Southern California CSU DNP Consortium

California State University, Fullerton
California State University, Long Beach
California State University, Los Angeles

FACTORS IN MEDICATION ERRORS ASSOCIATED WITH SEVERITY OF HARM

A DOCTORAL PROJECT

Submitted in Partial Fulfillment of the Requirements

For the degree of

DOCTOR OF NURSING PRACTICE

By

Lisa Matheson

Doctoral Project Committee Approval:

Beth Keely, MSN, MA, PhD, RN, Project Co-Chair
Nicholas Gorman, MPH, EdD, Project Co-Chair
Margaret Brady, PhD, RN, CPNP-PC, Committee Member

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ABSTRACT

Patient safety is a widely-accepted concept throughout health care and society. Preventable medication errors impact patient safety, which affect patient clinical outcomes, patient satisfaction, and healthcare economics. Databases have been created to document adverse patient events and are used to collect, analyze, and trend data associated with medication errors. Data analytics involve a systematic analysis to glean lessons learned and minimize errors from recurring. In the United States, adverse event data are collected by healthcare facilities and voluntarily submitted to Patient Safety Organizations (PSO). Analyzing big datasets provides an opportunity to conduct data mining and develop predictive modeling to identify variables contributing to the causation and severity of harm associated with medication errors. This project explored the impact of facility type, patient demographics, and anonymity of reporting on severity of harm associated with medication errors. A retrospectives analysis was completed of a PSO database of over 340,000 events involving medication errors. Findings showed that medication errors were reported more frequently for both pediatric and adult patients at general acute care hospitals compared to academic healthcare facilities. Within the facilities, the volume of these errors occurred varied among pediatric and adult units. Higher severity of injury occurred with errors in critical care settings. Patient age impacted the severity of harm. Most importantly, this project identified the need to

identify other key variables that could potentially minimize medication errors and the severity of harm resulting from adverse medication error events.

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BACKGROUND

Statement of the Problem

In 2000, the Institute of Medicine (IOM; 2007) estimated that up to 98,000 deaths were a result of preventable medical errors. Findings from a more recent study (Classen et al., 2011) analyzing data collected in 2004 demonstrated that incidents of deaths due to medical errors may be tenfold that of the 2000 estimate. Medical errors can result in significant morbidity and mortality. Errors can affect quality of life, up to and including death. Medical errors place a financial cost burden to the healthcare system. The estimated annual economic impact of medical errors is 735 to 980 billion dollars (Andel, Davidow, Hollander, & Moreno, 2012). Indeed, utilizing resources to minimize errors from occurring would cost far less than managing the damages resulting from medical errors. Instead, these financial resources could be used to improve patient outcomes.

Sari, Sheldon, Cracknell, and Turnbull (2007) estimated the rate of underreporting of medical errors is about 7% of all adverse events reported by organizations. Reporting medical errors is a voluntary process by the clinicians involved or aware of adverse events. Bayazidi, Zarezadeh, Zamanzadeh, and Paran (2012) found that the reason for much underreporting of medication errors was related to nurses' perceptions they would be blamed for the event. However, medical errors are often related to system failures and not sole individual practitioner error. To reduce medication errors, data are now collected through the adverse reporting database system established for tracking and trending of medication error events. It is clear that identifying a process to prevent medication adverse events from recurring may be life-saving.

Theoretical Framework

A theoretical framework provides the guide for a project (Bonnel & Smith, 2014). It can provide context and understanding as to why things occur. The theoretical framework used to guide this project is the Swiss Cheese model (SCM) by Dr. James Reason (1990). Reason studied the causation of human errors and asserted that being human is the characteristic that makes people vulnerable to errors resulting in adverse events. Human errors can be associated with an individual or system (Reason, 2000). The SCM has gained popularity in healthcare settings for reviewing and analyzing adverse events, in part because it involves a systems approach. Error will occur as humans are fallible and even in the best, most highly reliable hospital, errors will happen. Lessons learned are gleaned from a systematic analysis to diminish the risk of similar errors from recurring (Moyen, Camiré, & Stelfox, 2008; Reason, Hollnagel, & Paries, 2006).

It is important to investigate how medication errors occur by gathering critical information as to the factors involved and to then concentrate on how to prevent medication adverse events. There are two primary ways to do this (Bergeon & Hensley, 2009). The individual approach claims errors are related to carelessness on the part of the person who committed the error. Conversely, the systems approach asserts that errors are a result of a breakdown of multiple systems. Reason (2000) developed the SCM diagram to demonstrate the system failures that occur during an adverse event (see Figure 1). Each layer of cheese represents a layer of safety or 'defense' established to mitigate errors from occurring. Hospitals have many layers of safety practices established, particularly for medication administration (Moyen et al., 2008). Examples include locked medication storage units, cosigning of high alert medications, such as insulin, use of library infusion

pumps for accurate dosing, and bar coding verification prior to medication administration. Like Swiss cheese, each defense layer will have holes (see Figure 1). The

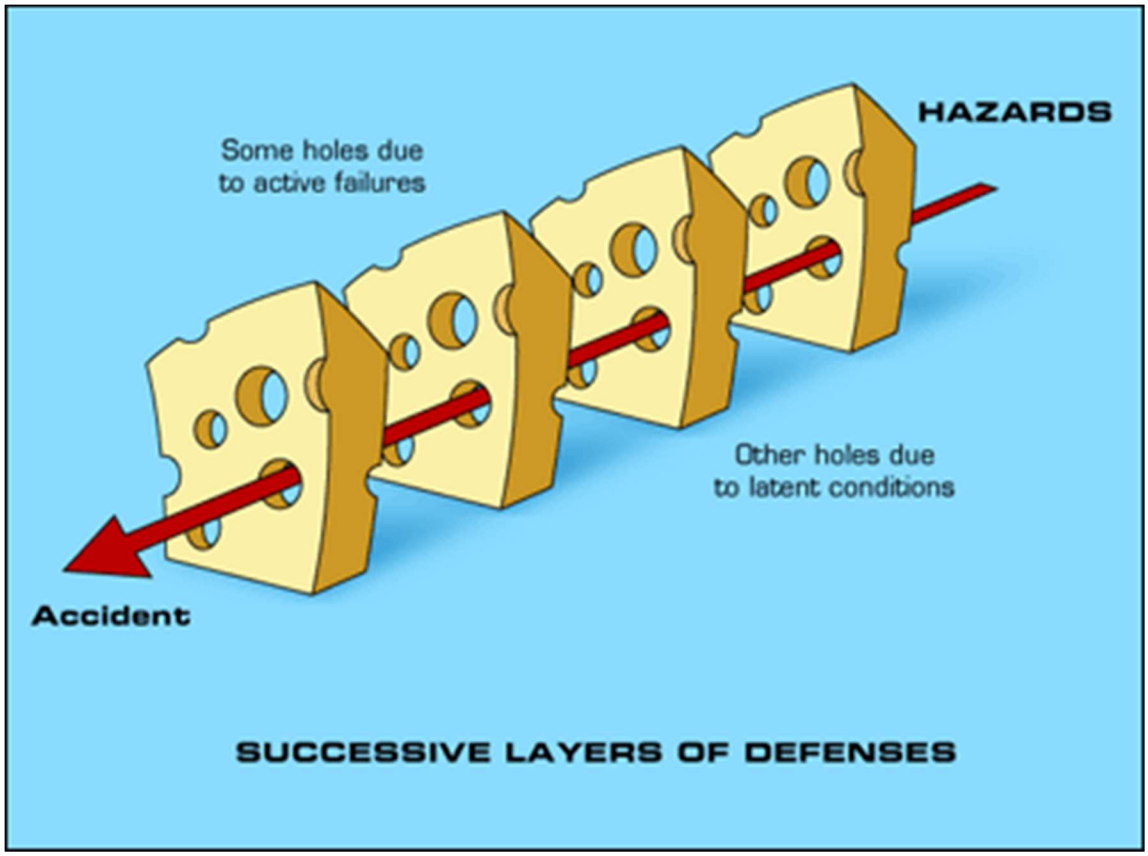

Figure 1. Diagram of the Swiss Cheese Model (Reason, 1990).

holes can vary in size and amount. These holes are dynamic—constantly changing and moving. The hole itself will not result in an error. However, when the holes become aligned, the potential risk for error is greatest. The holes represent risks or 'hazards' that result in failures. Failures arise related to latent or active conditions or a combination of both. Latent conditions are present in all systems. They may lie dormant until circumstances are present for an adverse event to occur. An example of a latent condition is the physical environment design of how medication is stored in relation to where the

nursing staff prepares medications. Active conditions are failures that occur by the individual directly involved with the error. Often, this is related to a lapse by the individual who is not identifying warning signs or not following procedures. An example of an active condition that leads to a medication error would be failure to test a patient's blood sugar level prior to the administration of insulin.

The advantage of using the SCM when analyzing errors is its ability to provide a framework for an in-depth analysis of the event (Bergeon & Hensley, 2009). A root cause analysis (RCA) facilitates the identification of failures contributing to the error and identification of system and process issues. Typically, RCAs are completed for more serious events (i.e., Sentinel Events), as defined by the Joint Commission (2017). The Joint Commission (JC) defined a sentinel event: "A sentinel event is a Patient Safety Event that reaches a patient and results in any of the following: (a) death, (b) permanent harm, or (c) severe temporary harm and intervention required to sustain life" (para. 2). The JC provided a list of responses required for a sentinel event:

1. A formalized process where the patient is stabilized. The event is disclosed to the patient and family. Provide support to patient and family.
2. Notify hospital leadership of the event.
3. Activate immediate investigation.
4. Complete RCA.
5. Create a corrective action plan to remove risks.
6. Develop a timeline to implement the corrective actions.
7. Implement corrective actions system-wide. Monitor for improvement.

8. Complete steps 1-7 within 45 days from when the event occurred or was first identified.

Medication errors may require intervention such as change in treatment plan or higher level of care to manage the patient safety event. The event is unrelated to the patient's underlying condition or natural progression of the patient's illness. System-related issues (latent conditions) vs. individual (active conditions) are examined. Although the SCM model was introduced in the early 1990s, change has been slow, Carlton and Blegen (2006) found that many reports identified the individual directly associated with the medication error as the primary cause of the error occurring. The SCM model is particularly beneficial when examining events, such as medication errors. Using this model, one can investigate the efficacy of established safety barriers and contributing factors that account for the event occurring. In some cases, the SCM has been used as a predictive tool (Bergeon & Hensley, 2009). When investigating an error, a comprehensive analysis can be performed to identify if the latent and active conditions involved will predict the outcome severity of the harm to the patient. Duffield's (2015) research supported this concept.

Application of the Model for this Project

The primary focus of this DNP project is to explore how a variety of factors (i.e., facility type, location within the facility, and population) impact medication errors in the hospital setting. These events are reported in a Patient Safety Organization (PSO) database established by the State of California. The SCM was the organizing framework used in identifying and categorizing the variables analyzed in the dataset studied for this project. The framework was also used to predict whether factors identified for this study

were associated with medication errors as predictors of severity of harm. These factors include two key variables: population age and location type (i.e., classification of agency and unit of care). The application of the SCM provided context to the role variables, such as systematic defense mechanisms (Swiss cheese slice) and latent and active conditions (holes), as contributors to medication errors in the hospital setting.

Project Purpose

The purpose of this project was to explore how a variety of factors (e.g., facility type, patient demographics, anonymity of reporting) relate to severity of harm resulting from medication errors. By recognizing key variables related to medication errors, this study provides the first step toward developing interventions for future research studies.

Research Questions

This project was guided by the following research questions:

1. How did factors associated with medication errors differ by population served (pediatric vs. adult)?
2. How did factors associated with medication errors differ by facility type?
3. How did factors associated with medication errors differ by location setting within the facility?
4. Which of the factors examined in questions 1-3 served as statistically significant predictors of severity of harm?
5. What effect did anonymous reporting of medication error have on severity of harm to the patient?

REVIEW OF LITERATURE

Search and Appraisal Methods

Prior to analyzing the factors associated with medication errors, it was important to assess the evidence related to this subject. A comprehensive literature search was conducted using the following database sources: ABI/INFORM Complete (ProQuest), Business Source Premier (EBSCO), Cochrane Database (Wiley), Cumulative Index of Nursing and Allied Health Literature (CINHAL), Google Scholar, PubMed (NLM), Ovid SP, SAGE Journals online, and Science Digest. Keywords searched included patient safety, systems errors, risk mitigation, adverse drug events, medication errors, medication statistics, causes of medication errors, preventing medication errors, predictive modeling, predictive analysis, data mining, big data, intensive care unit medication errors, Swiss cheese model, Dr. James Reason, human error, adverse event, error causation, latent factors, active factors, causal factors, data analytics, ethics, and patient safety research and factors. Reference lists of articles and studies identified were reviewed for additional studies to review. Studies were limited to human subjects. Articles published in English from 1990 to 2016 were considered for inclusion. The date range was extended over a 26-year period due to limited studies initially found related to the keyword search conducted.

This literature review addresses three topics. They are (a) the scope of medication errors, (b) strategies utilized to decrease the recurrence of medication errors, and (c) use of patient safety data for analysis and research.

Medication Errors

The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) is an independent group consisting of 27 national

organizations. The mission of NCC MERP is to increase awareness and create strategies for decreasing medication errors through transparency and the sharing of these preventative strategies. The California legislature defines a medication error as an adverse event that occurs in an acute care hospital (California Health and Safety Code, 2011). Key elements of NCC MERP's definition were incorporated as part of the California Health and Patient Safety Code 1330.63. The NCC MERP (2016) identified critical contributing factors associated with medication errors, including clinician competency, medical devices/equipment associated with prescribing, prescribing communication, dispensing procedures, taxonomy manufacturer packaging, education, and monitoring. All variables must be addressed when analyzing medication errors.

In 2012, the number of medication errors reported in the United States was 210,648, making this category of mistake one of the most frequently reported types of medical errors in healthcare (Safe Medication Practices, 2013). The IOM (2007) estimated that approximately 400,000 actual medication errors occur annually that result in harm to the hospitalized patient. Of those reported errors, 7,000 resulted in death. Classen et al. (2011) challenged this initial IOM report, stating that the actual volume of medication errors could, in reality, be tenfold higher. Classen et al. hypothesized that the underreporting of medication events was related to the fact that medication error reporting is voluntary. In reviewing the published literature, it is evident there is variance as to the volume of reported medication events in the hospital setting. The unfortunate reality is the evidence demonstrates hospitals continue to underreport errors. Stratton, Blegen, Pepper, and Vaughn (2004) estimated that approximately 67% of all medication errors are reported. If events are not reported, then organizations are unable to identify

the factors in their institutions associated with medication errors. Without analysis of the variables impacting this type of negative event, interventions cannot be identified to decrease the recurrence of medication errors (Parry, Barriball, & While, 2015).

A number of variables can impact reporting. For example, if the organizational culture is perceived to be punitive by the hospital staff, then a medication event may go unreported (Bayazidi et al., 2012; Mrayyan, 2012; Ulanimo, O'Leary-Kelley & Connolly, 2007). The concern of being punished deters staff from reporting errors if they believe they will be reprimanded by management or chastised by colleagues. A lack of awareness concerning the importance of reporting errors can also result in underreporting. Studies have shown that staff nurses are not always aware of what to report (Ulanimo et al., 2007). For example, researchers noted that many nurses did not report an error if a deviation from the medication administration procedure was recognized prior to when the patient received the medication and was corrected. This type of event was not viewed as an error. Furthermore, staff observed that if a patient experienced a medication error and there was no harm manifested as a result of the event, then the staff member did not identify the incident as an event needing to be reported (Mrayyan, Shishani, & AL-Faouri, 2007; Ulanimo et al., 2007).

The diagnosis given to a hospitalized patient is captured through a standardized coding system, known as International Classification of Diseases (ICD). Currently, version 10 (ICD-10) is utilized. ICD is under the auspices of the Centers for Medicare and Medicaid Services (CMS, 2015). From a systems design standpoint, if a patient's death is directly related to a medical error, then the error-associated death currently is not captured consistently through ICD-9 coding (McKenzie, 2009). McKenzie (2009)

conducted a systematic review investigating medication errors and concluded that ICD-9 coding accurately captured only 64% to 85% of medication errors resulting in harm. A number of variables influenced this gap, such as lack of documentation in the medical record by physicians, coders manually missing the event when reviewing the medical record, and the lack of an available diagnostic code to accurately reflect the medication error as a diagnosis requiring medical intervention. McKenzie concluded all of these factors are associated with the inability to identify a medication error through coding per se. Therefore, if a clinician does not identify the error when it occurs, then the error would go unreported because there is no existing process to capture the medication error, regardless of severity (Classen et al., 2011). In 2015, an updated version for diagnostic coding (ICD-10) was released by CMS that is now required to be used by healthcare institutions. Future studies are needed to determine whether coding has been sufficiently improved to identify harm or death associated with medication errors. Studies are needed to examine severity of harm directly related to a medication error together with its clinical impact for the patient's well-being and the financial burden to the organization and healthcare system as a whole.

Keers, Williams, Cooke, and Asheroft (2013) completed one of the most comprehensive systematic reviews related to medication errors. Their literature search recovered 19,362 medication error-related studies, with 91 medication-related research studies analyzed by his team. They concluded that 20% of medication administration events result in medication errors; however, most medication errors did not cause harm to the patient. Furthermore, Keers et al. acknowledged that reporting medical errors should not be driven by the severity of harm to the patient. All medication errors have

implications for the patient, the nurse, and the healthcare system. Furthermore, an analysis of medical errors allows healthcare providers to evaluate systems and processes to identify how patient safety and the quality of care can be improved. Transparency is essential if a successful review is to occur. Dolansky, Druschel, Helba, and Courtney (2013), analyzed the morbidity and mortality associated with errors. Their research findings underscored the need to utilize a root cause analysis (RCA) process when investigating medication errors. They encouraged a system review focus rather than pointing to an individual as the sole reason a medication error occurred.

An RCA can provide an in-depth systems analysis of why a medication error occurred and is a tool to identify factors directly contributing to the cause of the event (Wilson, Dell, & Anderson, 1993). An RCA can be conducted to examine the relationship between healthcare providers and the organization infrastructure as to how environmental factors influence the occurrence of an error. This relationship between employee, environment, and infrastructure may be attributed to what is known as human factors (Crayaon, 2011). Dr. Reason used the term *human factors* in his SCM, the conceptual framework of this project. Dolansky et al. (2013) demonstrated that a collaborative approach by a multidisciplinary team to identify causal factors contributing to a medication event provided an effective process to identify system issues, improve quality of care, and implement an action plan that had the potential to reduce the error from recurring.

Population Type and Location

When reviewing the research regarding the prevalence of medication errors by population type and location, the frequency of medication errors was found to be three

times greater in the pediatric population compared to the adult population (Antonow, Smith, & Silver, 2000, Ferranti, Horrath, Cozart, Whitehurst, & Eckstrand, 2008). A major variable contributing to increased risk of a pediatric medication error is related to weight-based medication dosing. Pediatric dosing is not standardized as it is in the adult population. Medications come in different concentrations that can lead to potential calculation errors when preparing a medication for pediatric administration. Manias, Kinney, Cranswick, and Williams (2014) found the most common medication errors during a pediatric hospitalization included overdose (21%) and dose omission (12.4%). Manias et al. also found the most common reason for pediatric errors was related to communication issues. Misreading the order or missing an order was identified as the cause of 29.2% of the errors reported. The highest risk for medication errors occurred when a child was transferred to a higher level of care. Manias and colleagues reported the hand-off communication between staff was not thorough, leading to 33.7% of the adverse events in administration. It is clear that further research is needed to determine what systems would need to be established to minimize these errors from occurring.

Tang, Sheu, Yu, Wei, and Chen (2007) conducted a study where nurses identified the variables they perceived contributed to the occurrence of medication errors. It is interesting that nurses indicated that the setting did not impact the error frequency. Rather, nurses reported factors such as illegible written orders, fatigue, and lack of knowledge regarding medication administration as key contributors linked to medication errors. Nurses surveyed in this study ranked their heavy workload as the second highest cause of medication errors. A frequent concern identified in Tang et al.'s and Ulanaimo et

al.'s (2006) studies was the staff's hesitancy to disclose errors for fear of being punished or ridiculed by management or colleagues.

Strategies to Decrease Medication Errors

After analyzing and identifying causes related to medication errors, the next step would be to identify strategies to prevent similar medication errors from recurring. Multiple studies have been conducted through the years analyzing medication errors (Keers et al., 2013; Manias et al., 2014; Rinke et al., 2014; Yoder & Schadewald, 2012). The strategies recommended to decrease medication errors can be summarized in three main categories: technology, education, and environment**.**

Technology

Strategies utilizing technology have the greatest impact in minimizing medication errors. Examples of technology to reduce the incidence of medication errors include computerized physical order entry (CPOE), bar code medication administration (BCMA), utilization of smart pumps for medication infusions, and pharmacy unit dose systems (PUDS; Keers et al., 2013; Manias et al., 2014; Rinke et al., 2014; Yoder, 2012). Each of these technological tools focuses on various steps in the medication administration process associated with error and provides a strategy to decrease the risk for error. Consequently, risk reduction is managed through clarification of an order (via CPOE), identification of medication administration to the correct patient (via BCMA), and accuracy of dosing (via smart pumps and PUDS).

Education

Educational interventions that are most effective in minimizing errors from recurring include debriefing in real time (i.e., when the medication error happens) and

conducting one-to-one meetings with a mentor staff member or the supervisor observing the event (Drach-Zahavy et al., 2014). Because these strategies may not always be realistic due to resource availability on the unit, it is important that medication errors be submitted through a risk management reporting system. Feedback needs to be given to the staff working on the unit so they can participate in the analysis of the event and take any corrective action needed to prevent its recurrence (Dolansky et al., 2013; Drach-Zahavy et al., 2014; Keers et al., 2013; Manias et al., 2014).

The most effective learning strategy in health care is the use of patient simulation (Bremner, Aduddell, Bennett, & VanGeest, 2006). This strategy provides an opportunity for staff to practice competencies needed for medication administration under the supervision of experienced staff. Studies have demonstrated that patient simulation is a most effective tool to learn a skill because of two key factors: (a) feedback is provided, and (b) staff are allowed repetition to learn the skill without fear of committing an error in a real-life situation. Thus, the simulation environment decreases the anxiety of staff members as they become competent in medication administration skills (Suplee & Solecki, 2010).

Environment

Parry et al. (2015) found that distractions and interruptions during the medication administration process were associated with many types of errors. Further studies are needed to examine the specific impact of how distractions and the environment impact the incidence of medication errors. For example, nurses need to have adequate space to prepare medications for administration. Yoder and Schadewald (2012) found a decrease in medication errors and increased RN satisfaction when *safe zones* were created for them

to prepare their medications. The *safe zones* provided decreased distractions (e.g., noise and interruptions), so nurses could focus on the many steps required during the medication administration process.

Use of Patient Safety Data for Analysis and Research

This section of the literature review can be categorized as the domain of patient safety research, and its relevance to examining medication errors is addressed. The study of patient safety as a domain in healthcare research is relatively new. Likewise, the terminology "patient safety" research is new. In 2013, the World Health Organization (WHO) published guidelines for research in patient safety. Ethical issues limit the type of studies that can be conducted, so most of the studies reviewed for this project were retrospective. For this project, recent studies were included to provide a framework for the design.

Data Analytics

Data mining was first introduced in the 1990s in the business sector. The phrase *data mining* has been used interchangeably with terminology such as *big data*. Twenty-two years later in 2013, the Institute of Health Technology Transformation (iHT^2) (Cottle et al., 2013) delivered a report to the United States Congress regarding the impact of healthcare data mining. Data mining provides large volumes of real time data and involves a process to capture the data, store, disseminate, and analyze the findings into meaningful information that is relevant and applicable to predict and identify trends.

Studies have shown that data mining provides opportunities to gain knowledge in the various domains of healthcare (Yoo et al., 2012). Historically, this process would have been a laborious manual task completed by an investigator. Data mining (collection)

can now provide hospitals with insight regarding opportunities to improve patient care, reduce costs, and maximize revenues. In 2013, using data analytic strategies, the Premier Health Network demonstrated a $7 billion cost savings through performance improvement initiatives (IBM, 2013). Data sources, such as electronic medical records, financial records, equipment/supplies utilization, and utilization resource management, were delineated and used for a comparative analysis to identify opportunities for financial improvement.

The literature search for this DNP project, however, provided limited studies demonstrating the financial gains associated with data analytics involving medication errors. One explanation for this scarcity of research may be that organizations may limit disclosing financial strategies for propriety reasons. Also, the use of data mining is relatively new in healthcare settings; therefore, organizations may be trying to ascertain how to utilize such analytics. Future studies are needed in this area of healthcare operational management.

Studies have also identified limitations to data mining. The type of data, specifically real time data generated at a high volume, can be overwhelming (Ragupathi & Ragupathi, 2014). The most important aspect to consider before starting an analysis is to know what the problem is (operationalize the problem statement) and what questions need to be answered. Without an adequate understanding of how to analyze and provide interpretation, meaningful analysis cannot be gleaned from the data collected. Clark, Hannan, and Raudenbush (2010) noted that analytical methods need to be practical and statistically valid. Resources and expertise are needed to interpret the data and use predictive modeling in health care.

Predictive Modeling

Predictive modeling techniques can be most successful and beneficial when utilized to create change that adds value. Predictive modeling allows one to analyze data to improve current outcomes (Crocket, 2013). Data can then drive decision points that may need to be made. Predictive modeling applied to medical errors can potentially lead to a decrease in harm to patients. This can result in decreased financial burden to society and the facilities where those errors occurred (Crockett, 2013).

The area of predictive modeling in health care needs further study. A consistent theme identified by several authors of systematic reviews examined for this project was the lack of generalizability that appeared to be associated with the extensive heterogeneity of many of the studies (Keers et al., 2013; Manias et al., 2014; Rinke et al., 2014). Although the use of predictive modeling in this DNP project has relevance, another theme that resonates throughout many of the studies was the lack of standardization with the denominator selection for the studies (Moyen et al., 2008). Studies that selected patient days as the denominator made it difficult to evaluate the rate of medication errors through statistical analysis. Some studies utilized volume of medications administered as a denominator, which appears to be the most effective measure to assess a medication error rate because it provides an opportunity to evaluate medical errors that occur compared to total opportunities involving medications that were administered (Keers et al., 2014). Although predictive modeling has relevance, the author acknowledges issues of heterogeneity and operationalization of an appropriate denominator. This is addressed in the study design of this DNP project.

METHODS

Design

This DNP project was a retrospective study involving a secondary data analysis of medication errors that occurred in 132 hospitals/healthcare facilities in California. The aim of this project was to identify how factors associated with medication errors differed by population type, facility type, and location within a healthcare institution.

The California-based Patient Safety Organization (PSO) surveys hospitals in California about safety issues, such as medication errors, and gave permission for this author to access a large dataset of information collected by this group (Appendix A). The medication error dataset contained information on events occurring in participating hospitals from the years 2013-2015. This timeframe of data collection was used to provide a sufficient dataset for an adequate sample to be analyzed.

Sample/Setting

One hundred thirty-two California hospital facilities voluntarily submitted annual data about safety issues to the PSO. They were recruited to join in the data collection processes through their membership with the California Hospital Association (CHA). The participating facilities represent a range of healthcare settings located within California. Facility types included acute inpatient community and academic healthcare hospitals. The facility submitted data to the PSO for the purpose of analyzing what factors contributed to the errors reported and to establish a benchmark for improvement. The dataset included many variables related to medication errors. The PSO used variables identified by the Agency for Healthcare Research and Quality (AHRQ) for the purpose of standardized analysis by PSOs across the nation.

The data in this study were exported from an established PSO dataset. Approximately 920,000 medical error events were submitted during the study timeframe of 2013 to 2015. Of those events, 350,355 were medication related errors.

Data Collection

Inclusion Criteria

All records from the years 2013 to 2015 were reviewed for medication error related events. All medication-related data were included in the dataset, whether the error did or did not cause harm to a patient. Data were retrieved by support staff at the PSO and sent in a de-identified format.

Records of actual vs. potential patient medication errors submitted for the years 2013 to 2015 were exported from the PSO database, with the assistance of support staff. The following variables associated with these events were analyzed and include population age, type of facility, and location type. All errors were included in the data analysis regardless of whether an event did or did not result in patient harm. Data were de-identified prior to being exported via an excel spreadsheet (see Table 1 for a list of variables) and transported to this author via a secure and protected electronic process.

Exclusion Criteria

All data pertaining to other types of medical errors were excluded. Table 1 includes a list of variables that were examined.

Measures

Variables central to the five research questions are severity of harm, population age, type of facility, and location type. How these variables were operationalized for this DNP project is discussed herein.

Table 1

Overview of Variables/Predictors of Severity of Harm

Variables	Definition*
Report Type	
Incident	Event reached the patient, regardless of harm
Near Miss	Event that did not reach the patient
Unsafe Condition	Any circumstance, increase probability of a patient safety event
Categories Associated w/ Event/Unsafe Condition	Medication or Other Substance
Date the event occurred	Discovery Data/Time
Initial Report Date	Date error occurred
Patient Gender	Female, Male, Unknown
Patient Age	Age at time of event
Neonate	(0-28 days) move all of these over
Infant	(>28 days <1 year)
Child	(1-12 years)
Adolescent	(13-17 years)
Adult	(18 + years)
Extent of Harm	Physical or psychological harm that can include pain, additional intervention directly related to the error, inconvenience (such as prolonged treatment), financial loss, and/or social isolation
Identity of Reporter (Anonymous Reporter)	Identity of Reporter Known or Anonymous
Location of event or unsafe condition	Where did the event and/or unsafe condition occur?
Inpatient general care area	e.g., medical/surgical unit
Special care area	e.g., ICU, CCU, NICU
Labor and delivery	
Operating room or procedure area	e.g., cardiac catheter lab, endoscopy area
Radiology/imaging department	e.g., onsite mobile unit
Pharmacy	
Laboratory	e.g., pathology department and blood bank
Emergency department	
Other area within the facility	
Immediate action taken	Interventions (rescue) executed to manage the error

Note. *Definitions of variables are from Agency for Healthcare Research and Quality (AHRQ).

Severity of Harm

Harm can have a subjective interpretation. The American Society for Healthcare Risk Management (ASHRM) states that a common definition must first be established for the extent of harm to be measured (Hoppes et al., 2014). Harm is considered a serious safety event that reaches the patient and can result in severe harm or death (Hoppes et al., 2012). Many harm severity classification scales are available to use as metrics. The PSO uses the AHRQ 6-point categorical scale based on the severity of harm the patient experienced associated with the medication error (see Table 2). To facilitate analysis in this project, the 6-point AHRQ scale was recoded into a dichotomous variable to distinguish between moderate and severe harm. Only events that can be categorized as no harm, moderate harm, and severe harm by the PSO were recorded (see Table 2).

Population Age

The PSO uses the AHRQ 8-point categorical scale to identify age ranges from birth to end of life (see Table 1). A dichotomous variable was created to differentiate between the pediatric population (birth to 18 years of age) and the adult population (>18 years of age).

Location Type

The PSO defines location type as physical locations within a healthcare facility (see Table 1). These areas were defined as patient care areas associated with the type of care provided in that location (e.g., surgery), patient acuity (e.g., the level of nursing care the patient requires) and physical environment. This categorization was operationalized by the facility based on the regulatory requirements mandated by the State of California under Title 22 (The California Office of Administrative Law, n.d). A dichotomous

Table 2

AHRQ Harm Scale (Used by Patient Safety Organization

Construct/Variables	Definition*	Dichotomous Variable for Study
Unknown	A situation that increases the chance of a patient safety event to occur	Unknown
No Harm	Error reached patient, but no harm was identified	Moderate
Mild Harm	Minimal indications, loss of function, or harm. Minimal change in treatment plan monitoring, and/or increased length of stay to manage harm from error	Moderate
Moderate Harm	Physical or psychological harm adversely affecting functional ability or quality of life. No severe harm. Change in treatment plan to manage effects of error.	Moderate
Severe Harm	Physical or psychological harm (including pain or defacement) that significantly affects functional capability or quality of life	Severe
Death	Death at the time of the assessment	Severe

Note. *Hoppes et al., 2014

variable was created by this author to distinguish between areas identified as critical and non-critical care. Critical care units manage patients admitted for life threatening illnesses and require monitoring and specialized care (The California Office of Administrative Law, n.d).

Ethical Considerations

Institutional Review Board (IRB) approval was obtained from California State University, Long Beach (CSULB). An administrative review was performed, as this study was a secondary analysis of an already de-identified dataset. To gain access to the PSO database, an agreement was made and signed per PSO guidelines. The approval letters from the IRB and PSO are shown in Appendices B and C.

Data Analysis

A statistician assisted with the data analyses. The PSO data were imported from an excel spreadsheet for analysis using the SPSS version 20.0.

Data Cleaning

Data cleaning occurred prior to analysis to ensure the integrity of the study. A random sample of the variables imported into SPSS from the PSO were reviewed through examination of frequency tables, descriptive statistics, and/or graphing for completeness, duplication, incorrect formatting, omissions, and other data entry errors.

Overview of Analyses

1. How did factors associated with medication errors differ by population served (pediatric vs. adult)?

   Analysis: A series of independent samples *t* tests and chi-square tests of independence.

   Variables: See Table 3 for an overview of variables that were analyzed.

2. How do factors associated with medication errors differ by facility type?

   Analysis: A series of independent samples one way ANOVAs and chi-square tests of independence.

Variables: See Table 4 for an overview of variables that were analyzed.

3. How do factors associated with medication errors differ by location setting within the facility?

   Analysis: A series of independent samples t tests and chi-square tests of independence.

   Variables: See Table 5 for an overview of variables that were analyzed.

4. Which of the factors examined in RQs 1-3 served as statistically significant predictors of severity of harm?

   Analysis: Logistic Regression Modeling.

   Variables:

      DV: Severity of Harm (dichotomous).

      IVs: See Tables 3-5 for list of potential predictors.

5. What effect did anonymous reporting of medication error have on severity of harm to the patient?

   Analysis: Chi-square test of independence.

   Variables: Severity of Harm (dichotomous); Anonymity of Reporter (dichotomous)

Results

Data Cleaning

All data were examined via frequency tables for responses outside the expected range prior to analysis. Although no data entry errors were detected, some variables contained response options not initially anticipated. Unanticipated response options were either included in the analysis or coded into a category of "other" at the discretion of the.

Table 3

Demographic Characteristics of Adult versus Pediatric Patients (n = 222,388)

	Patient Population					
	Pediatric *n* (valid %)	Adult *n* (valid %)	χ^2	*df*	Cramer's V	*p*
N	17,493	204,895				
Sex (*n* = 212,504)			305.8	1	.04	<.001
Male	6,339 (52.1)	88,205 (44.0)				
Female	5,818 (47.9)	112,142 (56.0)				
Facility Type (*n* = 221,094)			49.81	4	.02	<.001
Academic health care facility	180 (1.0)	3,542 (1.7)				
General acute care hospital	17190 (98.5)	199020 (97.7)				
Home health care	0	3 (< 0.1)				
Practitioner's Office	0	1 (< 0.1)				
Other	84 (0.5)	1074 (0.5)				
Report Type (*n* = 221,427)			7616.8	2	.19	<.001
Unsafe Condition	3,700 (21.2)	9,792 (4.8)				
Near Miss	5,899 (33.8)	89,487 (43.9)				
Incident	7,830 (44.9)	104,719 (51.3)				
Severity of Harm (*n* = 155,357)			59.0	4	.02	<.001
No Harm	7,047 (67.3)	92,980 (64.2)				
Mild Harm	3,192 (30.5)	47,858 (33.0)				
Moderate Harm	217 (2.1)	3,618 (2.5)				
Severe Harm	7 (0.1)	294 (0.2)				
Death	1 (< 0.1)	143 (0.1)				
Duration of Harm (*n* = 18,536)						
Temporary Harm	806 (99.9)	17623 (99.4)	3.0	1	.01	.08
Permanent Harm	1 (0.1)	106 (0.6)				

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Table 3, *cont.*

	Patient Population					
	Pediatric *n* (valid %)	Adult *n* (valid %)	χ^2	*df*	Cramer's V	*p*
Location of Occurrence (*n* = 164,996)			2166.1	10	.12	<.001
Inpatient general care area	663 (11.4)	54,304 (34.1)				
Special care area	893 (15.3)	18,034 (11.3)				
OR/procedure area	177 (3.0)	5,230 (3.3)				
Radiology/Imaging dept.	38 (0.7)	2178 (1.4)				
Pharmacy	2,727 (46.7)	63,236 (39.7)				
Laboratory	8 (0.1)	83 (0.1)				
Emergency department	915 (15.7)	10,615 (6.7)				
Outpatient care area	52 (0.9)	1,640 (1.0)				
Labor and delivery	358 (6.1)	3,219 (2.0)				
Outside Area	1 (< 0.1)	1 (< 0.1)				
Other	8 (0.1)	616 (0.4)				
Reporter Type (*n* = 4,923)			73.4	1	.12	<.001
Anonymous	484 (94.9)	3,491 (79.1)				
Not Anonymous	26 (5.1)	922(20.9)				

Note. N = 222,388

Table 4

Factors by Facility Type

	Facility Type								
	Academic Health Care Facility	General Acute Care Hospital	Home Health Care	Practitioner Office	Other	χ^2	*df*	Cramer's V	*p*
N	4,523	339,613	118	304	1,376				
Age at time of event (*n* = 221,094)						1646.2	28	.04	<.001
Neonate (0-28 days)	117 (3.1)	868 (0.4)	0	0	0				
Infant (>28 days <1 yr.)	51 (1.4)	2,456 (1.1)	0	0	0				
Child (1-12 yr.)	11 (0.3)	11,629 (5.4)	0	0	53 (4.6)				
Adolescent (13-17 yr.)	1 (< 0.1)	2,237 (1.0)	0	0	31 (2.7)				
Adult (18-64 yr.)	2.497 (67.1)	102,880 (47.6)	2 (66.7)	1 (100)	761 (65.7)				
Mature Adult (65-74 yr.)	603 (16.2)	39,364 (18.2)	0	0	160 (13.8)				
Older Adult (75-84 yr.)	318 (8.5)	35,451 (16.4)	1 (33.3)	0	98 (8.5)				
Aged Adult (85+ yr.)	124 (3.3)	21,326 (9.9)	0	0	55 (4.7)				
Sex (*n* = 229,091)						32.1	4	.01	<.001
Male	1,747 (49.1)	99,815 (44.5)	43 (37.7)	73 (42.4)	504 (43.7)				
Female	1,813 (50.9)	124,275 (55.5)	71 (62.3)	100 (57.8)	650 (56.3)				
Report Type (*n* = 291,944)						1517.5	8	.07	<.001
Unsafe Condition	1 (<0.1)	16,895 (5.9)	7 (5.9)	29 (9.6)	173 (13.5)				
Near Miss	1,287 (29.1)	135,186 (47.3)	6 (5.1)	23 (7.6)	595 (46.3)				
Incident	3,134 (70.9)	133,735 (46.8)	105 (89.0)	251 (82.8)	517 (40.2)				
Severity of Harm (*n* = 189,308)						246.8	16	.04	<.001
No Harm	2,019 (66.9)	122837 (66.4)	78 (78.8)	185 (74.6)	641 (79.3)				
Mild Harm	868 (28.7)	55458 (30.0)	19 (19.2)	47 (19.0)	152 (18.8)				
Moderate Harm	84 (2.8)	6214 (3.4)	1 (1.0)	15 (6.0)	14 (1.7)				
Severe Harm	41 (1.4)	470 (0.3)	0	1 (0.4)	1 (0.1)				
Death	8 (0.3)	154 (0.1)	1 (1.0)	0	0				
Duration of Harm (*n* = 20,085)									

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Table 4, *cont.*

	Facility Type								
	Academic Health Care Facility	General Acute Care Hospital	Home Health Care	Practitioner Office	Other	χ^2	*df*	Cramer's V	*p*
Temporary Harm	-	19,850 (99.4)	3 (100)	-	122 (100)	0.7	2	.01	.71
Permanent Harm	-	110 (0.6)	0	-	0				
Location of Occurrence (*n* = 232,880)						17920.2	40	.28	<.001
Inpatient general care area	1,109 (24.5)	80,243 (35.2)	13 (72.2)	0	250 (51.0)				
Special care area	1,543 (34.1)	28,646 (12.6)	1 (5.6)	0	46 (9.4)				
OR/procedure area	344 (7.6)	8,594 (3.8)	0	0	5 (1.0)				
Radiology/Imaging dept.	72 (1.6)	2,576 (1.1)	0	0	0				
Pharmacy	173 (3.8)	78,983 (34.7)	1 (5.6)	0	165 (33.7)				
Laboratory	1 (< 0.1)	157 (0.1)	0	0	0				
Emergency department	279 (6.2)	20,322 (8.9)	3 (16.7)	0	1 (0.2)				
Outpatient care area	789 (17.5)	1,240 (0.5)	0	1 (100)	22 (4.5)				
Labor and delivery	180 (4.0)	6,239 (2.7)	0	0	0				
Outside Area	1 (<0.1)	14 (<.01)	0	0	0				
Other	29 (0.6)	837 (0.4)	0	0	1 (0.2)				
Reporter Type (*n* = 6,139)						32.6	3	.07 small	<.001
Anonymous	5,008 (81.7)	-	5 (100)	1 (100)	0				
Not Anonymous	1,118 (18.3)	-	0	0	7 (100)				

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Table 5

Factors by Critical Care Setting

	Setting					
	Non Critical Care *n* (valid %)	Critical Care *n* (valid %)	χ^2	*df*	Cramer's V	*p*
N	204,960	30,288				
Age at time of event (*n* = 164,996)			2277.2	7	.12	<.001
Neonate (0-28 days)	343 (0.2)	489 (2.6)				
Infant (>28 days <1 yr.)	712 (0.5)	221 (1.2)				
Child (1-12 yr.)	2,643 (1.8)	106 (0.6)				
Adolescent (13-17 yr.)	1,249 (0.9)	77 (0.4)				
Adult (18-64 yr.)	73,285 (50.2)	8,870 (46.9)				
Mature Adult (65-74 yr.)	27,222 (18.6)	3,982 (21.0)				
Older Adult (75-84 yr.)	25,122 (17.2)	3,368 (17.8)				
Aged Adult (85+ yr.)	15,493 (10.6)	1,814 (9.6)				
Sex (*n* = 175578)			851.1	1	.07	<.001
Male	67,252 (43.4)	11,094 (54.1)				
Female	87,836 (56.6)	9,396 (45.9)				
Facility Type (*n* = 232,880)			1831.0	4	.09	<.001
Academic health care facility	2,977 (1.5)	1,543 (5.1)				
General acute care hospital	199,205 (98.3)	28,646 (94.7)				
Home health care	17 (<0.1)	1 (<0.1)				
Practitioner's Office	1 (<0.1)	0				
Other	444 (0.2)	46 (0.2)				
Report Type (*n* = 200,676)			60.2	2	.02	<.001
Unsafe Condition	6,777 (3.8)	1,153 (4.7)				
Near Miss	87,321 (49.6)	12,400 (50.6)				
Incident	82,059 (46.6)	10,966 (44.7)				

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Table 5, *cont.*

	Setting					
	Non Critical Care *n* (valid %)	Critical Care *n* (valid %)	χ^2	*df*	Cramer's V	*p*
Severity of Harm (*n* = 132,658)			57.5	4	.02	<.001
No Harm	76,438 (66.9)	12,386 (67.1)				
Mild Harm	33,680 (29.5)	5,392 (29.2)				
Moderate Harm	3,830 (3.4)	574 (3.1)				
Severe Harm	172 (0.2)	65 (0.4)				
Death	88 (0.1)	33 (0.2)				
Duration of Harm (*n* = 19,631)			4.3	1	.02	.04
Temporary Harm	17,071 (99.8)	2,523 (99.6)				
Permanent Harm	28 (0.2)	9 (0.4)				
Reporter Type (*n* = 5,439)			11.0	1	.05	.001
Anonymous	3,309 (83.3)	1163 (79.4)				
Not Anonymous	665 (16.7)	302 (20.6)				

author. The analyses were revised to reflect these additional response options. No other data cleaning issues were detected.

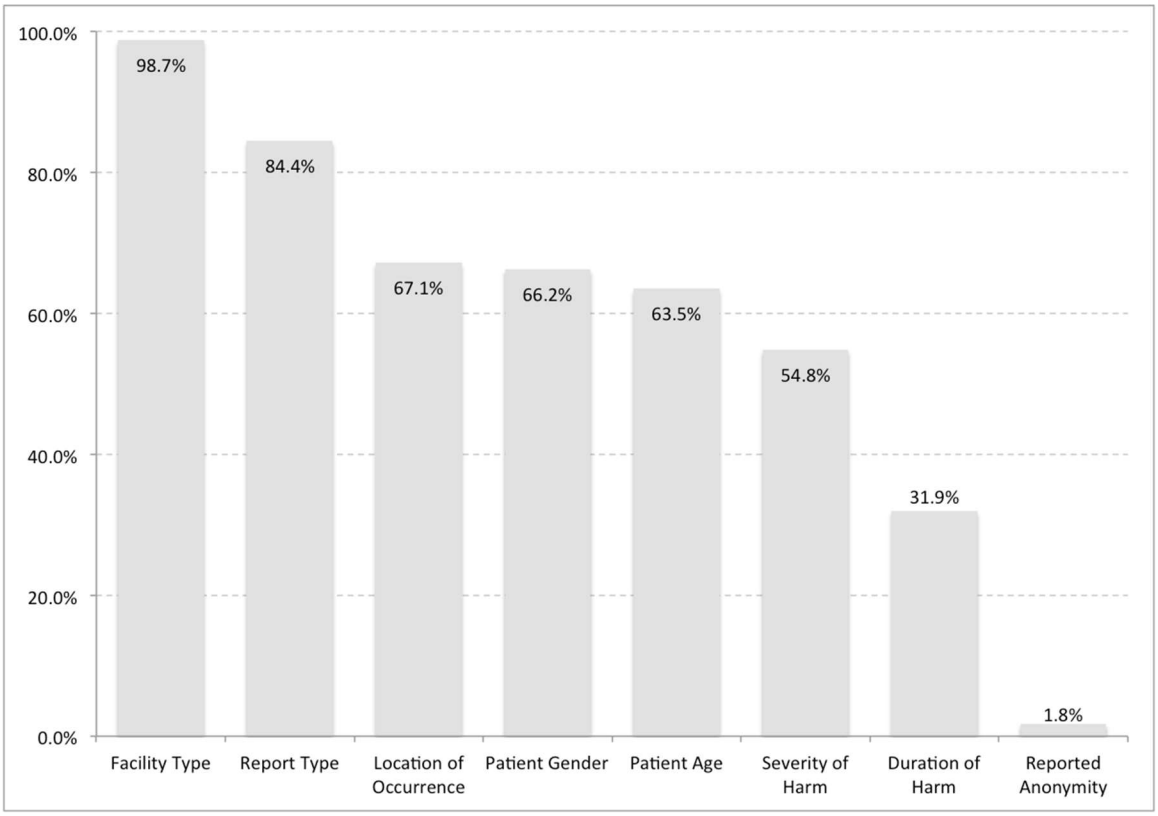
Missing Data

Although data cleaning revealed no data-entry errors in the dataset, it was important to quantify the amount of missing data in the available dataset, as significant heterogeneity was observed. Varying degrees of missing data were anticipated because rigorous, systematic data collection is a known challenge in voluntary adverse event reporting (Latif, Rawat, Pustavoitau, Pronovost, & Pham, 2013). However, quantifying the availability of data for each variable examined was important, as the availability of data and consistency of data collection and reporting bear implications for the validity and generalizability of the results presented.

As shown in Figure 2, reporting on the variables under study was inconsistent across the 350,355 entries retrieved, with only approximately 55% to 70% of entries containing information on the location where the medication error occurred, patient demographics, and severity of harm. Of particular concern, only 1.8% of entries explicitly stated whether or not the reporting of the medication error was anonymous.

How Do Factors Associated with Medication Errors Differ by Population Served (Pediatric Versus Adult)?

To compare how the factors associated with medication errors differ between pediatric vs. adult patients, a series of chi-square tests of independence were conducted (see Table 3). Given the large sample size, it was expected a priori that most, if not all, analyses would be statistically significant, regardless of clinical significance. Therefore, examination of effect sizes was prioritized over interpretation of *p*-values. The magnitude



Note: Response rates calculated as "# responses / 350,355" for all variables except Duration of Harm. Duration of harm was calculated as "# responses / # who sustained harm."

Figure 2. Response rates across dataset.

of effect size was interpreted using Cohen's guidelines for φ and Cramer's V, such that for analyses with 1 *df*, the following text anchors were used: 0.10 = small effect, 0.30 = medium effect, 0.50 = large effect. For analyses with more than 1 *df*, these values were adjusted by dividing each number by the square root of the *df* (i.e., for a test with 2 *df*, a small effect would be $(0.10/\sqrt{2}) = .07$).

Based on these criteria, three analyses emerged as not only statistically significant, but also possibly as clinically meaningful. Specifically:

1. A small-to-medium sized effect was seen for report type. Pediatric records were more likely due to reports of Unsafe Conditions, whereas adult records were more likely to reflect Near Misses or Incidents.

2. A small-to-medium sized effect was seen for the Location of Occurrence. Inpatient general care accounted for 34% of all adult incidence, whereas only 11.4% of pediatric incidents were accounted for in the same setting.
3. A small effect for Reported Anonymity was seen. Pediatric events were more likely to be reported anonymously than were adult events.

How Do Factors Associated with Medication Errors Differ by Facility Type?

To compare how factors associated with medication errors vary across differing facilities, a series of chi-square tests of independence were conducted (see Table 4). As was found with population type, given the large sample dataset, it was expected a priori that most, if not all, analyses would be statistically significant, regardless of clinical significance. Therefore, examination of effect sizes was prioritized over interpretation of *p*-values. Again, the magnitude of effect size was interpreted using Cohen's guidelines for φ and Cramer's V.

Based on these criteria, four analyses emerged as not only statistically significant, but also possibly clinically meaningful. Specifically:

1. A small-to-medium sized effect was seen for Age. Academic healthcare facilities reported more neonate and adult cases of medication errors than did the general acute care facilities. This difference can be attributed to neonates requiring a higher level of care that is often associated with hospitalization in academic healthcare facilities. Academic healthcare facilities have specialized advanced care units to manage the healthcare needs of both acutely ill neonates and adults, which general acute care hospitals may not be able to provide.

2. A small-to-medium sized effect was seen for Report Type. This could be associated with several factors, such as a culture within an organization to report near misses and or the severity of harm. The potential for increased severity of harm may be greater in an academic healthcare setting because the acuity of care is higher which heightens the risk of error.
3. A small effect was seen for severity of harm with increased severe harm and death noted in the academic healthcare setting. This effect could be associated with several factors such as a higher acuity of patient care and more medications administered to the patient in this type of facility which may increase the risk of medication administration error.
4. A large effect was seen for Location of Occurrence within the special care areas of the academic healthcare facilities. These locations are defined as critical care areas. This finding would be expected due to the higher level of care, increased workload, and typically increased patient co-morbidities.

How Do Factors Associated with Medication Errors Differ by Location Setting Within the Facility?

To compare how the factors associated with medication errors vary across critical care and non-critical care settings, a series of chi-square tests of independence were conducted (see Table 5). Given the large dataset, it was expected a priori that most, if not all, analyses would be statistically significant, regardless of clinical significance. Consequently, the examination of effect sizes was prioritized over interpretation of *p*-values. Again, the magnitude of effect sizes was interpreted using Cohen's guidelines for φ and Cramer's V.

Based on these criteria, only two variables emerged as statistically significant and also possibly clinically meaningful. Specifically:

1. A medium sized effect was seen for age, with critical care settings reporting more neonate, infant, and mature adult medication errors than would be expected by chance. Additionally, non-critical care settings reported more child, adolescent, and adult incidents than expected.
2. A small-to-medium sized effect was seen for Facility Type. Fewer errors occurred in the non-critical care areas of academic healthcare facilities. Conversely, fewer errors occurred in the critical care areas of the general acute care hospitals.

Which of the Factors Examined in the Dataset Are Statistically Significant Predictors of Severity of Harm?

To explore which factors predict the dichotomous outcome severity of harm (no harm vs. any harm), a logistic regression model was conducted using a forward conditional stepwise entry approach to model building. Prior to regression modeling, two modifications were made to the variables in the dataset:

1. Because reporter type (anonymous vs. non-anonymous) was available for only 1.7% of the entries in the dataset, its inclusion in the regression model would artificially limit the regression analysis to utilizing ≤1.7% of the dataset. As this drastic reduction in sample size was deemed a critical threat to the internal validity of the analysis, reporter type was dropped from the analysis.
2. Because of the relatively few home healthcare facilities, offices of licensed State-certified practitioners, and facilities marked “other” (representing 0.03%, 0.1%, and 0.4% of the total sample, respectively), these three facility types were combined into a single category labeled “other.” For the purpose of the regression

model, facility type was thus limited to three categories: academic healthcare facility, general acute care hospital, and other.

The final, overall logistic regression model was a statistically significant predictor of severity of harm ($\chi_{(12)}^2 = 82{,}845.51$, $p < .001$). The Nagelkerke R^2 showed that the four predictors together accounted for 58.5% of the observed variance in severity of harm. Prediction success overall was 79% (69.0% of no harm cases were successfully predicted, and 97.6% of any harm cases were successfully predicted). The contribution of individual predictors in the final regression model is summarized in Table 6.

What Effect Does Anonymous Reporting of Medication Error Have on Severity of Harm to the Patient?

To examine the relationship between anonymity of reporting and the severity of patient injury, a chi-square test of independence was conducted. The chi-square revealed a statistically significant association between anonymity and type of report ($\chi^2_{(4)} = 48.89$, $p < .001$, Cramer's V = .10). Examination of standardized residuals clarified the nature of this small-to-medium effect. Moderate and severe harm were significantly more likely to be reported by anonymous sources, while no difference was observed in the reporting of incidents of mild or no harm.

Based on these data, it appears that instances of moderate and severe harm are much more likely to be reported anonymously. There were 3879 anonymous reports filed,

Table 6

Logistic Regression Modeling of Age, Gender, Facility Type, and Report Type on Severity of Harm

Variable	*B*	*SE B*	Exp (*B)*	*p*
Constant	0.47	0.01	1.60	
Patient Age, Reference Category: Adult				
Neonate	-2.14	0.11	0.12	< .001
Infant	-0.39	0.07	0.68	< .001
Child	-0.36	0.04	0.70	< .001
Adolescent	-0.13	0.07	0.88	.054
Mature Adult	-0.02	0.02	0.98	.22
Older Adult	0.17	0.02	1.19	< .001
Aged Adult	0.25	0.03	1.29	< .001
Gender, Reference Category: Male	0.12	0.01	1.13	< .001
Facility Type, Reference Category: General Acute Care Hospital				
Academic HealthCare Facility	-1.18	.04	0.31	< .001
Other	-1.03	.10	0.36	< .001
Report Type, Reference Category: Incident				
Unsafe Condition	-2.45	.19	0.09	< .001
Near Miss	-9.55	.35	0.00007	< .001

Note. n = 149,129; Overall model statistics: $\chi_{(12)}^2 = 82{,}845.52$, $p < .001$, Nagelkerke's $R^2 = .59$

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and 88 of those cases represented severe harm. There were 928 non-anonymous reports filed. One of those cases resulted in severe harm. For comparison, severe harm incidents represented 2.3% of all anonymous reports but only 0.1% of all non-anonymous reports related to severe harm events.

Limitations

This study utilized a large dataset that was maintained by a major PSO. Several methodological limitations were identified by this author. First, the research method of this study is a correlational design. The findings highlight associational relationships, not causal relationships. This study represents a first step to identify where future studies are needed in medication error analysis. Further investigation is needed to identify potential contributing factors that may emerge through an analysis of the subjective reports found in the narrative field portion of the project's dataset. The narrative data field contains explanations and accounts by clinicians about the errors reported; however, this project did not review the qualitative data found in this field. Through a detailed analysis of the qualitative data found in the project's dataset, one may potentially identify factors linked to causation of medication errors that occur in a specific type of setting and/or population.

The large dataset used in this project had its own set of potential limitations. The issues common to research involving a large database are opposite those found in a smaller dataset analysis. A challenge with large datasets is the effect it has related to statistical power. As a result, statistical significance can be found for even small, clinically meaningless between-group mean differences when analyzing a large set of data. *P*-values will show statistical significance in a large dataset, such as the one used in

this project. For this reason, one must differentiate between spurious findings and those results that are clinically significant. Therefore, effect size was examined in addition to statistical significance. Effect size allows one to evaluate whether the data are clinically meaningful. Varying effect sizes were noted during the analysis portion of the project which provided the author with a degree of confidence that effect sizes actually discriminated between potentially clinically meaningful variables and those that were not.

Another limitation of this study stems from the validity of the AHRQ instrument. Although the AHRQ Severity of Harm Scale, a validated tool for measuring harm, was utilized in this project, there is an acknowledged degree of subjectivity associated with its use. Subjectivity is relevant because consistency in training in the use of the AHRQ tool by individuals who assigned the severity of harm scores remains unknown. Therefore, reliability in determining severity of harm scores at the time the event occurred is questionable.

In addition to the aforementioned limitations imposed by study methodology and the AHRQ instrument, missing data introduced a serious limitation. Because the PSO does not mandate that all database fields are filled in by the reporting agencies, the amount of missing data was sizeable. This omission in providing severity of harm data was described in Figure 2. There was only a 54.8% response rate in answering the severity of harm query.

Although the dataset provided a record of how many medication related errors were reported, it did not include the number of total opportunities in which medication errors could have occurred. This denominator is essential for future studies to optimize generalizability (Keers et al., 2013; Manias et al., 2014; Rinke et al., 2014). One needs to

assess the total volume of medications administered. This number can then be compared to how many administration events resulted in errors. This calculation would provide the rate of medication errors by number of administration events. This poses a challenge to the PSO, as data on patient hospital days are currently collected related to medication errors but not by the number of medications administered or the frequency of administration. Using patient days can make it difficult to calculate the rate of medication errors through statistical analysis, due to lack of standardization. (Moyen et al., 2008).

In addition, ICD-10 coding may not be used for reporting a medication error. Currently, voluntary self-reporting is the primary mechanism for reporting. Utilizing ICD-10 coding would provide more ease in collecting medication error data rather than relying on voluntary self-reporting. There is no indication in this project whether the data provided were exported from medical record review, voluntarily reported on behalf of the clinician, or both. This could be problematic, as not all events are necessarily captured through voluntary reporting, which can result in underreporting.

Finally, the generalizability of the project's findings is limited by how the variables under study were operationalized. The definitions of the variables (i.e., facility type, population type, and severity of harm) analyzed in this project may not correspond exactly to the data collected by other PSOs. This inconsistency limits the degree to which these findings will generalize to datasets compiled by other PSOs. Similarly, personnel reporting data can vary in their reliability in data inputting across healthcare facilities and locations within the facilities. For example, an individual at a facility reporting an event may give a severity of harm score that is significantly different from that of another outside person scoring the same type of event but at a different facility.

DISCUSSION AND RECOMMENDATIONS

Reason's (1990) SCM was used as the theoretical framework for this project. The project author identified that system variables can impact the incidence of adverse medication errors. Several interesting findings were identified in this project regarding the occurrence of medication errors. The following discussion addresses the impact of population (pediatric vs. adult), facility type and location, severity of harm, and anonymity in clinician disclosure as they relate to the reporting of medication errors.

Pediatric Population Versus Adult Population

Analysis of the data showed that relative to adults, the pediatric population had a higher proportion of near miss/unsafe condition events reported. The adult population findings noted a higher proportion of medication events that actually reached the patient as compared to the pediatric population. This finding did not support the literature review completed for this project. Antonow et al. (2000) and Ferranti et al. (2008), found the prevalence of medication error to be three-fold in the pediatric population. One could hypothesize the results found in this project may have been impacted by the following. First, the definition of a near miss vs. an actual error may vary between clinicians (Ulanimo et al., 2007). Further investigation is recommended as to how clinicians define a 'near miss' event vs. 'actual' event. Second, inquiry into the safety mechanisms for pediatric medication administration needs to be conducted to determine whether established safety mechanisms for pediatric medication administration are generalizable to the adult population. Safety steps taken during the medication administration process for pediatric patients may identify risk prior to a medication event occurring. The step is corrected and medication administration is resumed, thus minimizing the chance of an error actually occurring. This safety alert may result in a higher proportion of near miss

events vs. actual medication errors occurring and reaching the patient. This would be considered a favorable mechanism, as the reported near miss provided the opportunity to evaluate why an error nearly occurred. Ideally, one would want to educate the staff to document near miss events. Reporting near miss events could provide an opportunity for lessons to be learned and to correct the issue with a positive outcome (i.e, a medication error did not occur). Evaluation of strategies implemented to decrease medication errors in the adult population should be evaluated as to their effectiveness. This would include analyzing the impact of contributing factors on the incidence of medication errors as reported in the data facilities send to the PSO. An example of a contributing factor to analyze is whether the environment had a *safe zone* to prepare medication. *Safe zones* have been proven to decrease the risk of medication errors from occurring (Yoder & Schadewald, 2012). Evaluating the effect of such confounding variables can assist in identification of trends as well as share lessons learned from a deep dive analysis.

A third factor to investigate is whether actual errors that are reported in the pediatric setting are associated with the fact that providers are caring for children with a family member present 24 hours. Typically, parents are at the bedside of pediatric patients, advocating on behalf of the child. An adult patient may not always have a caregiver at the bedside who is monitoring or advocating for the patient throughout most of the day. Is it plausible that practitioners are more proactive in reporting unsafe conditions of a 'near miss' before it escalates to a medication error event? Is greater provider caution exercised in the pediatric setting? Further studies are needed to evaluate this factor.

Although there is no current system to label near misses in ICD-10 coding, there is the ability to capture errors with the ICD-10 coding process. It is dependent on the physician correctly identifying and documenting the error in the Electronic Medical Record (EMR) to capture the event. EMR coding can capture 64% to 75% of errors (McKenzie, 2009). It is conceivable that events voluntarily provided to the PSO are reported by clinicians into an incident reporting system set up by the facility that is separate from what is noted in the medical record and that EMR ICD-10 coding is not utilized. If ICD-10 coding were to be utilized for adverse event reporting, then one may hypothesize that reporting would increase. This would require physician education to include medication errors as part of ICD-10 coding and to document them in the patient's medical record. There would need to be a process to focus on reliability in data entry and correct labeling so medication errors could be assessed in a standardized manner (Classen et al., 2011). Utilizing the medical record to identify medication errors and export the data to an adverse database would increase validity and reliability of the data reported. Furthermore, the risk of not reporting medication errors due to human error would potentially decrease if the reporting of data were automated and exported from the medical record. To do so, future studies would need a denominator, such as total volume of medications administered. In coordination with the healthcare facility's data warehouse or IT department, such aggregate data could be exported into the electronic incident report post discharge. Post discharge would be significant, as one would capture the total volume of medication administration for the entire admission, along with the assessment of contributing factors, such as culture around reporting of medication errors and standardization of the definition of severity of harm.

Facility Type and Location Setting

Facility type and location setting can vary based on the acuity and underlying medical condition of the patient. The level of care is typically determined by facility type and location setting. In this study, academic healthcare facilities were 0.31 times less likely to experience any harm compared to general acute care hospitals. "Other" facilities were 0.36 times less likely to experience any harm compared to general acute care hospitals. The frequency of reporting medication errors, regardless of severity, was higher in the general acute care hospital area for both pediatrics and adults. It is interesting that the location of where the errors occurred within the hospital setting did not vary for the pediatric and adult populations, only the order of the four. The top four locations where pediatric medication errors occurred included the pharmacy, emergency department, special care areas, and inpatient general care areas. As discussed earlier, pediatric dosing is based on weight compared to standardize dosing used in the adult population. Further investigation as to whether children are weighed upon arriving at the emergency room vs. relying on a parent's estimate of their child's weight needs to be examined. Weighing of a pediatric patient should not be bypassed in the emergency department unless the child is in an emergent life support intervention. Inaccurate weights can result in incorrect dosing. Recommendations for identifying vigilance and standardized procedures in emergency rooms may potentially decrease the risk of medication errors (Doherty & McDonnell, 2012). Future research studies should examine whether emergency rooms are within a pediatric hospital vs. a general care hospital, as standards of care and best practices may vary in these two types of pediatric settings that currently were not subdivided in PSO medical error data provided.

For adult patients, the top four locations in order of frequency where errors occurred included the pharmacy, inpatient general care areas, special care areas and emergency rooms. It is plausible that the volume of medication errors being reported by the pharmacy are not actually occurring within the pharmacy or by pharmacy staff. It is possible that the pharmacy was the department documenting the medication errors that occurred in other departments within the facility. The reporting form should differentiate the primary location where the event occurred from the reporting department. This currently may not be the case.

The critical care area is one of the hospital units where pharmacy staff work closely with the critical care team due to the high acuity of the patient. The types of medications administered have the propensity to cause more harm. Although more errors occurred in non-critical care areas, higher severity errors occurred within critical care settings. Findings related to settings reported in this project related to setting were similar to those noted by Latif et al. (2013). Morbidity and mortality rates are greater in a critical care setting (Dolansky et al., 2013). Further research as to the facility type and location of errors using the PSO database hopefully can assist in decreasing errors and delineate systems contributing to the cause of the errors.

Severity of Harm

The incidence of severity of harm from medication errors is greater in critical care vs. non-critical areas. However, the issue of severity of harm should not be the driving force for medication error reporting (Keers et al., 2013). In documenting medication error, severity of the harm to the patient is evaluated. This is completed through a systematic approach, such as RCA (Reason, 1990). Examining severity of harm

provides a measure of the degree of injury from the error that may impact the plan of patient care. This has implications to nursing practice. Although some of the risk of serious harm may be attributable to non-modifiable factors like co-morbidities, others may point to modifiable factors that could impact medical intervention. For instance, the results showed that pediatric patients are at a lower risk of experiencing harm than the reference adult group (Table 2). Pediatric patients were 0.70 times less likely to experience any harm compared to adults. Mature adults also experienced equivalent risk of any harm compared to adults. Older adults were 1.19 times more likely to experience any harm compared to younger adults. Possible factors contributing to the older adult being at increased risk of harm could be related to factors such as pharmakinetics, complex co-morbidities, organ failure, and potential inappropriate prescribing of medications (Lund, Carnahan, Egge, Chrischilles, & Kaboli, 2010). Additional information, such as medications ordered and medication reconciliation, is needed to further evaluate whether they are contributing factors.

Report Type

It is not surprising that reports of unsafe conditions were 0.09 times less likely to result in any harm compared to incident reports that documented harm. Likewise, reports of near misses were 0.00007 times less likely to result in any harm compared to incident reports where injury did occur. It is plausible that staff are not aware of the value of reporting near miss events that may potentially prevent actual events from ever occurring. Furthermore, how near miss and adverse events are reported should be reviewed. Often, many databases can be cumbersome to navigate, and documenting events is time consuming for the clinician. The time to complete a report subtracts from time spent with

the patient. Finally, the culture or safety of an organization can impact reporting. This factor is further addressed in the discussion of anonymous reporting.

Anonymous Reporting

When reporting an adverse event, some organizations allow staff to report anonymously. The philosophy behind anonymous reporting focuses on the belief that it is better to hear about an adverse event than have an individual not report it. There are a number of reasons one may want to report anonymously. Data on anonymity were available for a very small subset of the overall records analyzed for this project; therefore, findings related to these data should be interpreted with some caution. Still, data showed severe outcomes are more likely to be reported anonymously. Regarding death, there were insufficient data to examine this outcome. With missing data and other variables, such as anonymous reporting may not be available to all facilities that reported or the initial severity on submitted events was not updated by the facility if severity changed, there were only seven deaths, too small of a sample to draw any conclusions about statistical significance. However, it is important to note that all seven deaths were reported anonymously. It would be beneficial to review the narrative descriptions of these seven events, which was not done for this study. The reasons individuals may have reported anonymously could be related to the organization's culture of patient safety or staff perception of a punitive environment (Pham, Girard, & Pronovost, 2013). These two possibilities could be addressed using Reason's (1990) SCM model and root cause analysis with a deeper dive into the latent and active factors identified. Management needs to investigate errors with compassion and in a systematic approach. Most errors are a result of systems and processes. Management provided with the skill set of utilizing a

just culture model may increase reporting of errors, with staff disclosing who they are when reporting such events. It provides an environment of shared accountability between staff and employee (Ulrich & Kear, 2014). The organization designs a system that evaluates errors fairly and justly.

Implications for Future Research

One of the primary reasons for completing this DNP project was to establish a future research agenda that would focus on decreasing the risk of medication errors and improving patient safety. Future research utilizing rate-based analysis is needed to identify the true rate of medication error occurrence in various healthcare facilities. By continuing the research started with this DNP project, medication errors can be reviewed from a systems perspective beyond the walls of an individual facility. Utilizing large datasets collected by PSOs gives opportunity for data mining. Healthcare organizations and clinicians can learn from lessons gleaned through big dataset analysis and predictive modeling to identify trends, minimize medication error, and thereby optimize patient safety outcomes.

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APPENDIX A

SWISS CHEESE MODEL PERMISSION OF USE

FW: FW: Permission Request Inbox x

Georgia Stratton <gstratton@cambridge.org> Mar 13 (5 days ago)
to me

Dear Ms Matheson,

1 figure from: James Reason, Human Error © Cambridge University Press 1990

Thank you for your request to reproduce the above material in your forthcoming PhD thesis, for non-commercial publication. We apologise for the delay in our reply. Cambridge University Press are pleased to grant non-exclusive permission, free of charge, for this specific one time use, on the understanding you have checked that we do not acknowledge any other source for the material. This permission does not include the use of copyright material owned by any party other than the author. Consent to use any such material must be sought by you from the copyright owner concerned.

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Yours sincerely,

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APPENDIX B

CHPSO LETTER

CHPSO
California Hospital
Patient Safety Organization

Eliminating preventable harm and improving the quality of health care delivery

November 23, 2016
To: The California State University, Long Beach Institution of Review Board
Re: Lisa Matheson , MSN, FNP-BC
Doctor of Nursing Practice Capstone Project

Ms. Matheson and I have discussed her proposed Doctor of Nursing Practice (DNP) capstone project to explore how a variety of factors (e.g.: facility type, patient demographics, anonymity of reporting) relate to severity of harm resulting from medication errors. I understand that she will collaborate with a statistician to 1) Complete a retrospective analysis of medication errors that occurred in hospitals/health care facilities who are members of the California Hospital Patient Safety Organization (CHPSO), 2) Identify how factors associated with medication errors differ by population type, facility type, and location within a healthcare institution, and 3) Provide the first step towards developing interventions in future research studies related to this area of patient safety.

I understand that the Institutional Review Board at California State University of Long Beach requires that the privacy of the participants be protected at all times. I am aware of the process used to obtain the data set. I will be providing data to Ms. Matheson via spreadsheets. The data will be de-identified prior to being exported via an excel spreadsheet. No patient identification linkage information will be recorded on the spreadsheets

The data will be transported to the researcher via a secure and protected electronic process. I understand that Ms. Matheson will store the data on a secured and password-protected computer that is located in Westminster, California. She will be the only one to have access to this secured computer. She will be completing her analysis in collaboration with a faculty assigned statistician. She will be utilizing SPSS software that will be stored and password protected on the same computer that is located in Westminster, California which is identified above.

Once Ms. Matheson has finished the data analysis, the data will be presented to the DNP committee members and myself.

Further recommendations for developing interventions in future research studies related medication errors and improving patient safety will be generated as a result of this project.

My staff and I fully support Ms. Matheson's project proposal. We will support her in obtaining the data needed to complete this project. We are confident that there will be no breach in patient safety or privacy.

Sincerely,

Rory Jaffe, MD, MBA
Executive Director
California Hospital Patient Safety Organization

1215 K Street, Suite 930 | Sacramento, CA 95814
(916) 552-2600 | fax (916) 554-2299 | email info@chpso.org | www.chpso.org

APPENDIX C

IRB APPROVAL

CALIFORNIA STATE UNIVERSITY, LONG BEACH

OFFICE OF RESEARCH & SPONSORED PROGRAMS

DATE:	November 30, 2016
TO:	Lisa Matheson, BScN, MSN,FNP
FROM:	California State University, Long Beach Institutional Review Board
PROJECT TITLE:	[993664-1] Factors in Medication Errors Associated with Severity of Harm
REFERENCE #:	17-166
SUBMISSION TYPE:	New Project
ACTION:	APPROVED
APPROVAL DATE:	November 30, 2016
EXPIRATION DATE:	November 29, 2017
REVIEW TYPE:	Administrative Review

This is to advise you that the Institutional Review Board for the Protection of Human Subjects (IRB) of California State University, Long Beach, has reviewed your protocol application.

Your application is approved as submitted.

Approval is for a period of one year from the November 30, 2016 and conditional upon your willingness to carry out your continuing responsibilities under University policy. If you would like to continue this research after this one year period, please submit a renewal application and an annual report to the Office of University Research two months prior to your expiration date of November 29, 2017.

1. You must clearly indicate in the header or footer of each page of your approved Informed Consent Form the approval and expiration dates of the protocol as follows: **"Approved from November 30, 2016 to November 29, 2017 by the CSULB IRB".**
2. You are required to inform the Director or Senior Associate Director, Office of Research & Sponsored Programs, in writing (email is acceptable) or through IRBNet within twenty-four hours of any adverse event in the conduct of research involving human subjects. The report shall include the nature of the adverse event, the names of the persons affected, the extent of the injury or breach of security, if any, and any other information material to the situation.
3. You may not change any aspect of your research procedure involving human subjects without permission from the Director, Office of Research & Sponsored Programs or the Chair of the IRB. Please use the Protocol Modification Form on IRBNet to request any changes.
4. Maintain your research records as detailed in the protocol.

Should you have any questions about the conduct of your research under this protocol, particularly about providing informed consent and unexpected contingencies, please do not hesitate to call the Office of Research & Sponsored Programs at (562) 985-8147. We wish you the best of success in your research.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within California State University, Long Beach Institutional Review Board's records.