurse check her interpretation of the verbal order for "40 of K" prior to ordering the medication? Did s/he enter the medication order into the EHR at the time she received? Was there a time delay, or no? Was "K" used for both vitamin K and potassium chloride frequently? If so, how was such confusion previously prevented?*
8	The hospital pharmacist contacted the physician to verify the order, concerned with the high dose and medication administration route chosen for the drug.	*How did the pharmacist become aware of this order? What was the time elapsed between the nurse entering the order, the pharmacist reviewing the order, and the verification with the physician? What are the hospital procedures for pharmacist verification of medication orders? Were they followed in this case, or no? Was this case handled at a*

		different priority level than other medication verifications handled by pharmacists?
9	After consulting the physician, the hospital pharmacist discovered that the intended order was "40 mEq of KCl po." (40 milliequivalents of potassium chloride orally.)	*How did the pharmacist communicate with the physician? Did the pharmacist correct the EHR, or did he correct it in the pharmacy management system? How long does it take these systems to sync up (if they are separate information systems)? What is the procedure to notify the dispensing nurse that there has been a medication change? Was it followed? If not, why not?*
10	The unit nurse obtained the Vitamin K medication on an override from the automated medication dispensing system and administered the dose intravenously.	*What was the hospital procedure for this nurse to obtain an override? Was it followed? What was her belief on the criticality of the patient's condition that prompted her to make that override of the system? What were the access controls to her getting the Vitamin K out of the automated dispensing system? Was there a procedure in place for her to wait for a pharmacist review prior to administering the medication? If this was the case, why was that procedure not followed? Did the patient ask any questions about the medication being administered? Was the patient informed of any potential drug interactions or treatment impact?*
11	The pharmacist wrote the clarification order for the correct medication.	*What was the elapsed time between the medication correction by the pharmacist and the propagation to the EHR system? Questions about the policies and procedures around notifying a dispensing nurse of a change to a medication order apply for this step of the process as well.*
12	The unit nurse attempted to contact the physician but told he was busy with procedures.	*What is the process for contacting/correcting a medication order if the physician is unavailable? Was there a back-up physician or another provider who would have been named as a backup to the physician in this case to consult about medication order changes? Was there another nurse that could have been consulted about the same question? Was the contact of the physician for clarification of the medication order, or to double-check what the pharmacist had changed?*
13	A routine order to increase warfarin from 2.5mg to 5mg was written later in the day.	*The question here is who made this order? The physician referred to in the case or another physician? What was the time stamp on this routine order with respect to the other events in the case? What was the documentation in the EHR specifically about the Vitamin K administration?*
14	Evening shift nurse interprets this routine order to increase warfarin as the physician's response to the medication event.	*What was the mental model for the evening shift nurse to interpret this order as a medication response event? How was the information presented in the EHR about the medication order change (from the pharmacist) and the medication administration of the Vitamin K? Was there a procedure in place to have the medication administration reviewed by another provider in light of the information on the medication change? Was this information easily accessible to the evening shift nurse in the HER? Was this nurse a staff nurse or a contract nurse? What was his/her typical working area (cardiac patients) or other specialty? Was there a hand-off between the unit nurse and the evening shift nurse?*
15	The physician was not actually informed that Vitamin K was administered until the next day.	*Why wasn't the physician (or someone with medication ordering responsibility) not made aware of this medication administration earlier? What is the process to notify a physician that a change has occurred with medication*

		administration for a patient or that a potential error has occurred (the Pharmacist noticed this earlier)? What was the likely timing for this supposed to be according to the policies and procedures for medication administration in the hospital?
16	Heparin was initiated, and warfarin was re-titrated to a therapeutic level.	
17	Patient's INR was subtherapeutic for 3 days. Patient recovered from this clinical incident.	

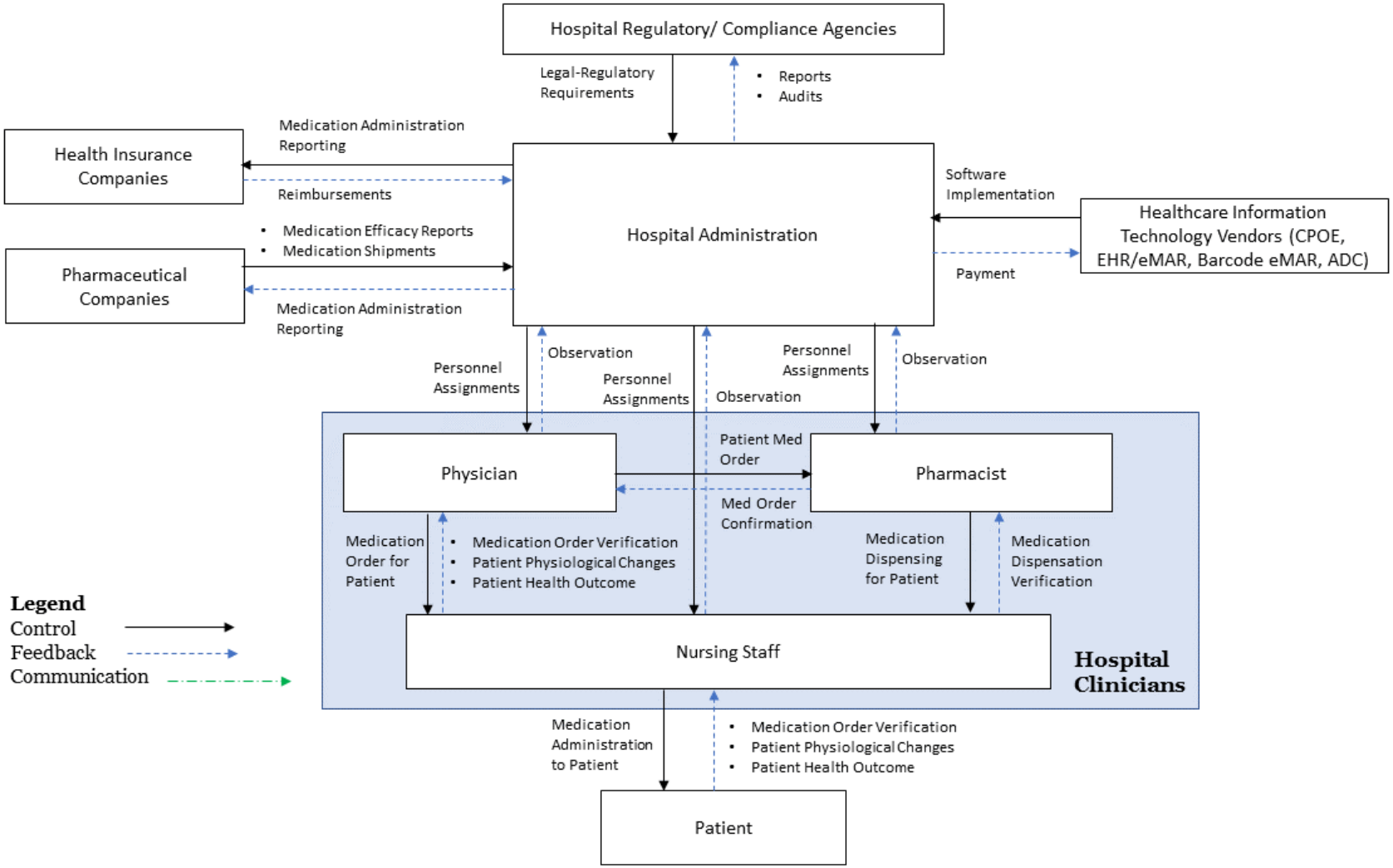
The medication ordering and administration process within a hospital is primarily a social process, rather than involving a complex and dangerous physical system and processes. This accident case of the improper administration of medication to a hospitalized patient does not involve a loss of physical equipment and controls.

In this accident case it is instructive to look at the unsafe interactions that happened in the system among the humans and the supporting information systems, as well as conduct a deeper analysis of the human actions and mental models in this case. The physical unsafe interaction was the administration of the incorrect medication to the patient. An analysis of the role of the information systems and hospital policy in this accident is premature, as these objects are not actors but used as controls in the process, which will be discussed later in this analysis. For each of the primary human roles in the accident, we discuss the responsibilities of the worker in that role, their contribution to the accident, any mental model flaws that the human held, and any contextual factors that would have had an influence on their behavior at the time.

A CAST analysis starts with describing the control structure used in the hospital to prevent medication errors. It then looks at (1) the contribution of each of the components in the control structure along with why they behaved the way they did and (2) an analysis of systemic properties in the control structure as a whole that contributed to the adverse event.

Control Structures - Hierarchical control structure for medication dispensing in hospital setting

The control structures for the CAST analysis are presented in Figures 1 and 2. Figure 1 shows a high-level overview of the control structure of hospital medication administration, with expanded detail on the clinicians involved in the process. Figure 2 shows the detailed control structure for the in-hospital medication ordering and transcribing process within hospital medication administration. This latter graphic shows the control and communication relationships among the key actors in the accident event. For the purposes of analyzing this accident, the unit nurse and the evening shift nurse are represented by the nursing staff indicated on the figure. The procedure area nurse is acting in concert with the physician in this accident, as she was the actor who relayed the medication order verbally to the unit nurse. This unit nurse then input the medication order into the CPOE system.


Hospital Regulatory/ Compliance Agencies
Legal-Regulatory Requirements
Reports
Audits
Health Insurance Companies
Medication Administration Reporting
Reimbursements
Hospital Administration
Software Implementation
Healthcare Information Technology Vendors (CPOE, EHR/eMAR, Barcode eMAR, ADC)
Payment
Medication Efficacy Reports
Medication Shipments
Pharmaceutical Companies
Medication Administration Reporting
Personnel Assignments
Observation
Personnel Assignments
Observation
Personnel Assignments
Observation
Physician
Patient Med Order
Pharmacist
Med Order Confirmation
Medication Order for Patient
Medication Order Verification
Patient Physiological Changes
Patient Health Outcome
Medication Dispensing for Patient
Medication Dispensation Verification
Nursing Staff
Hospital Clinicians
Legend
Control
Feedback
Communication
Medication Administration to Patient
Medication Order Verification
Patient Physiological Changes
Patient Health Outcome
Patient

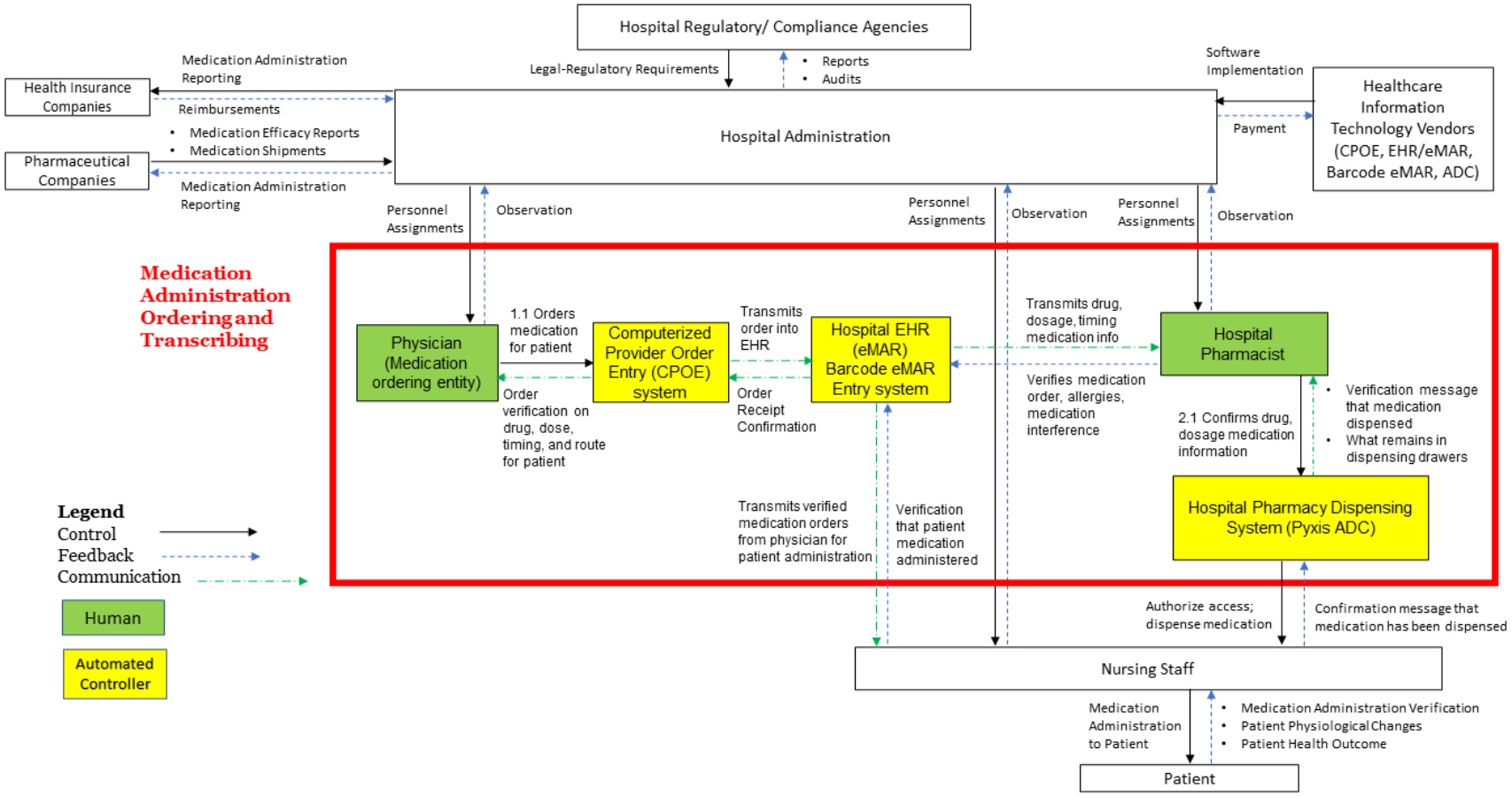


Figure 2: Detailed control structure for the in-hospital medication ordering and transcribing process within hospital medication administration

Analysis of Controllers

There are 4 parts of the analysis applied to the controllers in the control structure. Their responsibilities related to the events that occurred, how they contributed to the incident or accident and why in terms of any misconceptions they might have had in their mental models and what contextual factors influenced their behavior. A CAST analysis starts from the assumption that the people involved were well meaning (they did not want to harm a patient) and that all behavior is influenced by the system in which it occurs.

Patient

Responsibilities:

- Accept limited responsibility for their own health and treatment (if practical).
- Inform care providers of medication history, particularly cardiac medication.

Contribution to the Accident:

- Patient did not take an active role in the administration of her medication by the nurses.

Mental Model Flaws:

- Patient believed that the doctors and nurses at hospital should be in complete charge of her care and thus, the patient did not need to be an active participant.
- Patient believed that standard of care was being adhered to and did not feel the need to question any of the medication administration events (if he/she was able to)
- Patient believed the medication system in the hospital was trustworthy.

Context:

- Patient was not aware of the medication administration policies and procedures around hospital care. At no point was there any discussion that the doctor or nurses had spoken to the patient about her care or the policies/procedures that the care givers would be taking.
- The patent had no reason to question the doctor's or nurses' actions.

Unit Nurse (Medication Administration entity)

Responsibilities:

- Follow the orders of the shift supervisor and physician
- Follow documented, standard policies and procedures for patient care at the facility.
- Communicate with the physician on the medication administration for the patient.
- Communicate with the patient on the medication administration plan for her care.
- Communicate with other nurses and clinical staff on the medication administration for the patient.
- Question orders when they seem wrong if the nurse has the knowledge and information to do this.

Contribution to the Accident:

- The nurse accepted the medication order of "40 of K" verbally from the procedure area nurse.
- The nurse put in an override to the automated medication dispensing system for the IV Vitamin K.

- The nurse administered 40 mg of Vitamin K intravenously to the patient when the medication order from the physician was 40 mEq of potassium chloride (KCl) orally.

Mental Model Flaws:

- Believed that the medication order for "40 of K" meant 40 mg of Vitamin K intravenously rather than 40mEq of potassium chloride (KCl).
- Believed that it was not necessary to involve the patient more actively in her care.
- Believed it was not necessary to communicate with the other shift's nurses other than through the electronic patient records or other written communication to indicate care actions taken on the patient.
- Believed that overriding the automated medication dispensing system would allow for more effective patient care in the scenario.
- Believed that hospital pharmacist review of the medication was not going to change the medication administration specifics (drug, dose, pathway, timing).

Context:

- The unit nurse's past clinical experience was in neonatal intensive care, not cardiac care, which influenced her misinterpretation of the verbal medication order.
- It is unclear from the report how long this nurse had been working in the cardiac unit for this facility.
- It is unclear if there was a policy in place at the hospital to eliminate or limit verbal medication orders.
- It is unclear if there was a hospital policy with respect to overriding the automated medication dispensing system for medication access.
- This medication administration was considered to be a low-risk patient care activity and thus did not seem to warrant particular attention above the standard duty of patient care.
- The unit nurse attempted to contact the physician about the medication order prior to the medication administration but was unable to reach him due to his being busy with procedures.

Evening-shift Nurse

Responsibilities:

- Follow the orders of the shift supervisor and physician
- Follow documented standard policies and procedures for patient care at the facility
- Communicate with the physician on the medication administration for the patient.
- Communicate with the patient on the medication administration plan for her care.
- Communicate with other nurses and clinical staff on the medication administration for the patient.

Contribution to the Accident:

- None specified in the actions detailed in the report.

Mental Model Flaws:

- Believed that the medication administration policies and procedures were sufficient to ensure that the patient would receive their medications as orders instructed.

- Believed it was not necessary to communicate with the other shift's nurses other than through the electronic patient records to indicate care actions taken on the patient.
- Believed that the physician was aware that the Vitamin K medication administration had happened and that he/she ordered increased warfarin as a response to the medication event.

Context:

- Nurses frequently rely on the health information systems around patient care (EHRs and medication dispensing software and machines) to communicate with other clinical staff on patient care in a hospital, relying less on direct oral communication to relay care instructions for patients among themselves.

Hospital Automated Medication Dispensing System (Pyxis)

Responsibilities:

- Assist nurses in the medication administration process by dispensing medications as ordered by physicians, dispensing correct medicine and dosage ordered for the patient.
- Display information on the medications stored within the system, provide alerts, issue control actions on medication dispensing to nurse.
- Control access to medication to allow only authorized users to have the medication dispensed to the appropriate nurse for the correct patient.
- Control medication dispensing process so that only correct medication type and dosage are released to the nurse for the patient.

Contribution to the Accident:

- The Pyxis system dispensed the Vitamin K to the unit nurse using an override procedure.
- The Pyxis system did not verify the medication it was dispensing against the clarified (revised) medication order for the patient.

Process Model Flaws:

- The Pyxis system was designed to allow dispensing medication using an override process that prioritized nurse judgment over orders that resided in EHR.
- The Pyxis system was designed to control medication dispensing by verifying the medication dispensed against the physician's order for the medication. In this particular system, there was no verification process in place to check that the dispensed medication matched the physician's order.

Context:

- Hospitals are not required to have the Pyxis system directly communicating with the EHR to verify the medication order, although it is recommended by safety bodies for hospitals to do so.
- Hospitals are not required to have a hospital pharmacist review each medication order as it is written for an individual patient prior to a nurse being able to access medications from the Pyxis. This pharmacist review is recommended by safety bodies for hospitals, but it is not required for hospitals to do this.

Hospital Pharmacist

Responsibilities:

- To ensure the highest quality of care for the admitted patient.
- To verify that the medication orders for the admitted patient are appropriate to the patient's underlying medical conditions.
- To ensure that the medication orders for the admitted patient are dispensed correctly.

Contribution to the Accident:

- None specified in the actions detailed in the report.

Mental Model Flaws:

- Believed that the medication clarification order once it was put into the EHR would be read/checked by the nurse prior to administering the medication to the patient.

Context:

- The pharmacist was very likely not aware of the nurse's intended actions with the override process. S/he likely considered this specific medication order as a low-risk routine one and did not feel the need to follow-up with the nursing staff beyond standard procedures to alert them to the medication error.
- The pharmacist did write the clarification order for the medication to correct the medication and its dosage prior to medication administration to the patient.

Hospital Electronic Health Record (EHR)

Responsibilities:

- Assist hospital healthcare providers (nurses, pharmacists, physicians) in the medication administration process by facilitating the communication among the responsible parties throughout the process from ordering to administration.
- Display information on the medication orders and administrations for the patients within the system, provide alerts to providers on patient care status, issue control actions on medication dispensing to nurse and on medication ordering to physician and pharmacist.
- Control data entry on medication ordering process to minimize user input errors
- Control data entry on medication dispensing to minimize user input errors

Contribution to the Accident:

- The EHR did not alert the physician or the nursing staff to the medication change in the patient record.

Process Model Flaws:

- The EHR system was designed to facilitate communication among nurses, doctors, and pharmacists (among others) who participate in patient care. There are no controls on communication among providers that is NOT entered into the EHR system (verbal or written communication that occurs prior to or after recording in the system).
- The EHR system does not actively alert doctors, nurses, or pharmacists to changes to the patient record. This means that a provider has no way of knowing that a patient record has changed unless s/he is looking at the computer system.

Context:

- Patient care in a hospital requires nurses and doctors to spend significant amounts of time away from a computer, and thus, away from a patient's EHR. There are often patient electronic record changes that happen that the care provider is not aware of from the time an action is taken and when the provider can refer again to the record.
- Nurses frequently rely on the health information systems around patient care (EHRs and medication dispensing software and machines) to communicate with other clinical staff on patient care in a hospital, relying less on direct oral communication to relay care instructions for patients among themselves.

Procedure Area Nurse

Responsibilities:

- Follow the orders of the shift supervisor and physician.
- Follow documented, standard policies and procedures for patient care at the facility.
- Communicate with the physician on the medication administration for the patient.

Contribution to the Accident:

- The procedure area nurse accepted the medication order verbally from the physician.
- The procedure area nurse communicated the medication order verbally to the unit nurse.

Mental Model Flaws:

- Believed that the physician was giving the medication order for "40 of K" and that it meant 40mEq of potassium chloride (KCl) orally.
- Believed that the unit nurse understood that the medication order for "40 of K" meant 40mEq of potassium chloride (KCl) orally.

Context:

- It is not clear if the physician or the procedure area nurse gave the order as "40 of K."
- It is not clear if any confirmation process for the medication order happened between the physician and the procedure area nurse.
- It is not clear if any confirmation process for the medication order happened between the procedure area nurse and the unit nurse.
- The procedure area nurse was in the catheterization lab and, due to the sterile field requirements, was not able to type the order into the EHR directly.
- It is unclear if there was a policy in place at the hospital to eliminate or limit verbal medication orders.
- This medication administration was considered to be a low-risk patient care activity and thus did not seem to warrant particular attention above the standard duty of patient care.

Physician (Medication ordering entity)

Responsibilities:

- To ensure the highest quality of care for the admitted patient.
- To prescribe the appropriate medications for the admitted patient.
- To communicate those orders effectively to clinical staff for subsequent administration.
- To communicate with the patient to indicate the care actions that will be taken while the patient is in the hospital.

Contribution to the Accident:

- The physician gave a verbal order of "40 of K" to the procedure area nurse to relay to the unit nurse for the patient's medication order.
- The physician was not available for consultation with the nurse on the medication order at the time of administration.

Mental Model Flaws:

- Believed that the medication order given verbally was understood by the procedure area nurse to be 40 mEq of potassium chloride (KCl) orally.
- Believed that his medication orders would be interpreted correctly among the nurses and pharmacists without the need for verification.
- Believed that other physicians would be available to the unit nurse for consultation on his medication orders should s/he be unavailable.

Context:

- The physician was in the catheterization lab and, due to the sterile field requirements, was required to give the order verbally.
- The physician was focused on his procedures in the catheterization lab and not able to be fully focused on the medication order process.
- The physician in a hospital setting is not solely responsible for the care of a patient and is fully confident that the nurses will handle medication administration, as it is their job responsibility, not the doctor's.
- The physician was aware of the policy regarding hospital pharmacist review of medication orders and saw that as a fail-safe in case of medication order errors.

Systemic Factors Contributing to the Loss

The second part of the CAST analysis involves looking at systemic factors (system design flaws) that contributed to the events that span the individuals in the control structure.

There were several systemic factors that contributed to the loss that span individual controllers in the hospital medication administration process. These factors include lack of control responsibilities among hospital administration, communication processes, coordination among system controllers, workplace safety considerations resulting from economic factors, and the hospital's safety culture.

Lack of Hospital Administration Safety Responsibilities in Medication Administration Process

Absent in the accident analysis is any mention of a nursing supervisor or hospital administration personnel. The accident report focused only on those actors with direct responsibility in the accident. The report does not include an analysis of any indirect actors' actions that might have led to the accident. However, these professionals have significant responsibilities to create an environment for safe medication administration. Any accident report that does not investigate the role of the nursing supervisor and other hospital administrators will necessarily omit insights and recommendations for actions from these actors to prevent accidents in the future.

The hospital healthcare culture among the healthcare providers is fragmented, with a typical "free agent" employee operating structure. There are many shifting employees throughout a patient's hospital stay, with often a dotted-line reporting relationship among the entities working in the hospital facility. Nurses are often contracted and not necessarily full-time employees of the hospital.

This nurse staffing arrangement leads to nursing administration in a hospital having difficulty staffing their units with nurses. In this case, we saw the result of these staffing difficulties, as a nurse whose primary clinical background was neonatal intensive care being assigned to work in a cardiac care unit. Lack of familiarity with the care environment can lead to medication administration errors, yet staffing challenges make this a common nursing staff occurrence.

Physicians typically practice in the hospital facility as part of a more extensive practice to which the physician belongs. There might not be additional physicians on the hospital practice floor for a nurse to engage with for patient medication administration questions, a function of hospital administration physician staffing practices. Thus, a doctor performing procedures in a sterile environment, as in this medication error case, would also be responsible for simultaneously being available for patients outside of that environment, leading to compromises in care for all patients involved. The decisions made around physician staffing by the hospital administration are responsible controllers for this system's environmental condition, not the physician who responsibly handles the scenario to the best of their expert capability.

In this case, nursing supervisor and hospital administrator responsibilities must be upheld to facilitate safe medication administration in a care scenario such as this one. All administrators play a role in these events, even if their indirect involvement is not detailed and analyzed in the accident report.

Nursing Supervisor
Responsibilities:

- To ensure safe procedures for medication administration are implemented properly.
- To ensure all staff are aware of these procedures and if necessary, sufficiently trained.
- To ensure policy and procedures are in place and implemented to support adequate staffing levels and appropriate nursing expertise in the hospital.
- To ensure that medication information about drugs in the approved formulary and best practices for drug administration is available to nurses and other healthcare workers responsible for administering medications.

Hospital Administration
Responsibilities:

- To ensure policy and procedures disincentivize or prohibit oral medication orders in the hospital.
- To ensure other policy and procedures are in place to support safe medication administration (including those to support adequate staffing levels and appropriate medical expertise in the hospital.)
- To ensure approved drug formularies are approved and communicated to physicians and other hospital personnel effectively.

The fact that the original accident report did not include nursing supervisors or hospital administration demonstrates two separate and essential issues with accident reporting in hospital environments. It shows the inadequacies of the scope of accident investigations and how they are reported. Additionally, it subtly surfaces the inadequacies of how medical professionals think about the cause of accidents. An in-depth discussion of the role of hospital administration and external organizations (e.g., healthcare insurers, pharmaceutical companies, health information technology companies) impact medication administration safety is presented in Chapter 6. In this

chapter, the systems approach informs the discussion of a hospital safety management system guiding hospital management in supporting safe medication administration.

Communication Processes

The hospital environment is designed to have several different providers working to coordinate patient care. Often, communication related to patient care is very transactional, as each participant (nurse or doctor) is likely only interacting with that case for a particular amount of time with a nominal set of policies and procedures built to govern the patient care. Health information systems, including EHRs, are used as communication intermediates among the hospital caregivers to control care actions in the patient medication administration process. Thus, with different doctors and nurses on different shifts, the knowledge about the continuity of care for the patient is not in a human's mind, but it is in a computer system. This communication process places an extra burden on each healthcare provider to make certain that the information system is updated promptly to ensure safe patient care.

However, this process of putting the information into an information system is highly inefficient in a patient care setting, and thus, healthcare providers find themselves constantly having to navigate the tension of efficient care in conflict with safe and effective care. Inevitably, this consistent reliance on human judgment as a control mechanism in this scenario will break down and lead to losses because the system design is inherently hazardous. These systems provide decision support for the human caregivers in the patient's medication administration and overall care.

The rapid pace and constant pressures on the physicians and nurses in the hospital environment lead to policy and procedure workarounds and multi-tasking that can compromise patient safety by contributing to medication errors. There is regulatory guidance to have all medication orders be written and externally verified before administration. Yet, when the physician could not write the order because of duties in the catheterization lab, the care team reverted to verbal medication orders. Even if a verbal confirmation of the order was done, several safety checks in the EHR upon medication order entry and between care professionals are bypassed when an order is relayed through the providers verbally. Incorrect tacit knowledge is acted upon when the tacit knowledge would be made explicit in the EHR or on paper to allow for external verification if the workplace environment did not challenge the policies and procedures.

The conflicting nature of the communication between hospital administrators and the hospital medication administration health providers is not explicitly discussed in the case. The administration has developed policies over time that were instituted to ensure patient safety and quality care, and overall, these policies and procedures have been communicated well. What the administrators have *not* communicated to the physicians and nurses sufficiently are the implications of the policies and procedures administration *as a set of policies*. Prioritizing several conflicting policies rapidly in a highly dynamic hospital care environment is challenging to even the most capable care provider. The lack of clarity on how to appropriately prioritize is the hospital administration's responsibility to rectify. Otherwise, when enforcing multiple policies together, the healthcare providers will move the medication administration system to unsafe states in unusual circumstances and contribute to a specific loss, as it did in this case with the potassium chloride medication order. Alarmingly, by acting within the dynamic hospital environment and following the policies and procedures as written, the physicians and nurses contributed to the loss.

Coordination among System Controllers

As the complexity of the hospital medication administration system has increased to include more actors (human and computer), the more challenging it has become to manage the system safely. The complex coordination required in the care processes adds to this difficulty. In the hospital

scenario with a patient, care coordination is done through person-to-person interactions and human-computer interaction with patient electronic medical records and automated medication distribution systems that dispense medication to healthcare providers in a hospital setting. It was not clear from the case investigation if there was a warning either in the EHR or the Pyxis system that the medication order had been clarified/corrected by the hospital pharmacist to alert the nurse to the medication error before patient administration.

This lack of information systems coordination completely obviated the pharmacist's medication clarifications order, as no human healthcare actor was made aware that the medication ordering and administration process had been changed and the actor needed to take action. The health information systems could have alerted the nurse before medication dispensing (if it was at the Pyxis system level) or before medication administration at the EHR level that there was a change in the medication order. The nurse would not necessarily have had to call the ordering physician because the communications would have been made explicit in the health information systems to the nurse administering the medication. This type of coordination between the EHR and the automated medication dispensing system would have avoided the loss scenario and alerted the healthcare providers to the medication administration change.

Not adapting to system changes and dynamics over time in the hospital environment also contributed to the loss. The changes in the patient medication administration over the time of the care actions and the lagging documentation of those changes allow several unsafe states to occur in this hospital system. In this case, the change was a routine and expected one, a medication clarification order. Safety policies and procedures have been put in place to ensure patient care to minimize the impact of this change, but as mentioned previously, the changes could have been (and are routinely) circumvented through workarounds in other parts of the system.

Adding procedures for hospital pharmacist review of medication orders, physician availability to other medication administration actors (e.g., nurses, pharmacists), and nurse staffing with the relevant clinical care background will only strengthen the medication administration process safety if added in a systemically effective way. In this "40 of K" scenario, having a pharmacist review and the auto-dispensing system as safety measures still did not avoid the unsafe state because the actions of those actors were not appropriately coordinated with others in the system to ensure safety. Without a systemic look at the impact that new safety policies have on those that already exist, the hospital will always run the risk of unknown unsafe operating conditions when all healthcare provider personnel follow the rules exactly as they are written.

Safety Culture

Typically, hospitals are for-profit entities in the United States (although this is not universally true), and thus, focus on cost reduction and personnel efficiency are paramount while striving to keep the patient outcomes optimal. The focus on cost reduction and personnel efficiency will frequently be prioritized over that of patient health outcomes. Thus, healthcare providers are constantly being pressed to be more efficient and provide better care more quickly, leading to inevitable errors and subsequent losses. Nurses frequently find themselves needing to care for more patients in a shorter amount of time and thus will wait to complete all documentation of the care in the information system until after the care has been administered.

While this is helpful in terms of efficiency, it does leave potential unsafe medication administration conditions present. Additionally, it would be much easier and efficient for the nurse to have the medication administration record at the patient's bedside for easy reference and charting to verify and document medicine administrations. Still, often in the interest of cost-cutting, hospital facilities do not have those systems routinely at every bedside/patient care site.

This push for economic optimization is in eternal tension with patient care and safety – few safe actions are efficient in the moment, leaving healthcare providers pushing the boundaries of safe practice to save money.

A persistent culture of "swagger" within the hospital healthcare environment is common. As several aspects of this case illustrate, systemic conflicts result in the provider making the choice they did rationally, even if that choice goes against the hospital policies and procedures. As one provider mentioned, "it is about saving lives in a timely manner, not always following rules." Using abbreviations for names and dosages of commonly prescribed drugs (which leads to medication administration confusion and potential misinterpretation), taking verbal medication orders, EHR inputs delayed or worked around, and automated medication dispensing system overrides, each present in this case, are all examples of healthcare providers using workarounds to get their work accomplished within the environmental conditions presented in the hospital workplace (many patients with lessening time for direct patient care). This "swagger" has a negative impact on hospital medication administration safety. More diligent attention to the safety culture on behalf of hospital administration by actively engineering the hospital workplace environment might alleviate the need for such workarounds before they start.

The point that is lost on most is how much more expensive it is to have to compensate for a loss (economic compensation to those who suffer the loss as well as incalculable impacts such as provider mental health knowing that they made a mistake that harmed a patient, the aptly named "Second Victim" concept) than it is to engineer the environment for safe practices to exist without tension in the first place.

Safety Information Systems

A hospital would almost certainly have a safety information system to collect information on incidents at the facility and provide quality data and information to regulators and insurers (both commercial and government-based). The case discussed no such information system. It is possible that the facility only reactively used their safety information system – to report losses, assign blame, and develop a new policy – rather than a proactive way that would allow for data analysis to indicate where steps could be taken to enhance safety *prior* to a loss occurring.

Recommendations

There are several recommendations to enhance the control structure of the hospital medication administration process that arise from this CAST analysis that will improve safety and preventing similar losses in the future. These recommendations include:

- Change the system to require that medications cannot be dispensed without a pharmacist review documented in the EHR. This will decrease the attendant errors with ordering and documenting medication administration, including attenuating the potential negative impact of verbal orders.

- Require that physicians communicate directly with nurses and other clinical staff and subsequently document such communication about medication administration.

- Change the EHR system and the automated medication dispensing system so that they share data in real-time

- Change the EHR system and the automated medication dispensing system to have an alert or a hard lock-out in the medication dispensing system in the hospital.

- Change the EHR system to give notice to a health care provider that the pharmacist has either reviewed and confirmed, or reviewed and changed, a medication order without requiring the provider to consult the EHR before medication dispensing.

- Create and enforce a specific patient handoff procedure between shifts among health care providers on the ward to account for a second communication in addition to the EHR on patient care.

- Create a feedback pathway from nurses to hospital administrators to report on the operational impact of policies enacted for safe medication administration and report after-action steps taken to respond to the feedback.

- Take appropriate steps to change the safety culture at the facility level to have the facility assume the burden of creating/manufacturing the physical and social environment that optimizes financial resource utilization and patient health outcomes in the facility.

- Revisit safe medication administration practice policies every six months by a quality team at the facility level to ensure consistency and efficacy in clinical operation without conflict or unnecessary tension among the policies.

- The hospital quality team, consisting of both administrators and clinical staff, must assess the operational impact of policies before policy creation and change in the hospital environment.

An overarching concept that encompasses all of these recommendations is that it is easier, and often much more cost-effective long term, to change the engineered environment than to change a person (or personnel). Investing in the safety culture and building an effective safety control structure will ultimately impact the values and deep cultural assumptions of the hospital organization on safety. The dividends of this investment will be more effective organizational rules, policy, and procedures and more insightful and actionable accident investigation reports. Safe, quality hospital care is less expensive care.

Comparison with RCA evaluation

The nature of this case necessarily meant that many of the details of the specific loss scenario were omitted from the report. There were many places in this report where additional information would be necessary to make definitive recommendations for enhanced safety in the facility. The CAST process required and encouraged looking beyond what was in the report. RCA does not. Even with this caveat, these crucial redacted details would be available to an internal investigator who could fully report on the accident findings. It is possible that in those redacted details could lie information to broaden the recommendations given. This comparison is based on the publicly published root cause analysis report and the CAST report completed for this thesis on the same reported facts. Of course, it is possible that the internal investigators never considered the causal factors that STPA requires considering.

The results of my analysis and the recommendations of the RCA accident report are very similar concerning the individual actor control responsibilities. However, significant differences arise in my CAST-generated recommendations for the overall hospital medication administration process. The nature of my results/findings focused on the control structure of the entire medication administration system within the hospital and not on individual behaviors in the scenario. Thus, my recommendations are framed as procedural and environmental changes that can be taken at the hospital level rather than reinforcing policies for enhanced human compliance.

The RCA accident report focused on an encouragement of using checklists and additional policies and procedures to bringing human behavior into compliance, rather than addressing potential safety problems at the system level, which would make compliance a non-issue. By taking away the blame for the accident and focusing recommendations on the facility and its sociotechnical processes, there is the potential for the hospital facility and the health care providers to be more open in potentially accepting the recommendations. Looking at the systemic influences and processes to look at where those can be engineered to be safer as part of a system process, rather than focusing on the individual actor or technology behavior, is far superior to assigning blame and attempting to ensure better rule and policy compliance by the human actors in the system. And, of course, rule compliance will not help where the rules are deficient and do not include important but unusual cases.

Another significant difference between my recommendations and those of the accident report is my focus on how the hospital administration can improve its activities towards safety and how the facility's culture can be changed or evolved to avoid losses. Hospital administration and its involvement in hospital medication administration were omitted entirely in the analysis and recommendations of the RCA accident report. Almost all RCA analyses omit these factors, most likely because the process does not encourage examining them. My recommendations do not sidestep the issue and comprehensively discuss the control structure improvements at all levels of the hospital medication administration system.

Summary

When decomposing hospital medication administration from a sociotechnical perspective, the process involves tasks, people, organizational structure, and technology (see Figure 3). Root cause analysis techniques to investigate safety focus on each individual component and the errors that that specific component commits. This decompositional approach fails to consider the interdependencies of each of these components among each other and the emergent unsafe states that can result from these relationships. Taking a systems approach to accident analysis and focusing on the control structure of the system, rather than the individual components, allows for emergent properties of the hospital medication administration system to be accounted for proactively in safely engineering the hospital workplace and patient care environment to reduce medication administration errors.

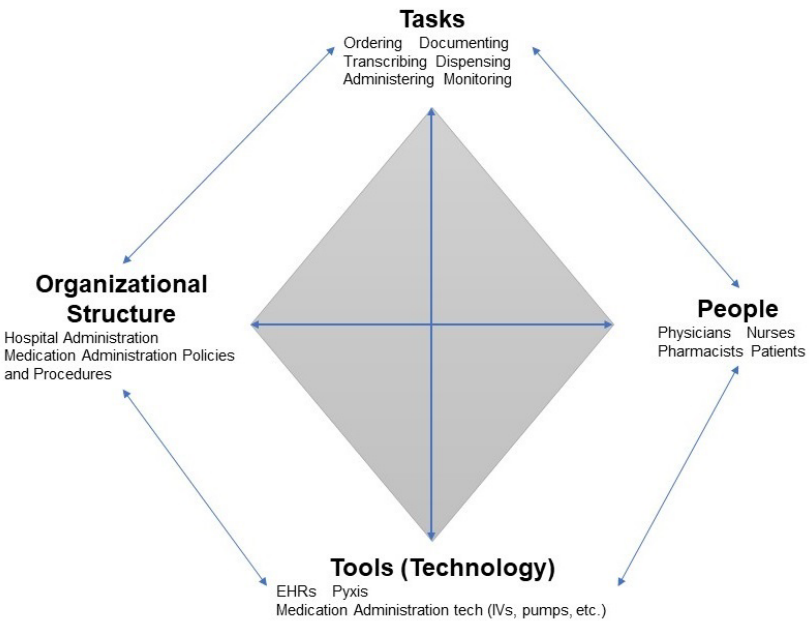


Figure 3: Components of Dynamic Sociotechnical Systems (adapted from Levitt [70])

Chapter 5: Applying STAMP-STPA to Hospital Medication Systems: A Case Study

This chapter presents a hazard analysis of the hospital medication administration process, including health information systems technologies and healthcare providers (human controllers). The overarching control structure is presented, then three different aspects of the process control structure are focused on. The hazard analysis identifies unsafe control actions, causal factors, and scenarios within the hospital medication administration process. This analysis allows for the generation of system requirements for a safer in-hospital medication administration process that includes human and technical factors germane to reinforcing the hospital safety environment and culture.

For this analysis, the definitions of loss and hazard are taken directly from the literature on STPA. A loss also referred to as an accident or adverse event in this analysis, is "any undesired and unplanned event that results in something the stakeholders want to avoid" [24, p. 16]. A hazard is "a state or set of conditions of a system that, together with a particular set of worst-case environmental conditions, will lead to a loss" [24, p. 17].

The key to STPA's efficacy in developing safer systems is its focus on hazards, system state, and the set conditions leading to a loss. In identifying hazards and analyzing the safety control structure to avoid these hazardous conditions, losses can be avoided or mitigated without hindsight bias or assigning blame. Applied to hospital medication administration, STPA provides a tool that considers the process at a systems level and can identify requirements potentially overlooked or incorrectly prioritized in the medication administration safety protocols currently in place.

The first step of the STPA analysis is to define the purpose of the analysis. This includes identifying the system to be analyzed, the system boundary, the environment the system operates within, losses to prevent, and hazards. The second step is to model the control structure for the system, detailing relationships and interactions as a set of feedback control loops. The third step is to analyze the control actions in the control structure to examine how they could lead to losses identified in the first step. The unsafe control actions are used to create functional requirements and constraints for the system. The fourth step identifies the reasons why unsafe control actions might occur in the systems. Scenarios are created to explain two things: 1) how incorrect feedback, inadequate requirements, design errors, component failures, and other factors could cause unsafe control actions and ultimately lead to losses; and 2) how safe control actions might be provided but not followed and executed properly, leading to a loss. Once scenarios are identified, they can be used to create additional requirements, identify mitigations, and for several other uses related to the design and operations of the system going forward.

System Description

The system under review is the in-hospital medication administration system. A high-level control structure for the system is shown in Figure 4. The human controllers include the medication ordering physician, the hospital pharmacist, the medication administration nurse, and the hospital patient. The four technical software systems include the hospital EHR (a communication and control system central to all six aspects of the hospital medication administration process), the hospital automated pharmacy dispensing system (ADM), the computerized provider order entry (CPOE) system, and the barcode electronic medication administration record (eMAR) system. Several environmental entities are outside of the system boundary for this analysis yet have significant influence on the behavior of the scoped medication administration system. These contributing entities will be discussed throughout the analysis, as they impact the control actions of the entities within the medication administration system boundary.

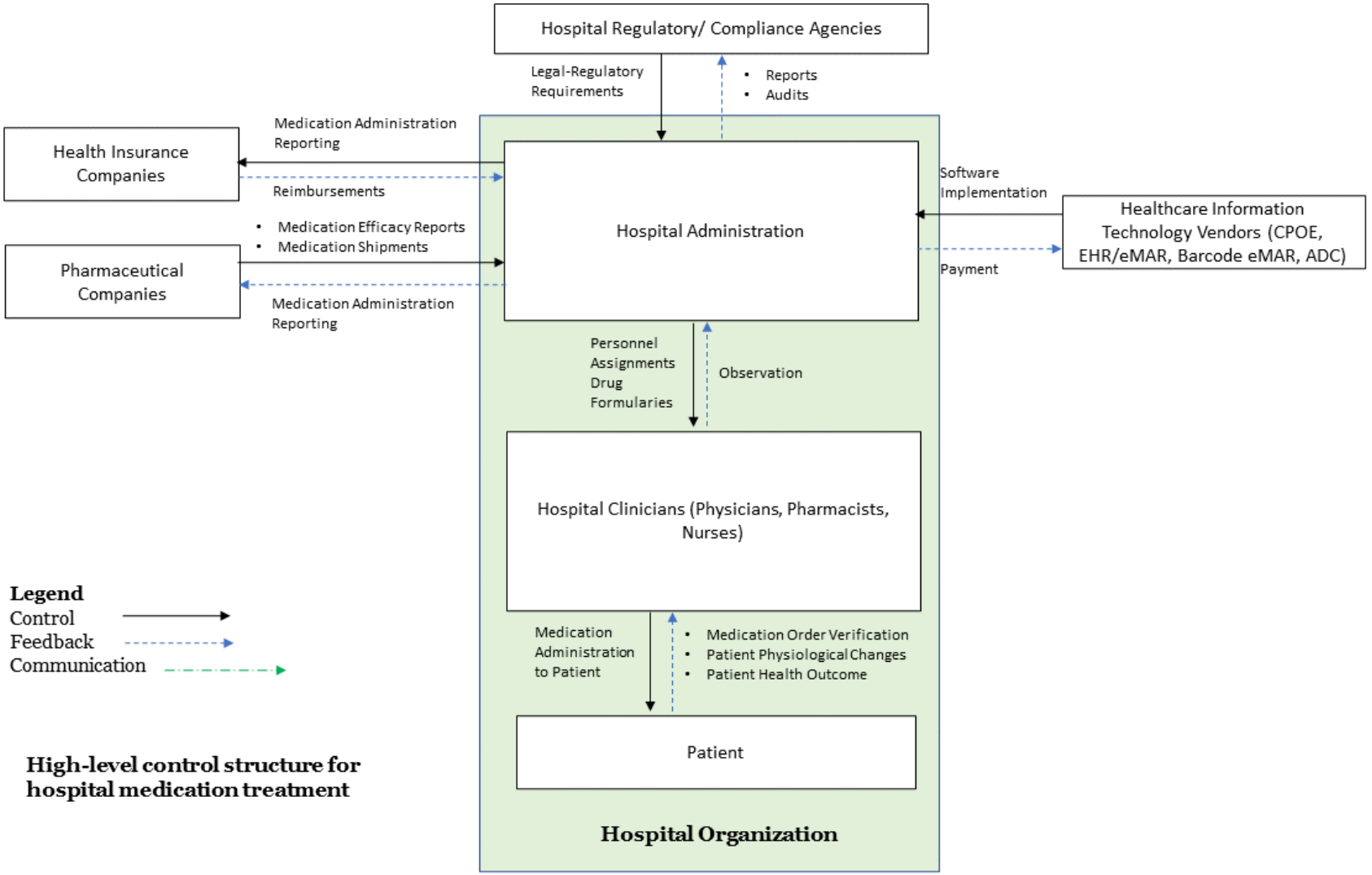


Figure 4: High-level control structure for in-hospital medication administration process

The system's goal is to provide safe and effective medication as it is prescribed to patients at the lowest cost possible for the overall hospital system while simultaneously delivering the highest possible patient health outcomes for a representative US hospital. This goal enables the patient to experience the physiological changes necessary to maximize their individual health outcome. Past accidents from hospital medication administration errors are well-documented and referenced in the literature review section of this thesis.

The system level losses for the in-hospital medication administration process are:
L-1: Loss of patient ability (harm) due to medication administration that negatively impacts health.
L-2: Loss of patient life (death) due to medication administration that negatively impacts health.
L-3: Loss of patient ability (harm) due to patient NOT receiving appropriate medication
L-4: Loss of patient life (death) due to patient NOT receiving appropriate medication

The relevant stakeholders in the hospital medication administration system are identified in Table 2 below. Losses relevant to each entity are listed, in addition to the four system-level losses that are listed above that pertain to every entity in the system.

Table 2: Relevant Stakeholders in the Hospital Medication Administration System

Stakeholders	**System Goals**	**Loss**
Hospital Patient	To attain the highest possible physiological health outcome intended by the medication prescribed	L-1, L-2, L-3, L-4
Nurse (Medication Administration Entity)	To maintain professional reputation To ensure correct medication is dispensed and administered to the patient To monitor the medication administration to see outcomes To advise patient on medications being administered	L-1, L-2, L-3, L-4 L-5: Loss of reputation/licensure
Hospital Pharmacist	To facilitate the correct ordering, documenting, transcribing, and dispensing of the medication prescribed	L-1, L-2, L-3, L-4 L-5: Loss of reputation/licensure
Physician (Medication Ordering Entity)	To maintain professional reputation To order the correct medication for the patient to meet intended physiological health outcome	L-1, L-2, L-3, L-4 L-5: Loss of reputation/licensure L-6: Loss of financial earnings L-7: Loss of customer satisfaction
Hospital Administration, including pharmacy and nursing administration	To monitor that medication administration to patient is performed accurately as prescribed	L-1, L-2, L-3, L-4 L-5: Loss of reputation/licensure L-6: Loss of financial earnings L-7: Loss of customer satisfaction

Hospital Regulators/Compliance	To regulate the performance of the hospital operations to meet obligated safety standards	L-1, L-2, L-3, L-4 L-5: Loss of reputation/licensure L-6: Loss of financial earnings L-7: Loss of customer satisfaction L-8: Loss of firm/hospital fiscal stability
Pharmaceutical companies	To provide economic value to the firm through sales to hospitals	L-1, L-2, L-3, L-4 L-6: Loss of financial earnings L-7: Loss of customer satisfaction L-8: Loss of firm/pharmaceutical company fiscal stability
Health insurance companies	To reimburse hospitals for medications administered to patients with insurance	L-1, L-2, L-3, L-4 L-6: Loss of financial earnings L-7: Loss of customer satisfaction L-8: Loss of firm/insurance company fiscal stability

Technical System Safety Requirements

This system's technical system safety requirements focus on four healthcare information technology systems: the electronic healthcare records (EHR) system; the computerized provider order entry (CPOE) system; the barcode electronic medication administration record (eMAR); and the automated medication dispensing cabinet (Pyxis ADC).

The Health Information Technology for Economic and Clinical Health (HITECH) Act passed in 2009 outlines the three stages of technical systems requirements that need to be met to achieve EHR interoperability and improved health outcomes as certified electronic health record technology (CEHRT). For EHRs and CPOEs, the US federal government requires "meaningful use" of the system for the hospital to be able to participate in incentive programs, and in some cases, require the system's use for reimbursement for those facilities that bill federal insurers (e.g., Medicare, Medicaid) [71].

The "meaningful use" statute outlines the required clinical function requirements for the EHR system, including those for clinical decision support systems, computerized physician order entry systems, electronic prescribing, and security of electronic patient data, among other objectives (Department of Health and Human Services (DHHS), Office of the National Coordinator for Health Information Technology (ONC), 45 CFR Part 170: Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for EHR Technology, with annual revisions/updates to the legislation through to the current year).

It is important to note that the requirements are only targeted for facility participation in an economic incentive program for payments to those who achieve the targets. There is no regulatory sanction on facilities that choose not to meet these EHR system software requirements.

Automated medication dispensing cabinets (ADCs), which are referred to as Pyxis machines in most facilities, have Drug Enforcement Agency (DEA) and state laws that govern their use and

inform regulatory compliance. Furthermore, there are Institute for Safe Medication Practices (ISMP) guidelines for the best practices of ADC implementation and usage. As is the case with EHRs, there are regulatory sanctions only in a certain set of scenarios with specific classes of drugs and not for the system usage overall.

Barcode eMAR entry systems are subject to Federal Drug Administration (FDA) compliance with barcode standards for drug labelling and HIPAA standards for security and privacy of health information. Best practices for these systems are also included in the ISMP *Guidelines for Safe Electronic Communication of Medication Information*. There are no regulatory technical requirements for these systems other than compliance with FDA and HIPAA standards.

Management or organizational requirements

The management requirements for hospital medication administration are found in Federal, State and local laws that govern hospitals and their operations more broadly. Pharmaceutical services are considered a basic hospital function, with conditions of participation listed with which each facility must comply (Title 42, Chapter IV, Subchapter G, Part 482, 482.25)

The specific regulatory guidance on medication administration errors is found in 482.25(b)(6), which states: "Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital's quality assessment and performance improvement program." Each facility can determine whether a medication administration error is reported into a safety reporting system absent a specific law requiring a facility to do so.

Top-Level Accidents, Hazards, and Safety Constraints

Although several different losses among the various hospital medication administration entities were identified, the focus of this STPA analysis are the system level losses that can occur. To reiterate, the system level losses for the in-hospital medication administration process are:

L-1: Loss of patient ability (harm) due to medication administration that negatively impacts health.
L-2: Loss of patient life (death) due to medication administration that negatively impacts health.
L-3: Loss of patient ability (harm) due to patient NOT receiving medication administration.
L-4: Loss of patient life (death) due to patient NOT receiving medication administration.

From these system-level losses, three system-level hazards are identified.

H-1: Incorrect medication administered (L-1, L-2)
H-2: Medication administered incorrectly (L-1, L-2)
H-3: Omission of medication administration when medication needed to be given (L-3, L-4)

These three system-level hazards can be broken down into several sub-hazards that assist with the determination of safety constraints. Table 3 lists the sub-hazards and safety constraints identified for the hospital administration system.

Table 3: Sub-hazards and Safety Constraints Identified for the Hospital Medication Administration System

Sub-hazards Identified	Safety Constraints
H-1: Incorrect medication administered (L-1, L-2)	
H-1.1: Incorrect patient	SC-1.1: The medication must be administered to the correct patient for whom it was ordered.
H-1.2: Incorrect medication (including incorrect timing, dose, route) ordered	SC-1.2: The medication must be ordered with the correct dosage, route, and timing as prescribed.
H-1.3: Unauthorized drug administered	SC-1.3: The medication must be authorized for administration to the patient for the indicated condition.
H-1.4: Adverse medication interaction with other medications (contraindication)	SC-1.4: The medication administered must have no contraindications with other medications administered to the patient.
H-1.5: Allergic medication interaction with patient	SC-1.5: The medication administered must trigger no allergic reactions when administered to the patient.
H-2: Medication administered incorrectly (L-1, L-2)	
H-2.1: Incorrect medication administered	SC-2.1: The correct medication must be administered to the patient for whom it was ordered.
H-2.2: Medication administered to incorrect patient	SC-2.2: The medication must be administered to the correct patient for whom it was ordered.
H-2.3: Incorrect timing/frequency/duration of medication administration	SC-2.3: The medication must be administered at the correct time, frequency, and duration as ordered.
H-2.4: Incorrect dose administered (overdose, underdose, extra dose, missed dose)	SC-2.4: The medication must be administered at the correct dosage as ordered.
H-2.5: Incorrect route of administration (e.g., oral, IV)	SC-2.5: The medication must be administered using the correct route of drug administration.
H-2.6: Incorrect rate of medication given	SC-2.6: The medication must be administered using the correct rate of drug intake/ingestion/infusion.
H-2.7: Incorrect medication compounded/dispensed	SC-2.7: The medication must be compounded and dispensed using the correct dosage and strength ordered.
H-2.8: Incorrect medication administration technique	SC-2.8: The medication must be administered using the correct administration techniques for that medication.
H-3: Omission of medication administration when medication needed to be given (L-3, L-4)	
H-3.1: Medication is not available for indication	SC-3.1: The medication must be authorized for the indication for which it is ordered.
H-3.2: Medication is not affordable for patient	SC-3.2: The medication must be affordable that is ordered for administration to the patient.
H-3.3: Medication is not delivered to the patient for administration.	SC-3.3: The medication must be delivered to the patient for administration.

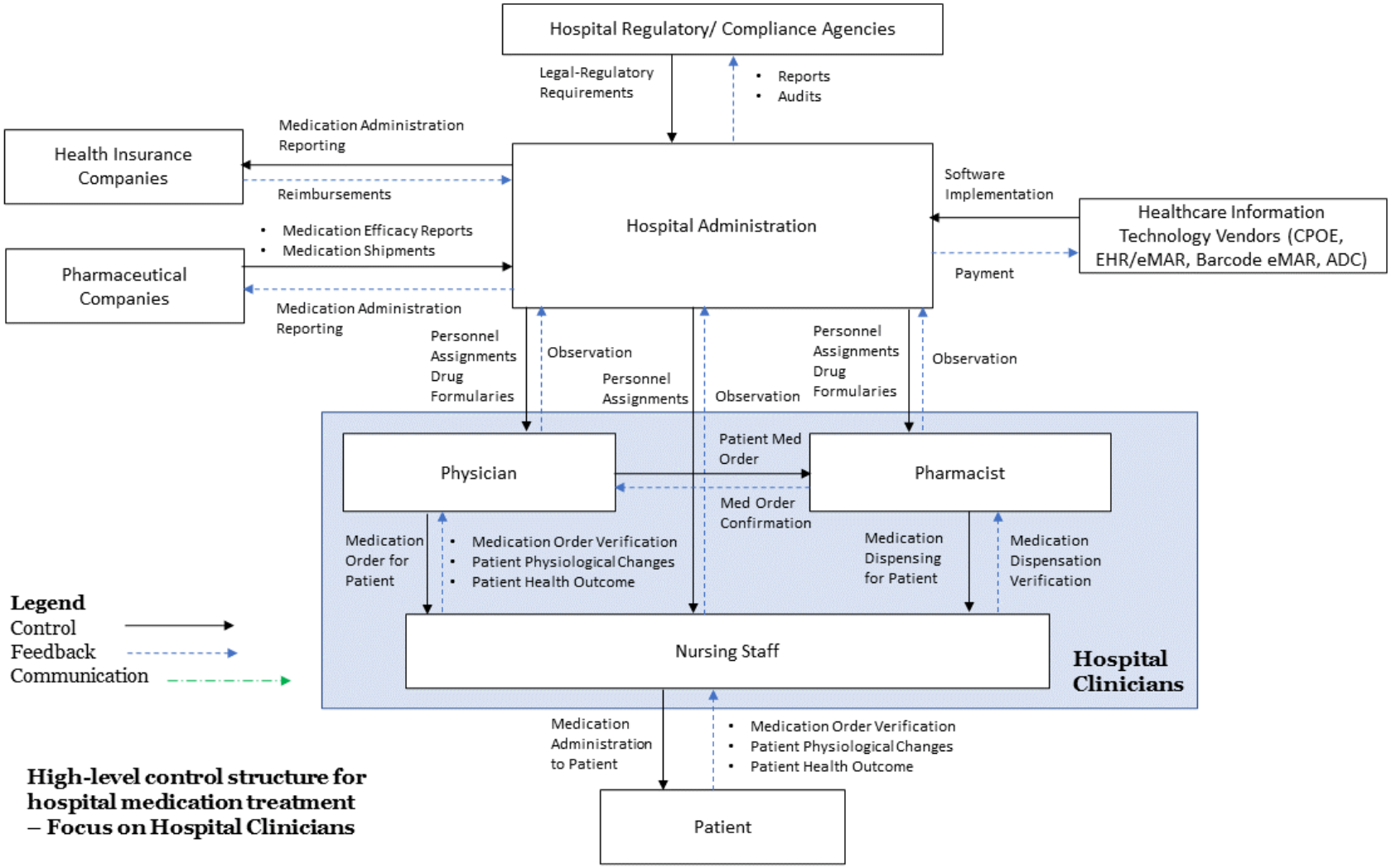
Traceability of each of the hazards and safety constraints to the losses allows for the ability to rank and prioritize hazards for mitigation efforts. The analysis results can be easily ranked and prioritized based on the losses to which they refer because STPA results are traceable to one or more losses.

Control Structures

The next step in this STPA analysis is modeling the hierarchical control structure for the hospital medication administration system. From observation and descriptions of the system in the preceding sections, the process is represented as a system model composed of feedback control loops with abstract functions and the controllers responsible for them. The analysis begins with a high-level control structure. This structure is then shown as more detailed structures mapped to specific subprocesses in the system.

High-Level Control Structure with a focus on clinicians

The high-level control structure for the hospital medication administration process is shown in Figure 4. Figure 5 shows this high-level control structure with a focus on the clinicians that are involved in the medication administration process.



High-level control structure for hospital medication treatment – Focus on Hospital Clinicians

Figure 5: High-level control structure for in-hospital medication administration process - focus on clinicians

The control structure analysis starts at the top-level with the hospital administration and hospital regulators/compliance entities and details the six subprocesses that make up medication administration: 1) ordering (prescribing) the medication; 2) transcribing (verifying) the medication order; 3) dispensing (delivering) the medication ordered; 4) administering the medication to the patient; 5) documenting the medication administration, and 6) monitoring the patient post-medication administration. The detailed analysis focuses on three separate aspects of the overall structure: 1) the management of the medication administration process overall at the hospital level; 2) the medication ordering and transcribing structure; and 3) the medication dispensing and administering structure.

Detailed Structure – Medication Administration Management

An essential, often under-analyzed aspect of the hospital medication administration process to focus on is the management structure of the hospital organization itself. The control actions from these entities have a significant impact on the medication administration clinical process. This management structure provides direct inputs to the controlled process and has several controllers of the control process, and thus, merits analysis for its impact on medication administration safety. The detailed organizational control structure and its relationship to the hospital medication administration process are shown in Figure 6.

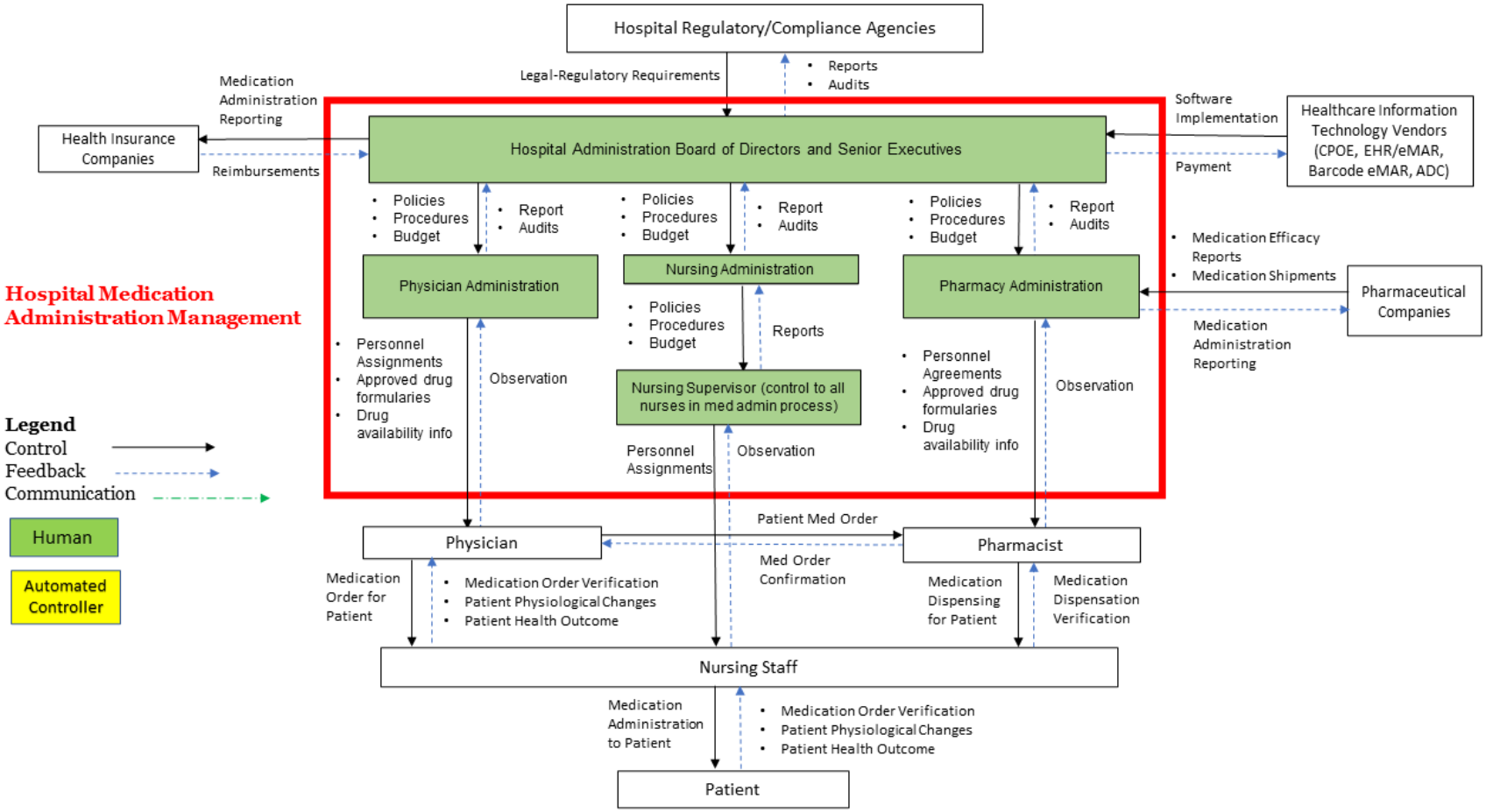


Figure 6: Detailed control structure for in-hospital medication administration management

There is the overall hospital administration within the hospital organization, consisting of both business and clinical entities. The three subgroups of overall hospital administration of interest in the control structure are the physician administration, pharmacy administration, and nursing administration groups. The physician and pharmacy administration groups control the budget and staffing for the hospital physicians and pharmacists respectively. Likewise, through its nursing supervisors, the nursing administration controls the budget and staffing of unit nurses, a key controller in the hospital medication administration process. Decisions that these personnel supervising groups make control the working conditions of the human controllers in the medication administration system. Therefore, those decisions have a direct impact on the safety of the medication administration system.

Adding to the complexity of the management control structure is the myriad of external organizations that govern or constrain hospital administration overall and have a direct control input to the medication administration process. Specific to medications in the hospital, pharmaceutical companies and health insurance companies directly impact control actions taken by pharmacy administration. The control and feedback actions of pharmaceutical and insurance companies are separate and contractual, which invites significant change over time in structural terms and conditions. Implementing the contracts, a manifestation of the control actions outlined in the contract, has implications for the control actions a pharmacist can take in the medication administration process in terms of approved drug formularies, availability of certain drugs, and drug cost reimbursements among other considerations.

Additional external groups of significance in the management control structure are the software vendors that build and maintain the information systems and technology used as tools in the medication administration process. These systems are the CPOE, the hospital EHR, the barcode eMAR, and the Pyxis ADC deployed in the hospital.

The vendors control decisions about the design and build of their systems, often without significant input from the hospital administration or the actors in the medication administration process – the physicians, pharmacists, and nurses. Thus, those vendors make information systems engineering decisions that directly control (through the user interface or other product design interfaces) the human actors' control actions in the medication administration system. The impact on medication administration safety that this software vendor control has within the system is the subject of intense scrutiny by many in the healthcare safety arena [39], [42]. The opaque nature of these software vendors to hospital administration control actions dictated through software system purchase and implementation contracts leads to many software feedback loops being severed and thwarting safe operation [72].

In addition to hospital administration, each of these external organizations has significant regulatory and legal requirements that must be met to fulfill compliance obligations. Federal and state laws and federal agency regulations (e.g., FDA, OSHA, among others) guide hospital administration, health insurance companies, pharmaceutical companies, and healthcare software systems vendors in their control actions throughout the medication administration management structure.

This regulatory structure in turn directly provides inputs to the medication administration control structure as control outputs. Thus, many control actions from the management structure that seem well removed from the actual clinical medication administration system will directly impact the safety of the system through these control outputs directly used as control inputs to the medication administration control structure, leading to several unsafe control action contexts that will have to be considered when focusing on hospital medication administration safety.

Analysis of the in-hospital medication management administration is performed for this system in Chapter 6, which investigates the safety management system overall for the hospital, rather than using the STPA techniques used for the medication ordering/transcribing process and the medication dispensing/administering process.

Detailed Structure for Medication Ordering (prescribing)/Transcribing (verifying)

The detailed control structure for the ordering/transcribing process is shown in Figure 7. The context of where this detailed process fits into the high-level structure is shown through inputs from the hospital medication administration management process and control output from this ordering/transcribing control structure to the medication dispensing/administering process below in the hierarchical structure.

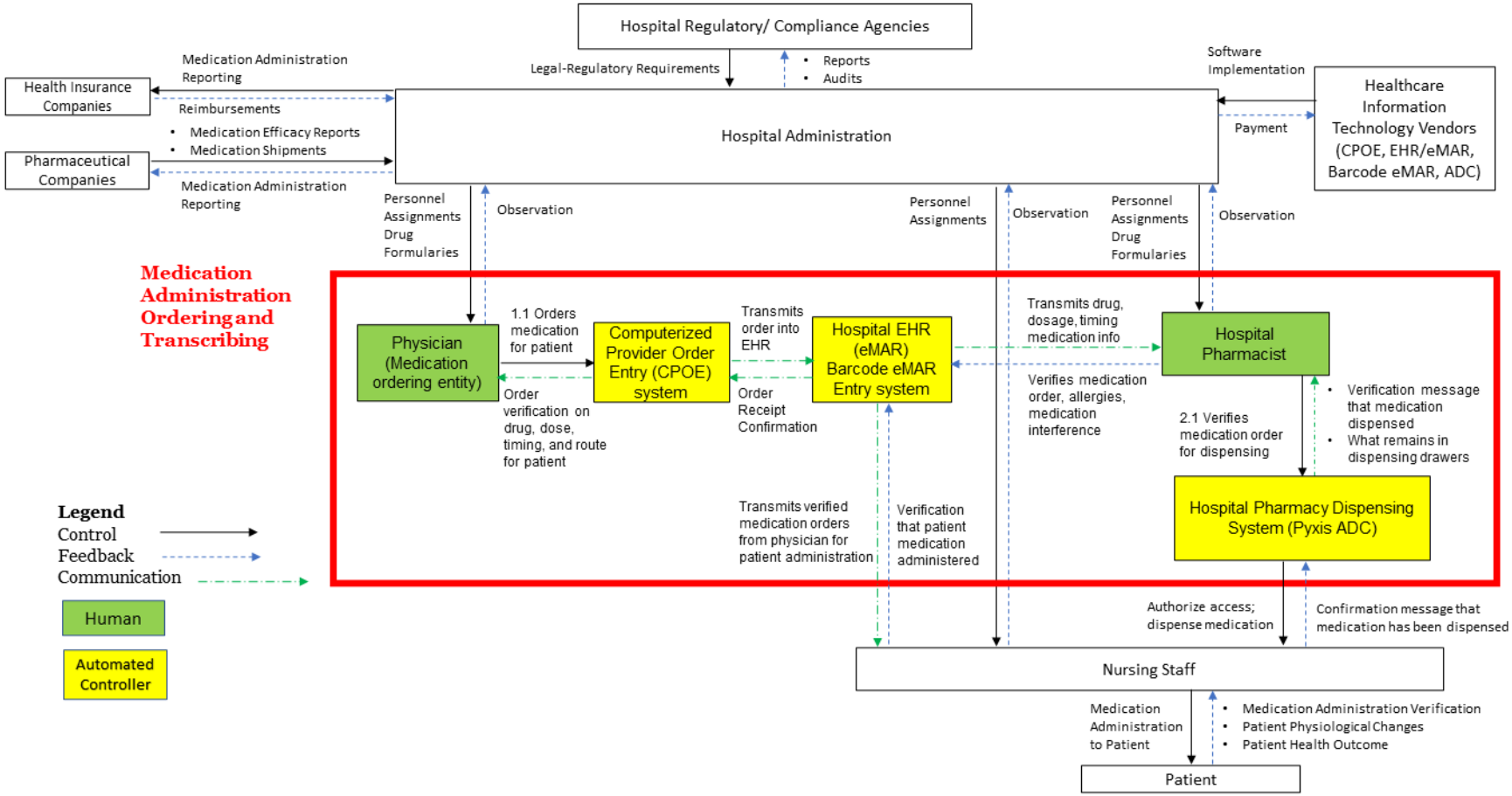


Figure 7: Detailed control structure for in-hospital medication ordering and transcribing process

The hospital medication ordering/transcribing process is responsible for indicating the correct medication, timing, route, and dosage for a patient to those providers involved in the medication administration process. This system goal aligns with the five rights of medication administration familiar to healthcare providers. The modeled process is the physician ordering the medication through the CPOE system, which provides checks and verifications on the medications ordered and transmits the information to the hospital EHR for the patient and the barcode medication administration system. This order is then reviewed and verified by a hospital pharmacist. Once verified, the medication order confirmation is sent to the automated pharmacy dispensing system and barcode eMAR system for subsequent dispensing and administration to the patient. The control actions for this process are numbered in Figure 7.

The physician ordering and transcribing control actions involve the physician entering the data into the CPOE about the medications he/she is prescribing to the patient. This input data includes information indicating the patient, the medicine, dosage, timing, and route for the order. As feedback to the control action, the pharmacist will verify the medication order by checking the medication specifics and any allergies or potential medication interference. The control output is the transcribed medication order from the physician.

CA-1.1: Physician orders medication for the patient.

This ordering and transcribing control action is made using two information systems to transmit data electronically between the physician and the pharmacist. The CPOE to hospital EHR communications involve transmitting and confirming medication ordering data for that specific patient to the broader healthcare provider team in the hospital who will be responsible for administering the medication. The EHR system receives this information from the CPOE and organizes it into the eMAR for the appropriate provider access to the order. The pharmacist reviews the medication order and provides feedback to the physician through the EHR system about potential allergic reactions, medication interference, and medication contraindications. The control output is the verified medication order that is sent on to the medication dispensing/administering subprocess.

CA-2.1: The hospital pharmacist verifies the medication order for dispensing.

Detailed Structure for Medication Dispensing (delivering)/Administering

The detailed control structure for the dispensing/administering process is shown in Figure 8. The context of where this detailed process fits into the high-level structure is shown through control inputs from the hospital medication administration management process and the medication ordering/transcribing control structure that leads to the medication administration to the patient.

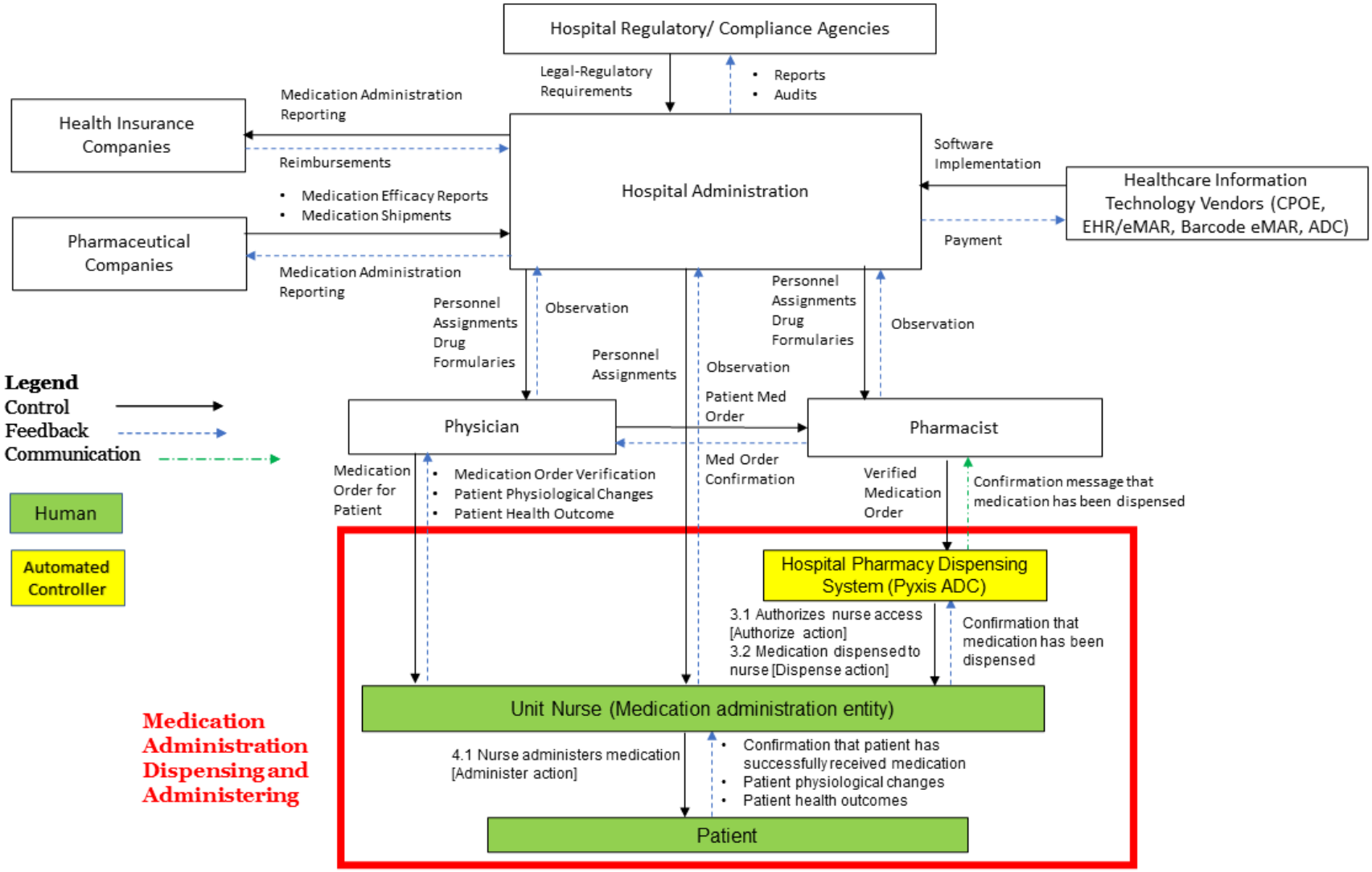


Figure 8: Detailed control structure for in-hospital medication dispensing and administering process

The hospital medication dispensing/administering process is responsible for physically acquiring the correct medication, timing, route, and dosage for a patient and assuring the patient's appropriate ingestion of the medications. The detailed process being modeled is the pharmacist sending the verified medication order to the Pyxis automated dispensing system, after which the nurse responsible for giving medication to this patient will dispense the medication to take to the patient for administering. Using the barcode eMAR system, the nurse will record each medication ingested by the patient during medication administering by scanning a barcode on the patient's wristband and then scanning the medication's barcode. Once the medication is administered and ingested, the patient is monitored for physiological changes in response to the medication and overall health outcomes. The control actions for this process are numbered in Figure Z and described below.

The hospital pharmacist transmits the medication, dosage, and route information to the automated pharmacy dispensing system (Pyxis ADC) to authorize a nurse's access to that medication and dispense the medication to that nurse. The Pyxis ADC system to unit nurse control actions involve authorizing the unit nurse's access to that specific medication and dispensing the medication to the nurse for patient medication administering. The Pyxis ADC system controls the unit nurse by only authorizing access and dispensing medications that he/she is to administer to the patient. The feedback from the unit nurse is confirmation that the Pyxis ADC dispensed the medication. The control output to this process is the medication ready to be given to the patient for ingestion.

> CA-3.1: The Pyxis ADC authorizes the unit nurse's access to the medications in the dispensing cabinet for the patient.
>
> CA-3.2: The Pyxis ADC dispenses the medication to the unit nurse for patient administering.

The barcode eMAR system transmits the medication orders to the unit nurse to facilitate medication administering, directing which medications he/she is to administer to the patient. The feedback from the unit nurse is verification that the medication is available to the patient through barcode scans of the individual medications as they are ready to be administered to the patient at the bedside.

The unit nurse to patient control actions involve the nurse facilitating patient ingestion of the medications ordered. The nurse controls the patient by enforcing the administering of these medications. The feedback from the unit nurse is confirmation in the hospital EHR/eMAR (and ultimately to the physician) that the patient has successfully received the medication as ordered. The control outputs to this process are the patient's physiological changes resulting from the medication administration and the patient's overall health outcome.

> CA-4.1: The unit nurse physically administers the medication to the patient.

Identification of Unsafe Control Actions

With the completed control structure for hospital medication administration, the next step in the STPA analysis is to identify unsafe control actions that can arise from the controller behavior. An unsafe control action (UCA) is a control action that, in a particular context and worst-case environment, will lead to a hazard, a loss as defined by the STPA analysis process [24]. These unsafe control actions identify whether there is any context under which the control action is unsafe given the following:

1. Not providing the control action leads to a hazard.
2. Providing the control action leads to a hazard.
3. Providing a potentially safe control action but too early, too late, or in the wrong order
4. The control action lasts too long or is stopped too soon (for continuous control actions, not discrete ones).

The unsafe control actions for the hospital medication administration system for the physician controller are listed in Table 4. The full UCA table for the hospital medication administration can be found in Appendix A. STPA enabled finding of 46 UCAs for this system.

Table 4: Examples of Unsafe Control Actions for the Hospital Medication Administration System

Control Action	Not providing causes hazard	Providing causes hazard	Too early, too late, out of order leads to hazard	Stopped too soon, applied too long leads to hazard
Ordering and Transcribing Subsystem				
CA-1.1: The physician orders medication for a patient. [Order action]	UCA-1.1.1: The physician does not order medication for a patient when the medication is not affordable to the patient. [H-3.2] UCA-1.1.2: The physician does not order the medication when the patient is prescribed medication. [H-3.3] UCA 1.1.3: The physician does not send drug information to the hospital pharmacist when the medication order is submitted. [H-3.3] UCA 1.1.4: The physician does not send drug dosage information to the hospital pharmacist when the medication order is submitted. [H-3.3] UCA 1.1.5: The physician does not send drug timing information to the hospital pharmacist when the	UCA-1.1.7: The physician orders medication for the patient when the medication is not available/approved for indication. [H-3.1] UCA-1.1.8: The physician orders medication for the patient when the patient is allergic to the medication ordered. [H-1.5] UCA 1.1.9: The physician orders medication for the patient when the patient is already taking a medication that is contraindicated. [H-1.4] UCA 1.1.10: The physician orders medication for the incorrect patient. [H-1.1] UCA 1.1.11: The physician sends incorrect drug information to the hospital pharmacist when the medication order is submitted. [H-1.2] UCA 1.1.12: The physician sends incorrect drug dosage information to the hospital	UCA-1.1.15: The physician orders medication for the patient too late when the patient is prescribed medication. [H-2.4] UCA 1.1.16: The physician sends drug information too late to the hospital pharmacist when the medication order is submitted. [H-2.4] UCA 1.1.17: The physician sends drug dosage information too late to the hospital pharmacist when the medication order is submitted. [H-2.4] UCA 1.1.18: The physician sends drug timing information too late to the hospital pharmacist when the medication order is submitted. [H-2.3] UCA 1.1.19: The physician sends drug route information too late to the hospital pharmacist when the	The medication order is a discrete action so this does not apply.

	medication order is submitted. [H-3.3] UCA 1.1.6: The physician does not send drug administration route information to the hospital pharmacist when the medication order is submitted. [H-3.3]	pharmacist when the medication order is submitted. [H-1.2] UCA 1.1.13: The physician sends incorrect drug timing information to the hospital pharmacist when the medication order is submitted. [H-1.2] UCA 1.1.14: The physician sends incorrect drug administration route information to the hospital pharmacist when the medication order is submitted. [H-1.2]	medication order is submitted. [H-2.5]	

Identification of Causal Scenarios and Requirements Generation
STPA enabled finding of 46 UCA's that lead to 99 different causal scenarios. The scenarios that lead to unsafe control actions from the physician are shown in this section; the full listing of causal scenarios and safety requirements for this STPA is in Appendix B.

Scenarios that lead to UCAs – Physician
These are causal scenarios that lead to unsafe control actions from the physician in the control structure.

UCA-1.1.1: The physician does not order medication for a patient when the medication is not affordable to the patient. [H-3.2]

> Scenario 1 for UCA-1.1.1: The physician is aware of a medication that would be suitable to treat the patient's condition but believes that the medication is not covered by the patient's healthcare plan. Thus, the physician does not order medication for a patient when the medication is not affordable to the patient [UCA-1.1.1]. As a result, the medication is not administered when the medication needs to be given because the medication is not affordable to the patient [H-3.2].

Safety Requirement 1: The medication ordering system shall inform the physician of medication cost to the patient at the time of ordering.

UCA-1.1.2: The physician does not order the medication when the patient is prescribed medication. [H-3.3]

> Scenario 1 for UCA-1.1.2: The physician gives an order to a duty nurse to put in a medication order for a patient. The duty nurse is tasked to put in the order but does not (the order got lost in paperwork, on busy shift nurse does not input into CPOE, etc.). Thus, the physician does not order the medication when the patient is prescribed medication. [UCA-1.1.2] As a result, the medication is not delivered to the patient for administration [H-3.3].

Safety Requirement 2: The ordering system shall notify the physician and the unit nurse if diagnosis has been made and medication order (including the medication, the dosage, the timing, and the administration route) has not been received by CPOE/EHR X minutes after diagnosis has been entered into EHR.

UCA 1.1.3: The physician does not send drug information to the hospital pharmacist when the medication order is submitted. [H-3.3]

> Scenario 1 for UCA 1.1.3: The physician sends the drug information to the hospital pharmacist upon ordering the medication, but drug information is not received by the pharmacist due to transmission errors, lost communication, or delays in communication among the CPOE and EHR information systems. Thus, the physician does not send drug information to the hospital pharmacist when the medication order is submitted [UCA-1.1.3]. As a result, the medication is not delivered to the patient for administration. [H-3.3].

> Scenario 2 for UCA 1.1.3: The physician sends the drug information to the hospital pharmacist upon ordering the medication, but the order information was not received correctly by the CPOE and/or EHR due to loss of power to systems, software update

conflicts, or inaccurate input due to UI confusion. Thus, the physician does not send drug information to the hospital pharmacist when the medication order is submitted [UCA-1.1.3]. As a result, the medication is not delivered to the patient for administration. [H-3.3].

Safety Requirement 3: The ordering system shall notify the physician and the unit nurse if a pharmacist has not verified the medication order (including the medication, the dosage, the timing, and the administration route) by X minutes after the order has been placed in the CPOE/EHR.

Safety Requirement 4: Addressed by SR2

UCA 1.1.4: The physician does not send drug dosage information to the hospital pharmacist when the medication order is submitted. [H-3.3]

Scenario 1 for UCA 1.1.4: The physician sends the drug dosage information to the hospital pharmacist upon ordering the medication, but drug dosage information is not received by the pharmacist due to transmission errors, lost communication, or delays in communication among the CPOE and EHR information systems. Thus, the physician does not send drug dosage information to the hospital pharmacist when the medication order is submitted [UCA-1.1.4]. As a result, the medication is not delivered to the patient for administration [H-3.3].

Scenario 2 for UCA 1.1.4: The physician sends the drug dosage information to the hospital pharmacist upon ordering the medication, but the order information was not received correctly by the CPOE and/or EHR due to loss of power to systems, software update conflicts, or inaccurate input due to UI confusion. Thus, the physician does not send drug dosage information to the hospital pharmacist when the medication order is submitted [UCA-1.1.4]. As a result, the medication is not delivered to the patient for administration [H-3.3].

Safety Requirement 5: Addressed by SR 3

Safety Requirement 6: Addressed by SR 2

UCA 1.1.5: The physician does not send drug timing information to the hospital pharmacist when the medication order is submitted. [H-3.3]

Scenario 1 for UCA 1.1.5: The physician sends the drug timing information to the hospital pharmacist upon ordering the medication, but drug timing information is not received by the pharmacist due to transmission errors, lost communication, or delays in communication among the CPOE and EHR information systems. Thus, the physician does not send drug timing information to the hospital pharmacist when the medication order is submitted [UCA-1.1.5]. As a result, the medication is not delivered to the patient for administration [H-3.3].

Scenario 2 for UCA 1.1.5: The physician sends the drug timing information to the hospital pharmacist upon ordering the medication, but the order information was not received correctly by the CPOE and/or EHR due to loss of power to systems, software update conflicts, or inaccurate input due to UI confusion. Thus, the physician does not send drug timing information to the hospital pharmacist when the medication order is submitted

[UCA-1.1.5]. As a result, the medication is not delivered to the patient for administration [H-3.3].

Safety Requirement 7: Addressed by SR 3

Safety Requirement 8: Addressed by SR 2

UCA 1.1.6: The physician does not send drug administration route information to the hospital pharmacist when the medication order is submitted. [H-3.3]

Scenario 1 for UCA 1.1.6: The physician sends the drug administration route information to the hospital pharmacist upon ordering the medication, but drug administration route information is not received by the pharmacist due to transmission errors, lost communication, or delays in communication among the CPOE and EHR information systems. Thus, the physician does not send drug administration route information to the hospital pharmacist when the medication order is submitted [UCA-1.1.6]. As a result, the medication is not delivered to the patient for administration [H-3.3].

Scenario 2 for UCA 1.1.6: The physician sends the drug administration route information to the hospital pharmacist upon ordering the medication, but the order information was not received correctly by the CPOE and/or EHR due to loss of power to systems, software update conflicts, or inaccurate input due to UI confusion. Thus, the physician does not send drug administration route information to the hospital pharmacist when the medication order is submitted [UCA-1.1.6]. As a result, the medication is not delivered to the patient for administration [H-3.3].

Safety Requirement 9: Addressed by SR 3

Safety Requirement 10: Addressed by SR 2

UCA-1.1.7: The physician orders medication for the patient when the medication is not available/approved for indication. [H-3.1]

Scenario 1 for UCA-1.1.7: The physician orders the medication for a patient when the medication is not available/approved for indication [UCA-1.1.7] because the physician believes that this medication is approved for use for this condition. This flawed process model will occur if the physician has no mechanism for updating the physician's information about the drug approval for a particular indication at the time the medication ordering decision is made. As a result, the medication ordered is not administered to the patient. [H-3.1]
Scenario 2 for UCA-1.1.7: The physician orders the medication for a patient when the medication is not available/approved for indication [UCA-1.1.7] because the physician believes that this medication is approved for use for this condition. This flawed process model will occur if the user interfaces of the actuators for the process (CPOE and/or EHR) incorrectly indicate to the physician that this medication is approved for the condition. This UI indicator could be incorrect if a software patch to update the drug approval status for the drugs available in the system is not provided or not applied correctly to the actuator system. As a result, an unauthorized drug is administered to the patient. [H-1.3]

Safety Requirement 11: The ordering system shall inform the physician of medication use approval for diagnosis indications at time of medication ordering.

Safety Requirement 12: The ordering system information systems (CPOE and EHR) shall be maintained with all software updates and patches in a timely manner.

UCA-1.1.8: The physician orders medication for the patient when the patient is allergic to the medication ordered. [H-1.5]

> Scenario 1 for UCA-1.1.8: The physician orders medication for the patient when the patient is allergic to the medication ordered [UCA-1.1.8] because the physician believes that this medication is safe to prescribe for the patient's condition. This flawed process model will occur if there is no information in the patient record (medication reconciliation) to indicate that the patient was allergic to the medication. As a result, the patient has an allergic medication interaction when the medication is administered. [H-1.5]

> Scenario 2 for UCA-1.1.8: The physician orders medication for the patient when the patient is allergic to the medication ordered [UCA-1.1.8] because the physician believes that this medication is safe to prescribe for the patient's condition. This flawed process model will occur if the medication reconciliation process for the patient when he/she is asked for information on known allergies was not conducted or it was not documented completely in the EHR for the physician to be able to access prior to ordering the medication. As a result, the patient has an allergic medication interaction when the medication is administered. [H-1.5]

Safety Requirement 13: The ordering system shall require the medication reconciliation for the patient to be completed prior to ordering the medication for the patient.

Safety Requirement 14: The ordering system shall require the physician to positively indicate the medication reconciliation has been reviewed and/or patient asked verbally about medication allergies prior to ordering medication for the patient.

UCA 1.1.9: The physician orders medication for the patient when the patient is already taking a medication that is contraindicated. [H-1.4]

> Scenario 1 for UCA-1.1.9: The physician orders medication for the patient when the patient is already taking a medication that is contraindicated [UCA-1.1.9] because the physician believes that this medication is safe to prescribe for the patient's condition. This flawed process model will occur if there is no information in the patient record (medication reconciliation) to indicate that the patient is currently taking a medication that is contraindicated to the one being ordered. As a result, the patient has an adverse medication interaction with other medications when the medication is administered. [H-1.4]

> Scenario 2 for UCA-1.1.9: The physician orders medication for the patient when the patient is already taking a medication that is contraindicated [UCA-1.1.9] because the physician believes that this medication is safe to prescribe for the patient's condition. This flawed process model will occur if the medication reconciliation process for the patient when he/she is asked for information on additional medications being taken was not documented completely in the EHR for the physician to be able to access prior to ordering the medication. As a result, the patient has an adverse medication interaction with other medications when the medication is administered. [H-1.4]

Safety Requirement 15: Addressed in SR 13

Safety Requirement 16: The ordering system shall indicate to the physician any contraindicated medications being ordered and require resolution prior to ordering medication for the patient.

UCA 1.1.10: The physician orders medication for the incorrect patient. [H-1.1]

> Scenario 1 for UCA-1.1.10: The physician orders medication for the incorrect patient [UCA-1.1.10] because the physician believes that he is ordering the medication for the correct patient. This flawed process model will occur if there is no information to indicate that an incorrect patient is being prescribed this medication. As a result, medication is administered to the incorrect patient. [H-1.1]

Safety Requirement 17: The ordering system shall require that the physician verify patient identity within CPOE/EHR prior to ordering medication for the patient.

UCA 1.1.11: The physician sends incorrect drug information to the hospital pharmacist when the medication order is submitted. [H-1.2]

> Scenario 1 for UCA-1.1.11: The physician sends incorrect drug information to the hospital pharmacist when the medication order is submitted [UCA-1.1.11] because the physician believes that he has input the correct and complete medication order in for the patient. This flawed process model will occur if the physician incorrectly interprets the user interface feedback from the actuators (CPOE and EHR) on the medication order or ignores the verification message from the actuators for the medication order. As a result, the incorrect medication (including incorrect drug, time, dose, route, frequency) is ordered for the patient. [H-1.2]

Safety Requirement 18: The ordering system shall require an active, two-step verification process of physician input of medication order, including verification of drug name, dosage, timing, and administration route.

UCA 1.1.12: The physician sends incorrect drug dosage information to the hospital pharmacist when the medication order is submitted. [H-1.2]

> Scenario 1 for UCA-1.1.12: The physician sends incorrect drug dosage information to the hospital pharmacist when the medication order is submitted [UCA-1.1.12] because the physician believes that he has input the correct and complete medication order in for the patient. This flawed process model will occur if the physician incorrectly interprets the user interface feedback from the actuators (CPOE and EHR) on the medication order or ignores the verification message from the actuators for the medication order. As a result, the incorrect medication (including incorrect drug, time, dose, route, frequency) is ordered for the patient. [H-1.2]

Safety Requirement 19: Addressed in SR 18

UCA 1.1.13: The physician sends incorrect drug timing information to the hospital pharmacist when the medication order is submitted. [H-1.2]

> Scenario 1 for UCA-1.1.13: The physician sends incorrect drug timing information to the hospital pharmacist when the medication order is submitted [UCA-1.1.13] because the physician believes that he has input the correct and complete medication order in for the patient. This flawed process model will occur if the physician incorrectly interprets the user

interface feedback from the actuators (CPOE and EHR) on the medication order or ignores the verification message from the actuators for the medication order. As a result, the incorrect medication (including incorrect drug, time, dose, route, frequency) is ordered for the patient. [H-1.2]

Safety Requirement 20: Addressed in SR 18

UCA 1.1.14: The physician sends incorrect drug administration route information to the hospital pharmacist when the medication order is submitted. [H-1.2]

Scenario 1 for UCA-1.1.14: The physician sends incorrect drug administration route information to the hospital pharmacist when the medication order is submitted [UCA-1.1.14] because the physician believes that he has input the correct and complete medication order in for the patient. This flawed process model will occur if the physician incorrectly interprets the user interface feedback from the actuators (CPOE and EHR) on the medication order or ignores the verification message from the actuators for the medication order. As a result, the incorrect medication (including incorrect drug, time, dose, route, frequency) is ordered for the patient. [H-1.2]

Safety Requirement 21: Addressed in SR 18

UCA-1.1.15: The physician orders medication for the patient too late when the patient is prescribed medication. [H-2.4]

Scenario 1 for UCA-1.1.15: The physician is aware that a medication order needs to be submitted for this patient but is unable to get the order submitted until an undetermined later time in his/her shift. This could be due to competing demands on the physician's attention during the work shift or the actuators (CPOE/EHR) being unavailable. Thus, the physician orders medication for the patient too late when the patient is prescribed medication. [UCA 1.1.15]. As a result, the incorrect medication dose (underdose, missed dose) is administered to the patient [H-2.4].

Scenario 2 for UCA-1.1.15: The physician orders the medication for the patient but is unaware that there have been changes in the patient's condition between the time of the original medication order and the time of the medication administration. This change in patient condition would require a change to the medication order. Thus, the physician orders medication for the patient too late when the patient is prescribed medication [UCA 1.1.15]. As a result, the incorrect medication dose (underdose, missed dose) is administered to the patient [H-2.4].

Safety Requirement 22: Addressed in SR 2

Safety Requirement 23: The ordering system EHR shall notify the physician and unit nurse if a change in patient medical condition requiring medication re-verification has occurred and medication order re-verification or revision has not been received by X minutes after system indication of change.

UCA 1.1.16: The physician sends drug information too late to the hospital pharmacist when the medication order is submitted. [H-2.1]

Scenario 1 for UCA 1.1.16: The physician sends the drug information to the hospital pharmacist upon ordering the medication, but this information is received late by the pharmacist due to transmission errors, lost communication, or delays in communication among the CPOE and EHR information systems. As a result, the correct medication is not administered when the medication needs to be given [H-2.1].

Scenario 2 for UCA 1.1.16: The physician sends the drug information to the hospital pharmacist upon ordering the medication, but the order information was not received correctly by the CPOE and/or EHR due to loss of power to systems, software update conflicts, or inaccurate input due to UI confusion. As a result, the correct medication is not administered when the medication needs to be given [H-2.4].

Safety Requirement 24: Addressed in SR 3.

Safety Requirement 25: Addressed in SR 2.

UCA 1.1.17: The physician sends drug dosage information too late to the hospital pharmacist when the medication order is submitted. [H-2.4]

Scenario 1 for UCA 1.1.17: The physician sends the drug dosage information to the hospital pharmacist upon ordering the medication, but this information is received late by the pharmacist due to transmission errors, lost communication, or delays in communication among the CPOE and EHR information systems. As a result, the correct medication is not administered with the right dose when the medication needs to be given [H-2.4]

Scenario 2 for UCA 1.1.17: The physician sends the drug dosage information to the hospital pharmacist upon ordering the medication, but the order information was not received correctly by the CPOE and/or EHR due to loss of power to systems, software update conflicts, or inaccurate input due to UI confusion. As a result, the correct medication is not administered with the right dose when the medication needs to be given [H-2.4]

Safety Requirement 26: Addressed in SR 3.

Safety Requirement 27: Addressed in SR 2.

UCA 1.1.18: The physician sends drug timing information too late to the hospital pharmacist when the medication order is submitted. [H-2.3]

Scenario 1 for UCA 1.1.18: The physician sends the drug timing information to the hospital pharmacist upon ordering the medication, but this information is received late by the pharmacist due to transmission errors, lost communication, or delays in communication among the CPOE and EHR information systems. As a result, the correct medication is not administered at the right time when the medication needs to be given [H-2.3]

Scenario 2 for UCA 1.1.18: The physician sends the drug timing information to the hospital pharmacist upon ordering the medication, but the order information was not received correctly by the CPOE and/or EHR due to loss of power to systems, software update conflicts, or inaccurate input due to UI confusion. As a result, the correct medication is not administered at the right time when the medication needs to be given [H-2.3]

Safety Requirement 28: Addressed in SR 3.

Safety Requirement 29: Addressed in SR 2.

UCA 1.1.19: The physician sends drug administration route information too late to the hospital pharmacist when the medication order is submitted. [H-2.5]

> Scenario 1 for UCA 1.1.19: The physician sends the drug administration route information to the hospital pharmacist upon ordering the medication, but this information is received late by the pharmacist due to transmission errors, lost communication, or delays in communication among the CPOE and EHR information systems. As a result, the correct medication is not administered with the correct administration route when the medication needs to be given [H-2.5]
>
> Scenario 2 for UCA 1.1.3: The physician sends the drug administration route information to the hospital pharmacist upon ordering the medication, but the order information was not received correctly by the CPOE and/or EHR due to loss of power to systems, software update conflicts, or inaccurate input due to UI confusion. As a result, the correct medication is not administered with the correct administration route when the medication needs to be given [H-2.5]

Safety Requirement 30: Addressed in SR 3.

Safety Requirement 31: Addressed in SR 2.

Summary

The full listing of causal scenarios and requirements generation analysis of the hospital medication administration system can be found in Appendix B. STPA enabled finding of 43 UCAs that lead to 99 different causal scenarios. From this analysis, 27 high-level requirements and 16 safety constraints were derived. Such requirements and safety constraints should guide a hospital safety team through the decision-making process to prioritize system improvements for safety.

An example of how a scenario could lead to improving safety in medication administration can be seen shown using Scenario 1 for UCA-1.1.2. The UCA itself, the physician does not order the medication when the patient is prescribed medication. [H-3.3], gives little indication of how this unsafe control action could be avoided. Of course, a physician is going to order medication for a patient when it is prescribed. However, the scenario provides a common circumstance in hospital operations where it is possible that a medication is not ordered in a timely manner – the physician gives an order to a duty nurse to put in a medication order for a patient, and the duty nurse is tasked to put in the order but does not (the order got lost in paperwork, on busy shift nurse does not input into CPOE, etc.). To control for these circumstances, the medication ordering system can be designed to include the safety requirement that it shall notify the physician and the unit nurse if diagnosis has been made and medication order (including the medication, the dosage, the timing, and the administration route) has not been received by CPOE/EHR X minutes after diagnosis has been entered into EHR. In this way, the likelihood that the unsafe control action occurs has been lowered without a significant additional burden on the hospital medication administration personnel, improving safety.

Chapter 6: Hospital Safety Management Systems

The CAST analysis performed in Chapter 4 on a medication administration accident highlighted the lack of hospital administration safety responsibilities in the medication administration process as a significant systemic factor contributing to the accident. Building and implementing a safety management system within the hospital organization would make explicit the safety control actions that hospital management is responsible for in order to provide the conditions for facilitating safe medication administration. The safety management system provides the structure to improve medication administration safety.

The STPA analysis of the in-patient hospital medication administration indicated that there were only two control actions from the hospital medication administration management system that impacted the medication ordering and administration systems (see Figure 6, the hospital administration control structure). Those two control actions were providing personnel assignments for hospital professionals (doctors, pharmacists, and unit nurses) and providing drug formularies of medications available for administration in the hospital. The fact that these are the only two control actions indicates there are many ineffective or missing safety management mechanisms within the hospital medication administration management concerning its impact on medication administration in hospitals.

By applying systems thinking principles (STAMP) and the results from applying STPA, the safety management system improved as well as the existing safety culture and practices. In this chapter, a safety management systems analysis is performed for the hospital to identify how the organization can develop an effective safety management system as a part of the STPA analysis.

Overview of Safety Management Systems Components for Hospital Environment

There are three basic organizational requirements to meet safety goals: implementing a strong safety culture in the organization and the ability to sustain this culture over time, an effective safety control structure, and a robust safety information system. These three requirements work in concert to form the safety management system for an organization [23].

The goals of designing an effective hospital safety management system will reflect the nature of the hospital organization itself and its environment. A hospital is a service provider organization focused on delivering safe, effective, and efficient health services. For service organizations, workplace safety and customer (in this case, patient) safety are inextricably linked [26].

Hospitals as large healthcare organizations are “complex, barely manageable places [...] Large healthcare institutions may be the most complex in human history.” [73] An engineering approach is rarely taken to address patient safety. With many of the hazards in a hospital and their associated safety constraints in conflict, finding acceptable safety problem solutions is more complex than in a typical service provider organization. There are significant safety management structures already built within hospitals, yet these structures do not seem effective beyond a certain level of adverse events occurring. While the goal of many hospitals is zero preventable accidents, many hospitals conclude that accidents are inevitable.

The United States does not have a nationalized health system; therefore, hospitals are private, commercial entities with some for-profits and others non-profit. The goal of providing optimal patient health outcomes is in constant contention with the goal of cost-effective care service delivery. Thus, hospitals will measure all safety investments to prevent accidents through a cost-benefit lens. Hospital organizations will not incur the cost of change necessary to affect the needed safety processes if the change outcomes do not produce a sufficient return on investment. These

short-term conflicts of economic goals with safety goals dissipate as the goals are evaluated over the long-term organizational horizon. Such short-term thinking has been shown in management theory to lead to achievement of none of the goals. In fact, safety and profits or productivity do not conflict but go hand in hand [Leveson, 2012].

The legal and regulatory environment for hospitals also impacts the organization's approach to safety. The complex regulatory requirements for US hospitals drive many safety efforts to attain the Joint Commission's accreditation, a minimum requirement for hospitals to be open and operating in the United States. Interestingly, hospitals define their risk management based on their economic goals and legal environment. Risk management as measured by hospitals is not related to patient outcomes. The choice to subordinate patient outcome goals to legal and economic goals leads hospitals to find themselves in continual reactionary mode concerning safety and unable to eliminate accidents beyond a certain level. They then may, ironically, find that they cannot meet their legal and economic goals.

The three parts of the safety management system are analyzed in the chapter using the questions and descriptions of effective practices provided by Leveson [2018].

Hospital Safety Culture

Safety culture is defined as the set of values and assumptions under which safety-related decisions are made. The boundaries of this safety culture delineate between desirable and acceptable behavior and that which is not. The culture also guides how safety decisions are made.

Healthcare safety culture has several historical and environmental factors that have been central in establishing the culture in hospitals today. This culture is based on deeply held values and cultural assumptions that ultimately undermine much of the safety guidance that is outlined by organizational rules, policies, and practices, in addition to that of external regulation and accreditation standards. In hospitals, safety culture is driven by personal provider responsibility, with the threat of litigation and cost-benefit analysis of safety interventions being weighed in the decisions. Examining the following cultural characteristics of a hospital provides evidence of how deeply held cultural beliefs undermine dedication to a strong safety culture.

Hospital administration at its roots has a culture of safety compliance. Hospitals must meet accreditation and other formidable operational safety requirements to operate in the United States. These requirements drive the majority of organizational safety efforts. There is also a culture of risk acceptance in that there is a cost-benefit to each intervention designed to improve patient safety. It is assumed that it would require too many resources, financial and otherwise, to completely eradicate all errors; thus, a cost-benefit analysis is done to determine the intervention's feasibility. This means that some level of risk and error is acceptable to satisfy the competing goals of all the hospital's stakeholders. But, of course, improving safety outcomes may not be more expensive if the right types of measures to improve them are used. Currently, as argued earlier, adverse events are blamed on individuals when the real problems in the overall system design are never fixed. Fixing them instead of relying on blaming nurses and doctors could eliminate large numbers of accidents.

Hospital healthcare personnel are also contributors to the current hospital safety culture. Through their actions in treating patients, where the need to "save lives" can overshadow certain safety concerns. Doing something rapidly and heroically to achieve a patient outcome might be at odds with the safest possible practice for the intervention. When errors are made, a reaction of contrition exists, but an overarching attitude that "we are too busy and have too many

responsibilities; we cannot focus on all of these operational policies and procedures and not focus directly on the patient."

When the hospital administration and hospital healthcare personnel combine their cultural beliefs, the overarching result is a culture of denial in the sense that they think there is only so much that can be focused on and fixed cost-efficiently. In reality, changes in the system may not cost anymore and may even lead to lower expenses.

The hospital environment is also highly complex. There are few proven interventions to lower risk. Errors result from the increased pressures of higher-level and more complex services being delivered under the stress of an even higher patient load and thus are assumed to be unavoidable. Perhaps potential ADEs (also known as near misses) are higher than ADEs, but again, there is only so much that can be effectively done. Today, the frequency of preventable harm remains high, and there is a call for new scientific and policy approaches to address medical error risk [6].

Thus, hospitals as organizations have established a safety culture based on the linear chain of events causality model and incomplete techniques (mostly RCA and FMEA) performed on different parts of the organization and not using a systems approach. The safety culture is deeply embedded in the hospital, so the organization is safety focused. Faulty analysis techniques and disjointed safety efforts leave hospital personnel overburdened in an already taxing work environment. Thus, error remains prevalent.

Management Commitment and Leadership

Top management support for and participation in safety efforts is the most effective way to control and reduce accidents [74]. Support for safety is shown to the employees by complete dedication and focused attention on providing the appropriate objectives and resources for organizational safety. Employees need to see tangible demonstrations of administration support (rather than blame or whistleblower treatment) if the employees show concern for safety [23].

Employees do not believe that hospital administration listens to their safety concerns and takes appropriate action. Managers have other objectives that take precedence over safety. Employees feel safe about reporting their concerns, but they have little belief that any action will be taken based on their reporting. In addition, poor control process designs in hospital medication administration set the workforce up to fail and to not be as safe as possible in their activities, regardless of how hard personnel tries.

Top management support and commitment are necessary to redesign systems of care (physical, environmental, and process) using humans and information technology to support safe hospital medication administration. Current accident investigation techniques and prevention approaches (FMEA) do not account for the role of management in safety processes and thus cannot recommend any safety control actions hospital administration can take to lower medication error rates.

Corporate Safety Policy

All hospitals have a significant number of policies that govern their safe operation. The primary safety policies relate to patient care and workplace health and safety, followed by more general policies on information technology usage, human resources, and codes of ethics. There is scant evidence that hospitals have an overarching short written safety philosophy. It is more akin to a values statement than a safety philosophy statement, if there is one. Instead, more detailed safety policies set up over several different areas with differing spans of control are in place. This policy

diffusion makes high-quality safety implementation difficult, as it is unclear to the safety decision-makers what the relationship of safety goals is to other goals.

This lack of clarity weakens employees' belief that the safety policy as it stands reflects a genuine commitment by management. Employees might not believe that hospital management will support them when they make reasonable decisions in favor of safety over alternative hospital organization goals. The flexibility to respond to safety problems needs to be built into the hospital's organizational procedures. Hospital management must reasonably set service quantity goals to allow for decision-making delays due to legitimate safety concerns by hospital patient care personnel.

Risk Awareness and Communication Channels

Poor safety-related decision-making on behalf of hospital administration and personnel is related to inadequate feedback from having no comprehensive or accurate error reporting system. (This is discussed in depth in Section 6.4.) Conflicting organizational goals lead to inaccurate process models, which is another factor in poor decision-making. Thus, risk awareness is not accurately perceived by those in the hospital medication administration system.

To hospital administrators, risk in the hospital environment is defined based on legal and economic risks to the hospital rather than risks to patient health outcomes. Hospital legal concerns can impede safety efforts and make accidents more likely by hampering the efforts of accident investigators. There can be a hesitancy on behalf of hospital care providers to thoroughly document accidents and investigate them for fear of having written documentation that could at some point be used to support a patient legal proceeding against the hospital. Similarly, documentation could be withheld from external accident investigators as well.) This organizational risk definition and focus guarantee a vicious cycle of more accidents in hospitals because access to accident safety data and information is justified under the guise of litigation protection.

Open communication in a hospital environment is challenging. Rigid hierarchical structures among healthcare workers separate the doctors and pharmacists from the nurses, with the communication channels often being unidirectional. Nurses are likely to be much closer to the patient and the process than the doctor, yet nurses do not feel comfortable questioning the physician or prescriber. Unhealthy work atmospheres with respect to safety and communication lead to a fear of response and reaction of hospital admin and other hospital patient care personnel to reported error [16].

Communication channels are distorted if personnel do not feel safe reporting their concerns; this is project risk misreporting. Passing information through the hospital management hierarchy allows for distortion and misreporting. In other cases, the feedback system is not available or not used. There might be informal “suggestion” processes to give feedback to management. Still, these suggestions are not seen as must-haves related to safety but more likely optional process improvement requests.

Controls and System Migration toward Higher Risk

Audits and performance assessments based on safety constraints identified can be used to detect system migration toward higher risk and the violation of safety constraints. Hospitals emphasize after-the-fact assessments of performance through mandatory reporting and accident analysis. With this emphasis, the hospital safety assessments can only tell if the safety environment has been successful or not. These efforts cannot make the hospital medication administration system safe if it is not already. The audits that are currently performed do not provide any indication that

the system is or is not migrating toward higher risk, and hospitals do not control for the increased risk due to system changes. Therefore, hospitals are unlikely to achieve medication administration safety targets lower than the levels that have been reached to this point.

A necessary step to improving hospital medication administration safety is to design in-situ performance assessments proactively and audits to anchor safety efforts beyond short-term organizational management processes. Unfortunately, the data does not exist to make informed, fact-based decisions on what actions need to be taken to improve safety. Medication administration prevalence data is missing, inaccurate, or contradictory, with a low rate of detected and reported errors. This lack of data makes assessing the effectiveness of ADE prevention strategies challenging, making it extremely difficult to reduce or eliminate ADEs. Hospitals are left basing safety decisions on their own local self-report error data, with little (if any) data sharing of error information among hospital organizations.

A Strong Corporate Safety Culture

The introduction of Section 6.2 discussed the current state of safety culture in a hospital organization. The incongruence between the hospital organization's values and deep cultural assumptions and its organizational rules, values, practices, and artifacts leads to a fragmented and inconsistent safety culture. Hospital administration demonstrates commitment to a strong safety culture in the hospital environment to meet the operational requirements set by their regulatory and accrediting entities. Yet, healthcare personnel (doctors and nurses) do not find this commitment to safety on behalf of hospital administration to be authentic based on decisions that they see administration making about hospital operations.

With so many disparate safety responsibilities across so many different areas of the hospital organization, it is exceptionally difficult to be able to effectively structure the organization to systematically prioritize safety and not simply target resources to achieve safety goals required by individual regulations or accreditation and operate the hospital organization from that safety stance. Hospitals must engineer a strong organizational safety culture by identifying the desired organizational safety principles and clarifying the priority of organizational goals and values throughout the organizational chart. Once this strengthened safety culture is enacted within the hospital, a safety control structure can be established to achieve the desired safety goals and sustain them over time. Hospitals have substantial, sustained work to achieve a just culture in their organizational environment [75].

Hospital Safety Control Structure (Management)

The goal of a safety control structure as part of the safety management system is “to ensure hazards are eliminated or, if not possible, controlled (mitigated) and to promote an effective safety culture” [24, p. 123]. This safety structure should eliminate or reduce losses. Achieving this goal requires a clear definition of expectations, responsibilities, authority, and accountability for safety tasks at all levels of the control structure.

The hospital environment is heavily regulated by several outside governmental and industry-focused safety groups and has a large number of internal controls. Creating an effective safety control structure is exceptionally difficult as an organizational problem to solve. With so many groups with widely disparate goals, levels of resources, and power, it is a vast undertaking to align all of these actors to achieve an effective safety control structure for a hospital. The distributed, decentralized nature of many of the safety efforts in a hospital and safety as a separate entity in the

organizational structure (rather than integrated into all hospital units) provides the opportunity for improving hospital safety with the systems approach to implementing a safety control structure.

Reengineering the safety control structure of a hospital requires safety being involved in all engineering development of policies, procedures, and service operations. The hospital's board of directors must support a top-level CEO cabinet position to a dedicated safety administrator who has the authority and responsibility to ensure that safety efforts can be carried out effectively, with safety integrated into design and decision-making activities. From this position, a chief safety officer would be empowered to implement JCHO and NQF (National Quality Forum) recommendations and best practices on safe medication administration in hospitals.

Explicit Assignment of Responsibility (Authority and Accountability) to Safety Functions

Hospitals rely heavily on individual healthcare professionals in the facility, such as nurses, pharmacists, and physicians, for achieving safety goals. Placing most of the responsibility at this organizational level leads to the belief that "everyone is responsible for the safety of themselves and others in the hospital, as well as the safety of the operations in the hospital." While this is true, when safety is the responsibility of everyone, it also deflects responsibility from those making decisions about the hospital environment that impact safety. There is insufficient accountability for who is responsible in the hospital organization for creating a safety-focused environment and making decisions that impact the ability of individual healthcare providers to do their jobs safely. Little further work is done on where explicitly the responsibility lies for controlling these actions.

The higher organizational levels in the hospital management environment do control the safety interactions among lower-level organizational actors in terms of accountability for accidents occurring. However, competing priorities sit at the desk of individual hospital administrators and managers, leading to scenarios where safety constraints can be ignored or bent to achieve a different, perhaps more critical, organizational objective. The decisions made by higher-level administrators can put individual healthcare professionals in an environment where safety is jeopardized. It is clear why safety is deprioritized in situations where there is inadequate or inexperienced staff, untenable patient volume, and acuity, an organizational climate that does not adequately defend against provider fatigue from lack of sleep and workplace distractions, and interruptions. Even technologies introduced into the hospital to make medication administration safer and more accessible for providers often contribute to medication adverse events [76].

Evidence of this burden on healthcare providers and away from hospital administration is evident in the statement of nursing rights for safe medication administration [77]. The idea of rights is that nursing personnel should be empowered to push back against hospital administration's decisions that degrade the workplace environment and threaten safety. One of these "rights" is the right to have policies on safe drug administration. While the accountability of an error in drug administration usually falls on the nurse, it is not the responsibility of nursing to create the policies on safe drug administration created in the first place. Another "right" is the right to stop, think, and be vigilant when administering medications. It is not clear whose responsibility it would be to ensure that a healthcare provider is given the workplace environment to do this. Hospital administration should be held accountable if the workplace environment does not support being vigilant in inpatient care, not the nurse who cannot control the staffing levels or time spent with patients, which would potentially threaten the ability to be vigilant. These responsibilities are not explicitly defined in the hospital environment, revealing a significant deficiency in the current safety control structure.

These safety control structure weaknesses and omissions provide some of the most robust evidence for the need to take a systems-based approach to safety in a hospital by applying a true systems approach. A list of responsibilities to be included in a safety control structure is given in Appendix D of the STPA handbook [24]. The list should be a starting point when developing a new safety control structure for a hospital safety organization. The critical hurdle will be in morphing the current hospital safety control structure, which is deeply ingrained, very familiar, and based on existing regulatory and accreditation requirements, into a safety control structure that provides a more effective and efficient way to achieve the internal and external safety goals of the hospital.

Place of Safety Activities in the Hospital Organization

Hospitals vary in how they manage safety activities in the organizational chart, including where they place responsibility for safety activities. One of two general structures is employed. In one hospital organizational design type, safety at the hospital is placed under a Vice President of Support Services (or equivalent title), a direct report to a chief operating officer for the hospital. The Vice President does not have executive-level influence, although the position does have complete responsibility for implementing and reporting on safety activities within the organization.

In the first approach to managing safety activities in the organizational chart, safety is bolted onto hospital support services, similarly to human resources or legal, rather than having safety incorporated into the entire hospital operations structure. Safety is a reporting function rather than a strategic input function in this organizational configuration. More concerning is that safety is driven by changes in regulation and accreditation requirements rather than objective feedback from operations on the effectiveness of the safety control structure.

The second organizational configuration found in hospitals is where a hospital has a Chief Quality and Safety Officer (or equivalent title), who is a direct report to the hospital chief executive officer. This officer with the highest level of administrative power and influence in the organization must collaborate, establish, and execute the hospital's strategic priorities and programmatic activities around safety. This role also has the power to assess the current state of safety with direct links to those who can provide safety data and information and build upon those strengths to design an effective safety control structure for the hospital, which a hospital would call "a unified approach to quality and safety." This officer could then establish direct communication channels among any part of the hospital where there are safety-related activities, based on the executive power of the Chief Quality and Safety Officer office.

Communication and Coordination of Activities and Responses to Events

The safety control structure in a hospital organization does have communication and coordination facilities for safety activities throughout the organization, although the facilities may be poorly designed or ineffective. Given the complexity of the safety requirements of hospital operations and the lack of executive influence of those administrators with safety responsibilities, coordination efforts often end up with safety activities fragmented and uncoordinated. The communications capabilities have not been implemented sufficiently to support a systems view of the hospital to coordinate safety activities proactively. Frequently a hospital will convene working groups to evaluate safety concerns, but often this is safety subordinate to a more considerable concern that the working group is addressing.

This disjointed, reactive safety structure is rife with communication failures among various administrators responsible for safety activities. Communication failures lead to increased error among the healthcare personnel involved in the medication administration process (nurses,

pharmacists, physicians). The communications failures or lack of communication capability between hospital administration and hospital healthcare personnel regarding safety lead to an indirect, but no less severe, impact on the persistent level of MAEs in the organization. These failures arise through unclear policies and procedures instituted or poor information systems implementation to facilitate communications among the medication administration process personnel. When Leapfrog, an independent hospital safety rating agency, gives a hospital facility a "C" grade for safety, there is an 88% greater risk of avoidable death at that facility than an "A" grade hospital. This grading system reflects the severe impact on patient outcomes that an incomplete and decentralized safety control structure can be.

Managing and Controlling Change (Planned and Unplanned)

Hospitals use hazard analyses that have been done in the past and other documentation to maintain compliance with regulators and accreditors. Planned changes are implemented concerning safety using the FMEA methods advocated by the Joint Commission. Unplanned changes occur differently, but safety is typically at the forefront when adapting to unplanned changes at the micro-level. This approach to unplanned changes leads to inconsistent safety decision-making because the micro level does not have the perspective to make decisions effectively, taking the entire hospital organization/system into account. Typically, frequent reporting required for safety does not give decision-makers sufficient information before safety margins are eroded if others are even aware of safety concerns that do not affect their department or unit. As increasing medication administration complexity, such as complicated doctor-initiated orders and complicated prescriptions, develops in today's hospital organization, a poorly defined safety control structure cannot respond to the operational changes safely.

Designing and Encouraging Feedback

Risk assessment in hospitals is difficult to determine confidently in light of serious concerns regarding information flow which lead to poor or non-existent feedback channels. All three hospital implementations of feedback channels (audits and performance assessment, accident/incident causal analysis, and reporting systems) have been compromised in their efforts to support safety in the face of increasing organizational complexity for hospitals. These concerns result from the safety culture adherence to linear causal analysis models and techniques for quality improvement processes in an environment of increasing operational demand.

Audits and performance assessments are standard in the hospital environment. Personnel performance assessments are done at the individual staff member level, with financial performance assessments and most safety measures conducted at the unit level within the hospital. All are done in response to the dictates of compensation, regulation, and accrediting requirements. The piecemeal fashion in which safety is audited and assessed reflects the disjointed nature of the safety control structure of the hospital. A systems approach is not used for hospitals when interpreting these assessments; rather, safety at the overall hospital level with safety processes reflects an aggregation of safety information from across the organization, independently evaluated from each other. This aggregation results in many systemic factors contributing to unsafe actions being overlooked and omitted.

Incident analysis and accident investigation are conducted using Joint Commission sanctioned approaches in accreditation reporting, which are familiar to the Commission accreditation review teams. These accident investigations are done using RCA or FMEA techniques. Considering the difficulty in assessing if any accident investigation interventions made a meaningful difference in safety, recommendations are often misguided. FMEA techniques do not address systemic safety

risks in the hospital environment, leaving gaps in the depth of incident analysis and accident investigation findings. CAST is not commonly used in healthcare accident investigations, although it is now more recognized among healthcare safety professionals. An unfortunate consequence of using FMEA techniques is that the same accidents repeatedly occur, even after causal incident analysis has been conducted and interventions implemented.

Hospital error (including medication error) safety reporting systems are weak. These institutional reporting systems gather incomplete incident data based on provider self-reporting, with many incidents of error missing entirely from the database. Despite several efforts to aggregate medication error information across hospital organizations, these reporting systems are not better at the state and federal levels. The result is no comprehensive system or standardization of system configuration to collect safety data. There is a wide variation in error data aggregated in each facility due to the lack of a national reporting system or systems that collect errors and near misses reliably. The lack of standardization among the error categories to be reported, in addition to incomplete reporting, clouds the conclusions that can be drawn from reported error data on where it is most effective to intervene and what interventions to implement.

Data from each hospital organization suffers from significant bias inherent in single institution, self-report data in local efforts to improve safety. Without sharing mediation error reporting data across hospital organizations and deriving information from that aggregation, there is a strong possibility that biased data from the local reporting system will be presented when hospitals are incentivized to report positive quality measures when required to report that data for reimbursements. Compounding the problem is that there is only a tiny research basis for most intervention strategies currently recommended to improve medication safety.

In practice, hospital incident analysis and accident investigations are often not publicly reported so as not to be the target of litigation. The bare minimum of data is reported to satisfy the regulatory or accreditation reporting requirements, and often, these reports do not lead to effective interventions to improve safety. Even with mandatory MAE reporting systems, there remains the concern of inadequate safety information. Data from voluntary self-reports are not reliable or valid when not all medication errors are detected and not all detected errors are reported, leaving an enormous gap. Yet this data is the primary data used for safety feedback within a hospital.

When personnel self-report medication errors into these safety systems and then see no effective action taken, personnel feel no evident appreciation for these self-reporting efforts. There is little satisfaction or incentive to continue to self-report other than what is legally required, as personnel perceives their safety concerns ignored. This reinforcing cycle further reduces the quantity and level of safety data collected in the hospital, even if the hospital culture supports the move away from individual blame for safety incidents and identifying system factors to increase safety error reporting.

Hospitals use data analysis to drive patient safety and quality efforts, as spurious as the data collected may be to support effective interventions. Closing the feedback loop on hospital medication error safety reports is not comprehensively conducted, although hospitals require objective quality evidence for certification. The safety reports only address the specific care unit the safety team is focused on within the hospital. The gaps in the feedback process within the hospital might be central to the fact that many safety initiatives undertaken based on data from reporting systems and accident/incident investigations lead to changes in the two top layers of organizational change (policies and procedures; artifacts) and not at the lowest layer (deeply held

cultural values and assumptions), leading to temporary changes in safety behavior that do not remain effective over time.

Risk Management

Risk in a hospital is currently defined as the legal and economic risk to the hospital organization and not by risk to patient outcomes unless those patient outcomes are deemed to have a high probability of negatively impacting legal and economic risk. Currently, the processes to control risk are performed under the auspices of the hospital's quality improvement (QI) function. This function is characterized as complex, multi-faceted, and multi-disciplinary by implementing organizational changes and evaluating the impact. The need to determine leading indicators on a consistent level is often informally done at the level of the individual employee based on his/her experience, training, education level, and expertise, familiarity with the operating scenario and organization.

QI is not sufficient to lower safety concerns within the hospital because the QI process does not include assessing the effectiveness of these activities or producing safety knowledge for safety interventions. Also, QI efforts are local to the hospital organization and designed to minimize disruption to the organization and contain costs rather than maximize patient outcomes safely. To move beyond the current state of multiple projects targeting similar changes, the healthcare industry needs evidence of the effects of specific changes. This movement beyond the current state will not happen by continuing down the current safety process path, although that is the industry's hope. A more fundamental transformation needs to occur, moving from Reason's framework and linear causal analysis approaches to STAMP techniques to lower risk within the hospital organization.

Education and Training

Change to a systems approach to safety would require significant investments in education and training for hospital safety engineers, hospital healthcare practitioners, and hospital administration from implementing FMEA techniques that hospitals use today to STAMP techniques. Hospitals would need to conduct CAST and STPA training to implement these approaches within the organization on this method of analyzing their safety decision-making processes and control structure, including training on hazards associated with the operation of the system and their role in the operation. This effort would deviate from any approach that has been done before, requiring a new generation of safety training to be developed for hospitals and then those healthcare workers there trained to do so.

Education on what controllers in the process need to know is essential to pass along to all of those in the safety control structure, including nurses, physicians, pharmacists, and other health staff participants. Of particular importance is effectively training healthcare personnel management on these safety techniques as learning from managers, rather than outside trainers, has proven to be more effective in safety practice.

Initiatives undertaken to educate physicians in QI and systems engineering by teaching nurses, pharmacists, and physicians QI techniques and methods used in RCA, FMEA, and process mapping show that education in healthcare QI for hospital healthcare personnel improved understanding of how they could meaningfully participate in QI efforts [54]. The primary concern here is that these hospital practitioners are learning ineffective safety techniques – RCA and FMEA, as opposed to CAST and STPA techniques. What is evident from this Mayo Clinic study is that those bilingual in healthcare and systems engineering need to develop and implement training education and programs for those clinicians to practice safety in the hospital organization

effectively. Current initiatives to introduce STAMP processes into hospitals and make the training easier for healthcare personnel include those by Wong [78] in the United States and Grimmett [79] in Australia.

Learning and Continual Improvement

Continuing education is a deeply ingrained initiative throughout the healthcare industry and in medication safety specifically. Healthcare personnel must continually train and update their knowledge base to maintain licensure in their respective professions. These continuing education credits are focused on clinical care and patient outcomes, rarely on issues pertaining to safety engineering in healthcare. With this culture of continuous learning, it would not be challenging to implement STAMP-based safety training as hospital safety practice advances. It is more a matter of the material being so new and different from what is in practice already. It would take a consistent, sustained effort to get the controllers trained to the new way of assessing safety and implementing the best safety practices.

Convincing hospital management to support learning on these safety initiatives can be challenging. While the hospital organization supports healthcare professionals in their continuing education efforts, there is little to no formal assessment of the actual impact of learning on hospital error rates and, subsequently, resource return on investment. Thus, hospitals have no evidence-based data to support resource investment in safety engineering training on STAMP-based techniques.

Hospital Safety Information Systems

The third piece of effective safety management is the safety information system. A hospital's safety information system is responsible for providing the information necessary to make the management structure successful in achieving the desired safety culture. This repository is a source of information about the effectiveness of the safety control structure of the organization. Several systems (typically siloed) are used across the hospital organization to gather safety information.

Currently, safety information systems are designed to collect information required for regulatory or accreditation reporting purposes and not for evaluating the effectiveness of safety controls or detecting trends toward unsafe control actions. EHRs, dedicated safety reporting systems, pharmacy systems, and many others contribute data after the fact for safety analysis. This facility-wide safety information is only kept in a database for a particular facility. It is not shared with other hospitals unless the hospital is part of a group of hospitals under one management ownership group where safety information might be aggregated across several sites of the hospital system. As we advance, it might be more useful to create a safety information system for one single project or area, then tie them all together as each project area is built out.

All patient safety events go into the same system in a hospital called PSNet. Reporting errors into this system is only required for accidents defined as sentinel events, which is a patient safety event that reaches a patient and results in any of the following outcomes: death, permanent harm, severe temporary harm. In efforts to augment facility self-report safety data, hospitals can also use automated systems with triggers, incident/accident reports, direct observation by the administration, patient record reviews, and surveillance by pharmacists to gather more comprehensive safety data.

There are documented and challenging to overcome issues with data collection on safety incidents (near misses not reported, etc.). Accident reports focus primarily on proximal events and assess liability and accountability in terms of litigation outcomes rather than proactive safety efforts. Data analysis suffers from the fact that there is no data to make credible decisions because of the

deficiencies in terms of the data collected and much data distortion. Hospitals are not able to process the data effectively that has been collected, and data is not used to justify interventions to improve safety. Data dissemination can be problematic because there are often competing interests to keep this data from being transparent or widely available across the organization. [I have found the problem in hospitals not that they don't collect data, but they don't process it once the collect it or use the data to fix things.]

Errors concerning health information technology in the medication administration process have increased in quantity and level of impact. Health information technology has become more technologically sophisticated in hospitals to where IS can now act as controllers in the control structure, not just a communications conduit among actors. Technology adoption (smart pumps, etc.) has not always been as successful as administrators thought to increase safety. Smart pumps and integrated DSS healthcare personnel users have bypassed the drug library meant to provide additional medication information and are frequently overriding alerts. This user behavior decreases system safety.

Safety compromises are made in designing equipment and software interfaces, as there is a trade-off between usability for the healthcare information system and its safety. The challenge is to maximize capability while maintaining as safe as possible of an operating environment. These challenges will increase as more AI and automated DSS are brought into hospitals. Hospitals cannot be blinded by advanced software capabilities to ignore software safety.

Ultimately, there is great promise in health information technology designed to increase medication safety, but more research needs to be conducted to demonstrate the potential benefits. There is needed conversation among hospital administration and EHR/HIT software vendors on how to handle these challenges for safety. The idea of using accident investigation teams highlights the barriers to this interaction between administration and software vendors: 1) Software houses fear violations of trade secrets; 2) individual developers fear scapegoating; 3) private company management and hospital want accountability for errors induced by healthcare information technology. [80].

Summary

This discussion of safety management systems as they currently exist in hospitals outlines the deficiencies that exist in lowering the medication error rate throughout the organization. Arguments made within this chapter support the application of STAMP techniques to safety activities within a hospital, including reengineering the safety management system within the hospital to be more effective. There will be some difficulty getting STAMP methods diffused into the healthcare environment. The application of engineering to healthcare is still considered novel.

The hospital organization will have to be committed to cross-training the engineering and healthcare workforce to understand each other's perspectives and concerns and not depend on physicians/nurses who have read a book or taken one seminar in SE and operations to be experts. [55]. As safety practice in hospitals advances, the idea of building systems engineering infrastructure in healthcare will require going beyond "smart sandboxes" where engineering academics and healthcare practitioners can work for better-engineered healthcare solutions to safety problems. The practice will introduce more advanced systems engineering to be applied in hospitals [81].

Chapter 7: Overview of CAST, STPA and SMS findings

The CAST analysis on a hospital medication administration accident presented in chapter 4 showed gaps between the RCA and CAST methods of incident analysis. RCA is not designed to consider systemic factors as having a direct impact on the accident. This deficiency leaves those in hospital administration responsible for hospital safety without sufficient insight to effectively remediate the conditions that facilitated the accident.

Healthcare medication administration personnel, frustrated by the continuing occurrence of such errors, adopt a "fixing and forgetting" mindset because they believe reporting the error will not impact improving the conditions or process error behind the event [82]. While this fixing and forgetting mindset does result in the healthcare personnel feeling more confident that they quickly and competently fix an error, an additional impact is that significant resources are wasted having to address the error repeatedly. Should hospitals adopt the CAST method of accident analysis, which would make recommendations addressing systemic factors that contribute to medication errors, this cycle of fixing and forgetting would cease as hazardous conditions leading to accidents could be more effectively eliminated or mitigated. This CAST analysis could be used at any US hospital to review its medication administration processes and implement recommendations.

Applying STPA to the hospital medication administration process highlighted the complexity of making processes safer that involve several actors who communicate through health information systems. This technology was brought into hospitals to improve safety and efficiency. Yet, the safety improvements achieved were replaced by a new set of safety concerns emanating from health information technology. CPOE significantly reduced transcription errors by having doctors directly input medication orders into electronic format to submit to pharmacy staff for dispensing [38]. However, new errors arose with data input errors and incorrect process models in the CPOE system [83]. In 2021 the number two top healthcare technology hazard as listed by ECRI was a CPOE data input error caused by similarly spelled drug names [68]. A similar effort occurred around barcode eMAR systems being adopted by hospitals [40].

These systems introduced for safety and efficiency imposed an additional burden on hospital healthcare personnel: data input and communication facilitation on top of the already high-paced, intellectually demanding work environment. In a standard nursing shift, a nurse might be responsible for data input into a healthcare information system requiring between 5,000 and 7,000 clicks to chart information on their patient encounters, with charting often done after a shift has ended. The increased cognitive and physical workload has increased hazardous scenarios in the hospital and led to healthcare professional burnout [84]. Considering that a hospital is one of the most complex socio-technical entities, STAMP approaches are necessary to address the safety concerns resulting from the increasingly complex interactions among so many people and technologies focused on the same goal.

The STPA analysis presented in this thesis provides a generalized hierarchical control structure for medication administration in an inpatient hospital setting. This control structure can be used to perform a more specific facility-based STPA. The utility of the recommendations from the STPA provides broad support for additional application of system theoretic models in healthcare overall.

Performing a safety management systems analysis using STAMP showed clearly the factors in hospitals that facilitate the conditions for medication error. A solid but misguided safety culture based on safety approaches that are not capable of assessing the complex, socio-technical

organization that is the modern hospital. A decentralized and disempowered safety control structure that results from their organizational culture hamper significant reductions in errors throughout the organization. The weakest link in the safety management system of the hospital is the safety information system. With the safety information system designed to reflect the current safety control structure, there is insufficient and misleading data on which to base decisions on which safety interventions to implement.

The main challenge in patient safety is developing and implementing safety information systems that gather meaningful data to learn what errors are happening, when they happen, and the salient conditions systemically surrounding the errors. Developing and implementing such a safety information system will require substantial change in the culture and safety control structure of the hospital before the safety information system can be successful. This goal has data supporting this premise; Liukka [85] finds that incident reporting (within an SIS) leads to analyzing and learning using a systems approach (through a safety control structure), and sharing such information (within deep cultural support) will lead to improved performance patient safety outcomes.

Hospital administration alone cannot be responsible for the organizational system transformation necessary for hospital patient safety to improve. Healthcare professionals who practice in hospitals must also be an integral part of learning and implementing CAST and STPA to effect changes to patient medication administration culture as members of their respective professions. Initiatives among physicians, nurses, and pharmacists already exist to facilitate learning more about technology and safety in the hospital environment and could be extended to include more training on STAMP method implementation. Safety engineering professionals should also be brought in to help facilitate such a fundamental transformation, helping develop the most effective tools to augment human capability to provide healthcare in the safest manner possible with processes that measure and reduce patient harm.

Further work to facilitate governmental, legal, and medical institutions' ability to operate collaboratively to remove the culture of blame while retaining accountability must be conducted. It is only once this challenge has been met that hospitals will not be constrained from accurately and comprehensively measuring targets for safety improvement, including errors with adverse outcomes, which organizations might be hesitant to report [8]. These measurements can be gathered and analyzed in a safety information system to facilitate data-driven patient care using sufficiently representative data. Additional insight into simplifying and prioritizing safety interventions once they have been identified from SIS data is also necessary to empower hospital administration to make the best use of the data that the SIS aggregates and analyzes.

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Appendix A. Unsafe Control Actions for the Hospital Medication Administration System (Full Table)

Control Action	Not providing causes hazard	Providing causes hazard	Too early, too late, out of order leads to hazard	Stopped too soon, applied too long leads to hazard
Ordering and Transcribing Subsystem				
CA-1.1: The physician orders medication for a patient. [Order action]	UCA-1.1.1: The physician does not order medication for a patient when the medication is not affordable to the patient. [H-3.2] UCA-1.1.2: The physician does not order the medication when the patient is prescribed medication. [H-3.3] UCA 1.1.3: The physician does not send drug information to the hospital pharmacist when the medication order is submitted. [H-3.3] UCA 1.1.4: The physician does not send drug dosage information to the hospital pharmacist when the medication order is submitted. [H-3.3] UCA 1.1.5: The physician does not send drug timing information to the hospital pharmacist when the medication order is submitted. [H-3.3]	UCA-1.1.7: The physician orders medication for the patient when the medication is not available/approved for indication. [H-3.1] UCA-1.1.8: The physician orders medication for the patient when the patient is allergic to the medication ordered. [H-1.5] UCA 1.1.9: The physician orders medication for the patient when the patient is already taking a medication that is contraindicated. [H-1.4] UCA 1.1.10: The physician orders medication for the incorrect patient. [H-1.1] UCA 1.1.11: The physician sends incorrect drug information to the hospital pharmacist when the medication order is submitted. [H-1.2] UCA 1.1.12: The physician sends incorrect drug dosage information to the hospital pharmacist when the	UCA-1.1.15: The physician orders medication for the patient too late when the patient is prescribed medication. [H-2.4] UCA 1.1.16: The physician sends drug information too late to the hospital pharmacist when the medication order is submitted. [H-2.4] UCA 1.1.17: The physician sends drug dosage information too late to the hospital pharmacist when the medication order is submitted. [H-2.4] UCA 1.1.18: The physician sends drug timing information too late to the hospital pharmacist when the medication order is submitted. [H-2.3] UCA 1.1.19: The physician sends drug route information too late to the hospital pharmacist when the medication order is submitted. [H-2.5]	The medication order is a discrete action so this does not apply.

	UCA 1.1.6: The physician does not send drug administration route information to the hospital pharmacist when the medication order is submitted. [H-3.3]	medication order is submitted. [H-1.2] UCA 1.1.13: The physician sends incorrect drug timing information to the hospital pharmacist when the medication order is submitted. [H-1.2] UCA 1.1.14: The physician sends incorrect drug administration route information to the hospital pharmacist when the medication order is submitted. [H-1.2]		

CA-2.1: The hospital pharmacist verifies the medication order for medication dispensing. [Confirm action]	UCA 2.1.1: The hospital pharmacist does not verify the medication order for medication dispensing. [H-3.3]	UCA 2.1.2: The hospital pharmacist sends the incorrect drug information for medication dispensing. [H-1.2] UCA 2.1.3: The hospital pharmacist sends the incorrect drug dosage information for medication dispensing. [H-1.2] UCA 2.1.4: The hospital pharmacist sends the incorrect drug timing information for medication dispensing. [H-1.2] UCA 2.1.5: The hospital pharmacist sends the incorrect drug administration route information for medication dispensing. [H-1.2]	UCA 2.1.6: The hospital pharmacist verifies the medication order too late for medication dispensing. [H-2.4]	Pharmacist medication order confirmation is a discrete action so this does not apply.
Dispensing and Administering Subsystem				
CA-3.1: The Pyxis ADC authorizes the unit nurse's access to the medications in the dispensing cabinet for the patient. [Authorize action]	UCA 3.1.1: The Pyxis ADC does not authorize the unit nurse's access to the medications for the patient. [H-3.3]	UCA 3.1.2: The Pyxis ADC authorizes the improper unit nurse for access to the medications for the patient. [H-3.3]	UCA 3.1.3: The Pyxis ADC authorizes the unit nurse's access to the medications in the dispensing cabinet too late for patient administering. [H-3.3]	Authorize is a discrete action so this does not apply.

CA-3.2: The Pyxis ADC dispenses the medication to the unit nurse for patient administering. [Dispense action]	UCA 3.2.1: The Pyxis ADC does not dispense the medication to the unit nurse for patient administering. [H-3.3]	UCA 3.2.2: The Pyxis ADC dispenses the medication to the incorrect unit nurse for patient administering. [H-3.3] UCA 3.2.3: The Pyxis ADC dispenses the incorrect drug to the unit nurse for patient administering. [H-2.7] UCA 3.2.4: The Pyxis ADC dispenses the incorrect drug dosage to the unit nurse for patient administering. [H-2.4] UCA 3.2.5: The Pyxis ADC dispenses the drug based on incorrect drug timing information to the unit nurse for patient administering. [H-2.3] UCA 3.2.6: The Pyxis ADC dispenses the drug based on incorrect drug administration route information to the unit nurse for patient administering. [H-2.5]	UCA 3.2.7: The Pyxis ADC dispenses the medication to the unit nurse too late for patient administering. [H-2.4] UCA 3.2.8: The Pyxis ADC dispenses the medication to the unit nurse too early for patient administering. [H-2.4]	Dispense is a discrete action so this does not apply.
CA-4.1: The unit nurse physically administers the medication to the patient. [Administer action]	UCA 4.1.1: The unit nurse does not physically administer the medication to the patient. [H-3.3]	UCA 4.1.2: The unit nurse physically administers the medication to the incorrect patient. [H-2.2] UCA 4.1.3: The unit nurse physically administers the incorrect drug to the patient. [H-2.1]	UCA 4.1.9: The unit nurse physically administers the medication too late to the patient. [H-2.4] UCA 4.1.10: The unit nurse physically administers the medication too early to the patient. [H-2.4]	

		UCA 4.1.4: The unit nurse physically administers the incorrect drug dosage to the patient. [H-2.4] UCA 4.1.5: The unit nurse physically administers the drug to the patient with incorrect timing. [H-2.3] UCA 4.1.6: The unit nurse physically administers the drug using the incorrect administration route to the patient. [H-2.5] UCA 4.1.7: The unit nurse physically administers the drug to the patient at the incorrect rate. [H-2.6] UCA 4.1.8: The unit nurse physically administers the medication to the patient using the incorrect technique. [H-2.8]		

Appendix B. Casual Scenarios and Requirements Generation for the Hospital Medication Administration System

B.1 Scenarios that lead to UCAs – Physician

These are causal scenarios that lead to unsafe control actions from the physician in the control structure.

UCA-1.1.1: The physician does not order medication for a patient when the medication is not affordable to the patient. [H-3.2]

> Scenario 1 for UCA-1.1.1: The physician is aware of a medication that would be suitable to treat the patient's condition but believes that the medication is not covered by the patient's healthcare plan. Thus, the physician does not order medication for a patient when the medication is not affordable to the patient [UCA-1.1.1]. As a result, the medication is not administered when the medication needs to be given because the medication is not affordable to the patient [H-3.2].

Safety Requirement 1: The medication ordering system shall inform the physician of medication cost to the patient at the time of ordering.

UCA-1.1.2: The physician does not order the medication when the patient is prescribed medication. [H-3.3]

> Scenario 1 for UCA-1.1.2: The physician gives an order to a duty nurse to put in a medication order for a patient. The duty nurse is tasked to put in the order but does not (the order got lost in paperwork, on busy shift nurse does not input into CPOE, etc.). Thus, the physician does not order the medication when the patient is prescribed medication. [UCA-1.1.2] As a result, the medication is not delivered to the patient for administration [H-3.3].

Safety Requirement 2: The ordering system shall notify the physician and the unit nurse if diagnosis has been made and medication order (including the medication, the dosage, the timing, and the administration route) has not been received by CPOE/EHR X minutes after diagnosis has been entered into EHR.

UCA 1.1.3: The physician does not send drug information to the hospital pharmacist when the medication order is submitted. [H-3.3]

> Scenario 1 for UCA 1.1.3: The physician sends the drug information to the hospital pharmacist upon ordering the medication, but drug information is not received by the pharmacist due to transmission errors, lost communication, or delays in communication among the CPOE and EHR information systems. Thus, the physician does not send drug information to the hospital pharmacist when the medication order is submitted [UCA-1.1.3]. As a result, the medication is not delivered to the patient for administration. [H-3.3].

> Scenario 2 for UCA 1.1.3: The physician sends the drug information to the hospital pharmacist upon ordering the medication, but the order information was not received correctly by the CPOE and/or EHR due to loss of power to systems, software update conflicts, or inaccurate input due to UI confusion. Thus, the physician does not send drug information to the hospital pharmacist when the medication order is submitted [UCA-1.1.3]. As a result, the medication is not delivered to the patient for administration. [H-3.3].

Safety Requirement 3: The ordering system shall notify the physician and the unit nurse if a pharmacist has not verified the medication order (including the medication, the dosage, the timing, and the administration route) by X minutes after the order has been placed in the CPOE/EHR.

Safety Requirement 4: Addressed by SR2

UCA 1.1.4: The physician does not send drug dosage information to the hospital pharmacist when the medication order is submitted. [H-3.3]

Scenario 1 for UCA 1.1.4: The physician sends the drug dosage information to the hospital pharmacist upon ordering the medication, but drug dosage information is not received by the pharmacist due to transmission errors, lost communication, or delays in communication among the CPOE and EHR information systems. Thus, the physician does not send drug dosage information to the hospital pharmacist when the medication order is submitted [UCA-1.1.4]. As a result, the medication is not delivered to the patient for administration [H-3.3].

Scenario 2 for UCA 1.1.4: The physician sends the drug dosage information to the hospital pharmacist upon ordering the medication, but the order information was not received correctly by the CPOE and/or EHR due to loss of power to systems, software update conflicts, or inaccurate input due to UI confusion. Thus, the physician does not send drug dosage information to the hospital pharmacist when the medication order is submitted [UCA-1.1.4]. As a result, the medication is not delivered to the patient for administration [H-3.3].

Safety Requirement 5: Addressed by SR 3

Safety Requirement 6: Addressed by SR 2

UCA 1.1.5: The physician does not send drug timing information to the hospital pharmacist when the medication order is submitted. [H-3.3]

Scenario 1 for UCA 1.1.5: The physician sends the drug timing information to the hospital pharmacist upon ordering the medication, but drug timing information is not received by the pharmacist due to transmission errors, lost communication, or delays in communication among the CPOE and EHR information systems. Thus, the physician does not send drug timing information to the hospital pharmacist when the medication order is submitted [UCA-1.1.5]. As a result, the medication is not delivered to the patient for administration [H-3.3].

Scenario 2 for UCA 1.1.5: The physician sends the drug timing information to the hospital pharmacist upon ordering the medication, but the order information was not received correctly by the CPOE and/or EHR due to loss of power to systems, software update conflicts, or inaccurate input due to UI confusion. Thus, the physician does not send drug timing information to the hospital pharmacist when the medication order is submitted [UCA-1.1.5]. As a result, the medication is not delivered to the patient for administration [H-3.3].

Safety Requirement 7: Addressed by SR 3

Safety Requirement 8: Addressed by SR 2

UCA 1.1.6: The physician does not send drug administration route information to the hospital pharmacist when the medication order is submitted. [H-3.3]

Scenario 1 for UCA 1.1.6: The physician sends the drug administration route information to the hospital pharmacist upon ordering the medication, but drug administration route information is not received by the pharmacist due to transmission errors, lost communication, or delays in communication among the CPOE and EHR information systems. Thus, the physician does not send drug administration route information to the hospital pharmacist when the medication order is submitted [UCA-1.1.6]. As a result, the medication is not delivered to the patient for administration [H-3.3].

Scenario 2 for UCA 1.1.6: The physician sends the drug administration route information to the hospital pharmacist upon ordering the medication, but the order information was not received correctly by the CPOE and/or EHR due to loss of power to systems, software update conflicts, or inaccurate input due to UI confusion. Thus, the physician does not send drug administration route information to the hospital pharmacist when the medication order is submitted [UCA-1.1.6]. As a result, the medication is not delivered to the patient for administration [H-3.3].

Safety Requirement 9: Addressed by SR 3

Safety Requirement 10: Addressed by SR 2

UCA-1.1.7: The physician orders medication for the patient when the medication is not available/approved for indication. [H-3.1]

Scenario 1 for UCA-1.1.7: The physician orders the medication for a patient when the medication is not available/approved for indication [UCA-1.1.7] because the physician believes that this medication is approved for use for this condition. This flawed process model will occur if the physician has no mechanism for updating the physician's information about the drug approval for a particular indication at the time the medication ordering decision is made. As a result, the medication ordered is not administered to the patient. [H-3.1]
Scenario 2 for UCA-1.1.7: The physician orders the medication for a patient when the medication is not available/approved for indication [UCA-1.1.7] because the physician believes that this medication is approved for use for this condition. This flawed process model will occur if the user interfaces of the actuators for the process (CPOE and/or EHR) incorrectly indicate to the physician that this medication is approved for the condition. This UI indicator could be incorrect if a software patch to update the drug approval status for the drugs available in the system is not provided or not applied correctly to the actuator system. As a result, an unauthorized drug is administered to the patient. [H-1.3]

Safety Requirement 11: The ordering system shall inform the physician of medication use approval for diagnosis indications at time of medication ordering.
Safety Requirement 12: The ordering system information systems (CPOE and EHR) shall be maintained with all software updates and patches in a timely manner.

UCA-1.1.8: The physician orders medication for the patient when the patient is allergic to the medication ordered. [H-1.5]

Scenario 1 for UCA-1.1.8: The physician orders medication for the patient when the patient is allergic to the medication ordered [UCA-1.1.8] because the physician believes that this medication is safe to prescribe for the patient's condition. This flawed process model will occur if there is no information in the patient record (medication reconciliation) to indicate that the patient was allergic to the medication. As a result, the patient has an allergic medication interaction when the medication is administered. [H-1.5]

Scenario 2 for UCA-1.1.8: The physician orders medication for the patient when the patient is allergic to the medication ordered [UCA-1.1.8] because the physician believes that this medication is safe to prescribe for the patient's condition. This flawed process model will occur if the medication reconciliation process for the patient when he/she is asked for information on known allergies was not conducted or it was not documented completely in the EHR for the physician to be able to access prior to ordering the medication. As a result, the patient has an allergic medication interaction when the medication is administered. [H-1.5]

Safety Requirement 13: The ordering system shall require the medication reconciliation for the patient to be completed prior to ordering the medication for the patient.

Safety Requirement 14: The ordering system shall require the physician to positively indicate the medication reconciliation has been reviewed and/or patient asked verbally about medication allergies prior to ordering medication for the patient.

UCA 1.1.9: The physician orders medication for the patient when the patient is already taking a medication that is contraindicated. [H-1.4]

Scenario 1 for UCA-1.1.9: The physician orders medication for the patient when the patient is already taking a medication that is contraindicated [UCA-1.1.9] because the physician believes that this medication is safe to prescribe for the patient's condition. This flawed process model will occur if there is no information in the patient record (medication reconciliation) to indicate that the patient is currently taking a medication that is contraindicated to the one being ordered. As a result, the patient has an adverse medication interaction with other medications when the medication is administered. [H-1.4]

Scenario 2 for UCA-1.1.9: The physician orders medication for the patient when the patient is already taking a medication that is contraindicated [UCA-1.1.9] because the physician believes that this medication is safe to prescribe for the patient's condition. This flawed process model will occur if the medication reconciliation process for the patient when he/she is asked for information on additional medications being taken was not documented completely in the EHR for the physician to be able to access prior to ordering the medication. As a result, the patient has an adverse medication interaction with other medications when the medication is administered. [H-1.4]

Safety Requirement 15: Addressed in SR 13

Safety Requirement 16: The ordering system shall indicate to the physician any contraindicated medications being ordered and require resolution prior to ordering medication for the patient.

UCA 1.1.10: The physician orders medication for the incorrect patient. [H-1.1]

Scenario 1 for UCA-1.1.10: The physician orders medication for the incorrect patient [UCA-1.1.10] because the physician believes that he is ordering the medication for the correct patient. This flawed process model will occur if there is no information to indicate that an incorrect patient is being prescribed this medication. As a result, medication is administered to the incorrect patient. [H-1.1]

Safety Requirement 17: The ordering system shall require that the physician verify patient identity within CPOE/EHR prior to ordering medication for the patient.

UCA 1.1.11: The physician sends incorrect drug information to the hospital pharmacist when the medication order is submitted. [H-1.2]

Scenario 1 for UCA-1.1.11: The physician sends incorrect drug information to the hospital pharmacist when the medication order is submitted [UCA-1.1.11] because the physician believes that he has input the correct and complete medication order in for the patient. This flawed process model will occur if the physician incorrectly interprets the user interface feedback from the actuators (CPOE and EHR) on the medication order or ignores the verification message from the actuators for the medication order. As a result, the incorrect medication (including incorrect drug, time, dose, route, frequency) is ordered for the patient. [H-1.2]

Safety Requirement 18: The ordering system shall require an active, two-step verification process of physician input of medication order, including verification of drug name, dosage, timing, and administration route.

UCA 1.1.12: The physician sends incorrect drug dosage information to the hospital pharmacist when the medication order is submitted. [H-1.2]

Scenario 1 for UCA-1.1.12: The physician sends incorrect drug dosage information to the hospital pharmacist when the medication order is submitted [UCA-1.1.12] because the physician believes that he has input the correct and complete medication order in for the patient. This flawed process model will occur if the physician incorrectly interprets the user interface feedback from the actuators (CPOE and EHR) on the medication order or ignores the verification message from the actuators for the medication order. As a result, the incorrect medication (including incorrect drug, time, dose, route, frequency) is ordered for the patient. [H-1.2]

Safety Requirement 19: Addressed in SR 18
UCA 1.1.13: The physician sends incorrect drug timing information to the hospital pharmacist when the medication order is submitted. [H-1.2]

Scenario 1 for UCA-1.1.13: The physician sends incorrect drug timing information to the hospital pharmacist when the medication order is submitted [UCA-1.1.13] because the physician believes that he has input the correct and complete medication order in for the patient. This flawed process model will occur if the physician incorrectly interprets the user interface feedback from the actuators (CPOE and EHR) on the medication order or ignores the verification message from the actuators for the medication order. As a result, the incorrect medication (including incorrect drug, time, dose, route, frequency) is ordered for the patient. [H-1.2]

Safety Requirement 20: Addressed in SR 18

UCA 1.1.14: The physician sends incorrect drug administration route information to the hospital pharmacist when the medication order is submitted. [H-1.2]

Scenario 1 for UCA-1.1.14: The physician sends incorrect drug administration route information to the hospital pharmacist when the medication order is submitted [UCA-1.1.14] because the physician believes that he has input the correct and complete medication order in for the patient. This flawed process model will occur if the physician incorrectly interprets the user interface feedback from the actuators (CPOE and EHR) on the medication order or ignores the verification message from the actuators for the medication order. As a result, the incorrect medication (including incorrect drug, time, dose, route, frequency) is ordered for the patient. [H-1.2]

Safety Requirement 21: Addressed in SR 18

UCA-1.1.15: The physician orders medication for the patient too late when the patient is prescribed medication. [H-2.4]

Scenario 1 for UCA-1.1.15: The physician is aware that a medication order needs to be submitted for this patient but is unable to get the order submitted until an undetermined later time in his/her shift. This could be due to competing demands on the physician's attention during the work shift or the actuators (CPOE/EHR) being unavailable. Thus, the physician orders medication for the patient too late when the patient is prescribed medication. [UCA 1.1.15]. As a result, the incorrect medication dose (underdose, missed dose) is administered to the patient [H-2.4].

Scenario 2 for UCA-1.1.15: The physician orders the medication for the patient but is unaware that there have been changes in the patient's condition between the time of the original medication order and the time of the medication administration. This change in patient condition would require a change to the medication order. Thus, the physician orders medication for the patient too late when the patient is prescribed medication [UCA 1.1.15]. As a result, the incorrect medication dose (underdose, missed dose) is administered to the patient [H-2.4].

Safety Requirement 22: Addressed in SR 2

Safety Requirement 23: The ordering system EHR shall notify the physician and unit nurse if a change in patient medical condition requiring medication re-verification has occurred and medication order re-verification or revision has not been received by X minutes after system indication of change.

UCA 1.1.16: The physician sends drug information too late to the hospital pharmacist when the medication order is submitted. [H-2.1]

Scenario 1 for UCA 1.1.16: The physician sends the drug information to the hospital pharmacist upon ordering the medication, but this information is received late by the pharmacist due to transmission errors, lost communication, or delays in communication among the CPOE and EHR information systems. As a result, the correct medication is not administered when the medication needs to be given [H-2.1].

Scenario 2 for UCA 1.1.16: The physician sends the drug information to the hospital pharmacist upon ordering the medication, but the order information was not received correctly by the CPOE and/or EHR due to loss of power to systems, software update conflicts, or inaccurate input due to UI confusion. As a result, the correct medication is not administered when the medication needs to be given [H-2.4].

Safety Requirement 24: Addressed in SR 3.

Safety Requirement 25: Addressed in SR 2.

UCA 1.1.17: The physician sends drug dosage information too late to the hospital pharmacist when the medication order is submitted. [H-2.4]

Scenario 1 for UCA 1.1.17: The physician sends the drug dosage information to the hospital pharmacist upon ordering the medication, but this information is received late by the pharmacist due to transmission errors, lost communication, or delays in communication among the CPOE and EHR information systems. As a result, the correct medication is not administered with the right dose when the medication needs to be given [H-2.4]

Scenario 2 for UCA 1.1.17: The physician sends the drug dosage information to the hospital pharmacist upon ordering the medication, but the order information was not received correctly by the CPOE and/or EHR due to loss of power to systems, software update conflicts, or inaccurate input due to UI confusion. As a result, the correct medication is not administered with the right dose when the medication needs to be given [H-2.4]

Safety Requirement 26: Addressed in SR 3.

Safety Requirement 27: Addressed in SR 2.

UCA 1.1.18: The physician sends drug timing information too late to the hospital pharmacist when the medication order is submitted. [H-2.3]

Scenario 1 for UCA 1.1.18: The physician sends the drug timing information to the hospital pharmacist upon ordering the medication, but this information is received late by the pharmacist due to transmission errors, lost communication, or delays in communication among the CPOE and EHR information systems. As a result, the correct medication is not administered at the right time when the medication needs to be given [H-2.3]

Scenario 2 for UCA 1.1.18: The physician sends the drug timing information to the hospital pharmacist upon ordering the medication, but the order information was not received correctly by the CPOE and/or EHR due to loss of power to systems, software update conflicts, or inaccurate input due to UI confusion. As a result, the correct medication is not administered at the right time when the medication needs to be given [H-2.3]

Safety Requirement 28: Addressed in SR 3.

Safety Requirement 29: Addressed in SR 2.

UCA 1.1.19: The physician sends drug administration route information too late to the hospital pharmacist when the medication order is submitted. [H-2.5]

Scenario 1 for UCA 1.1.19: The physician sends the drug administration route information to the hospital pharmacist upon ordering the medication, but this information is received late by the pharmacist due to transmission errors, lost communication, or delays in communication among the CPOE and EHR information systems. As a result, the correct medication is not administered with the correct administration route when the medication needs to be given [H-2.5]

Scenario 2 for UCA 1.1.3: The physician sends the drug administration route information to the hospital pharmacist upon ordering the medication, but the order information was not received correctly by the CPOE and/or EHR due to loss of power to systems, software update conflicts, or inaccurate input due to UI confusion. As a result, the correct medication is not administered with the correct administration route when the medication needs to be given [H-2.5]

Safety Requirement 30: Addressed in SR 3.

Safety Requirement 31: Addressed in SR 2.

B.2 Scenarios that lead to UCAs – Pharmacist

These are causal scenarios that lead to unsafe control actions from the pharmacist in the control structure.

UCA 2.1.1: The hospital pharmacist does not verify the medication order for medication dispensing. [H-3.3]

Scenario 1 for UCA-2.1.1: The pharmacist is aware that a medication order is waiting for verification prior to the medication being dispensed to the nursing staff but does not believe that this medication order needs verification. Thus, the hospital pharmacist does not verify the medication order for medication dispensing [UCA-2.1.1]. As a result, the medication is not delivered to the patient for administration. [H-3.3]

Scenario 2 for UCA-2.1.1: The hospital pharmacist does not verify the medication order for medication dispensing [UCA-2.1.1] because the pharmacist believes that the medication has been verified but in reality, the medication has not been verified. This flawed process model will occur if some data error led to the system incorrectly indicating the order verification status. As a result, the medication is not delivered to the patient for administration. [H-3.3]

Safety Requirement 32: The ordering system shall require indication of reasoning behind pharmacist non-verification or review before medication is dispensed for administration.

Safety Requirement 33: The ordering system shall require an active, 2-step verification process of pharmacist reviewing medication orders, including drug name, dosage, timing, and administration route.

UCA 2.1.2: The hospital pharmacist sends the incorrect drug information to the Pyxis ADC for medication dispensing. [H-1.2]

Scenario 1 for UCA-2.1.2: The hospital pharmacist sends the incorrect drug information to the Pyxis ADC because the physician sent the incorrect drug information to the Pyxis ADC for medication dispensing [UCA-2.1.2]. As a result, the incorrect medication is ordered for dispensing to administration. [H-1.2]

Scenario 2 for UCA-2.1.2: The hospital pharmacist sends the incorrect drug information to the Pyxis ADC for medication dispensing [UCA-2.1.2] because the hospital pharmacist believes that a specific medication in an order is incorrectly prescribed for a patient. This flawed process model will occur if the pharmacist does not have complete information from the EHR/eMAR to know which medication is indicated for which specific patient condition. As a result, the incorrect medication is ordered for dispensing to administration. [H-1.2]

Safety Requirement 34: Addressed in SR 18.

Safety Requirement 35: Addressed in SR 11. (Medications have to be matched for indication to meet this safety requirement, thus at this point, pharmacist would not be able to have incomplete information.)

UCA 2.1.3: The hospital pharmacist sends the incorrect drug dosage information to the Pyxis ADC for medication dispensing. [H-1.2]

Scenario 1 for UCA-2.1.3: The hospital pharmacist sends the incorrect drug dosage information to the Pyxis ADC [UCA-2.1.3] because the physician sent the incorrect drug dosage information to the hospital pharmacist for medication dispensing. As a result, the incorrect medication is ordered for dispensing to administration. [H-1.2]

Scenario 2 for UCA-2.1.3: The hospital pharmacist sends the incorrect drug dosage information to the Pyxis ADC for medication dispensing [UCA-2.1.3] because the hospital pharmacist believes that a specific medication dose in an order is incorrectly prescribed for a patient. This flawed process model will occur if the pharmacist does not have complete information from the EHR/eMAR to know what medication dose is indicated for which specific patient condition. As a result, the incorrect medication is ordered for dispensing to administration. [H-1.2]

Safety Requirement 36: Addressed in SR 18.

Safety Requirement 37: Addressed in SR 11.

UCA 2.1.4: The hospital pharmacist sends the incorrect drug timing information to the Pyxis ADC for medication dispensing. [H-1.2]

Scenario 1 for UCA-2.1.4: The hospital pharmacist sends the incorrect drug timing information to the Pyxis ADC [UCA-2.1.4] because the physician sent the incorrect drug timing information to the hospital pharmacist for medication dispensing. As a result, the incorrect medication is ordered for dispensing to administration. [H-1.2]

Scenario 2 for UCA-2.1.4: The hospital pharmacist sends the incorrect drug timing information to the Pyxis ADC for medication dispensing [UCA-2.1.4] because the hospital pharmacist believes that a specific medication in an order is incorrectly prescribed for a patient. This flawed process model will occur if the pharmacist does not have complete information from the EHR/eMAR to know what medication timing is indicated for which specific patient condition. As a result, the incorrect medication is ordered for dispensing to administration. [H-1.2]

Safety Requirement 38: Addressed in SR 18.

Safety Requirement 39: Addressed in SR 11.

UCA 2.1.5: The hospital pharmacist sends the incorrect drug administration route information to the Pyxis ADC for medication dispensing. [H-1.2]

Scenario 1 for UCA-2.1.5: The hospital pharmacist sends the incorrect drug administration route information to the Pyxis ADC [UCA-2.1.5] because the physician sent the incorrect drug administration route information to the hospital pharmacist for medication dispensing. As a result, the incorrect medication is ordered for dispensing to administration. [H-1.2]

Scenario 2 for UCA-2.1.5: The hospital pharmacist sends the incorrect drug administration route information to the Pyxis ADC for medication dispensing [UCA-2.1.5] because the hospital pharmacist believes that a specific medication in an order is incorrectly prescribed

for a patient. This flawed process model will occur if the pharmacist does not have complete information from the EHR/eMAR to know which medication administration route is indicated for which specific patient condition. As a result, the incorrect medication is ordered for dispensing to administration. [H-1.2]

Safety Requirement 40: Addressed in SR 18.

Safety Requirement 41: Addressed in SR 11.

UCA 2.1.6: The hospital pharmacist verifies the medication order too late for medication dispensing. [H-2.4]

Scenario 1 for UCA-2.1.6: The physician delays sending the medication order to the hospital pharmacist, causing the pharmacist to verify the medication order too late for medication dispensing [UCA-2.1.6]. As a result, the incorrect dose (underdose or missed dose) is administered to the patient. [H-2.4]

Scenario 2 for UCA-2.1.6: The hospital pharmacist verifies the medication order too late for medication dispensing [UCA-2.1.6] because the pharmacist believes that a specific medication in an order is incorrectly prescribed for a patient. This flawed process model will occur if the hospital pharmacist receives incomplete clarification from the physician on the medication order (through an unclear voice message or other communication). As a result, the incorrect dose (underdose or missed dose) is administered to the patient. [H-2.4]

Scenario 3 for UCA-2.1.6: The hospital pharmacist verifies the medication order too late for medication dispensing [UCA-2.1.6] because the pharmacist ignores the messages from the pharmacy system that indicate that the medication order is waiting in the queue to be verified. This flawed process model will occur if the pharmacist is interrupted or distracted away from appropriately responding to system messages. As a result, the incorrect dose (underdose or missed dose) is administered to the patient. [H-2.4]

Scenario 4 for UCA-2.1.6: The hospital pharmacist verifies the medication order too late for medication dispensing [UCA-2.1.6] because the pharmacist is unaware that the medication order needs to be verified. This flawed process model will occur if there is no indication or signal from the EHR/eMAR or pharmacy system that the medication needs to be verified. As a result, the incorrect dose (underdose or missed dose) is administered to the patient. [H-2.4]

Safety Requirement 42: Addressed in SR 2.

Safety Requirement 43: Addressed in SR 3.

Safety Requirement 44: The ordering system shall notify the pharmacist if a medication order has not been verified by X minutes after the order has been placed.

Safety Requirement 45: Addressed in SR 44.

B.3 Scenarios that lead to UCAs – Pyxis ADC

These are causal scenarios that lead to unsafe control actions from the automated dispensing cabinet (Pyxis) in the control structure.

UCA 3.1.1: The Pyxis ADC does not authorize the unit nurse's access to the medications for the patient. [H-3.3]

Scenario 1 for UCA-3.1.1: An authentication software error is prohibiting personnel access to the Pyxis ADC, causing the ADC to not authorize the unit nurse's access to the medications in the dispensing cabinet for the patient [UCA-3.1.1]. As a result, the medication is not delivered to the patient for administration. [H-3.3]

Scenario 2 for UCA-3.1.1: The Pyxis ADC does not authorize the unit nurse's access to the medications in the dispensing cabinet for the patient [UCA-3.1.1] because the Pyxis ADC has an incorrect access control list, authorizing staff that should not be authorized and denying access to staff that should be authorized. This flawed process model will occur if the correct access control list was sent to the Pyxis ADC, but it was not received by the machine. This could have been caused by transmission errors, lost communication, or delays in communication. As a result, the medication is not delivered to the patient for administration. [H-3.3]

Scenario 3 for UCA-3.1.1: The Pyxis ADC does not authorize the unit nurse's access to the medications in the dispensing cabinet for the patient [UCA-3.1.1] because the Pyxis ADC has an incorrect access control list, authorizing staff that should not be authorized and denying access to staff that should be authorized. This flawed process model will occur if the access control list for the Pyxis ADC is correct, but software errors in the authentication system lead to inadequate efforts to get nurses authorized. As a result, the medication is not delivered to the patient for administration. [H-3.3]

Scenario 4 for UCA-3.1.1: The Pyxis ADC does not authorize the unit nurse's access to the medications in the dispensing cabinet for the patient [UCA-3.1.1] because the Pyxis ADC has an incorrect access control list, authorizing staff that should not be authorized and denying access to staff that should be authorized. This flawed process model will occur if the updates to the Pyxis ADC access control list are never sent to the Pyxis ADC. As a result, the medication is not delivered to the patient for administration. [H-3.3]

Safety Requirement 46: The dispensing system shall notify the Pyxis ADC system administrators of any failed authentication attempts that prohibit medication dispensing.

Safety Requirement 47: The dispensing system shall notify the Pyxis ADC system administrators if authentication directory on Pyxis ADC has not been successfully updated or verified over an interval of X minutes.

Safety Requirement 48: Addressed in SR 46.

Safety Requirement 49: Addressed in SR 47.

UCA 3.1.2: The Pyxis ADC authorizes the improper unit nurse for access to the medications for the patient. [H-3.3]

Scenario 1 for UCA-3.1.2: The Pyxis ADC authorizes the improper unit nurse for access to the medications in the dispensing cabinet for the patient [UCA-3.1.2] because the Pyxis ADC incorrectly believes that a specific nurse is to have this medication dispensed to him/her for medication administration when it is actually a different nurse. This flawed process model will occur if the correct unit nurse information was sent to the Pyxis ADC, but it was not received by the machine. This could have been caused by transmission errors, lost communication, or delays in communication. As a result, the medication is not delivered to the patient for administration. [H-3.3]

Scenario 2 for UCA-3.1.2: The Pyxis ADC authorizes the improper unit nurse for access to the medications in the dispensing cabinet for the patient [UCA-3.1.2] because the update to the access control list was not applied correctly to the Pyxis controller. This flawed process model will occur if the Pyxis ADC is missing a necessary software patch required to have the access control process work correctly. As a result, the medication is not delivered to the patient for administration. [H-3.3]

Scenario 3 for UCA-3.1.2: The Pyxis ADC authorizes the improper unit nurse for access to the medications in the dispensing cabinet for the patient [UCA-3.1.2] because the update to the access control list was not applied correctly to the Pyxis controller. This flawed process model will occur if the updated access control list is never sent to the Pyxis ADC. As a result, the medication is not delivered to the patient for administration. [H-3.3]

Safety Requirement 50: The dispensing system shall notify Pyxis ADC system administrators if synchronization with ordering system has not been successfully completed and verified over an interval of X minutes.

Safety Requirement 51: The dispensing system information systems (Pyxis ADC, barcode eMAR) shall be maintained with all software updates and patches in a timely manner.

Safety Requirement 52: Addressed by SR 47 and SR 50.

UCA 3.1.3: The Pyxis ADC authorizes the unit nurse's access to the medications in the dispensing cabinet too late for patient administering. [H-3.3]

Scenario 1 for UCA-3.1.3: The Pyxis ADC authorizes the unit nurse's access to the medications in the dispensing cabinet too late for patient administering [UCA-3.1.3] because the Pyxis ADC has an incorrect access control list, authorizing staff that should not be authorized and denying access to staff that should be authorized. This flawed process model will occur if the updates to the access control list were sent to the Pyxis ADC, but they were not processed by the machine in a timely manner. This could have been caused by hardware or software errors within the Pyxis ADC system. As a result, the medication is not delivered to the patient for administration. [H-3.3]

Scenario 2 for UCA-3.1.3: The Pyxis ADC authorizes the unit nurse's access to the medications in the dispensing cabinet too late for patient administering [UCA-3.1.3] because the Pyxis ADC has an incorrect access control list, authorizing staff that should not be authorized and denying access to staff that should be authorized. This flawed process model will occur if the updates to the access control list were never sent to the Pyxis ADC. As a result, the medication is not delivered to the patient for administration. [H-3.3]

Safety Requirement 53: Addressed in SR 47.

Safety Requirement 54: Addressed in SR 47.

UCA 3.2.1: The Pyxis ADC does not dispense the medication to the unit nurse for patient administering. [H-3.3]

Scenario 1 for UCA-3.2.1: A drawer opening malfunction, or some other physical component failure, keeps the cabinet from opening, causing the ADC to not dispense the medication to

the unit nurse for patient administering [UCA-3.2.1]. As a result, the medication is not delivered to the patient for administration. [H-3.3]

Scenario 2 for UCA-3.2.1: The Pyxis ADC does not dispense the medication to the unit nurse for patient administering [UCA-3.2.1] because the Pyxis ADC has not received the command to dispense the medication. This flawed process model will occur if there are transmission errors, lost communication, or delays in communication of the dispensing order to the Pyxis ADC. As a result, the medication is not delivered to the patient for administration. [H-3.3]

Safety Requirement 55: The dispensing system shall notify Pyxis ADC system administrators of any failed medication dispensing actions that are the result of Pyxis ADC mechanical malfunction within X minutes.

Safety Requirement 56: The dispensing system shall notify the pharmacist and the unit nurse if medication order has been received for dispensing and medication has not been dispensed by X minutes after dispensing order is received.

UCA 3.2.2: The Pyxis ADC dispenses the medication to the incorrect unit nurse for patient administering. [H-3.3]

Scenario 1 for UCA-3.2.2: The Pyxis ADC dispenses the medication to the incorrect unit nurse for patient administering [UCA-3.2.2] because the Pyxis ADC incorrectly believes that a specific nurse is to have this medication dispensed to him/her for medication administration when it is actually a different nurse. This flawed process model will occur if the correct unit nurse information is sent to the Pyxis ADC machine, but the information is not received due to transmission errors, lost communication, or delays in communication. As a result, the medication is not delivered to the patient for administration. [H-3.3]

Scenario 2 for UCA-3.2.2: The Pyxis ADC dispenses the medication to the incorrect unit nurse for patient administering [UCA-3.2.2] because the update to indicate the correct unit nurse was not applied correctly to the Pyxis controller. This flawed process model will occur if the Pyxis ADC is missing a necessary software patch required to have the unit nurse assignment process complete correctly. As a result, the medication is not delivered to the patient for administration. [H-3.3]

Scenario 3 for UCA-3.2.2: The Pyxis ADC dispenses the medication to the incorrect unit nurse for patient administering [UCA-3.2.2] because the update to indicate the correct unit nurse was not applied correctly to the Pyxis controller. This flawed process model will occur if the update for the Pyxis ADC was never sent. As a result, the medication is not delivered to the patient for administration. [H-3.3]

Safety Requirement 57: Addressed in SR 50.

Safety Requirement 58: Addressed in SR 51.

Safety Requirement 59: Addressed in SR 50.

UCA 3.2.3: The Pyxis ADC dispenses the incorrect drug to the unit nurse for patient administering. [H-2.7]

Scenario 1 for UCA-3.2.3: The Pyxis ADC dispenses the incorrect drug to the unit nurse for patient administering [UCA-3.2.3] because the Pyxis ADC believes it is administering the correct medication and releases that drawer; however, the wrong medication has been loaded into the medication drawer. This flawed process model will occur because there is no feedback within the Pyxis ADC to alert that incorrect medication has been loaded before drug released for dispensing. As a result, the incorrect medication is dispensed to the unit nurse. [H-2.7]

Safety Requirement 60: The dispensing system shall have an active verification process where unit nurse must verify drug dispensed matches that on medication order.

UCA 3.2.4: The Pyxis ADC dispenses the incorrect drug dosage to the unit nurse for patient administering. [H-2.4].

Scenario 1 for UCA 3.2.4: The Pyxis ADC dispenses the incorrect drug dosage to the unit nurse for patient administering [UCA-3.2.4] based on incorrect medication order information. The incorrect order information is the result of transmission errors, lost communication, or delays in communication. As a result, the incorrect medication dose is administered to the patient [H-2.4].

Scenario 2 for UCA 3.2.4: The Pyxis ADC dispenses the incorrect drug dosage to the unit nurse for patient administering [UCA-3.2.4] based on incorrect medication order information. The incorrect order information is the result of loss of power to systems, software update conflicts, or inaccurate output by the Pyxis ADC. As a result, the incorrect medication dose is administered to the patient [H-2.4].

Safety Requirement 61: Addressed in SR 50.

Safety Requirement 62: Addressed in SR 50.

UCA 3.2.5: The Pyxis ADC dispenses medication based on incorrect drug timing information to the unit nurse for patient administering. [H-2.3].

Scenario 1 for UCA 3.2.5: The Pyxis ADC dispenses medication based on incorrect drug timing information to the unit nurse for patient administering [UCA-3.2.5] based on incorrect medication order information. The flawed order information is the result of transmission errors, lost communication, or delays in communication. As a result, the medication dose is administered to the patient with incorrect timing/frequency/duration [H-2.3].

Scenario 2 for UCA 3.2.5: The Pyxis ADC dispenses medication based on incorrect drug timing information to the unit nurse for patient administering [UCA-3.2.5] based on incorrect medication order information. The incorrect order information is the result of the order information not being received correctly by the Pyxis ADC due to loss of power to systems, software update conflicts, etc. As a result, the medication dose is administered to the patient with incorrect timing/frequency/duration [H-2.3].

Safety Requirement 63: Addressed in SR 50.

Safety Requirement 64: Addressed in SR 50.

UCA 3.2.6: The Pyxis ADC dispenses medication based on incorrect drug administration route information to the unit nurse for patient administering. [H-2.5].

Scenario 1 for UCA 3.2.6: The Pyxis ADC dispenses the drug based on incorrect drug administration route information to the unit nurse for patient administering [UCA-3.2.6] based on incorrect medication order information. The incorrect order information is the result of drug administration route information not received by the Pyxis ADC due to transmission errors, lost communication, or delays in communication. As a result, the medication dose is administered to the patient using the incorrect drug administration route [H-2.5].

Scenario 2 for UCA 3.2.6: The Pyxis ADC dispenses the drug based on incorrect drug administration route information to the unit nurse for patient administering [UCA-3.2.6] based on incorrect medication order information. The incorrect medication order information is the result of the order information not being received correctly by the Pyxis ADC due to loss of power to systems, software update conflicts, etc. As a result, the medication dose is administered to the patient using the incorrect drug administration route [H-2.5].

Safety Requirement 65: Addressed in SR 50.

Safety Requirement 66: Addressed in SR 50.

UCA 3.2.7: The Pyxis ADC dispenses the medication to the unit nurse too late for patient administering. [H-2.4]

Scenario 1 for UCA-3.2.7: The pharmacist delays sending the medication order to the Pyxis ADC, causing the Pyxis ADC to dispense the medication to the unit nurse too late for patient administering [UCA-3.2.7]. As a result, the incorrect drug dose (underdose, missed dose) is administered to the patient. [H-2.4]

Scenario 2 for UCA-3.2.7: The Pyxis ADC dispenses the medication to the unit nurse too late for patient administering [UCA-3.2.7] because the Pyxis ADC does not know that there is medication to be dispensed; the medication dispensing order was sent to the Pyxis ADC but it was not received by the machine. This flawed process model will occur if the medication dispensing order was lost as the result of transmission errors, lost communication, or delays in communication. As a result, the incorrect drug dose (underdose, missed dose) is administered to the patient. [H-2.4]

Safety Requirement 67: Addressed in SR 56.

Safety Requirement 68: Addressed in SR 56.

UCA 3.2.8: The Pyxis ADC dispenses the medication to the unit nurse too early for patient administering. [H-2.4]

Scenario 1 for UCA-3.2.8: The pharmacist sends the dispensing order to the Pyxis ADC earlier than the order indicates, causing the Pyxis ADC to dispense the medication to the unit nurse too early for patient administering [UCA-3.2.8]. As a result, an incorrect dose (overdose or extra dose) is administered to the patient. [H-2.4]

Safety Requirement 69: The dispensing system shall have a verification process where medication is not able to be dispensed within X hours/minutes of its target administration time for the patient.

B.4 Scenarios that lead to UCAs – Unit Nurse

These are causal scenarios that lead to unsafe control actions from the unit nurse in the control structure.

UCA 4.1.1: The unit nurse does not physically administer the medication to the patient. [H-3.3]

> Scenario 1 for UCA-4.1.1: The unit nurse does not physically administer the medication to the patient [UCA-4.1.1] because the unit nurse believes that the medication has already been administered to the patient. This flawed process model will occur if the unit nurse sees that the medication has been administered in eMAR record when medication administration was not completed by the prior unit nurse. As a result, the medication is not delivered to the patient for administration. [H-3.3]
>
> Scenario 2 for UCA-4.1.1: The unit nurse does not physically administer the medication to the patient [UCA-4.1.1] because the unit nurse believes that the medication ordered is not safe to administer to the patient. This flawed process model will occur if the unit nurse is not able to find information in the EHR on what condition the medication is indicated for as the patient is exhibiting conflicting symptoms. The unit nurse is concerned that the ordered medication might be harmful if administered considering the incomplete information in the EHR. As a result, the medication is not delivered to the patient for administration. [H-3.3]

Safety Requirement 70: The administration system will alert the unit nurse if there were drugs dispensed that were not administered to the patient within X minutes of ordered medication administration time.

Safety Requirement 71: Addressed in SR 11.

UCA 4.1.2: The unit nurse physically administers the medication to the incorrect patient. [H-2.2]

> Scenario 1 for UCA-4.1.2: The unit nurse physically administers the medication to the incorrect patient [UCA-4.1.2] because the unit nurse believes that this is the correct patient to whom he should administer the medication, but in reality, it is not the correct patient. This flawed process model will occur if the unit nurse receives the incorrect patient identification information when referring to the barcode eMAR for medication administration. As a result, the medication is administered to the incorrect patient. [H-2.2]
>
> Scenario 2 for UCA-4.1.2: The unit nurse physically administers the medication to the incorrect patient [UCA-4.1.2] because the unit nurse believes that this is the correct patient to whom he should administer the medication, but in reality, it is not the correct patient. This flawed process model will occur if the unit nurse is interrupted during the medication administration process, causing a cursory glance at the EHR to verify patient identity prior to medication administration. As a result, the medication is administered to the incorrect patient. [H-2.2]
>
> Scenario 3 for UCA-4.1.2: The unit nurse physically administers the medication to the incorrect patient [UCA-4.1.2] because the unit nurse believes that this is the correct patient to whom he should administer the medication, but in reality, it is not the correct patient. This flawed process model will occur if the unit nurse is unable to speak to the patient directly to verify identity (patient is sedated/unconscious), and the ID wristband on the

patient is not being read correctly by the barcode eMAR system. As a result, the medication is administered to the incorrect patient. [H-2.2]

Safety Requirement 72: Addressed by SR 17 and SR 50.

Safety Requirement 73: The dispensing system shall require an active, two step verification process of the unit nurse verifying patient identity within the EHR prior to administering medication to the patient.

Safety Requirement 74: Addressed in SR 73.

UCA 4.1.3: The unit nurse physically administers the incorrect drug to the patient. [H-2.1]

Scenario 1 for UCA-4.1.3: The Pyxis ADC dispenses the incorrect drug to the unit nurse, causing the unit nurse to physically administer the incorrect drug to the patient [UCA-4.1.3]. As a result, the incorrect medication is administered to the patient. [H-2.1]

Scenario 2 for UCA-4.1.3: The unit nurse physically administers the incorrect drug to the patient [UCA-4.1.3] because the unit nurse believes that this is the correct medication to administer to the patient, but in reality, it is not the correct drug. This flawed process model will occur if the unit nurse uses the barcode eMAR to verify the medication for this patient, and the system does not indicate to the unit nurse that the drug is incorrect. As a result, the incorrect medication is administered to the patient. [H-2.1]

Scenario 3 for UCA-4.1.3: The unit nurse physically administers the incorrect drug to the patient [UCA-4.1.3] because the unit nurse reaches for the incorrect medication based on the medication order. This flawed process model will occur if the unit nurse is interrupted or distracted away from appropriately attending to the medication administration process. As a result, the incorrect medication is administered to the patient. [H-2.1]

Scenario 4 for UCA-4.1.3: The unit nurse physically administers the incorrect drug to the patient [UCA-4.1.3] because the because the unit nurse believes that this is the correct medication to administer to the patient, but in reality, it is not the correct drug. This flawed process model will occur if the unit nurse uses the barcode eMAR to verify the medication for this patient, and the correct drug information was never received by the barcode eMAR. As a result, the incorrect medication is administered to the patient. [H-2.1]

Safety Requirement 75: Addressed in SR 60.

Safety Requirement 76: The dispensing system shall notify barcode eMAR administrators if synchronization with ordering system has not been successfully completed and verified over an interval of X minutes.

Safety Requirement 77: The dispensing system shall require the unit nurse to verify the dispensed medication (including drug, dosage, timing, rate, and administration route) in the barcode eMAR/EHR prior to administering medication to the patient.

Safety Requirement 78: Addressed in SR 76.

UCA 4.1.4: The unit nurse physically administers the incorrect drug dosage to the patient. [H-2.4]

Scenario 1 for UCA-4.1.4: The unit nurse physically administers the incorrect drug dosage to the patient [UCA-4.1.4] because the unit nurse believes that this is the correct medication dosage to administer to the patient, but in reality, it is not the correct dosage. This flawed process model will occur if the unit nurse uses the barcode eMAR to verify the medication for this patient, and the system does not indicate to the unit nurse that the drug dosage is incorrect. As a result, the incorrect medication dose is administered to the patient. [H-2.4]

Scenario 2 for UCA-4.1.4: The unit nurse physically administers the incorrect drug dosage to the patient [UCA-4.1.4] because the unit nurse is unaware that some of the medication has been left unadministered. This flawed process model will occur if the unit nurse is interrupted or distracted away from appropriately attending to the medication administration process. As a result, the incorrect dose (underdose or missed dose) is administered to the patient. [H-2.4]
Scenario 3 for UCA-4.1.4: The unit nurse physically administers the incorrect drug dosage to the patient [UCA-4.1.4] because the unit nurse believes that this is the correct medication dosage to administer to the patient, but in reality, it is not the correct dosage. This flawed process model will occur if the unit nurse uses the barcode eMAR to verify the medication for this patient, and the correct drug dosage information was never received by the barcode eMAR. As a result, the incorrect medication dose is administered to the patient. [H-2.4]

Safety Requirement 79: Addressed in SR 76.

Safety Requirement 80: Addressed in SR 77.

Safety Requirement 81: Addressed in SR 76.

UCA 4.1.5: The unit nurse physically administers the drug to the patient with incorrect timing. [H-2.3]

Scenario 1 for UCA-4.1.5: The unit nurse physically administers the drug to the patient with incorrect timing [UCA-4.1.5] because the unit nurse believes that this is the correct medication timing for administering the drug to the patient, but in reality, it is not the correct timing. This flawed process model will occur if the unit nurse uses the barcode eMAR to verify the medication for this patient, and the system does not indicate to the unit nurse that the drug timing is incorrect. As a result, the medication is administered to the patient with incorrect timing/frequency/duration. [H-2.3]

Scenario 2 for UCA-4.1.5: The unit nurse physically administers the drug to the patient with incorrect timing [UCA-4.1.5] because the unit nurse does not realize that he is taking longer to administer the medication than should be taken. This flawed process model will occur if the unit nurse is interrupted or distracted away from appropriately attending to the medication administration process. As a result, the medication is administered to the patient with incorrect timing/frequency/duration. [H-2.3]

Scenario 3 for UCA-4.1.5: The unit nurse physically administers the drug to the patient with incorrect timing [UCA-4.1.5] because the unit nurse believes that this is the correct medication timing for administering the drug to the patient, but in reality, it is not the correct timing. This flawed process model will occur if the unit nurse uses the barcode eMAR to verify the medication for this patient, and the correct drug timing information was never

received by the barcode eMAR. As a result, the medication is administered to the patient with incorrect timing/frequency/duration. [H-2.3]

Safety Requirement 82: Addressed in SR 76.

Safety Requirement 83: Addressed in SR 77.

Safety Requirement 84: Addressed in SR 76.

UCA 4.1.6: The unit nurse physically administers the drug using the incorrect administration route to the patient. [H-2.5]

Scenario 1 for UCA-4.1.6: The unit nurse physically administers the drug using the incorrect administration route to the patient [UCA-4.1.6] because the unit nurse believes that this is the correct medication administration route to administer the drug to the patient, but in reality, it is not the correct drug administration route. This flawed process model will occur if the unit nurse uses the EHR/eMAR to verify the medication administration route for this drug, and the system does not indicate to the unit nurse that the drug administration route is incorrect. As a result, the medication is administered to the patient using the incorrect drug administration route. [H-2.5]

Scenario 2 for UCA-4.1.6: The unit nurse physically administers the drug using the incorrect administration route to the patient [UCA-4.1.6] because the unit nurse administers the drug using the most frequent and familiar route. This flawed process model will occur if the unit nurse is interrupted or distracted away from appropriately attending to the medication administration process, not realizing that the EHR/eMAR indicated a different (and the correct) drug administration route. As a result, the medication is administered to the patient using the incorrect drug administration route. [H-2.5]

Scenario 3 for UCA-4.1.6: The unit nurse physically administers the drug using the incorrect administration route to the patient [UCA-4.1.6] because the unit nurse believes that this is the correct medication administration route to administer the drug to the patient, but in reality, it is not the correct drug administration route. This flawed process model will occur if the unit nurse uses the barcode eMAR to verify the medication for this patient, and the correct drug administration route information was never received by the barcode eMAR. As a result, the medication is administered to the patient using the incorrect drug administration route. [H-2.5]

Safety Requirement 85: Addressed in SR 76.

Safety Requirement 86: Addressed in SR 77.

Safety Requirement 87: Addressed in SR 76.

UCA 4.1.7: The unit nurse physically administers the drug to the patient at the incorrect rate. [H-2.6]

Scenario 1 for UCA-4.1.7: The unit nurse physically administers the drug to the patient at the incorrect rate [UCA-4.1.7] because the unit nurse believes that this is the correct medication rate to administer the drug to the patient, but in reality, it is not the correct rate. This flawed process model will occur if the unit nurse uses the EHR/eMAR to verify the medication

administration rate for this drug, and the system does not indicate to the unit nurse that the drug administration rate is incorrect. As a result, the incorrect medication is administered to the patient at the incorrect rate. [H-2.6]

Scenario 2 for UCA-4.1.7: The unit nurse physically administers the drug to the patient at the incorrect rate [UCA-4.1.7] because the unit nurse administers the drug at the most common rate. This flawed process model will occur if the unit nurse is interrupted or distracted away from appropriately attending to the medication administration process, not realizing that the EHR/eMAR indicated a different (and the correct) drug administration rate. As a result, the incorrect medication is administered to the patient at the incorrect rate. [H-2.6]

Scenario 3 for UCA-4.1.7: The unit nurse physically administers the drug to the patient at the incorrect rate [UCA-4.1.7] because the unit nurse believes that this is the correct medication rate to administer the drug to the patient, but in reality, it is not the correct rate. This flawed process model will occur if the unit nurse uses the barcode eMAR to verify the medication for this patient, and the correct drug rate information was never received by the barcode eMAR. As a result, the incorrect medication is administered to the patient at the incorrect rate. [H-2.6]

Safety Requirement 88: Addressed in SR 76.

Safety Requirement 89: Addressed in SR 77.

Safety Requirement 90: Addressed in SR 76.

UCA 4.1.8: The unit nurse physically administers the medication to the patient using the incorrect technique. [H-2.8]

Scenario 1 for UCA-4.1.8: The unit nurse physically administers the medication to the patient using the incorrect technique [UCA-4.1.8] because the unit nurse believes that he is using the correct technique to administer the drug to the patient, but in reality, it is not the correct drug administration technique. This flawed process model will occur if the unit nurse recalls prior training and experience to choose the medication administration technique for this patient, and the system does not indicate to the unit nurse that the drug administration technique chosen is incorrect. As a result, the incorrect medication administration technique is used to deliver the drug to the patient. [H-2.8]

Scenario 2 for UCA-4.1.8: The unit nurse physically administers the medication to the patient using the incorrect technique [UCA-4.1.8] because the unit nurse administers the drug using the most common technique/the technique the unit nurse is most familiar with. This flawed process model will occur if the unit nurse is interrupted or distracted away from appropriately attending to the medication administration process, not realizing that the EHR/eMAR indicated a different (and the correct) drug administration rate. As a result, the incorrect medication administration technique is used to deliver the drug to the patient. [H-2.8]

Scenario 3 for UCA-4.1.8: The unit nurse physically administers the medication to the patient using the incorrect technique [UCA-4.1.8] because the unit nurse believes that he is using the correct technique to administer the drug to the patient, but in reality, it is not the correct drug administration technique. This flawed process model will occur if the unit nurse uses the barcode eMAR to verify the medication for this patient, and the correct drug

administration technique information was never received by the barcode eMAR. As a result, the incorrect medication administration technique is used to deliver the drug to the patient. [H-2.8]

Safety Requirement 91: Addressed in SR 76.

Safety Requirement 92: Addressed in SR 77.

Safety Requirement 93: Addressed in SR 76.

UCA 4.1.9: The unit nurse physically administers the medication too late to the patient. [H-2.4]

Scenario 1 for UCA-4.1.9: The Pyxis ADC is delayed in dispensing the medication to the unit nurse due to a mechanical failure, causing the unit nurse to physically administer the medication too late to the patient [UCA-4.1.9]. As a result, the incorrect medication dose (underdose or missed dose) is administered to the patient. [H-2.4]

Scenario 2 for UCA-4.1.9: The unit nurse physically administers the medication too late to the patient [UCA-4.1.9] because the unit nurse believes that it will be clinically acceptable to administer the medication to the patient later than indicated by the medication order. This flawed process model will occur if the unit nurse uses the EHR/eMAR to verify the drug information, and the system indicates to her that the medication is effective within a range of administration times, when in reality, the drug is not clinically effective outside of the timing indicated on the medication order. As a result, the incorrect medication dose (underdose or missed dose) is administered to the patient. [H-2.4]

Scenario 3 for UCA-4.1.9: The unit nurse physically administers the medication too late to the patient [UCA-4.1.9] because the unit nurse is unaware of the messages from the EHR/eMAR that indicate that the medication order is waiting to be administered. This flawed process model will occur if the unit nurse is interrupted or distracted away from appropriately responding to system messages. As a result, the incorrect dose (underdose or missed dose) is administered to the patient. [H-2.4]

Scenario 4 for UCA-4.1.9: The unit nurse physically administers the medication too late to the patient [UCA-4.1.9] because the Pyxis ADC is delayed in dispensing the medication to the unit nurse. This flawed process model will occur if there is no indication or signal from the EHR/eMAR or pharmacy system that the medication needs to be dispensed. As a result, the incorrect dose (underdose or missed dose) is administered to the patient. [H-2.4]

Safety Requirement 94: Addressed in SR 55.

Safety Requirement 95: The administering system be synchronized with the latest medication efficacy information and notify system administrators if this synchronization with the drug information database does not occur successfully within X minutes of synchronization trigger.

Safety Requirement 96: Addressed in SR 70.

Safety Requirement 97: Addressed in SR 56.

UCA 4.1.10: The unit nurse physically administers the medication too early to the patient. [H-2.4]

Scenario 1 for UCA-4.1.10: The unit nurse physically administers the medication too early to the patient [UCA-4.1.10] because the unit nurse believes that it will be clinically acceptable to administer the medication to the patient earlier than indicated by the medication order. This flawed process model will occur if the unit nurse uses the EHR/eMAR to verify the drug information, and the system indicates to her that the medication is effective within a range of administration times, when in reality, the drug is not clinically effective outside of the timing indicated on the medication order. As a result, the incorrect medication dose (overdose or extra dose) is administered to the patient. [H-2.4]

Scenario 2 for UCA-4.1.10: The unit nurse physically administers the medication too early to the patient [UCA-4.1.10] because the unit nurse sees the medication waiting to be administered and does not verify with the system that it is the appropriate time prior to administering the drug. This flawed process model will occur if the unit nurse is interrupted or distracted away from appropriately attending to the medication administration process. As a result, the incorrect medication dose (overdose or extra dose) is administered to the patient. [H-2.4]

Safety Requirement 98: Addressed in SR 95.

Safety Requirement 99: Addressed in SR 70.