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UNIVERSITY OF SAN DIEGO

Hahn School of Nursing and Health Science

DOCTOR OF PHILOSOPHY IN NURSING

THE RELATIONSHIP BETWEEN RACE AND ETHNICITY AND SERIOUS
SAFETY EVENTS IN HOSPITALIZED PATIENTS

By

Samantha Crandall

A dissertation presented to the
FACULTY OF THE HAHN SCHOOL OF NURSING AND HEALTH SCIENCE
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In partial fulfillment of the
Requirements for the degree
DOCTOR OF PHILOSOPHY IN NURSING

May 2020

Dissertation Committee

Eileen Fry-Bowers, PhD, JD, CPNP, FAAN Chairperson

Ann Mayo, DNSc, RN, FAAN

Laurie Ecoff, PhD, RN, NEA-BC

UNIVERSITY OF SAN DIEGO
Hahn School of Nursing and Health Science
DOCTOR OF PHILOSOPHY IN NURSING

CANDIDATE'S

NAME: Samantha Crandall

TITLE OF

DISSERTATION: The Relationship Between Race and Ethnicity and
Serious Safety Events in Hospitalized Patients

DISSERTATION

COMMITTEE:

Eileen Fry-Bowers, PhD, JD, CPNP, FAAN
Chairperson

Ann Mayo, DNSc, RN, FAAN
Committee Member

Laurie Ecoff, PhD, RN, NEA-BC
Committee Member

ABSTRACT

Purpose. This study explored the association between patient sociodemographic characteristics and the occurrence of serious safety events (SSE) in hospitalized patients. Specific aims were to describe among patients who have experienced an SSE: 1) patient sociodemographic variables (age, gender, race, ethnicity and language spoken), health insurance coverage, patient zip code, payer mix, site of care location, and severity of event; 2) the relationships between the select patient sociodemographic variables, health insurance coverage, patient zip code, payer mix, site of care location and SSE level of harm; and 3) what factors increase or decrease the odds of experiencing higher levels of harm or death from an SSE.

Background. Preventable harm and death in health care is a concern for all, but structural barriers and implicit bias inherent in the U.S. health care system may increase the risk of injury and poor outcomes for some populations.

Methods. This study utilized a retrospective, cross-sectional cohort design. Data acquired from a health care system in southern California covering an 8-year period was extracted from the organization's SSE database and electronic health record.

Findings. There was a statistically significant association between level of harm and hospital location, $p = .007$, ethnicity, $p = .038$; and insurance (yes/no), $p = .040$. Race and language were not found to be significantly associated with those patients who experienced an SSE. Patients were 1.22 times more likely to experience higher levels of harm or death if they were non-Hispanic/non-Latino, 1.88 times more likely to experience higher levels of harm if they did not have insurance, and 11.45 times more

likely to experience higher levels of harm if they received care at Site 3.

Implications. The findings of this study increase understanding of patient safety and health care disparities. It provides guidance for future nursing research leveraging racial and ethnic data as a proxy for implicit bias, demonstrates use of voluntary reported events to support administrative patient safety data, and encourages consistent education to healthcare professionals regarding implicit bias. Better understanding how implicit bias can influence nurse's decision making and critical thinking is important in preventing patient harm.

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DEDICATION

I dedicate this dissertation to my family. To my incredibly supportive husband, Channing, this would not have happened without our partnership – we did it! Thank you for your unwavering support and encouragement. To my kiddos, Murray and Emmeline, your smiles, hugs and love for life make me so happy and gave me reason to power through during hard times – thank you! To my parents, yet another dream that would not have been possible without your support. Thank you for everything, and for teaching me about hard work and grit – seems to be working out ok for me! To my brother, Russ, thank you for checking in on me no matter the distance between us. And to my in-laws, Pat and John; you weren't able to see me through this part of my journey, but I never doubted your belief in me to achieve great things.

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CHAPTER I

INTRODUCTION

Serious safety events are the third leading cause of death in the U.S., responsible for one in six of all deaths each year (James, 2013). More than 440,000 patients die unnecessarily as a result of serious safety events yearly in American hospitals.

Preventable harm and death in healthcare is a concern for all, but some populations may be more vulnerable to injury and poor outcomes than others due to structural barriers and implicit bias inherent within the U.S. health care system. These populations include African Americans, Pacific Islanders, Hispanics, Asians, American Indians, Native Alaskans, those from lower socioeconomic backgrounds, vulnerable rural and urban dwelling Americans and the underserved (Giger et al., 2007).

Patient safety can be traced as far back as the 14th century to Galen, a physician, scholar and philosopher of the Roman Empire. Some historians attribute the term *primum non nocere* (first, do no harm) to Galen and not Hippocrates (Ilan & Fowler, 2005). The term was introduced to medical culture in America and Britain in 1847 by Worthington Hooker (Hooker, 1849). Florence Nightingale wrote *Notes on Nursing* in 1859, and included, “It may seem a strange principle to enunciate as the very first requirement in a hospital that it should do the sick no harm” (p.ii). Dr. Harvey Cushing, known as the “father of neurosurgery”, published detailed accounts of harm inflicted on his patients due to his own performance in the early 1900’s (Pinkus, 2001), and beginning in the 1960’s, aggregated data started to suggest a high proportion of hospitalized patients experienced preventable iatrogenic harm (Entwistle & Quick, 2006).

In 2000, the Institute of Medicine (now known as the National Academy of Medicine) published findings around the rate of patient harm (*To Err is Human: Building a Safer Health System*), which subsequently initiated the movement in “patient safety” to understand and prevent errors in care. Numerous consequences result from adverse events within hospitals and care systems - ranging from temporary injury with minimal intervention needed, to severe permanent disability and death.

Background and Significance

Patient Safety and Harm

Measuring patient safety and harm rates across hospitals and states has proven challenging. Preventable harm includes events where there was a deviation in generally accepted performance standards (GAPS), also referred to as a medical error or adverse event, and each of these terms may be used interchangeably. Identifying preventable harm events is problematic because standardization in defining and identifying patient safety adverse events is lacking (Nabhan et al., 2012; Pronovost & Colantuoni, 2009). In an effort to better track adverse events in hospitals, the Agency for Healthcare Research and Quality (AHRQ) developed patient safety indicators (PSIs) (Agency for Healthcare Research and Quality [AHRQ], 2007; Rivard, Elwy, & Loveland, 2005). The PSIs were first released in 2003, and since then, multiple studies have leveraged PSI data in an attempt to measure preventable harm in healthcare (Okoroh, Uribe, & Weingart, 2017).

Serious safety events (SSEs) are defined as a deviation in generally accepted performance standards practice or process that reaches the patient and causes severe harm or death (Hoppes, Mitchell, Venditti, & Bunting, 2012). Hospitals and health care

organizations can identify SSEs through a variety of ways including administrative data (PSIs and hospital acquired conditions (HACs), performance and quality indicators, staff voluntary reporting, patient complaints and peer review indicators.

Vulnerable Populations, Health Disparities and Health Inequities

Individuals who live in under-resourced communities, experience poverty and/or homelessness, who are members of racial and/or ethnic minority groups, or who have substance use disorders or mental illness, as well as those who are politically marginalized (e.g., the LGBTQ+ community), experience worse health care outcomes than those who do not. Collectively, these persons have historically been termed “vulnerable” (Flaskerud & Winslow, 1998; Fiscella & Shin, 2005). “Health disparities” refers to the differences in the burden and prevalence of disease, health outcomes, or access to health care among specific population groups (Giger et al., 2007). Broadly speaking, members of vulnerable populations frequently experience health disparities. The Department of Health and Human Services defines a racial or ethnic health disparity as “a particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage” (U.S. Department of Health and Human Services [HHS], 2016). More specifically, when these differences in health are unnecessary and avoidable, rooted in social injustices and thus, considered unfair and unjust, they are termed “health inequities.”

Social determinants of health (SDOH) can be defined as social, environmental and economic conditions that impact individual and group health status. Disparities in health occur when certain social groups are more advantaged or disadvantaged (Walters

et al., 2016; Braveman, 2003). By considering factors that contribute to and are associated with underlying social disadvantage, causes of inequities may become more apparent (Griffith, Moy, Reischl, & Dayton, 2006). Overall, individuals with lower socioeconomic status tend to live in less ideal circumstances and have a higher exposure to risk factors for disease (Andermann, 2016).

Vulnerable Populations and Patient Safety Outcomes

When measuring health disparities and inequities in healthcare, research most often focuses on mortality, life expectancy, morbidity and health status (Bailey et al., 2017). Many studies acknowledge patients who are members of ethnic and/or racial minority groups receive lower quality of care compared to whites even after adjusting for socioeconomic status and insurance coverage (Mayberry, Nicewander, Qin, & Ballard, 2006; Mays, Cochran, & Barnes, 2007; Kington & Smith, 1997). It is clear there are differing and worse outcomes for diabetes, cardiovascular heart disease, obesity, hypertension, arthritis and preterm births between African Americans and whites (Kington & Smith, 1997). Moreover, African Americans, Hispanics and Native Americans have higher incidence rates of chronic disease, disabilities and disease complications (Mayberry, Nicewander, Qin, & Ballard, 2006).

While the majority of research regarding health care disparities among vulnerable populations has explored chronic illness and burden of disease morbidity, disability and mortality, far fewer specifically examine disparities in adverse events in the hospital setting. Researchers can leverage information on patient characteristics and SDOH data, including information on housing, income, crime, education, transportation, domestic

circumstances and food insecurity, in an attempt to identify and understand factors that may influence risk for poor outcomes, including PSIs, once persons are admitted into inpatient settings for care (Daniel, Bornstein & Kane, 2018). In 2005, Coffey et al. looked at PSI rates among different racial and ethnic groups and found African Americans had 1.25 to over 1.5 times the rate of certain PSIs. These PSIs included more infections due to medical care, postoperative sepsis, decubitus ulcers, postoperative respiratory failure, and postoperative pulmonary embolism or deep vein thrombosis, as compared to their white counterparts. More recently, in 2016, Shen et al. found non-white patients covered by Medicaid were more likely to experience higher rates of PSIs than their white counterparts. Similar studies have found differences in risk of infection following infusion, injection or transfusion, postoperative physiologic and metabolic derangements and sepsis based on race and/or ethnicity (Shen et al., 2016; Romano et al., 2003). Hispanics have 1.25 to 1.5 times the rate of postoperative sepsis and metabolic derangements as non-Hispanic whites, and Asian/Pacific Islanders have 1.25 to 1.5 the rate of postoperative sepsis, hemorrhage, respiratory failure and metabolic derangement as their white non-Hispanic counterparts (Coffey, Andrews, & Moy, 2005).

Numerous studies have attempted to identify preventable harm in health care, and to further stratify harm events based on race and/or ethnicity (Okoroh, Uribe, & Weingart, 2017; Shen et al., 2016; Hines, Andrews, Moy, Barrett, & Coffey, 2014; Shimada et al., 2008; Flores & Ngui, 2006; Coffey, Andrews, & Moy, 2005); however, without also including staff reported events, a subset of adverse events, SSEs, are going unnoticed. In addition to PSIs, SSEs identified via the organization's voluntary reporting

system should also be treated as a valuable learning opportunity. Serious safety events are often not flagged by administrative coding, but through staff reporting, and there is limited research leveraging these types of events as current patient safety research generally relies on retrospective chart review and/or PSIs (Shen et al., 2016; Classen et al., 2001; Wet & Bowie, 2009; Shimada et al., 2008; Lewis & Fletcher, 2005). Although there are limitations with relying on staff reported events of harm, SSEs can be seen as a valuable additive to administrative data in gaining a more holistic perspective of patient harm.

The Institute of Medicine, after publishing *To Err is Human*, also published *Crossing the Quality Chasm: A New Health Care System for the 21st Century* in which it identified six aims for health care improvement, one being, “Equitable – providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status” (Committee on Quality of Health Care in America and Institute of Medicine, 2001, p. xxx). To improve quality and prevent patient injury, hospitals must address health inequity. This study examined SSEs through the lens of race and ethnicity, as well as other patient characteristics. In so doing, it tested one mechanism by which institutions may predict plausible harm based on patient characteristics. Results may aid institutions in examining whether the care they provide is equitable and provides information to guide quality improvement.

Study Purpose and Specific Aims

The purpose of this retrospective, cross-sectional cohort study was to describe the relationship between select patient demographic characteristics, payer mix, and patient zip code among patients who have experienced a SSE, defined as moderate to severe harm up to death as a result of a deviation in generally accepted performance standards, in a healthcare system with four acute care and three specialty hospitals in Southern California, over a 48-month period. The specific aims of this study were as follows:

- 1) To describe select patient demographic variables (age, gender, race, ethnicity and language spoken), health insurance coverage (yes/no), patient zip code, and payer mix (private, Medicaid, Medicare, Dual, Tricare, etc.), and site of care location among patients who have experienced a serious safety event.
- 2) To examine the relationships between the select patient demographic variables (age, gender, race, ethnicity, language spoken) health insurance coverage (yes/no), patient zip code, payer mix (private, Medicaid, Medicare, Dual, Tricare, etc.), and site of care location and SSE level of harm (moderate temporary harm, severe temporary harm, moderate permanent harm, severe permanent harm, or death) experienced by the patient.
- 3) To identify what variables of age, gender, race, ethnicity, language spoken, health insurance coverage (yes/no), patient zip code, payer type (private, Medicaid, Medicare, Dual, Tricare, etc.), and site of care location increase or decrease the odds of experiencing moderate temporary harm, severe

temporary harm, moderate permanent harm, severe permanent harm, or death from a SSE.

Summary

Content of this Dissertation

Chapter 1 discusses the background and significance of patient harm in relation to race, ethnicity and other patient characteristics and provides description of the specific aims for the conduct of this study.

Chapter 2 provides a review of the literature and conceptual framework, which guided this research.

Chapter 3 describes the methods and procedures used to quantitatively examine the relationships between patient characteristics and serious safety events reported by a large healthcare system located in southern California.

Chapter 4 presents the results of this research study.

Chapter 5 concludes the dissertation, discusses the study findings within the context of current evidence and policy, describes the implications for nursing practice and education, and makes recommendations for further research in the area of patient safety and health equity.

CHAPTER II

LITERATURE REVIEW

Serious safety events are the third leading cause of death in the U.S., responsible for 1 in 6 of all deaths each year (James, 2013). More than 440,000 patients die unnecessarily as a result of serious safety events yearly in American hospitals. In 2000, the Institute of Medicine (now known as the National Academy of Medicine) published findings around the rate of patient harm (*To Err is Human: Building a Safer Health System*), which subsequently initiated the movement in “patient safety” to understand and prevent errors in care. There are a large range of consequences resulting from adverse events within hospitals and care systems - ranging from temporary injury with minimal intervention needed, to severe permanent disability and death.

Measuring patient safety has been and continues to be challenging. The Agency for Healthcare Research and Quality (AHRQ) released a list of patient safety indicators (PSIs), to give hospitals heightened awareness of potential in hospital complications and adverse events following surgeries, procedures and childbirth (Agency for Healthcare Research and Quality [AHRQ], 2007). The panel of assembled clinicians completed a comprehensive literature review and analyzed international classification of disease (ICD-9-CM) codes to guide the development of the PSI list. Because PSIs are identified through administrative coding, conceptually, all U.S. hospitals can use this data for performance improvement efforts and hospitals can be compared on a regional level (Agency for Healthcare Research and Quality [AHRQ], 2007). National organizations continue to develop additional ways to measure and/or communicate patient safety to the

public; however, an area ripe for measurement, yet unexplored, is the subset of safety events identified via other methods (e.g. voluntary staff reporting and patient complaints).

More recently, researchers have leveraged PSI data to compare quality and safety of care across regions and healthcare systems, assessing safety of care based on day of the week, estimating harm impact, and disparities in PSI rates based on race and/or ethnicity and/or language spoken (Okoroh, Uribe, & Weingart, 2017; Ricciardi et al., 2016; Shen et al., 2016; Hines, Andrews, Moy, Barrett, & Coffey, 2014; Rivard, Elwy, & Loveland, 2005). Very few studies however, have leveraged voluntary staff reporting systems to look at disparities in race and/or ethnicity; those that have involved pediatric populations exclusively (Lion et al., 2013; Cohen, Rivara, Marcuse, McPhillips, & Davis, 2005).

Literature Review and Conceptual Framework

Literature was reviewed to better understand the current state of defining and measuring patient safety and harm, current practices of identifying and reporting adverse events and knowledge around disparities in adverse events and harm related to race and/or ethnicity. Literature for review was obtained from the following bibliographic databases and online searches: PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Medline and Cochrane. Literature regarding the terms *adverse event*, *medical error*, *patient harm*, *patient safety*, *social determinants of health*, *health disparities*, *event*, *race*, *ethnicity*, *payer*, *language* and *hospital* were sought.

Measuring Patient Safety

Data extrapolated from two large patient safety studies (the 1984 Harvard Medical Practice Study and the 1992 Utah and Colorado Study) and applied to all U.S. hospital admissions (33.6 million) implied at least 44,000 and as many as 98,000 Americans die from preventable adverse events in hospitals every year (Leape et al., 1991). Another study in 1999 claimed preventable hospital deaths (deaths caused by medical error) exceeded those attributed to motor vehicle accidents, breast cancer or AIDS (Kohn, Corrigan, & Donaldson, 2000). In a more recent analysis of medical research, Makary and Daniel (2016) rightly argue this often-cited report is limited and outdated, and share that Lucien Leape, a prominent investigator in the Harvard Study, published an article not long after it was finalized, arguing the conclusion of the study *underestimated* the amount of preventable deaths every year. Others have observed the Harvard Study was lacking in that it only looked at specific harm levels and only included errors that were documented in the medical record (Andrews et al., 1997). Studies published after Leape's 1993 article support his claim of previously underestimated preventable deaths in health care (e.g., Baines et al., 2012; James, 2013; Romano et al., 2003; Classen et al., 2011).

The Agency for Healthcare Quality and Research (AHRQ) performed a study in 2004 examining Patient Safety Indicators (Table 1) in the Medicare population between 2000 and 2002 and estimated 575,000 deaths were caused by medical error (roughly 195,000 deaths per year) (Coffey, Andrews, & Moy, 2005). Estimated deaths caused by medical error continue to rise as more studies emerge. In 2008, the US Department of

Health and Human Services Office of the Inspector General estimated 180,000 preventable deaths a year among Medicare beneficiaries alone after reviewing medical records of hospital inpatients that same year (Department of Health and Human Services Office of Inspector General, 2008).

Table 1.

AHRQ Patient Safety Indicators, Provider (or Hospital) Level

PSI 2	Death in Low-Mortality Diagnosis Related Groups (DRGs)
PSI 3	Pressure Ulcers
PSI 4	Death Rate among Surgical Inpatients with Serious Treatable Complications
PSI 5	Retained Surgical Item or Unretrieved Device Fragment Count
PSI 6	Iatrogenic Pneumothorax
PSI 7	Central Venous Catheter-Related Blood Stream Infection
PSI 8	In Hospital Fall with Hip Fracture
PSI 9	Postoperative Hemorrhage or Hematoma
PSI 10	Postoperative Acute Kidney Injury Requiring Dialysis
PSI 11	Postoperative Respiratory Failure
PSI 12	Perioperative Pulmonary Embolism or Deep Vein Thrombosis
PSI 13	Postoperative Sepsis
PSI 14	Postoperative Wound Dehiscence
PSI 15	Unrecognized Abdominopelvic Accidental Puncture or Laceration
PSI 17	Birth Trauma – Injury to Neonate
PSI 18	Obstetric Trauma – Vaginal with Instrument
PSI 19	Obstetric Trauma – Vaginal without Instrument

(Agency for Healthcare Research and Quality [AHRQ], 2019)

In 2011, Classen et al estimated a rate of 1.13% of patients die from medical error every year, which when applied to all US hospital admissions (per Makary & Daniel) would result in over 400,000 deaths a year (Makary & Daniel, 2016). In 2013, a new estimate based on a literature review of four studies using the Global Trigger Tool (an instrument used in retrospective chart reviews), estimated roughly 440,000 preventable adverse events contribute to the death of hospital patients every year (James, 2013). If the study by James is accurate, it would place medical error as the third leading cause of death on the Centers for Disease Control and Prevention (CDC) rankings, and preventable adverse events would be responsible for 1/6 of all deaths in the United States each year. There is intense debate amongst physicians and scholars around the accuracy of these studies; many of these studies fail to produce a formal methodology, have forgotten about other levels of harm classification, and it is questioned if results from study to study are comparable (Shojania & Dixon-Woods, 2016).

If the toll of preventable lost lives is not enough to motivate some, the financial toll should. National Quality Forum's (NQF) National Consensus Standards for the reporting of Healthcare-Associated Infection Data and the Institute of Medicine's report on medication error estimated the financial toll on healthcare each year is \$4.5 billion to \$5.7 billion (National Quality Forum, 2011). Losses seen in health care are often times transferred to consumers through taxes, lost wages, and insurance premiums.

The significance of patient safety in healthcare should be obvious, but there are many challenges when trying to address adverse events. The need for a common language in the patient safety community has been an ongoing challenge and attempted

multiple times. The development of standard definitions, taxonomy, and measurement would have multiple benefits including allowing for the development of regional and national event reporting systems, better comparison of patient safety research findings, development of benchmarking across healthcare organizations, and allowing for components of the taxonomy to drive additional performance improvement (system and individual) efforts. The American Society for Healthcare Risk Management (ASHRM), U.S. Pharmacopeia's MEDMARX, Institute of Healthcare Improvement (IHI), and the National Quality Forum-endorsed Patient Safety Event Taxonomy (PSET) created by The Joint Commission are just a few of the organizations attempting to undertake this task (American Society for Healthcare Risk Management [ASHRM], 2008).

The development of standard definitions related to and pertaining to patient safety is much needed. "Patient safety" concept analyses cover a broad reach and include work environment, effective dissemination of safety information, prevention of medical error, protection of patients from harm and collaborative efforts of staff to prevent harm (Lin, Lin, & Lou, 2017; Kim, Lyder, McNeese-Smith, Leach, & Needleman, 2015). Although adverse events are antecedents to patient harm and the term "harm" is used liberally in the literature, agreement on what harm is, is lacking.

Defining Harm

Etymology and Concept Uses

The concept of harm can be found in a variety of disciplines and literature. The most unsurprising being in medicine and nursing, where harm is defined as "an outcome that negatively affects a person's health and/or quality of life"; and an *adverse event* as:

“an event which results in unintended harm to the patient and is related to the care and/or service provided to the patient, rather than to the patient’s underlying conditions” (Parry, Cline, & Goldmann, 2012, pp. 2155). Health care policy defines adverse event and attempts to estimate the associated social costs (Goodman, Villarreal, & Jones, 2011). Social sciences have attempted to explore patient harm from the patient’s perspective as a way to enhance knowledge around medical and social processes involved in harm and address patient safety using a broader framework (Ocloo, 2010). Bioethical disciplines have debated the presence of harm by comparing what happened in a given situation with the “counterfactuals”; for example, what would have occurred had the said harmful event never taken place versus harm being a state in which a person has a rational preference not to be (Purshouse, 2016). Philosophical and phenomenological disciplines have attempted to dispute many definitions of harm, but one analysis in particular supports the ‘causal comparative account’, which asserts, “an event is harmful to someone if and only if its total causal consequence is worse for that person than its total prevention” (Bradley, 2012, pp. 409). Harm and adverse events are also covered in law, where an adverse event is defined as “any harm to the patient which is due to the administration of health care” (Guillod, 2013, pp. 182). Although the term “harm” is seen frequently throughout patient safety literature, there is an underdeveloped sense of what “harm” is, as well as a lack of standardization in how each hospital organization classifies, measures and responds to patient harm.

In order to put harm into the context of health care, both “harm” and “patient” will be examined independently, and then together.

Patient. Middle English *pacient*, from Anglo-French, from Latin *patient-*, *patiens*, from present participle of *pati* to suffer; perhaps akin to Greek *pema* suffering (Merriam-Webster, 2019).

Patient is defined as (Patient, 2015):

- “an individual awaiting or under medical care and treatment”
- “one that is acted upon”

Harm. Middle English, from Old English *hearm*, akin to Old High German *harm* injury, Old Church Slavonic *sramu* shame. Merriam-Webster Harm is defined as (Merriam-Webster, 2019):

- “physical or mental damage”
- “mischief, hurt”

Patient harm. Definitions of patient harm can be seen across a variety of literature, and since the late 1900’s has been discussed at length, but there is limited evidence of the validity and reliability of the current definitions (Nabhan et al., 2012). There has been limited historical consensus on the definition of harm, which obstructs health care’s ability to recognize and quantify it (Resar, Rozich, & Classen, 2003).

Some definitions include:

- “preventable harm that results from the delay or failure to treat a condition actually present or from treatment provided for a condition not actually present” (Newman-Toker & Pronovost, 2009);

- “...all unexpected and harmful experience that a patient encounters as a result of being in the care of a medical professional or system because high quality, evidence-based medical care was not delivered during hospitalization” (James, 2013);
- “an outcome that negatively affects a patient’s health and/or quality of life” (Parry et al., 2012);
- “unexpected, adverse condition resulting from medical care” (Larsen, Donaldson, Parker, & Grant, 2007);
- “unintended injury that was caused by medical management that resulted in measurable disability” (Leape et al., 1991); and
- “any physical or psychological injury or damage to the health of a person, including both temporary and permanent injury” (National Quality Forum, 2009).

For purposes here, patient harm is defined as an unexpected adverse condition, unrelated to the natural course of the patient’s illness and resulting from substandard care, an error or complication, that leads to injury, worsening health outcomes or death.

Defining Attributes

Walker and Avant (2011) promote clustering attributes most frequently associated with a concept to allow the broadest insight into the concept. Through literature review, four attributes were found to be closely associated with patient harm: unintended, unrelated to underlying disease, non-disease specific outcomes and negative outcomes (Table 2).

Unintended. The definition of iatrogenic is “induced inadvertently by a physician or a surgeon or by a medical treatment or diagnostic procedures (Merriam-Webster, 2019). Although the term “iatrogenic” could be used as an attribute, more often than not, the terms “unintended” or “unanticipated” (and occasionally “accidental”) are used in association with patient harm. The literature supports patient harm being an unintended or unanticipated outcome of the patient’s exposure to the health care system (James, 2013; Landrigan et al., 2010; Larsen et al., 2007; Leape et al., 1991; Parry et al., 2012; Shojania, Duncan, McDonald, & Wachter, 2002).

Unrelated to underlying disease. When patient harm occurs, it is a result of the patient’s exposure to the health care system, and the consequence of the exposure is unrelated to the disease process with which they first presented. The harm incurred is unrelated to the patient’s underlying disease process (Goodman et al., 2011).

Non-disease specific and negative outcomes. The types of outcomes that result from harm are unrelated to the patient’s disease or complaint and their outcomes range from an increased length of stay, temporary or permanent injury, and in severity can be mild to severe injury or death (Leape et al., 1991; Newman-Toker & Pronovost, 2009). Other sources specifically state negative outcomes encompass both physical and psychological injury or damage as examples of negative outcomes related to accidental injury (Stafos et al., 2017).

Table 2.

Attributes of Patient Harm

Sources	Number of attributes	Unintended (error)	Unrelated to underlying disease	Non disease specific outcomes	Negative outcomes
Andrews <i>et al.</i> , 1997	3 of 4	+		+	+
Bradley, 2012	1 of 4				+
Brennan <i>et al.</i> , 2004	3 of 4		+	+	+
Brilli <i>et al.</i> , 2010	2 of 4	+			+
Brilli <i>et al.</i> , 2013	2 of 4	+			+
Classen <i>et al.</i> , 2011	3 of 4	+	+		+
De Wet & Bowie, 2009	3 of 4	+	+		+
Emanuel <i>et al.</i> , 2008	3 of 4	+	+	+	
Entwistle & Quick, 2006	4 of 4	+	+	+	+
Gitte <i>et al.</i> , 2007	2 of 4	+	+		
Goodman <i>et al.</i> , 2011	4 of 4	+	+	+	+
Guillod, 2013	2 of 4	+			+
Hogan <i>et al.</i> , 2015	2 of 4	+			+
Ilan & Fowler, 2005	3 of 4	+	+	+	
James, 2013	4 of 4	+	+	+	+
Kizer & Stegun, 2005	2 of 4	+			+
Kohn, 1999	4 of 4	+	+	+	+

Table 2.
(Continued)

Sources	Number of attributes	Unintended (error)	Unrelated to underlying disease	Non disease specific outcomes	Negative outcomes
Kuzel <i>et al.</i> , 2004	4 of 4	+	+	+	+
Landrigan <i>et al.</i> , 2010	4 of 4	+	+	+	+
Leape <i>et al.</i> , 1991	4 of 4	+	+	+	+
Localio <i>et al.</i> , 1996	4 of 4	+	+	+	+
Makary & Daniel, 2016	2 of 4	+			+
McCaughan & Kaufman, 2013	3 of 4	+	+		+
McGivern & Sorial, 2017	1 of 4				+
Michel, 2004	3 of 4	+	+		+
Nabhan <i>et al.</i> , 2012	2 of 4	+	+		
Newman-Toker & Pronovost, 2009	2 of 4	+		+	
Ocloo, 2010	4 of 4	+	+	+	+
Parry <i>et al.</i> , 2012	4 of 4	+	+	+	+
Pinkus, 2001	2 of 4	+			+
Pronovost & Colantuoni, 2009	1 of 4	+			
Pronovost <i>et al.</i> , 2016	0 of 4				
Pryor <i>et al.</i> , 2011	1 of 4				+
Purshouse, 2016	1 of 4				+
Resar <i>et al.</i> , 2003	4 of 4	+	+	+	+

Table 2.
(Continued)

Sources	Number of attributes	Unintended (error)	Unrelated to underlying disease	Non disease specific outcomes	Negative outcomes
Shojania <i>et al.</i> , 2002	2 of 4			+	+
Stafos <i>et al.</i> , 2017	2 of 4	+			+
Thompson-Moore & Liebl, 2012	2 of 4	+	+		
Tingle, 2017	of 4				+
Vincent & Coulter, 2002	of 4				

Antecedents

Walker and Avant (2011) define antecedents as conditions and events that precede a concept. In relation to patient harm, four antecedents have been identified in the literature: 1) error; 2) adverse event; 3) substandard care; and 4) complication.

Errors have been categorized as errors in commission, omission, communication, context and diagnostic errors, and it is important, when searching for harm, investigators be aware of what to look for (James, 2013). Adverse events are considered injury caused by medical management (Brennan et al., 1991). Substandard care, or acting outside of best medical practice, is also an antecedent, and aids in identifying whether harm was preventable. By definition, when a patient arrives with an illness, something has already gone “wrong”, so in medical situations, failing to provide appropriate and timely interventions can result in patient harm and would be considered substandard care (Emanuel et al., 2008). The last antecedent identified was complications.

Complications in health care that contribute to patient harm are most often categorized as unintended or unexpected. When a complication resulting in harm occurs it does not necessarily mean an error also occurred (Hogan et al., 2015; Resar et al., 2003).

Consequences

The outcomes of the concept are labeled consequences (Walker & Avant, 2011). Many consequences were identified as a result of the concept patient harm, and include: 1) injury, 2) longer length of stay, 3) measurable disability, 4) life shortening/death, 5) suffering, 6) emotional or physical stress, 7) set back to interests 8) worsening health outcomes 9) increased hospital costs and 10) process improvement measures and system fixes to promote safer practices and patient safety.

Although most of the literature measures deaths and there is much discussion around preventable versus unpreventable death, discussion of the varying degrees of harm severity is less prevalent. Types of harm discussed include injury leading to prolonged length of stay and varying degrees of disability (Brennan et al., 1991). Kizer & Stegan (2005) describe serious events as those resulting in death or loss of a body part, or loss of bodily function or disability lasting longer than 7 days. Although emotional and mental harm should also be defined and measured, many studies focus on physical harm, hoping to provide a base for which hospitals can build upon, and eventually find ways of measuring emotional harm (Resar et al., 2003). Emotional harm can include the loss of trust; patients have been unintentionally harmed by people in whom they placed their trust (Vincent & Coulter, 2002).

There is a high financial cost to patient harm. In 2008, medical errors in the United States were estimated to cost \$1 trillion and included costs relating to additional medical examinations, treatments, prolonged hospital stays, investigations, and paying compensation to patients (Tingle, 2017). As a result of multiple studies illustrating the rate in which patient harm occurs, accreditation bodies, governments, non-profit organizations, hospitals and payers have invested resources and launched initiatives to help improve patient safety (Landrigan et al., 2010).

Many hospitals have adopted safety practices and high reliability principles such as those seen in other high-risk industries (e.g., nuclear power) in order to reduce patient harm and improve health care quality (Pryor, Hendrich, Henkel, Beckman, & Tersigni, 2011). Processes have been developed to attempt to track preventable harm, and region wide collaboration between hospitals around patient safety is becoming more prevalent (Brilli et al., 2010; Resar et al., 2003). Campaigns launched by the Institute of Healthcare Improvement (IHI) include the *100,000 Lives Campaign*, and the *5 Million Lives Campaign*, which are focused on reducing preventable deaths and supporting the improvement of medical care in the United States. Hundreds of hospitals across the nation have participated (Classen et al., 2011). Global awareness around patient safety has also grown, thanks in part to the World Health Organization's World Alliance for Patient Safety (Emanuel et al., 2008).

Empirical Referents

Empirical referents are the categories or groups of actual phenomena that, by their existence, demonstrate the occurrence of the concept itself (Walker & Avant,

2011). There are multiple ways in which the prevalence of patient harm has been measured and tracked. The Agency for Healthcare Research and Quality (AHRQ) introduced the term “Never Events” in 2011; a list of 29 events, which encompasses medical errors that are measurable (unambiguous), result in serious outcomes (disability/death), and are usually preventable. Never events are considered sentinel events and are reported to The Joint Commission (Agency for Healthcare Research and Quality, 2017). Hospital mortality rate, although important, is considered a crude measurement of patient safety as it only captures the most extreme events. The AHRQ has developed Patient Safety Indicators (PSI), which rely on an automated review of discharge codes to detect and track adverse events. The Utah/Missouri approach (a subset of AHRQ’s PSIs) is even more sensitive because it uses more diagnostic codes. There is controversy around these automated measures because some argue they are not sensitive or specific enough to accurately identify adverse events (Classen et al., 2011). Conversely, the Harvard Medical Practice Study used physicians and nurses to review patient’s complete medical records, however, most avoid this type of review to measure patient safety because of its labor-intensive nature (Leape et al., 1991).

The Global Trigger Tool was created after a review sponsored by the Institute of Medicine revealed reporting systems miss many adverse events, and voluntary reporting was not an accurate measurement of patient harm and adverse events. Development of the Global Trigger Tool aimed to provide a more practical and less labor-intensive approach to measuring patient safety. The instrument has been adopted by the Department of Health and Human Services Office of Inspector General, which used it in

a study to help measure the rate of adverse events and patient harm in hospitalized Medicare patients (Classen et al., 2011). “Triggers” are defined as easily identifiable flags or prompts in patient records that alert the reviewers to potential adverse events or patient harm that were previously undetected (Wet & Bowie, 2009).

Constructed Cases

Model Case

At one-and-a-half, Emily was diagnosed with a malignant tumor at the base of her spine. She underwent multiple surgeries and chemotherapy sessions, and when she turned two, MRI images showed the tumor had disappeared. The decision was made for one more rounds of chemotherapy to ensure the cancer was gone. On the third day of her last chemotherapy treatment, Emily was fatigued, vomiting, and complaining of a headache. She was taken to the Intensive Care Unit, placed on life support, and the following morning was declared brain dead (*non-disease specific outcome, negative outcome*). Upon investigation, it was found the pharmacy technician who prepared Emily’s chemotherapy inadvertently filled the bag with a concentrated sodium chloride solution of 23.4%, which she compounded herself, rather than using a pre-made bag with less than 1% sodium chloride (*error*).

This illustrates a model case because it includes all identified attributes and epitomizes the identified operational definition of patient harm. Emily’s death was an unintended, negative outcome of an error and not related to her disease state. This case illustrates antecedents to patient harm (error and adverse event), and consequences of patient harm (death).

Borderline Case

A physician orders a CT scan with contrast for a patient presenting with gross hematuria. When asked if he has any known allergies, the patient responds “no”. A quick review of the patient’s medical records shows no signs of allergies. During the scan, the patient starts to complain of shortness of breath and requires resuscitation and transfer to the ICU.

This is a borderline case because it encompasses some, but not all, attributes, antecedents and consequences. The patient’s change in status was not related to his underlying disease and was unintended (attributes). This case is missing antecedents associated with the concept of patient harm as defined in this paper as there was no error or substandard care. The consequences associated with this event include a longer length of stay and set back to interests.

Limitations

The lack of a gold standard to define and measure harm remains a barrier to reducing healthcare associated adverse events and harm. The term “harm” is used liberally in the literature, but agreement on what harm is, is lacking. There is vast discussion around whether the harm incurred was preventable or not, and far less discussion around defining what it means to be harmed and what perspectives should be explored (e.g., patient perception, health care provider perception, etc.) (Hogan et al., 2015; Lawton et al., 2015). Not all, but most studies focus purely on physical harm, but documented pain or psychological or social injury should also be considered. The majority of studies looking at adverse event and harm rates focus on acute care and are

not inclusive of all levels of care outside of the acute healthcare setting (Michel, Quenon, Sarasqueta, & Scemama, 2004). Little work has been generated around patient's experience of medical errors and harm in both inpatient and outpatient settings (Kuzel et al., 2004).

There are large initiatives and collaboratives aimed at reducing patient harm, however, consensus on a common definition does not yet exist. Through the identification of attributes, antecedents, and consequences an operational definition of patient harm has been suggested here in order to further discussion around adverse events, create a global understanding of patient harm and help standardize measurement of patient harm.

In addition to the healthcare community lacking a clear definition of harm, limited research on disparities in harm rates based on race and/or ethnicity exists. Current studies use PSIs, hospital acquired conditions, and hospital acquired infections to compare harm rates but have not attempted to stratify patient harm events identified through staff reporting by race and/or ethnicity. One limitation to using staff identified events for research, is the variation in expectations of reporting of harm and adverse events at the local and national levels.

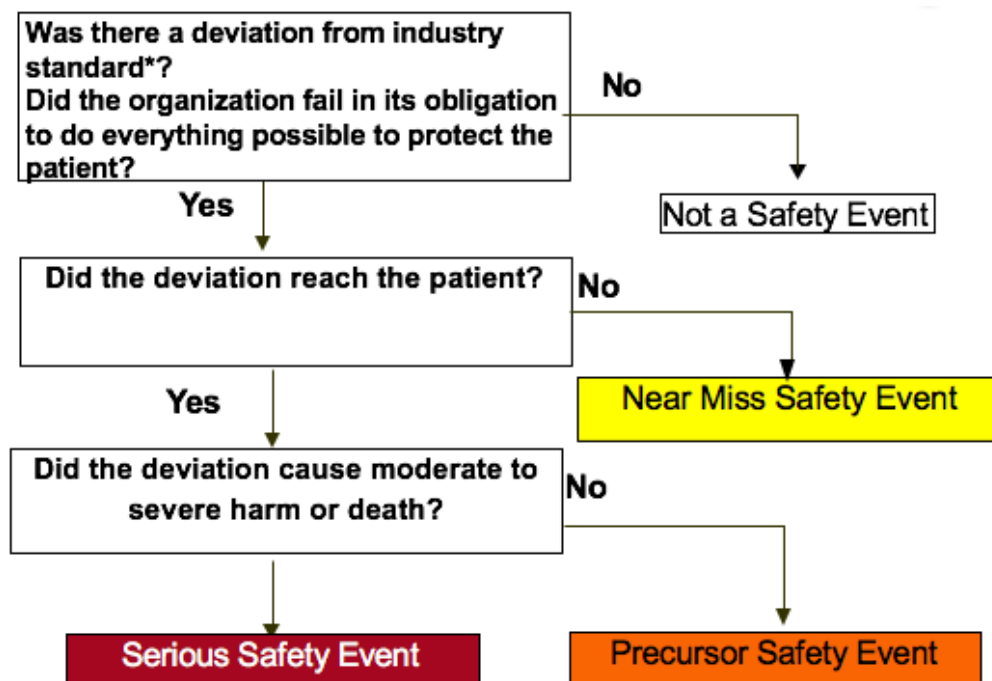
Healthcare Performance Improvement (HPI) and Harm Classification

There are many patient safety organizations across the globe attempting to identify the "best" way to identify and classify harm. A common classification method adopted by large health systems was developed by Healthcare Performance Improvement, LLC (HPI) classification methods. HPI developed the Safety Event

Classification (SEC) and the Serious Safety Event Rate (SSER). The SEC provides a common definition for an SSE as well as an algorithm (Figure 1) for the classification of harmful events (Throop & Stockmeier, 2011).

Not all unwanted outcomes in healthcare are considered harm events. There are outcomes related to known complications and there are unwanted outcomes related to the natural progression of disease (despite best efforts). Events of harm are outcomes that result from defects in care. Of the multiple organizations discussed in this chapter, HPI's approach is novel in that instead of leveraging a taxonomy based on event type or category (e.g., fall with injury or medication error), HPI promotes an outcome-based classification system. (Throop & Stockmeier, 2011). It is important to understand how events are classified, to best understand the occurrence of serious safety events. There are three main steps in determining if an unwanted outcome is truly a harm event, they are deviation, causation and harm (Figure 1).

Figure 1. HPI's Safety Event Classification Algorithm



Deviation

In order to be considered an event of harm, the first question in HPI's provided algorithm is, "was there a deviation in generally accepted performance standards (GAPS)?" In order to identify deviation, an organization must compare expected performance to actual performance. In cases where there is a difference between the two, there is a deviation in generally accepted performance standards. GAPS should include both internal practice expectations as well as nationally recognized best practice (in case

current policies and procedures are not up to industry best practice) (Throop & Stockmeier, 2011).

Causation

The second step in determining safety event classification is a direct cause-and-effect relationship between the deviation and harm to the patient. This can be a challenging question because hospitalized patients often present with co-morbidities and ascertaining if the deviation caused the outcome (and not an underlying condition) can be difficult. HPI warns against under- classification, and instead suggests organizations reflect on if they did the best possible to protect the patient from harm (Throop & Stockmeier, 2011).

Harm

The last step in safety event classification is the level of harm experienced by the patient. There are three “buckets” harm can fall in, per HPI. Serious Safety Events (SSEs) are those in which the patient experienced moderate to severe harm or death, Precursor Safety Events (PSEs) resulted in minimal, no detectable or no harm, and Near Miss Events (NMEs) are those in which the deviation did not reach the patient (Throop & Stockmeier, 2011).

Guiding Organizations for Patient Safety

Currently, federal efforts are lacking around the issue of adverse event reporting. State legislatures have been busy addressing the problem, however, they have not been collaborating with one another. The different and sometimes contradictory use of terminology in relation to patient safety and patient harm, complicates the development

and comparison of reporting mechanisms. These complications are further compounded by clinicians, consumers, regulators and administrators who all have differing opinions on appropriate terminology (Weinberg, Hillborne, & Nguyen, 2005). Different support and oversight agencies have attempted to address this problem with none garnering full buy-in. Not only is there disagreement on terminology and types of events that should be reported, but also a lack of consensus on what type of patient information would be valuable to include with these reports.

National Quality Forum (NQF)

NQF is an organization funded in part by Congress, which brings together public and private sector organizations in an attempt to reach consensus in how to best measure quality and patient safety in healthcare. NQF is a membership-based organization that is nonprofit and nonpartisan (National Quality Forum, 2017). In 2002, the National Quality Forum published a report called *Serious Reportable Events in Healthcare: A Consensus Report*, in an attempt to create a list states could use to guide standardized reporting around healthcare errors and patient harm. The ultimate goal was to provide a basis for a national reporting system, and influence improvements in patient safety. Criteria needing to be met, to be included on the list includes events that are: a public health concern, clearly measurable and identifiable, strongly influenced by the policies and structures within the healthcare setting, adverse, indicative of a problem and important for public accountability (National Quality Forum, 2007). The list is broken in to six different domains: surgical, product or device, patient protection, care management, environmental and criminal events, and is driven by consensus among providers, purchasers, researchers

and healthcare stakeholders. Although it was implemented in 2002, there is opportunity for continuing evolution of the list through NQF, and involvement in further development is open to all (National Quality Forum, 2017; AHRQ Patient Safety Network, 2017).

Although events identified here are clearly measurable, there are no studies comparing differences in rates by race and/or ethnicity or other social determinants of health.

The State Alliance for Error Reporting (SAFER)

In response to NQF's 29 item Never Event list, a workgroup of ten states convened under the guidance of the National Academy for State Health Policy to review and seek clarity around recommendations given by NQF. A comparison matrix was developed to illustrate gaps in definitions and/or reporting from state to state in relation to NQF's list. SAFER identified major drawbacks to having such a defined list. These challenges include: limited intent may not meet all states' needs for regulatory and/or reporting requirements, the list omits learning opportunities from events that did not result in serious harm (e.g. near-miss events), and the list may have omitted some controversial elements based on the nature of consensus agreements (Rosenthal & Booth, 2003). Initially, there was federal government buy-in to pilot standardized definitions to garner feedback from the states, however this never came to fruition.

The NQF developed a straight-forward list of unambiguous events that should "never" happen, yet response to this list, state to state, differed. States had differing requirements as to what types of facilities were required to report adverse events (hospitals, ambulatory surgical centers, long term care centers, ambulatory clinics and/or home care providers), and there continues to be a wide variation of what events are

reported from state to state. Although some have adopted NQF's definitions straight-out, other states have modified the definitions, adding to the inability to compare and benchmark patient safety from state to state (Hanlon, Sheedy, Kniffin, & Rosenthal, 2014). Some states have definitions that closely match those of NQF, others have definitions that are more narrowly defined than NQF (possibly leading to *fewer* events being captured), others have definitions more broadly defined than NQF (most likely capturing *more* events than others), and some states may include the event but not explicitly state it, or may have an event not captured by NQF at all; all of which complicates ways in which adverse events can be measured from one state to the next (Rosenthal & Booth, 2003). Another barrier to garnering buy-in from states in changing current definitions includes reportable events that are defined in statute, which would require return to the legislature for approval if changes are requested (Marchev, Rosenthal, & Booth, 2003).

The Joint Commission (TJC)

The Joint Commission (formerly The Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) has had major influence over patient safety through their patient safety policies and general requirements. Requirements include the 1996 sentinel event policy, the 2001 patient-safety standards, and the 2002 patient safety goals (Devers, Pham, & Liu, 2004). Adding to confusion around reporting requirements, TJC's "sentinel event" definition differs from "adverse event" from state to state. The sentinel event policy requires each accredited hospital to define for themselves what "sentinel event" means and at a minimum requires the definition to include those events subject to

review under the sentinel event policy (The Joint Commission, 2013). The Joint Commission's formal list of sentinel events contains 15 events reviewable according to their policy. Reporting to this body is voluntary, and therefore, most likely represents only a small portion of actual events. The discrepancy between definitions and terminology around adverse events between this major accrediting body and the states hinders full understanding and complicates processes. When an adverse event occurs, it is sometimes difficult to discern to whom the event should be reported (i.e., the state, The Joint Commission or both).

Some states also have statutes requiring aggregate data on adverse events to be sent for legislative review and involve the governor and leaders of the state legislatures. Reviewing aggregate data can help health care organizations focus on leading problems, and more states should follow this example. Past exemplars include Rhode Island and Tennessee which targeted legislation toward patient safety concerns, particularly around reporting of adverse events (Marchev, Rosenthal, & Booth, 2003). Legislation, which requires engagement by elected officials, can further help raise awareness and support around patient safety initiatives.

Agency for Healthcare Research and Quality (AHRQ)

The Agency for Healthcare Research and Quality (AHRQ) is a federal agency tasked with improving quality and safety of healthcare in the United States. This agency drives research and funding to enhance knowledge, create instruments to measure patient harm and gathers data to help provide safe care and give needed information to policymakers to aid in decision making. AHRQ provides access to latest news and

research around patient safety but does not enforce or provide oversight or accountability to healthcare organizations (AHRQ Patient Safety Network, 2017).

In an attempt to standardize capture of patient safety events AHRQ developed Patient Safety Indicators (PSIs). PSIs are a set of administrative data-based indicators used to identify preventable patient safety events. This measurement strategy utilizes International Classification of Diseases (ICD) codes to identify and alert hospitals of events. ICD codes are used by physicians, insurance companies and public health agencies to represent diagnoses. Compared to medical record review and voluntary reporting systems, leveraging data-based indicators offers advantages such as they are relatively inexpensive, readily available, and devoid of subjective interpretation (Rivard, Elwy, & Loveland, 2005).

The Center for Medicare and Medicaid Services (CMS) uses select AHRQ PSIs in “pay for performance” demonstration projects and some organizations use the data to build comparative reports on hospital quality. There are 18 provider (or hospital) PSIs (Table 1), some overlapping with NQF never events and some unique to this list. Common terms such as medical error, preventable adverse event and patient safety are defined – again adding to the large library of definitions provided by multiple bodies (Agency for Healthcare Research and Quality [AHRQ], 2007).

Centers for Medicare and Medicaid Services (CMS)

The Centers for Medicare and Medicaid Services (CMS) is a federal agency within the Department of Health and Human Services that administers the Medicare program and works with state governments to manage Medicaid, the Children’s Health

Insurance Plan (CHIP) and health insurance portability standards. On February 8, 2006, President George W. Bush signed the Deficit Reduction Act (DRA) of 2005, which requires events that could have been prevented through the application of evidence-based guidelines be identified. In July of 2008, in the Inpatient Prospective Payment System (IPPS) 2009 Final Rule, CMS included 10 categories of conditions that were selected for the Hospital Acquired Condition payment provision – events when identified, CMS will not reimburse the hospital for costs (Centers for Medicare and Medicaid Services [CMS], 2014). In 2011, CMS launched the Partnership for Patients (PfP) campaign with the goal of reducing preventable hospital-acquired conditions (HACs) by 40 percent and 30-day readmissions to the hospital by 20 percent. This campaign's strategy has been to align healthcare stakeholders, federal, public and private healthcare payers, patients and providers in hopes to have multiple bodies all working towards the same goal (Center for Medicare and Medicaid innovation, 2014).

In 2013, CMS sent a memorandum to all state survey agency directors, sharing the obstacles limiting the effectiveness of hospitals in identifying adverse events. They acknowledged the widespread variation in reporting systems and the significant underreporting of adverse events. The CMS hospital Condition of Participation (CoP) for Quality Assessment and Performance Improvement (QAPI) (42 CFR §482.21) requires hospitals to track adverse patient safety events. Hospitals are required to identify causes of events and implement actions to prevent recurrence. Although hospitals are not required under QAPI to use AHRQs common formats, using it puts the organization in a

better position to meet CMS QAPI requirements (Department of Health and Human Services, 2013).

World Health Organization (WHO)

The World Health Organization's strategy is to provide global leadership and to identify expertise and innovation to share across the globe to improve patient safety.

WHO has evolved over the years and the World Alliance for Patient Safety was launched in 2004. Multiple campaigns have been run to enhance awareness and innovation around particular patient safety issues. In 2016, global summits were held to organize political commitment to patient safety (World Health Organization, 2017). WHO has defined key elements of meaningful measurement, including clear definitions of patient safety events, defining indicators and measurement methodologies, and development of reporting systems (World Health Organization, 2017; World Health Organization, 2008).

Centers for Disease Control and Prevention (CDC)

The Centers for Disease Control and Prevention (CDC) has identified healthcare-associated infections (HAIs) as a major and often preventable patient safety concern and has created the National Healthcare Safety Network (NHSN), which has become the nation's most widely used HAI tracking system. Some examples of HAI include *clostridium difficile* infections, catheter associated urinary tract infections (CAUTI) and central line associated blood stream infections (CLABSI). Information entered into the system is used to track progress and aggregate data used to look at the nation as a whole (Centers for Disease Control and Prevention, 2016). A yearly executive summary/progress report is released by the CDC and uses displays of information that

make it easy for the general public to understand and can serve as a template for other preventable patient safety harm reports.

Over the past decade, many (but not all) states have created laws mandating that acute care hospitals report HAIs to their departments of health. Although this could be considered forward movement, there is variation in the mandates around how the data is to be submitted, whether or not the data is provided for public review, and if facility identifiers are required (Herzig, Reagan, Pogorzelska-Maziarz, Srinath, & Stone, 2015). As seen with other patient safety measurements, once elements are defined by law, it can take heroic effort to make changes. Patient demographic information is not required when reporting HAIs, therefore missing an opportunity to further delve into the provided data.

The Leapfrog Group

The Leapfrog Group is an independent, national not-for-profit organization that focuses on measuring and publicly reporting hospital performance. Hospitals can voluntarily choose to submit data to the group, and many defined elements are directed to measuring patient safety. Elements pulled from publicly reported CMS data, the Leapfrog Survey, and some IT supplemental data are pulled together to develop consumer-friendly score, which is published as an A, B, C, D, or F letter grade. The ultimate goal is to help consumers (patients) make informed decisions when choosing where to receive care.

Not all hospital types are eligible to participate (long-term care, and skilled nursing facilities, federal hospitals, mental health facilities and more) due to lack of

needed data. Currently 2,400 hospitals across the United States participate in the survey and receive a score. There are three HACs and seven HAIs included in the patient safety grade; they are: retained foreign object, air embolism, falls and trauma, pressure ulcer rate, death among surgical inpatients with serious treatable conditions, iatrogenic pneumothorax rate, postoperative respiratory failure rate, perioperative PE/DVT rate, postoperative wound dehiscence rate, and unrecognized abdominopelvic accidental puncture/laceration rate (Leapfrog Hospital Safety grade, 2018). Leapfrog even has a measurement including policies around handling Never Events.

An element lacking in Leapfrog's safety assessment is disparities in care related to social determinants of health. If the purpose of the organization is to give each hospital a safety grade to help guide patients to the best care possible, it should also include information related to disparities in care, so vulnerable populations can seek care in hospitals with the greatest equity.

Reporting of Patient Safety Events

The Tax Relief and Health Care act of 2006 mandated the Office of Inspector General (OIG) to investigate the incidence of NQF's "never events" in Medicare beneficiaries and report findings to Congress. The findings concluded that, in the absence of both a national system and federal guidelines regarding state reporting systems only half of the states had taken the initiative to develop a reporting system. The OIG uncovered systems from state to state were tracking different events, employing different report criteria, and requiring different accompanying information. CMS expressed concern that research should better address the challenges facing the federal

government and CMS as a result of the fragmented systems and variability in states' identification of adverse events. Due to lack of standardization from state to state in what types of events are reported, state reporting of adverse events is currently unsuitable for national-level analyses (Department of Health and Human Services Office of Inspector General, 2008).

Another challenge in addressing adverse event reporting includes avoiding penalizing institutions for honestly seeking opportunities for improvement. Some states have been fearful of recriminations, increased litigation, or unfair press. These fears however, have not been realized in states with the highest level of transparency (Minnesota, New York). Some states have developed web-based systems that enable consumers to review adverse events from hospital to hospital coverage (AHRQ Patient Safety Network, 2007).

In July 2005, Congress enacted the Patient Safety and Quality Improvement Act (P.L. 109-41; 42 U.S.C. ch. 6A subch. VII part C), which encouraged reporting of patient safety events, and created a certification process for patient safety organizations to collect and analyze data from hospitals (Editorial Board, 2013). The Patient Safety Act was developed to meet the needs of improving patient safety by reducing medical errors, and to promote accountability of healthcare providers through transparency. The Patient Safety Organizations (PSOs) offer broad privilege and confidentiality protections for Patient Safety Work Product (PSWP), which alleviates concerns of reports being used for litigation purposes (Facility Requirements to Report, Analyze, and Correct, 2003/2017). The final Patient Safety Rule (42 C.F.R. Part 3 (73 FR 70732)) was adopted in November

of 2008, and became effective January of 2009, however hospitals were given until 2017 to start using PSOs (Hanlon et al., 2014).

Patient safety organizations receive staff reported events from hospitals and are able to share aggregate data with their members. The California Hospital Patient Safety Organization (CHPSO) has hospital members from California, Arizona, Texas, Colorado, Hawaii, Nevada, New Mexico, Oregon, Rhode Island and Washington. The purpose of the organization is to review incident reports, track and trend event types, and look for clusters of related issues and events related to known vulnerabilities in health care delivery (California Hospital Patient Safety Organization [CHPSO], 2018). CHPSO is only able to mine data that is included in the incident report form, and because there are no standardized expectations of fields included in report forms, focus is placed on free text. If, however, certain patient characteristics were mandatory or connected to the file, trends in healthcare disparities may be more easily identified.

Vulnerable Populations and Patient Safety

Vulnerable Populations, Health Disparities and Health Inequity

Vulnerable populations are social groups who have an increased risk or susceptibility to adverse health outcomes, which can include persons of low social and economic status, persons subject to discrimination due to factors such as race and/or ethnicity, disability, substance use disorder, mental illness, homelessness, and those who are politically marginalized, “othered” or denied basic human rights (Flaskerud & Winslow, 1998; Fiscella & Shin, 2005). Many who are categorized as “vulnerable” experience worse health care outcomes than those who are not.

Health disparities are differences between burden of and prevalence of disease, and mortality as well as other adverse health conditions identified in specific populations. In the United States, some of these groups include African Americans, Pacific Islanders, Hispanics, Asians, American Indians, Native Alaskans, those from lower socioeconomic backgrounds, vulnerable rural and urban dwelling Americans and the underserved (Giger et al., 2007).

Many studies acknowledge that patients who are members of racial and/or ethnic minority groups receive lower quality of care compared to patients who are white even after adjusting for socioeconomic status and insurance coverage. A common question explored in the literature is, “Are racial disparities a result of minority patients seeking care from lower quality providers/hospitals or a result from discrimination, lack of cultural competence and bias on behalf of care providers and organizations?” (Hasnain-Wynia et al., 2007; Okoroh, Uribe, & Weingart, 2017). A few studies have concluded hospitals where patients are at higher risk for mortality, complications and adverse events, it is not only the minority population suffering these consequences, but all patients alike (Gaskin et al., 2008).

African Americans, Hispanics and Native Americans have a higher incidence rate of chronic disease, disabilities and disease complications (Mayberry, Nicewander, Qin, & Ballard, 2006). Studies acknowledge patients who are members of ethnic and/or racial minority groups receive lower quality of care compared to whites even after adjusting for socioeconomic status and insurance coverage (Mayberry, Nicewander, Qin, & Ballard, 2006; Mays, Cochran, & Barnes, 2007; Kington & Smith, 1997). It is clear there are

differing and worse outcomes for diabetes, cardiovascular heart disease, obesity, hypertension, arthritis and preterm births between African Americans and whites (Kington & Smith, 1997). In 2014, Hispanic males and females had the longest life expectancy, and non-Hispanic black males and females had the shortest. From 1999-2013, infant mortality was highest in infants born to non-Hispanic black mothers, and lowest in infants born to non-Hispanic Asian or Pacific Islander mothers. From 1999-2015, Hispanic adults had the highest percentage of adults without insurance coverage, and non-Hispanic whites had the lowest percentage without insurance coverage (National Center for Health Statistics, 2016). The majority of research in health care disparities among vulnerable populations has explored chronic illness and burden of disease morbidity, disability and mortality, with fewer specifically studying disparities in adverse events in the hospital setting, once care has been received.

Some authors suggest that health disparities between patients who are white and those from racial and/or ethnic minority groups can be attributed to differing cultural lifestyle patterns, inherited health risks, social inequities, residential segregation, and socioeconomic status, which impacts access to health insurance, health care and health care providers (Mays, Cochran, & Barnes, 2007; Weech-Maldonado et al., 2015). In racially segregated communities or poor neighborhoods, the acute and chronic stressors of everyday life can add to premature weathering of the body and an increased risk of developing specific disease processes. Weathering partially explains the impact of socioeconomic disadvantage on health over the life course (Nazroo, 2003).

One in five children in the United States grows up in underserved, under-resourced or poor neighborhoods, and for African Americans the number is even higher. Those growing up in these neighborhoods are at greater risk for teen pregnancy, substance abuse, poor dietary habits, poor exercise habits, smoking, and dropping out of school at an earlier age than their more affluent counterparts (Mays, Cochran, & Barnes, 2007). Further work is exploring how social inequalities relate to psychological and biological markers of stress, and how these are then translated into disease outcomes; for example, how social inequality may translate to hypertension-related disorders and diseases in the African American population (Nazroo, 2003). The unequal allocation of power and resources, resulting from structural inequities, are manifested in the social, environmental and economic conditions of under-resourced communities and likely contributes to inequitable health outcomes (Baciu, Negussie, & Geller, 2017).

Vulnerable Populations and Patient Safety Outcomes

The Centers for Medicare and Medicaid Services (CMS) uses select AHRQ patient safety indicators in pay for performance demonstration projects and some organizations use the data to build comparative reports on hospital quality. There are 27 PSIs, some overlapping with NQF Never Events and some unique to this list (Agency for Healthcare Research and Quality [AHRQ], 2007). One important question that needs more attention is, “Are there differences in patient safety events across racial and/or ethnic groups?”. Studies *have* leveraged PSI data (not staff reported incident data) to compare harm rates across race and/or ethnicity, language spoken and/or payer type.

Rates from Coffey's 2005 study found African Americans had 1.25 to over 1.5 times the rate of the following: infections due to medical care, postoperative sepsis, decubitus ulcers, postoperative respiratory failure, and postoperative pulmonary embolism or deep vein thrombosis as their white counterparts. An interesting finding from the same study suggested the lower rate of complications of anesthesia, iatrogenic pneumothorax, postoperative hip fracture in African Americans may be due to lower utilization of sophisticated surgeries (coronary bypass graft surgery) by these patients, which therefore results in fewer complications. Hispanics have 1.25 to 1.5 times the rate of postoperative sepsis and metabolic derangements as non-Hispanic whites, and Asian/Pacific Islanders have 1.25 to 1.5 the rate of postoperative sepsis, hemorrhage, respiratory failure and metabolic derangement as their white non-Hispanic counterparts (Coffey, Andrews, & Moy, 2005).

Similar studies that have also leveraged PSI data, have found that inpatients who were African American and Pacific Islander had a much higher risk of infection following infusion, injection or transfusion, postoperative physiologic and metabolic derangements and sepsis (Esper et al., 2006; Russo, Andrews, & Barrett, 2008,). Another study found the following to be true for African American patients: less frequent use of effective cardiac medications, less timely use of antibiotic stewardship, and overall poorer quality of care (Romano et al., 2003).

Studies have questioned if members of racial and/or ethnic minorities receive the same standard of care compared to patients who are white. Research shows these patients are less likely to receive high-technology and discretionary procedures, and a

general lower quality of care received across a range of conditions and processes (Coffey, Andrews, & Moy, 2005). Care received while in a health care setting and while interacting with health care professionals is also an important factor to take in to account, and often differs patient to patient based on ethnic and/or racial identity (Giger et al., 2007).

Racism

Many would attribute the poor outcomes experienced by African Americans, as well as Hispanics, Pacific Islanders and Native or Indigenous Peoples, to be a direct result of structural and/or individual racism. Studies have found individuals who report having experienced racism exhibit worse health than people who do not (Mays, Cochran, & Barnes, 2007; Gee, Walsemann, & Brondolo, 2012). Structural racism is defined as macro level systems, social forces, ideologies and institutions that interact with one another to generate and reinforce inequities among racial and ethnic groups (Gee & Ford, 2011). The deep-seated history of slavery, racism and segregation in the United States still influences health outcomes today and needs to be examined more thoroughly to better understand its detrimental effects on individual and group members of minority populations. Hall et al. (2015) conducted a systematic review of implicit bias (attitudes or associated stereotypes towards people without conscious awareness) among health care professionals and found low to moderate levels of implicit racial and/or ethnic bias in all but one study. Of the 15 studies included in this systematic review, health care professionals included physicians, dentists, nurses, physician assistants, rehabilitative health services, dieticians, and clinical psychologists among others who provide health

services to patients. All reviewed studies were cross-sectional studies, the majority convenience sampling (with some using snowball sampling), and some taking samples from across the United States, and others focusing on specific states.

All reviewed studies had measured and reported data on implicit attitudes toward racial and/or ethnic groups. Implicit bias was found to be related to patient-provider interactions, treatment decisions and adherence and patient health outcomes. Across all studies, levels of implicit bias against Black, Hispanic/Latina/Latino, and dark-skinned people were similar (Hall et al., 2015).

Understanding why health disparities and inequities persist among certain groups remains challenging. A socioeconomic model looks at the overrepresentation of some racial and ethnic groups in lower socioeconomic positions and correlation to worse outcomes; the structural-constructivist model explores how health disparities may stem from centuries of exploitation, structural racism, and differences in power; and the fundamental determinants of health model suggests racial and socioeconomic disparities still exist due to social factors involving access to resources (money, knowledge, social connections, prestige, etc.) (Griffith, Moy, Reischl, & Dayton, 2006). Moreover, the influence of implicit bias on health outcomes, which explores the effect of bias and interpersonal relationships on patient outcomes may also be implicated (Bailey et al., 2017; Hall et al., 2015; Blair, Steiner, & Havranek, 2011; Griffith, Moy, Reischl, & Dayton, 2006;).

When looking at preventable harm within the hospital and patient safety events, it would be prudent to apply the framework around the effects of implicit bias on patient

outcomes. Although care providers may not be conscious of it, cultural stereotypes influence how individuals process information and their mere existence can influence one's behavior, judgement and treatment of individuals from that stereotyped groups (e.g. men, women, Blacks, Whites) (Chapman, Kaatz, & Carnes, 2013, Devine, 1989). How individuals process information and potentially respond differently to members of different race and/or ethnicities can influence error rates, adverse events, and patient safety.

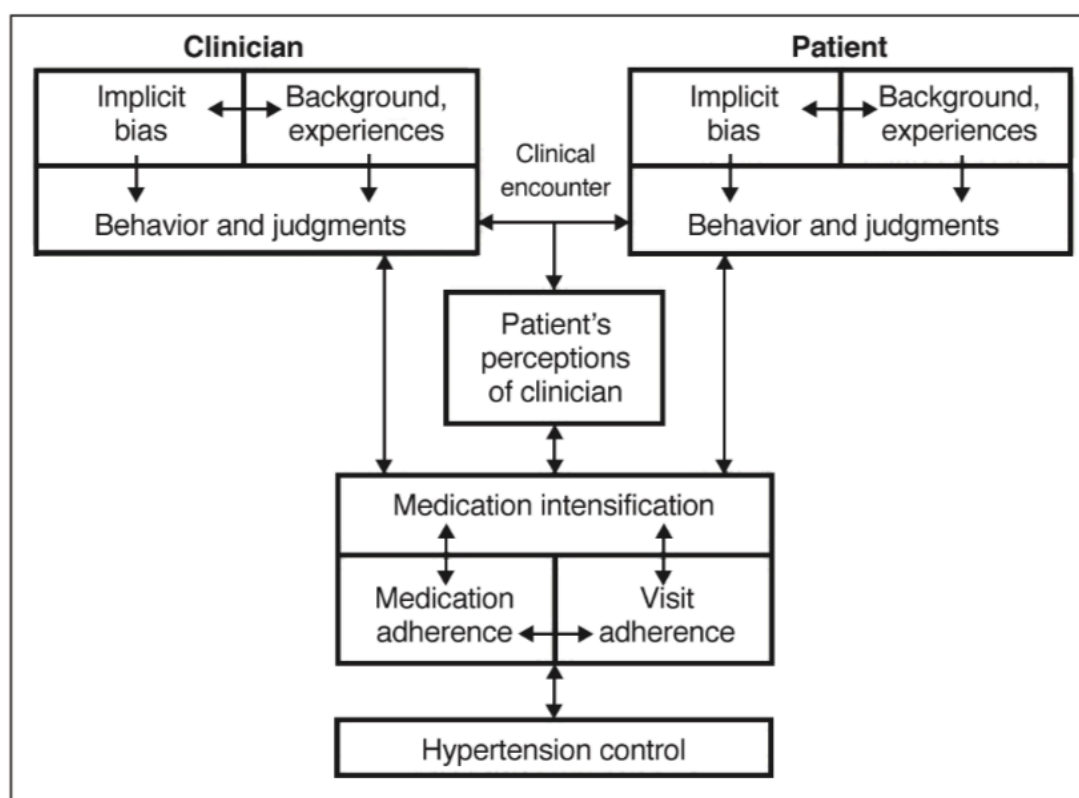
Implicit Bias

Bias is the positive or negative evaluation of one group and its members relative to another. Explicit bias indicates a person is aware of their feelings of the group and has time and motivation to act a certain way. Implicit bias, also called “unconscious bias” is defined as unintentional. Implicit bias cannot be measured with standard survey questions. Given the unrecognized nature of this bias, association tests provide a more accurate means of measurement (Blair et al., 2011).

Blair et al (2011) have developed a framework to best describe the multiple ways in which implicit bias can affect the patient-clinician relationship and related processes (Figure 2). Two potential concepts to be measured that could help explain the differences in preventable harm across racial and/or ethnic backgrounds are the provider's perception of the patient (a proxy for implicit bias) and patient's perception of the provider/patient relationship. Implicit attitudes are difficult to measure because, unlike their explicit counterpart, which are identified by deliberate actions, they are seen more in nonverbal behaviors, such as eye-contact and anxiety (measured by eye-blinking and/or heartrate)

(Dovidio et al., 2008). There are current limitations in efforts to better understanding this issue since data collected in the electronic health record may be inherently flawed (i.e., staff understanding race is not the same as ethnicity, staff reliably asking the patient each time for their race and/or ethnicity and not making assumptions, etc.).

Figure 2. Implicit bias and the patient-clinician relationship



(Blair, Steiner, & Havranek, 2011)

Past studies have attempted to measure provider perceptions and differing treatments and outcomes based on race (Shen et al., 2016; Hall et al., 2015; Clark-Hitt, Malat, Burgess, & Friedemann-Sanchez, 2010, Shi, Stevens, Lebrun, Faed, & Tsai, 2008). One such study asked primary care physicians at a national conference to view video tapes of actors playing patients presenting with chest pain. The gender and race of the actors was systematically manipulated, and the authors found that whites were significantly more likely to be referred for further testing than their African American counterparts (Schulman et al., 1999). Another study included hypothetical cardiac case studies, also with the race systematically varied, and concluded African Americans were perceived as more uncooperative than whites and were less likely to be recommended thrombolytics to help manage their disease (Green et al., 2007). A further study surveyed physicians after they interacted with black and white patients and found physicians were more likely to describe black patients as likely to use drugs, less intelligent, less likely to comply with medical recommendations and less educated (Van Ryn, Burgess, Malat, & Griffin, 2006). Cooper-Patrick et al (1999) designed a survey to measure if patients who were members of ethnic and/or racial minority groups rated their physician's decision-making style as less participatory than white patients and whether there a race discordance in the patient-physician relationship and participatory decision-making style. Moreover, health care providers and the general public hold misperceptions regarding racial and ethnic health inequities. In a recent national survey, 67% of whites indicated they believed African Americans received the same quality of care they did, indicating

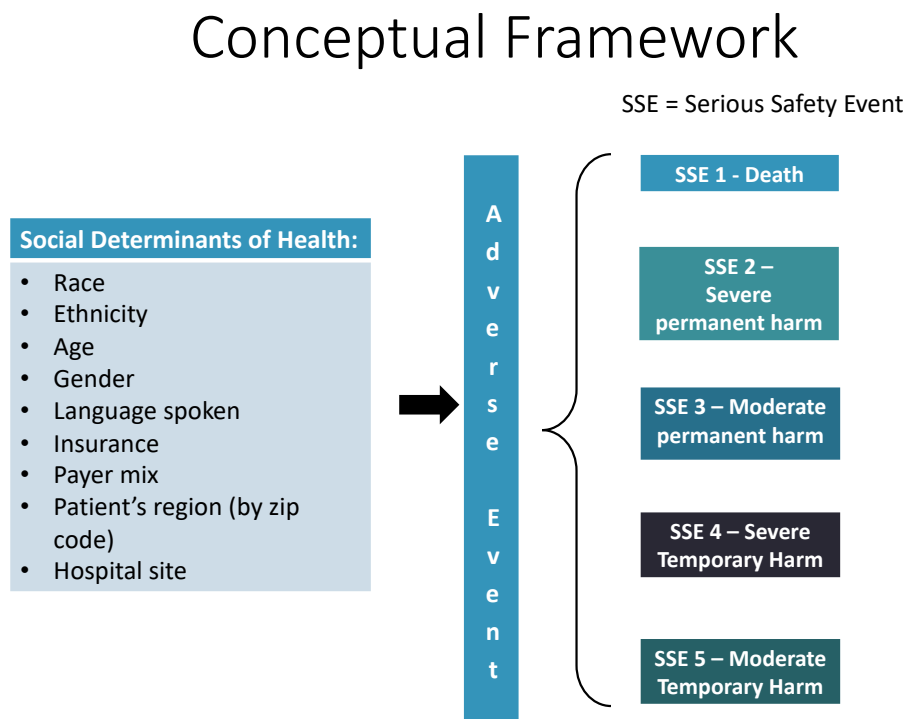
only a marginal awareness that bias may affect health outcomes (Mayberry, Nicewander, Qin, & Ballard, 2006).

Much remains unknown regarding the relationships between racial and ethnic disparities and/or inequities in health outcomes broadly, as well as health system level related outcomes such as adverse events, particularly with regard to the influence of latent variables such as implicit bias. Additional answers may be revealed by re-evaluating seminal studies in patient safety, with broader consideration of patient race and ethnicity. A multi-dimensional approach is needed to determine factors that contribute to the persistence of disparity or inequity in the delivery of health care services.

The evidence is clear: patient characteristics and demographics, as well as social, environmental and economic conditions (SDOH) influence health outcomes and even rates of patient safety indicators. Whether there are links between these variables and patient safety events identified via other methods, such as institutional event reporting systems, is not as well documented. By leveraging voluntary reporting systems, this study contributes to closing that gap in knowledge by examining whether patient characteristics and demographics, including age, gender, race, ethnicity, language spoken, insurance, where patient lives (zip code), payer mix, and hospital site where patient received care are related to staff reported serious safety events across a large multi-facility health system. Specifically, this study has explored whether the patient's age, gender, race and/or ethnicity, language spoken, zip code and payer mix are associated with whether or not the patient experiences preventable serious harm within

the hospital. A conceptual framework (Figure 3) presented herein illustrates proposed relationships between patient characteristics and serious safety events based upon the preceding review of the literature.

Figure 3. Conceptual Framework



Summary

Measuring patient safety has been and continues to be challenging. Different national and global organizations that guide patient safety are mal-aligned in measurement strategies, but studies consistently find inequities in patient safety outcomes based on patient characteristics. Current literature shows some populations may be more vulnerable to injury and poor outcomes than others due to structural barriers and implicit bias inherent within the U.S. health care system. These populations include African Americans, Pacific Islanders, Hispanics, Asians, American Indians, Native Alaskans, those from lower socioeconomic backgrounds, vulnerable rural and urban dwelling Americans and the underserved. Explanations for these findings include structural and/or individual racism and bias, which ultimately can influence treatment methods chosen by providers, medical decision making and behavior and judgement of medical providers, nursing, and staff members.

CHAPTER III

METHODS

The purpose of this retrospective, cross-sectional cohort study was to describe the relationship between select patient sociodemographic characteristics, health insurance coverage, hospital location, and patient region among patients who experienced a serious safety event (SSE), defined as moderate temporary harm up to death as a result of a deviation in generally accepted performance standards, in a healthcare system with four acute care and three specialty hospitals in Southern California, over a 8-year period.

The study specific aims are:

Aim 1: To describe select patient demographic variables (age, gender, race, ethnicity and language spoken), health insurance coverage (yes/no), patient zip code, and payer mix (private, Medicaid, Medicare, Dual, Tricare, etc.), and site of care location among patients who have experienced a serious safety event.

Aim 2: To examine the relationships between the select patient demographic variables (age, gender, race, ethnicity, language spoken) health insurance coverage (yes/no), patient zip code, payer mix (private, Medicaid, Medicare, Dual, Tricare, etc.), site of care location and SSE level of harm (moderate temporary harm, severe temporary harm, moderate permanent harm, severe permanent harm, or death) experienced by the patient.

Aim 3: To identify what variables of age, gender, race, ethnicity, language spoken, health insurance coverage (yes/no), patient zip code, payer type (private, Medicaid, Medicare, Dual, Tricare, etc.), and site of care location increase or

decrease the odds of experiencing moderate temporary harm, severe temporary harm, moderate permanent harm, severe permanent harm, or death from a SSE.

Research Design

This descriptive retrospective cross-sectional cohort design included data for 758 patients who experienced an SSE and received care at one of the seven participating hospitals in southern California.

Research Sample and Setting

The data utilized in this study was derived from the records of a comprehensive health care system in Southern California comprised of four acute care hospitals, two of which have Magnet designation, and three specialty hospitals. The specialty hospitals included a women's and newborn hospital, a psychiatric hospital and a substance abuse treatment hospital. This hospital system supports 950,000 admissions per year with an estimated 100 SSEs identified per year.

Estimated sociodemographic information, from 2019, for each location's service area is as follows: Site 1's service area has 40% of people between the ages of 18-44 and 13.93% of the population at greater than 65 years. Females make up 49.8% of the population's service area. Whites make up 41.1% of the service area, followed by 33.2% Hispanic, 15.1% Asian/Pacific Islander, 6.5% black. Site 2's service area has 35.9% of residents aged 18-44, with a 50% mix of male and female. Whites make up 43% of the service area, followed by 35.6% Hispanic, 8.3% Asian/Pacific Islander, and 8.9% black. Site 3's service area has 36% of residents aged between 18-44, and 13.5% older than 65 years. Hispanics make up 59% of the population, followed by 16% white, 13.8%

Asian/Pacific Islander, and 7.7% black. Site 4's service area has 36.7% of residents between 18-44 and 14.2% older than 65. With 50% split between male and females. Hispanic population makes up 39.7%, followed by 37.8% white, 12.3% Asian/Pacific Islander and 6.2% black.

This study utilized the 758 cases of SSEs that have been reported over an 8-year period as discussed above. A case represents each patient who received care and experienced a preventable medical error which resulted in serious harm. Distinctions between harm levels will be based off definitions provided by Health Performance Improvement (HPI). This study's research aims require multiple regression analysis to explore the effects of predictor variables on level of harm. According to Tabachnick and Fidell (2007), a minimum of 20 cases is recommended for each predictor in the model; however, when total sample size is large, adequate predictive performance can be attained with 10 events per variable (de Jong et al., 2017). With eight predictors and one outcome, the sample size for this study should be 180 to obtain statistical significance. The available 758 SSEs will be adequate to detect a moderate standardized effect size of .30 using a two-tailed significance level of .05 and a power of .80 (Cohen, 1988; Polit & Beck, 2017). A recent meta-analysis investigating prevalence, severity and nature of preventable harm found small to moderate effect size (magnitude of relationship) in most studies (Panagioti et al., 2019).

Inclusion and Exclusion Criteria. All health system patients who received care and who experienced an SSE during the study time frame were included. Patients who received care at one of the seven hospitals but did not experience a SSE were excluded,

as well as those who may have experienced an SSE but the event did not meet all defined criteria of deviation, causation and harm.

Data Sources

Electronic Medical Record. Per institutional protocol, sociodemographic characteristics are collected by admissions staff at each hospital location and include age, address, gender, race, ethnicity and language spoken. Health insurance coverage and hospital location where patients received care are also available from the EMR.

Serious Safety Event (SSE) Database. At this institution SSEs are initially entered into the organization's voluntary reporting system. Events can be reported by any staff member within the organization, regardless of their role. Upon reporting, the staff member completing the report is asked to include impact to the patient (i.e., not a safety event, no harm to minimal harm, or moderate to severe harm or death). Quality staff at each site, the majority being registered nurses, review and flag events that may need to be considered as SSEs. Event review occurs within 48 hours of the event being reported. Possible SSEs are escalated to leadership, and the process for a comprehensive systematic analysis started.

Each site has at least one quality staff member who is a Certified Professional in-Patient Safety who helps the team determine what events need to be reviewed as a potential SSE. Events recognized as possible SSEs and events difficult to classify are discussed at a system meeting, with representation from the system Vice President of Quality and Patient Safety, system Director of Patient Safety, system Patient Safety Specialist, site Directors of Quality and Patient Safety and all safety specialists from across the system. The system meeting takes place monthly, and consensus is reached on

harm classification for every event submitted. The process of event review with system representation serves to aid in interrater reliability – to ensure all sites are classifying events similarly and maintaining a shared mental model as well as serving to ensure consistency in classification over time. Harm classification can be overturned when there is consensus and/or when case precedent exists. After the comprehensive systematic analysis is complete (within 45 days of the event), the event and action plan is entered into the Serious Safety Event database.

Data Collection and Management

The organization's SSE databased was used to access all events classified as SSEs, their specific level of harm (SSE1 -SSE5), the hospital site, and the patient's financial identification number (FIN). The FIN was then used to link SSE to patient data in the EMR. Patient sociodemographic data which included age, address, gender, race, ethnicity and language spoken, as well as health insurance coverage and hospital location where patients received care were obtained from the EMR. All data was initially extracted by the organization's data analyst, transferred into an MS Excel file database by the primary investigator (PI) and then ultimately transferred into SPSS statistics software, inspected and cleaned per general statistical principles (Tabachnick & Fidell, 2007). All participants' data were reviewed for missing or incomplete data. If missing or incomplete data was found, the PI reviewed participants' EMR to determine if missing data could be obtained. Any safety event with a repeating FIN (indicating the patient experienced more than one serious safety event) was excluded to ensure all data were independent. The first FIN was kept and any subsequent repeat FINs were removed. Patient electronic data was de-identified using a unique subject identifier linked to the data, with only the PI having

access to the link. Electronic data was stored in a password-protected HIPPA compliant computer.

Protection of Human Subjects

To ensure compliance with protection of human subjects and protected health information the study proposal was submitted to the Institutional Review Boards of both the research site and the University of San Diego. The IRB of the research site served as the primary IRB and after observing a presentation on the proposed research study and asking questions of the PI, determined the study did not fall under human subjects research and was deemed exempt from review.

The USD IRB determined the study did not fall under the definition of human subjects research and was deemed exempt from review.

Study Variables

Independent variables include patient sociodemographic characteristic (i.e., age, gender, race, ethnicity, and language spoken), health insurance coverage, hospital location, and patient zip code (see Table 3). Of notice, age was originally recorded as a string variable (in the EMR) in days for children up to age 15 and in years thereafter. Age was then categorized in years as follows: 0-4, 5-14, 15-24, 25-34, 35-44, 45-54, 55-64, 65-74, 75-84, and 85 or older. These age cohorts have been recently used in nation patient safety report systems and research (Liberatore & Rose, 2019). Patient zip code was categorized in regions as follows: San Diego Central, San Diego East, San Diego North Central, San Diego North Coastal, San Diego North Inland, San Diego South, and Outside San Diego County and Other States. Regions were based on regions assigned by the Superior Court of California, County of San Diego. There were seven participating

hospitals, with four sharing one campus and being considered as one site; in total there were four site variables.

The dependent variable is the occurrence of a preventable medical error categorized as moderate to severe harm or death (a serious safety event). Harm levels are defined as follows:

SSE 1 - Death: A deviation in Generally Accepted Performance Standards (GAPS) resulting in death.

SSE 2 – Severe Permanent Harm: A deviation in GAPS resulting in critical, life-changing harm.

SSE 3 – Moderate Permanent Harm: A deviation in GAPS resulting in significant harm with no expected change in clinical condition, yet not sufficiently severe to impact activities of daily living.

SSE 4 – Severe Temporary Harm: A deviation in GAPS resulting in critical, potentially life-threatening harm yet lasting for a limited time with no permanent residual.

SSE 5 – Moderate Temporary Harm: A deviation in GAPS resulting in significant harm lasting for a limited time; requires transfer to higher level of care/monitoring or an additional minor procedure or treatment to resolve the condition.

Data Analysis

In order to meet study aims, different statistical analyses were leveraged. Both descriptive, bivariate and inferential statistics were used; using non-parametric tests when appropriate. Descriptive statistics were calculated for all analysis variables and data were examined for normality, missing values, and outliers. Missing data were analyzed to

determine if data were missing at random versus specific data missing on all patients. This helped guide decision-making around managing missing fields using list wise or pair wise deletion. After missing data was evaluated, 758 patients were included in the analysis.

Aim 1 describes patient sociodemographic characteristics, health insurance coverage, hospital location, and patient region among patients who have experienced a SSE. In order to address this aim, descriptive statistics were conducted, including frequencies and bar charts with categorical (nominal, ordinal) variables. None of the study variables were measured on a continuous (ratio) scale.

Aim 2 examines relationships among patient sociodemographic characteristics, health insurance coverage, hospital location, and patient region, in terms of the SSE level of harm (moderate temporary harm, severe temporary harm, moderate permanent harm, severe permanent harm, or death) experienced by the patient. In order to address this aim, bivariate analyses were conducted using Chi-square Tests of Association (or Fisher's Exact Tests with small response groups). For statistically significant associations, the strength of the association was reported as the phi coefficient (2 by 2 tables) or Cramer's V (for larger tables). Furthermore, Kruskal-Wallis Tests were used to evaluate group differences in patients' age, gender, race, ethnicity, language spoken, insurance coverage, hospital location, and patient region in terms of the level of harm experienced. Test assumptions were assessed. Post-hoc analysis were conducted with statistically significant different groups using pairwise comparisons using Dunn's (1964) procedure with a Bonferroni correction for multiple comparisons.

Aim 3 identifies what factors increase or decrease the odds of experiencing

moderate temporary harm, severe temporary harm, moderate permanent harm, severe permanent harm, or death from a SSE. To address this third aim, the researcher conducted multinomial logistic regression. Variables significant at $p < .5$ in the bivariate analysis were considered for entry into the multivariate logistic regression model. Test assumptions were assessed. Of notice, the researcher examined multicollinearity and outliers and none of the predictors were measured on a continuous scale.

All statistical analysis was conducted using IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp., Armonk, N.Y., USA, 2016).

Limitations

Using incident reporting to identify serious safety events has potential drawbacks, including the possibility that serious safety events are occurring, but not being reported, or are being reported but not accurately identified as *serious*. The use of HPI's safety event classification algorithm can be challenging, and the organization continues to safeguard against under classification of events by using inter-rater reliability forums, however, developing a shared mental model around event classification has been challenging. Although the organization has been using the algorithm for six years, robust discussions and disagreements about classification still arise. Capturing accurate information on the patient's race and/or ethnicity can also be challenging due to variation in information collection and standardization of expectations of those gathering information.

Table 3.
Definitions of Study Variables

Variable	Definition	Date Source
Age	<i>Categories:</i> 0-4, 5-14, 15-24, 25-34, 35-44, 45-54, 55-64, 65-74, 75-84, and 85 or older. Age cohorts used in nation patient safety report systems and research (Field, Finley, & Deutsch, 2019; Liberatore & Rose, 2019).	Patient report at admissions, EHR
Gender	<i>Categories:</i> Male and female.	Patient report at admissions, EHR
Race	<i>Categories:</i> White, Black/African American, Asian, American Indian/Alaska Native, Native Hawaiian/Pacific Islander, and Other Race.	Patient report at admissions, EHR
Ethnicity	<i>Categories:</i> Non-Hispanic/Non-Latino, and Hispanic/Latino.	Patient report at admissions, EHR
Language spoken	<i>Categories:</i> English, Spanish, English & Spanish, English & Other, and Other. <i>Categories:</i> English yes, and English no.	Patient report at admissions, EHR
Health insurance coverage	<i>Categories:</i> Medicare (fee for service), Medicare supplemental (gap insurance), Medicaid or MediCal, Medicare plus MediCal (dual eligible), Private (PPO, HMO, commercial, military, government, workers comp.), State (not federally subsidized MediCal, State specific plan), and No insurance, self-pay.	EHR
Hospital location	<i>Categories:</i> Site 1, Site 2, Site 3, Site 4, Site 5, Site 6, Site 7	EHR
Patient zip code	<i>Categories:</i> San Diego Central, East, North Central, North Coastal, North Inland, South, and Outside San Diego County & Other States. Regions established by the Superior Court of California, County of San Diego.	Patient report at admissions, EHR
Serious safety event level of harm	Patient experienced a serious safety event, level of harm. <i>Categories:</i> SSE1: Death, SSE2: Severe permanent harm, SSE3: Moderate permanent harm, SSE4: Severe temporary harm, and SSE5: Moderate temporary harm.	Voluntary reporting system, uses Safety Event Classification algorithm to determine level of harm.

CHAPTER IV

RESULTS

The purpose of this retrospective, cross-sectional cohort study was to describe the relationship between select patient demographic variables (age, gender, race, ethnicity, and language spoken), payer mix, patient zip code, and site of care among patients who have experienced a SSE, defined as moderate temporary harm up to death as a result of a deviation in generally accepted performance standards, in a healthcare system with four acute care and three specialty hospitals in southern California, over an eight year period. This chapter will present the results of the study.

Study Aim 1

Describes select patient demographic variables (age, gender, race, ethnicity and language spoken), health insurance coverage (yes/no), patient zip code, and payer mix (private, Medicaid, Medicare, Dual, Tricare, etc.), and site of care location among patients who have experienced a serious safety event. In order to address this aim, descriptive statistics were conducted, including frequencies and bar charts with categorical (nominal, ordinal) variables. None of the study variables were measured on a continuous (ratio) scale.

The study sample size consisted of 758 cases representing unique patients who experienced a SSE. All study variables examined in this study were categorical, therefore data was not reviewed for normality or outliers. Ethnicity and zip code were the only two variables with greater than six missing values at 12 and 27 respectively. The cases containing these missing variables represent a small portion of the study sample and should not impact the results of the study.

Age was coded into ten age ranges, as described in Chapter 3, with the highest frequency occurring with 55-64 year-old range ($n = 141, 18.7\%$) and lowest frequency occurring with 15-24 year-old range ($n = 31, 4.1\%$). Males accounted for 42.1% ($n = 319$) of events and females 57.9% ($n = 439$). Race was split into 5 categories with the highest frequency observed in white patients ($n = 368, 48.9\%$), and lowest frequency observed in the American Indian or Alaskan Native patient population ($n = 4, .5\%$). Non-Hispanic, non-Latino patients accounted for 69.7% ($n = 520$) of events and Hispanic, Latino patients 30.3% ($n = 226$) of events. Language was coded into 5 categories with English speaking patients accounting for 82.2% ($n = 622$), Spanish accounting for 10.2% ($n = 77$) and 3% ($n = 23$) categorized as “other”. Other included Amharic, Arabic, Cambodian, Chinese, Farsi, Italian, Japanese, Laotian, Persian, sign language, Tagalog, and Vietnamese.

Insurance was grouped into seven categories: Medicare (fee for service), Medicare supplemental (gap insurance), Medicaid (which is called MediCal in California), Medicare plus Medicaid (covering patients that are dually eligible), private (commercial insurance including PPO, HMO, workers comp., as well as government and military coverage), state (not federally subsidized MediCal but a state specific plan), and no insurance or “self-pay.” The highest frequency was observed in patients with Medicare (fee for service) 35.4% ($n = 267$) followed by private insurance ($n = 218, 28.9\%$).

Location descriptors include: 50.3% ($n = 381$) of patients received services at Site 1 (location includes one acute care and three specialty hospitals), 29.6% ($n = 224$) at Site 2, 16.6% ($n = 126$) at Site 3, and 3.6% ($n = 27$) at Site 4. The patient’s zip code was split

into seven categories and represent different areas of San Diego: Central, East, North Central, North Coastal, North Island, South, and outside SD county and other states. The highest frequency observed was those living in East San Diego ($n = 221$, 30.2%) and lowest frequency observed was patients living in North Coastal San Diego ($n = 11$, 1.5%).

Finally, the variable, SSE, was categorized into levels of harm, as defined in Chapter 3. The greatest frequency was observed in SSE4 (severe temporary harm) making up 36.7% ($n = 278$) of all events and lowest frequency was observed in SSE3 (moderate permanent harm) making up 5.9% ($n = 45$) (Table 4).

Table 4.

Sociodemographic Characteristics of Study Population (N = 758)

Characteristic	<i>n</i>	%
Age		
0-14 years	46	6.1
15-24 years	31	4.1
25-34 years	85	11.2
35-44 years	65	8.6
45-54 years	89	11.8
55-64 years	141	18.7
65-74 years	130	17.2
75-84 years	109	14.4
85+ years	60	7.9
Gender		
Female	439	57.9
Male	319	42.1

Race		
White	368	48.9
Black, African American	46	6.1
Asian	45	6.0
American Indian, Alaska Native	4	0.5
Native Hawaiian, Pacific Islander	3	0.4
Other Race	286	38.0
Ethnicity		
Non-Hispanic	520	69.7
Hispanic	226	30.3
Language		
English	622	82.2
Spanish	77	10.2
English and Spanish	22	2.9
English and other	13	1.7
Other	23	3.0
Characteristic	<i>n</i>	%
English Language		
Yes	657	86.8
No	100	13.2
Insurance		
Medicare (fee for service)	267	35.4
Medicare (supplemental, gap)	23	3.1
Medicaid or MediCal	162	21.5
Medicare plus Medical	47	6.2
Private (commercial, PPO, HMO, military, gov., workers comp.)	218	28.9
State (non-federally subsidized MediCal, State-specific plan)	12	1.6
No insurance, self-pay	25	3.3
Hospital Location		
Site 1	381	50.3
Site 2	224	29.6

Site 3	126	16.6
Site 4	27	3.6
Zip Code		
San Diego Central	109	14.9
San Diego East	221	30.2
San Diego North Central	136	18.6
San Diego North Coastal	11	1.5
San Diego North Inland	44	6.0
San Diego South	170	23.3
Out of San Diego County & Out-of-State	40	5.5
Level of Harm		
Death (SSE1)	122	16.1
Severe permanent harm (SSE2)	52	6.9
Moderate permanent harm (SSE3)	45	5.9
Severe temporary harm (SSE4)	278	36.7
Moderate temporary harm (SSE5)	261	34.4

Study Aim 2

Specific aim 2 examined the relationships between the select patient demographic variables (age, gender, race, ethnicity, language spoken) health insurance coverage (yes/no), patient zip code, payer mix (private, Medicaid, Medicare, Dual, Tricare, etc.), site of care location and SSE level of harm (moderate temporary harm, severe temporary harm, moderate permanent harm, severe permanent harm, or death) experienced by the patient. In order to address this aim, the researcher conducted Chi-square test for independence using a contingency table to explore the relationships between the

categorical variables. Pearson's significance was used when minimum cell count assumption was met, Fisher's exact test when not met.

A Chi-square test of independence was conducted between patient sociodemographic characteristics and Level of Harm (Table 5). A chi-square test of independence was conducted between hospital location where the patient received services and Level of Harm. Fifteen percent (15%) of all expected cell frequencies were less than five; Fisher's Exact Tests were reported for variables with expected cell frequencies less than five. There was a statistically significant association between hospital location and Level of Harm, $\chi^2(12) = 26.02$; $p = .007$. The association was small (Cohen, 1988), Cramer's $V = .108$. Site 3 and SSE2 (severe permanent harm) differed most from the chi square null hypothesis, followed by site 4 and SSE5 (moderate temporary harm) in that they demonstrated the greatest adjusted standardized residuals.

A Kruskal-Wallis H test was conducted to determine if there were significant differences in Level of Harm scores between different hospital locations: Site 1 ($n = 381$), Site 2 ($n = 224$), Site 3 ($n = 126$), and Site 4 ($n = 27$). Values are mean ranks unless otherwise stated. Distributions of Level of Harm scores were not similar for all groups, as assessed by visual inspection of a boxplot (Figure 4). The mean ranks of Level of Harm were significantly different between groups, $\chi^2(3) = 15.482$, $p = .001$, $\epsilon^2 = .020$ (weak effect). Pairwise comparisons were performed using Dunn's (1964) procedure with a Bonferroni correction for multiple comparisons. Adjusted p -values are presented. The post hoc analysis revealed statistically significant differences in Level of Harm between Site 3 (Mean rank = 334.56) and Site 4 (Mean rank = 496.26), $p = .002$ and Site 2 (Mean rank = 373.20) and Site 4 (Mean rank = 496.26); no other group combination was

significantly different (Table 6).

In addition to hospital site where patient received care, there was a statistically significant association between Ethnicity and Level of Harm, $\chi^2=10.17$; $p = .038$; Cramer's $V = .117$, small effect and a statistically significant association between insurance (yes/no) and Level of Harm, $\chi^2=9.12$; $p = .040$; Cramer's $V = .108$, small effect. Neither race, $\chi^2=11.27$; $p = .941$, nor language, $\chi^2=15.38$; $p = .413$, were found to be significantly associated with those patients who experienced a serious safety even.

Table 5.

Sociodemographic Characteristics of Study Population by Serious Safety Event (N = 758)

Characteristic	Total		SSE1		SSE2		SSE3		SSE4		SSE5		χ^2	<i>p</i>
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%		
Age													30.90	.522
0-14 years	46	6.1	5	10.9	4	8.7	0	0.0	20	43.5	17	37.0		
15-24 years	31	4.1	4	12.9	1	3.2	0	0.0	12	38.7	14	45.2		
25-34 years	85	11.2	10	11.8	9	10.6	4	4.7	31	36.5	31	36.5		
35-44 years	65	8.6	12	18.5	4	6.2	2	3.1	28	43.1	19	29.2		
45-54 years	89	11.8	12	13.5	6	6.7	8	9.0	32	36.0	31	34.8		
55-64 years	141	18.7	23	16.3	5	3.5	11	7.8	49	34.8	53	37.6		
65-74 years	130	17.2	24	18.5	7	5.4	5	3.8	54	41.5	40	30.8		
75-84 years	109	14.4	18	16.5	9	8.3	9	8.3	34	31.2	39	35.8		
85+ years	60	7.9	14	23.3	7	11.7	5	8.3	17	28.3	17	28.3		
Gender													4.88	.301
Female	439	57.9	64	14.6	31	7.1	32	7.3	159	36.2	153	34.9		
Male	319	42.1	58	18.2	21	6.6	13	4.1	119	37.3	108	33.9		
Race													11.27	.941 ^a
White	368	48.9	61	16.6	22	6.0	23	6.3	134	36.4	128	34.8		
Black, African American	46	6.1	12	26.1	2	4.3	2	4.3	15	32.6	15	32.6		
Asian	45	6.0	6	13.3	4	8.9	2	4.4	13	28.9	20	44.4		
American Indian, Alaska Native	4	0.5	1	25.0	0	0.0	0	0.0	2	50.0	1	25.0		
Native Hawaiian, Pacific Islander	3	0.4	1	33.3	0	0.0	0	0.0	1	33.3	1	33.3		
Other Race	286	38.0	41	14.3	23	8.0	16	5.6	111	38.8	95	33.2		
Ethnicity													10.17	.038
Non-Hispanic	520	69.7	87	16.7	28	5.4	35	6.7	186	35.8	184	35.4		
Hispanic	226	30.3	32	14.2	24	10.6	8	3.5	87	38.5	75	33.2		

Characteristic	Total		SSE1		SSE2		SSE3		SSE4		SSE5		χ^2	<i>p</i>
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%		
Language													15.38	.413 ^a
English	622	82.2	102	16.4	37	5.9	37	5.9	235	37.8	211	33.9		
Spanish	77	10.2	12	15.6	9	11.7	3	3.9	26	33.8	27	35.1		
English and Spanish	22	2.9	3	13.6	4	18.2	3	13.6	5	22.7	7	31.8		
English and Other	13	1.7	3	23.1	1	7.7	1	7.7	4	30.8	4	30.8		
Other Language	23	3.0	2	8.7	1	4.3	1	4.3	7	30.4	12	52.2		
English Language													3.79	.436
Yes	657	86.8	108	16.4	42	6.4	41	6.2	244	37.1	222	33.8		
No	100	13.2	14	14.0	10	10.0	4	4.0	33	33.0	39	39.0		
Insurance													30.98	.109 ^a
Medicare (fee for service)	267	35.4	44	16.5	18	6.7	23	8.6	100	37.5	82	30.7		
Medicare (supplemental, gap)	23	3.1	5	21.7	1	4.3	1	4.3	7	30.4	9	39.1		
Medicaid or MediCal	162	21.5	23	14.2	6	3.7	5	3.1	64	39.5	64	39.5		
Medicare plus Medical	47	6.2	9	19.1	4	8.5	1	2.1	13	27.7	20	42.6		
Private (commercial, PPO, HMO, military, government, workers comp., etc.)	218	28.9	29	13.3	21	9.6	12	5.5	83	38.1	73	33.5		
State (non-federally subsidized MediCal, State-specific plan)	12	1.6	3	25.0	0	0.0	0	0.0	7	58.3	2	16.7		
No insurance, self-pay	25	3.3	8	32.0	2	8.0	3	12.0	4	16.0	8	32.0		
Insurance													9.12	.040 ^a
Yes	733	96.7	114	15.6	50	6.8	42	5.7	274	37.4	253	34.5		
No	25	3.3	8	32.0	2	8.0	3	12.0	4	16.0	8	32.0		
Hospital Location													44.59	.004 ^a
Site 1	91	12.0	8	8.8	10	11.0	4	4.4	32	35.2	37	40.7		
Site 2	224	29.6	40	17.9	14	6.3	13	5.8	82	36.6	75	33.5		

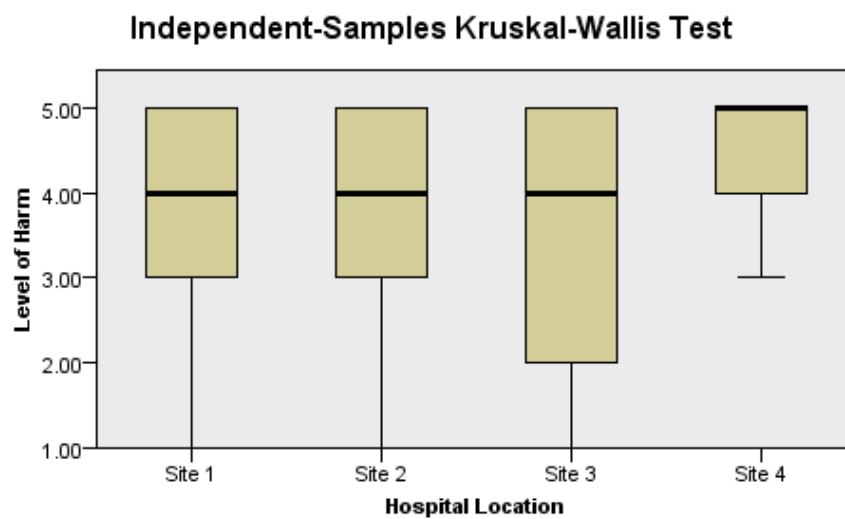
Site 3	264	34.8	42	15.9	11	4.2	21	8.0	100	37.9	90	34.1		
	Total		SSE1		SSE2		SSE3		SSE4		SSE5			
Characteristic	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	χ^2	<i>p</i>
Hospital Location (cont.)														
Site 4	126	16.6	25	19.8	17	13.5	4	3.2	48	38.1	32	25.4		
Site 5	27	3.6	0	0.0	0	0.0	2	7.4	10	37.0	15	9.3		
Site 6	25	3.3	7	28.0	0	0.0	1	4.0	6	24.0	11	44.0		
Site 7	1	0.1	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0		
Zip Code													22.17	.521 ^a
San Diego Central	109	14.9	13	11.9	8	7.3	7	6.4	43	39.4	38	34.9		
San Diego East	221	30.2	40	18.1	11	5.0	12	5.4	81	36.7	77	34.8		
San Diego North Central	136	18.6	20	14.7	7	5.1	12	8.8	44	32.4	53	39.0		
San Diego North Coastal	11	1.5	0	0.0	1	9.1	1	9.1	4	36.4	5	45.5		
San Diego North Inland	44	6.0	13	29.5	2	4.5	2	4.5	12	27.3	15	34.1		
San Diego South	170	23.3	29	17.1	18	10.6	9	5.3	64	37.6	50	29.4		
Out of San Diego														
County & Out-of-State	40	5.5	5	12.5	4	10.0	1	2.5	17	42.5	13	32.5		

Note. SSE1 = Serious Safety Event 1 (death); SSE2 = Serious Safety Event 2 (severe permanent harm); SSE3 = Serious Safety Event 3 (moderate permanent harm); SSE4 = Serious Safety Event 4 (severe temporary harm); SSE5 = Serious Safety Event 5 (moderate temporary harm).

χ^2 = Pearson's Chi-square unless otherwise specified.

^aFisher's Exact Test, Monte Carlo Sig. (2-sided).

Figure 4. Kruskal-Wallis Distributions of Level of Harm Scores (N = 758)



Total N	758
Test Statistic	15.482
Degrees of Freedom	3
Asymptotic Sig. (2-sided test)	.001

1. The test statistic is adjusted for ties.

Table 6.

Kruskal-Wallis H Test Results of Serious Safety Events in Terms of Hospital Location (N = 758)

Hospital Location	<i>n</i>	<i>Mean Rank</i>	<i>H (df)</i>	<i>p</i>
Site 1	91	411.79	18.22 (6)	.006
Site 2	224	373.20		
Site 3	264	381.53		
Site 4	126	334.56		
Site 5	27	496.26		
Site 6	25	387.46		
Site 7	1	628.00		
Dunn's Multiple Comparisons Test with Bonferroni Correction				.005

Note. SSE1 = Serious Safety Event 1 (death); SSE2 = Serious Safety Event 2 (severe permanent harm); SSE3 = Serious Safety Event 3 (moderate permanent harm); SSE4 = Serious Safety Event 4 (severe temporary harm); SSE5 = Serious Safety Event 5 (moderate temporary harm).

Study Aim 3

Specific aim 3 identified what factors increase or decrease the odds of experiencing moderate temporary harm, severe temporary harm, moderate permanent harm, severe permanent harm, or death from a SSE. Site 4 had zero occurrences of both SSE 1 and 2, so in order to meet all test assumptions, SSE 1, 2 and 3 were merged. A multinomial logistic regression was performed to ascertain the effects of ethnicity, insurance, and hospital location on the likelihood that patients die or received permanent harm from a serious safety event in select Southern California Hospitals. No significant outliers or multicollinearity issues were found; no continuous predictors were entered

into the model. The multinomial logistic regression model was statistically significant, $\chi^2(10) = 24.350, p = .007$ (Table 7).

Although the predictive power is somewhat low (able to predict 3.2-3.6% of variability between hospitals) the model was statistically significant. The most influential risk predictor was where the patient received care. When compared to the lowest level of harm (moderate temporary harm), patients were more likely to die or receive permanent harm (severe or moderate) if they received care at Site 1, $\text{EXP(B)} = 5.534, p = .025$, Site 2, $\text{EXP(B)} = 6.881, p = .013$, or Site 3, $\text{EXP(B)} = 11.454, p = .002$; with Site 3 being the biggest contributor.

When compared to the lowest level of harm (SSE 5), patients were 1.22 times more likely to experience death, or severe harm (permanent or temporary) if they were non-Hispanic/non-Latino and 1.88 times more likely to experience higher levels of harm if they did not have insurance (self-pay). When compared to Site 4, patients receiving care at Site 1 were 5.53 times more likely to experience higher levels of harm from a serious safety event, patients who received care at Site 2 were 6.81 times more likely to receive higher levels of harm and 11.45 times more likely to experience higher levels of harm if they received care at Site 3.

Table 7.

Logistic Regression Predicting Death and Permanent Harm (Severe and Moderate) from a Serious Safety Event in Select Southern California Hospitals (N = 758)

Predictor	<i>B</i>	<i>SE</i>	<i>OR</i>	95% CI	Wald	<i>p</i>
Ethnicity						
Non-Hispanic, non-Latino	0.20	0.22	1.22	[0.79, 1.87]	0.81	.368
Insurance						
Not having insurance, self-pay	0.63	0.46	1.88	[0.76, 4.66]	1.85	.174
Hospital Location						
Site 1	1.71	0.77	5.53	[1.23, 24.83]	4.99	.025
Site 2	1.92	0.77	6.81	[1.50, 30.97]	6.17	.013
Site 3	2.44	0.80	11.45	[2.39, 54.88]	9.30	.002

$$\chi^2(10) = 24.35, p = .007$$

$$-2 \text{ Log likelihood} = 120.11, \text{ Nagelkerke } R^2 = 3.6\%$$

Note. CI = Confidence interval for odds ratio (OR). Ethnicity coded as 1=Non-Hispanic or non-Latino, Reference category=Hispanic or Latino; Insurance coded as 0=No, Reference category=Yes;

Summary

In terms of level of harm, there was a relationship between not having insurance and level of harm, ethnicity and level of harm, but ultimately, where care was received had the most influence over harm levels. Not found to be significant in this study, were the relationships between race and level of harm and language and level of harm.

CHAPTER V

DISCUSSION OF FINDINGS

Serious safety events (SSE) are the third leading cause of death in the U.S., responsible for 1 in 6 of all deaths each year (James, 2013). Annually, more than 440,000 patients die unnecessarily as a result of serious safety events in American hospitals. Preventable harm and death in healthcare is a concern for all, but some populations may be more vulnerable to injury and poor outcomes than others due to structural barriers and implicit bias inherent within the U.S. health care system. Following its landmark report, *To Err is Human*, which shed light on the issue of patient safety, the Institute of Medicine published *Crossing the Quality Chasm: A New Health Care System for the 21st Century*. The report identified six aims for health care improvement, one being that health care should be “[e]quitable – providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status” (Committee on Quality of Health Care in America and Institute of Medicine, 2001, p. xxx). To improve quality and prevent patient injury, hospitals must address health inequity.

SSEs identified via the organization’s voluntary reporting system should be treated as a valuable learning opportunity. Current patient safety research generally relies on retrospective chart review (which is time and resource intensive) and/or PSIs (which are very specific and not all-inclusive) (Shen et al., 2016; Classen et al., 2001; Wet & Bowie, 2009; Shimada et al., 2008; Lewis & Fletcher, 2005). Although there are limitations with relying on staff reported events of harm, SSEs can be seen as a valuable additive to administrative data in gaining a more holistic perspective of patient harm

levels and trends. This study examined SSEs through the lens of race and ethnicity, as well as other patient characteristics. In so doing, it tested one mechanism by which institutions may predict plausible harm based on patient characteristics.

Chapter 1 of this dissertation reviewed the background and significance of patient safety and harm, vulnerable populations and health inequities, and relayed the importance of this study and leveraging staff reported patient safety events. It also provided a synthesis of current findings related to disparate healthcare outcomes related to specific demographics and social determinants of health. Chapter 2 offered in-depth review of the literature, which included ways in which patient safety is measured, defining the term “patient harm”, the mal-alignment of national organizations that guide patient safety and their recommendations on how to best measure harm. The chapter also reviewed current policies and differences in reporting expectations from state to state, vulnerable populations and health inequities, racism and how it’s related to health and safety outcomes, and implicit bias. Chapter 3 described the study design, study measures, data collection procedures, data management, data analysis, and measures taken to ensure compliance with the protection of human subjects of research, as well as the maintenance of confidentiality and integrity of data. Chapter 4 described the results of the study, analyzing the relationship between select patient demographic variables (age, gender, race, ethnicity, and language spoken), payer mix, patient zip code, and site of care among patients who have experienced a serious safety event while in the hospital.

Specifically:

Study Aim 1. Described patient sociodemographic characteristics, health insurance coverage, hospital location, and patient region among patients who had experienced a

serious safety event. Of patients who had experienced a serious safety event while receiving care, the age group with the highest frequency was 55-64 year-old range ($n = 141, 18.7\%$) and lowest frequency was with 15-24 year-old range ($n = 31, 4.1\%$). The majority of patients were female 57.9% ($n = 439$), and White ($n = 368, 48.9\%$). The greatest frequency was seen in Non-Hispanic, non-Latino patients ($n = 520, 69.7\%$) and English speaking ($n = 622, 82.2\%$) patients. The greatest frequency was observed in SSE4 (severe temporary harm) making up 36.7% ($n = 278$) of all events and lowest frequency was observed in SSE3 (moderate permanent harm) making up 5.9% ($n = 45$).

Study Aim 2. Described the relationships among the select patient demographic variables (age, gender, race, ethnicity, language spoken) health insurance coverage (yes/no), patient zip code, payer type and site of care location among patients who have experienced a serious safety event. There was a statistically significant association between hospital location and level of harm, $\chi^2(12) = 26.02; p = .007$, ethnicity and level of harm, $\chi^2=10.17; p = .038$; Cramer's $V = .117$, small effect and insurance (yes/no) and level of harm, $\chi^2=9.12; p = .040$; Cramer's $V = .108$, small effect. Race, $\chi^2=11.27; p = .941$, and language, $\chi^2=15.38; p = .413$, were not found to be significantly associated with those patients who experienced a serious safety event.

Study Aim 3. Identified predictors that increase or decrease the odds of experiencing an SSE. The multinomial logistic regression model was statistically significant, $\chi^2(10) = 24.350, p = .007$. The most influential risk predictors for experiencing a serious safety event levels 1-3 (moderate to severe permanent harm or death) was location where the patient received care. When compared to the lowest level of harm (moderate temporary harm), patients were more likely to die or receive permanent harm (severe or moderate) if

they received care at Site 1, $\text{EXP(B)} = 5.534$, $p = .025$, Site 2, $\text{EXP(B)} = 6.881$, $p = .013$, or Site 3, $\text{EXP(B)} = 11.454$, $p = .002$; with Site 3 being the biggest contributor.

Discussion

Many studies acknowledge that patients who are members of racial or ethnic minority groups receive lower quality of care compared to patients who are white even after adjusting for other factors (e.g., socioeconomic status, insurance coverage etc.) (Hasnain-Wynia et al., 2007; Metersky et al., 2011; Okoroh, Uribe, & Weingart, 2017). This study leveraged a voluntary error reporting system to further support and substantiate findings related to administrative data (e.g., PSIs) and preventable harm within healthcare. In this study, the relationship between SSEs and ethnicity was found to be statistically significant, but race was not. The study sample was comprised of 69.7% non-Hispanic patients and 30.3% Hispanic, which may help explain why there was a significant relationship between non-Hispanic patients and SSEs. Site 3 was the only site that serves an area in which Hispanics make up the majority of the population.

In this study, race was not found to be a significant factor in observed SSEs. The two largest race categories within the sample were White (48.9%) and Other (38%). American Indian/Alaska Native and Native Hawaiian/Pacific Islander made up only 0.5% and 0.4% of the sample, respectively, and Black/African Americans made up 6.1%. It is difficult to draw any conclusions around race when the sample sizes are not comparable. As language is closely tied to race and ethnicity, this was also examined. However, language was not found to be significantly related to SSEs is congruent with other study findings.

Extant evidence suggests patient sociodemographic status and patient factors tied to poorer safety outcomes include language spoken at home, age, gender, availability of health insurance coverage, patient zip code (as a proxy for socioeconomic status), and type of insurance (Chin, Walters, Cook, & Huang, 2007; Coffey, Andrews, & Moy, 2005; Cohen, Rivara, Marcuse, McPhillips, & Davis, 2005; Lion et al., 2013; Shen et al., 2016; Spencer, Roberts, & Gaskin, 2015). A few studies have concluded hospitals where patients are at higher risk for mortality, complications and adverse events, it is not only the minority population suffering these consequences, but all patients alike (Gaskin et al., 2008). Despite previously reported relationships between the variables selected for analysis in this study and decreased patient safety, this study did not find statistically significant relationships among these variables. There were limitations to this study that could help explain why that may be.

Limitations

Using incident reporting to identify serious safety events has potential drawbacks, including the possibility that SSEs are occurring, but not being reported, or are being reported but not accurately identified as *serious*. The use of HPI's safety event classification algorithm can be challenging, and the organization which served as the site of this study continues to safeguard against under classification of events by using interrater reliability forums; however, developing a shared mental model around event classification has been challenging. Although the organization has been using the algorithm for seven years, robust discussions and disagreements about classification still arise.

This study may not be consistent with prior research findings around patient safety outcomes because many prior studies focus on the presence of either PSIs or adverse events (AE) and not on the final level of harm of those events. A patient can experience a preventable adverse event that does not ultimately result in moderate to severe harm or death, meaning they would have been precluded from this study. This study focused solely on those events resulting in serious harm. Previous studies indicate a small percentage (7%) of all identified adverse events result in serious harm or death (deVries, Ramrattan, Smorenburg, Gouma, & Boermeester, 2007). Future studies should leverage voluntary reporting systems and include all levels of harm to help substantiate past research findings.

This study did not adjust for a number of patient and hospital characteristics. Certain hospital characteristics that should be considered in future studies include the percentage of minority patients served by the hospital, nurse-patient ratio, staff race and ethnicity make-up, procedural volumes, and hospital size (Gaskin et al., 2008; Rivard, Elwy, & Loveland, 2005). Patient characteristics that should be included in future studies include comorbidities, length of stay, level of education and income (Edmonds, Yehezkel, & Moore Simas, 2013).

This study did not measure implicit bias. In addition, this study is limited in capturing accurate information on the patient's race and ethnicity due to variation in information collection and expectations, as well as potential bias, of those gathering information. Although best practice is self-reported race and ethnicity, many patients and healthcare admitting staff are unclear on definitions and, at times, for the sake of time, a staff member may make assumptions about race and ethnicity and not ask the patient how

they identify themselves in regard to race and ethnicity (Jarrin, Nyandege, Grafova, Dong, & Lin, 2020). These actions facilitate implicit bias.

Strengths

What is novel about this study is that voluntary reported data was leveraged to determine relationships between preventable harm and key patient sociodemographic characteristics. Most studies use administrative data (Patient Safety Indicators) or retrospective chart review (IHI's Global Trigger Tool) to determine events of harm, and then draw conclusions about relationship of those events to specific patient characteristics. The sample size of 758 observed cases over 8 years provided enough data points to perform the desired statistical analyses. Ensuring the classified harm level is as reliable as possible is important to the findings of this study. The reliance upon an effective interrater reliability system ensured the accuracy of the data used.

Implications for Nursing Practice

This research study contributes to research analyzing the relationships between serious safety events and patient sociodemographic characteristics, health insurance coverage, hospital location, and patient region. All healthcare organizations strive to achieve the safest care possible, and most studies focus on variables within the hospital's control (e.g., nurse-patient ratio, staff race and ethnicity make-up, procedural volumes, and hospital size). It seems hospitals would benefit from also looking at patient characteristics that may ultimately influence decision making of the nurses and the interdisciplinary team. Nursing and health system leadership should also consider looking at education and training around implicit bias to help staff's awareness of their own preferences, and how that may ultimately impact the care given to their patients.

Previous studies have attempted to measure provider perceptions and differing treatment modalities and outcomes based on race (Shen et al., 2016; Hall et al., 2015; Clark-Hitt, Malat, Burgess, & Friedemann-Sanchez, 2010, Shi, Stevens, Lebrun, Faed, & Tsai, 2008). Other studies have found differing diagnostics, medication management and patient-provider relationships based on race and or ethnicity (Green et al., 2007; Schulman et al., 1999; Van Ryn, Burgess, Malat, & Griffin, 2006). More recently, similar studies now include nurses, which is an important development because providers do not work in silos, and nurses serve as an important link in the safety chain.

Although some SSEs are attributed to provider decision making and judgement, it is more often observed that nurses and other members of the interdisciplinary team also had a role in contributing to or failing to prevent harm to the patient. Such events include (but are not limited to) deviations in medication administration, failure to escalate concerns, failure to recognize patient deterioration and failure to effectively communicate concerns. Nurses play an integral role in any hospitalized patient's care.

On an individual level, nurses should be familiar with measurement methods around implicit bias, and familiar with their own biases. Actively understanding one's biases gives the individual time and motivation to act differently, effectively changing implicit bias to explicit bias.

Implications for Research

This dissertation and study contribute to research exploring the relationships between sociodemographic variables and patient safety outcomes. Future studies should continue to stratify baseline characteristics by race and ethnicity because capturing patient outcomes based on race and/or ethnicity can serve as a proxy for implicit bias and

racism. Implicit attitudes are difficult to identify, yet correlate with patient outcomes, so research leveraging proxy measures is important in furthering research in this arena. Better understanding how implicit bias can influence nurse's decision making and critical thinking is important in preventing patient harm. There is a gap in the literature related to nursing focused implicit bias and patient outcomes. Many studies include multiple members of the interdisciplinary team and others focus solely on providers (e.g. MDs, NPs), and very few focus on outcomes based on possible bias from nurses (Green et al., 2007; Haider et al., 2015; Hall et al., 2015; Wittenauer, Ludwick, Baughman, & Fishbein, 2015).

Current studies leverage implicit association tests to measure bias, however, these studies do not ultimately tie back patient outcomes (Bean, Stone, Moskowitz, Badger, & Focella, 2013; Colon-Emeric et al., 2017); Waller, Lampman, & Lupfer-Johnson, 2012). One study used vignettes to determine the presence of nursing bias and found nurses have a preference for white and upper-class patients, but also found those preferences did not translate to proxy of the provision of care (Haider et al., 2015). Future studies should continue to attempt to tie implicit bias to patient outcomes.

There is also opportunity to continue research using voluntary reported adverse events. In order to better appreciate how many SSEs are captured by voluntary reporting systems, the relationships between incident reporting, PSIs and AEs identified by IHI's Global Trigger Tool should be studied. In addition, so as to develop a more sophisticated predictive model, the hospital, staff and patient characteristics discussed above should be accounted and controlled for in any analysis.

Implications for Education

In 1998, Project Implicit, a non-profit organization was founded by researchers interested in implicit social cognition and offers a way for the public to measure their implicit attitudes regarding any one of many available topics. Educators and researchers are beginning to advocate for implicit bias education and activities in nursing education, and often use the Implicit Association Test (IAT) to expose students to attitudes and beliefs they may not have willing or able to recognize within themselves (Bellack, 2015; Gatewood, Broholm, Herman, & Yingling, 2019). Ultimately, being aware of one's own biases can help decrease behaviors associated with said biases in the clinical setting.

Simulation activities with standardized patients from different racial and ethnic backgrounds who speak different languages and have differing levels of education could help expose nursing students to the variety of patients they may interact with in the field. Ensuring a range of variety in standardized patient sociodemographic makeup can help nursing students understand how their decision making could be influenced by patient characteristics.

Conclusion

This dissertation has synthesized the literature surrounding patient safety, measurement of patient safety, and vulnerable populations and inequities in healthcare outcomes. In terms of level of harm, there was a relationship between not having insurance and level of harm, ethnicity and level of harm, but ultimately, where care was received had the most influence over harm levels. Not found to be significant in this study, were the relationships between race and level of harm and language and level of harm.

The findings of this study add to the body of knowledge around patient safety and health care disparities and provide guidance for future nursing research leveraging racial and ethnic data as a proxy for implicit bias, voluntary reported events to support administrative patient safety data, and consistent education to healthcare professionals regarding implicit bias. By capturing events not captured via AHRQ's PSIs, this investigation supports the importance of leveraging voluntary reporting systems to identify and measure patient safety within hospital organizations and helps provide guidance for education, practice and future nursing research.

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APPENDIX A

USD Institutional Review Board Approval



Dec 5, 2019 10:02 AM PST

Samantha Crandall
Hahn School of Nursing & Health Science

Re: Initial - IRB-2020-109 The Relationship between Race and Ethnicity and Serious Safety Events in Hospitalized Patients

Dear Dr. Samantha Crandall:

University of San Diego Human Subjects Review Board has rendered the decision below for The Relationship between Race and Ethnicity and Serious Safety Events in Hospitalized Patients.

Decision: No Human Subjects Research

Findings: None

Research Notes:

Internal Notes:

Note: We send IRB correspondence regarding student research to the faculty advisor, who bears the ultimate responsibility for the conduct of the research. We request that the faculty advisor share this correspondence with the student researcher.

The next deadline for submitting project proposals to the Provost's Office for full review is N/A. You may submit a project proposal for expedited or exempt review at any time.

Sincerely,

Dr. Thomas R. Herrinton
Administrator, Institutional Review Board

Office of the Vice President and Provost
Hughes Administration Center, Room 214
5998 Alcalá Park, San Diego, CA 92110-2492
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Date: 5 March 2020
 To: Samantha Crandall
 University of San Diego
 10805 Caminito Cuesta
 San Diego, CA 92131
 via email: samcrandall@me.com

Dear Ms Crandall:

Requested material: Blair IV, Steiner JF, Havranek EP. Unconscious (implicit) bias and health disparities: Where do we go from here? *The Permanente Journal* 15(2):71-8. © 2011 The Permanente Press.

Proposed use: To be included in the dissertation: The relationship between race and ethnicity and serious safety events in hospitalized patients

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