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Disparities In Patient Safety Events For Hospitalized Patients

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DISPARITIES IN PATIENT SAFETY EVENTS FOR HOSPITALIZED PATIENTS

by

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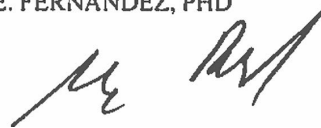
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2020

DEDICATION

To Emma Ude Akpeh

DISPARITIES IN PATIENT SAFETY EVENTS FOR HOSPITALIZED PATIENTS

by

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Presented to the Faculty of The University of Texas

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in Partial Fulfillment

of the Requirements

for the Degree of

DOCTOR OF PUBLIC HEALTH

THE UNIVERSITY OF TEXAS
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PREFACE

When most patients present to a healthcare provider, they are in a vulnerable state. They often put their trust in the provider and the facility to get them back to a good health status or at least to "*do no harm*". The occurrence of patient safety events represents a betrayal of this trust, especially when there are no active efforts to prevent or reduce reoccurrence. As a physician, I am mindful of this trust that patients bestow on me when they present. This is my main motivation in exploring safety events experienced by patient as they navigate the healthcare process. This work builds upon my prior research work on *care experiences of low-income individuals*.

ACKNOWLEDGEMENTS

The journey to completing this dissertation and the doctoral program was long, with many detours along the way. I thank Dr. Robert Morgan for his guidance and help when it mattered. Thanks also to Drs Luisa Franzini, Maria E. Fernandez, and Charles Chima for their input as part of my committee.

The best part of my education was the practical experience acquired by working on numerous projects for UT Physicians. Thanks to Drs Charles Begley and Sandra Tyson for making that opportunity possible.

Thanks to all my friends and colleagues who have provided a support system to me through this journey. I appreciate you all.

Finally, to my growing family: *Chika, Chinedum, Adannia, and Nnabuchi II* . . . thank you for being there.

DISPARITIES IN PATIENT SAFETY EVENTS FOR HOSPITALIZED PATIENTS

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School of Public Health, 2020

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ABSTRACT

Background: Twenty years post IOM's landmark publication, "To Err is Human: Building a Safer Health System", still no consensus on case definition for patient safety events (PSEs). Available data on incidence and magnitude of PSEs are more than 10 years old, while data on disparities are ambiguous.

Objective: To examine the racial and socioeconomic disparities in reported patient safety events (PSEs) among hospitalized individuals.

Design, Setting, and Participants: Cross-sectional study of patient safety events using the 2016 National Inpatient Sample (NIS) from the Healthcare Cost and Utilization Project (HCUP). A total of 6,753,100 discharges were identified as being at risk for PSEs using AHRQ's patient safety indicator (PSI) algorithm.

Main Outcome Measure: Patient Safety events (PSE).

Results: 1299 PSEs occurred per 100000 discharges in 2016. Racial and ethnic minority groups were significantly more likely to experience at least one or more PSEs when compared to White non-Hispanic group (AOR: Blacks-1.33, Asians-1.51, and Hispanics-1.06). Black patients were more likely to experience Pressure Ulcer, Central Venous Catheter-Related Blood Stream Infection, Perioperative Pulmonary Embolism or Deep Vein

Thrombosis; Asian patients were more likely to experience Obstetric traumas and in-hospital deaths among patients with serious treatable conditions. Hispanics were more likely to experience pressure ulcers. Discharges with Medicaid insurance coverage and those without coverage appear to be less likely to experience a PSE when compared to those on private insurance coverage. In contrast, discharges with Medicare insurance coverage were more likely to experience at least one or more PSEs when compared to those on private insurance coverage.

Conclusions: The burden of patient safety events remain high. Pressure ulcers appears to be driving overall burden of PSEs for Blacks and Hispanics; whereas obstetric traumas appear to be the driving force for Asians. Further research is required to understand the factors that predispose each group to these PSEs.

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BACKGROUND

Introduction

There has been focus on preventing potential lapses in patient safety since the publication of the 1999 Institute of Medicine (IOM) report "To Err is Human". The report highlighted the various ways a patient could be harmed from lapses¹ in the healthcare process. According to the report, lapses in the health care delivery process resulted in approximately two million healthcare-associated infections, death of about 98,000 individuals, and added an additional \$29 billion to healthcare expenditures each year (Kohn, Corrigan, & Donaldson, 2000). Recent estimates suggest that lapses in patient safety is now the third leading cause for mortality within the United States, accounting for at least 250,000 deaths annually (Makary & Daniel, 2016; Anderson & Abrahamson, 2017).

Such lapses in the process of care have been termed "patient safety events" (PSE) in literature (Miller, Elixhauser, Zhan, 2003). Research in this area is still growing with very few studies on disparities that might exist in occurrence of patient safety events (Flores, Rabke-Verani, Pine, & Sabharwal, 2002; Flores & Ngui, 2006). This study examined socioeconomic disparities (racial, income, and insurance type) in patient safety events among hospitalized patients using the Agency for Healthcare Research and Quality's (AHRQ) patient safety indicators.

¹ Lapses as used here refers to both acts of omission and commission.

Literature Review

Though it has been two decades since the landmark IOM report titled "To Err is Human", there is still lack of a common definition for patient safety. Some common definitions of patient safety include:

"Freedom from accidental Injury" ~ Institute of Medicine (Kohn, Corrigan, & Donaldson, 2000)

"The prevention of harm to patients" ~ Institute of Medicine (Aspden, Corrigan, Wolcott, et al., 2004)

"freedom from accidental or preventable injuries produced by medical care" ~ AHRQ PSNet Patient Safety Network (AHRQ PSNet, 2020)

"The prevention of errors and adverse effects to patients associated with health care"
~ World Health Organization (WHO, 2020)

"The avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of health care itself" ~ National Patient Safety Foundation (Cooper, Gaba, Liang, Woods, & Blum, 2000)

Flowing from these definitions, patient safety events result from a patient's interaction with different components of the health care system. The Institute of Medicine's definition of patient safety as outlined above and in the landmark report, *"To Err is Human"* is very narrow

and implies that patient safety events only result from accidents. In contrast, the definition by the National Patient Safety Foundation (NPSF) is broad enough to include all the processes of care. It is this definition that is adopted in this study.

This study uses the Joint Commission's definition of patient safety event - "*an event, incident, or condition that could have resulted or did result in harm to a patient*" (Joint Commission, 2016). Thus, patient safety events can occur even when no harm has been done to the patient. Patient safety events can be grouped into the following broad categories: errors and deviations, dangerous situations, near misses, and accidents (J. B. Battles, Kaplan, Van der Schaaf, & Shea, 1998). An accident usually results from a combination of near misses, dangerous situations and errors. The usage of these terms is explained below (AHRQ, 2011; Reason, 1990; Thomas & Petersen, 2003):

- **Accidents/Incidents**—patient safety events that reached the patient, whether or not there was harm;
- **Near misses/close calls**—patient safety events that did not reach the patient
- **Dangerous/Unsafe conditions**—circumstances that increase the probability of a patient safety event.
- **Errors and Deviations** – acts that raise the risk of occurrence of a patient safety event. This could be skill-based acts of omission (knowing what to do but doing nothing) and commission (inadvertently doing the wrong thing); knowledge-

based acts in situations where there are no standard protocols; or rule-based acts selecting the wrong therapy or applying the right one wrongly.

The risk of patient safety events is higher for children and elderly (Weingart, Wilson, Gibberd, & Harrison, 2000). For the elderly, the risk is driven by reduced multiple comorbid conditions and frailty. While for children, it is mostly driven by communication issues. Other risk factors for patient safety events include disease severity and complexity, receiving care in the emergency department, higher number of hospital beds, a higher number of hospital beds in intensive care units, and language barriers (Kohn et al., 2000; Weingart, Wilson, Gibberd, & Harrison, 2000; Miller et al., 2001). Cultural and linguistic barriers often set in motion a cascade leading to miscommunication, inaccurate patient history, disparities in diagnostic evaluation and/or wrong diagnosis, and non-adherence to therapy (Flores, 2000; Flores et al., 2002). Other studies have found the effect of patient safety events on the individual patient to include increased length of hospital stay, tripling of hospital charges, high utilization of hospital resources for acute/intensive care, increased total healthcare expenditure (Kalish et al., 1995).

Patient Safety Indicators

Various studies define patient safety events in different ways, using varying case ascertainment methodology. To promote consistency in measuring patient safety events, researchers at the Agency for Healthcare Research and Quality (AHRQ) developed a set of

patient safety indicators (PSI) to identify potentially preventable events that occur because of a patient's interaction with the healthcare system. Patient safety indicators are a set of clinical algorithms that capture potentially preventable complications amongst hospitalized patients. They were designed to be used as a screening tool for problems that patients experience as a result of exposure to the healthcare system (AHRQ, 2019). These indicators detect events that are amenable to prevention through changes at the provider or area level, ensured consistency in measuring patient safety events, and provided the opportunity to assess patient safety events using administrative data (AHRQ, 2019). Patient safety indicators are measured as rates: *the number of hospitalizations with the outcome of interest divided by the population at risk for that outcome* (AHRQ, 2019). The numerator is the number of patients with the outcome of interest, while the denominator is the number of patients at risk for the numerator event (AHRQ, 2019).

When PSIs were initially developed by Miller et al (2001), there were 12 individual indicators and one summary indicator. The indicators were initially tested using the Healthcare Cost and Utilization Project's (HCUP) New York State Inpatient Database (NY SID) and validated using the HCUP National Inpatient Sample (NIS) (Miller, Elixhauser, Zhan, & Meyer, 2001; Romano et al., 2003). One of the biggest strengths of PSIs is that they were specifically designed as a case finding tool to aid quality improvement methods using administrative databases. Since the original development, the patient safety indicators have undergone a continuous process of enhancement and refinement that involved comprehensive review of literature, evidence

scans, user feedback, review of clinical practice changes, validation studies, testing for validity and reliability, input from expert panels, and risk adjustment (AHRQ, 2019). This process had led to variation in the number of patient safety indicators over time through the introduction of new indicators and retirement of others. Currently, there are 17 hospital or provider-level patient safety indicators spanning medical, surgical and obstetric discharges. The patient safety indicators are listed below:

- PSI #2 - Death Rate in Low-Mortality Diagnosis Related Groups (DRGs)
- PSI #3 - Pressure Ulcer Rate
- 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 Rate
- PSI #7 - Central Venous Catheter-Related Blood Stream Infection Rate
- PSI #8 – In Hospital Fall with Hip Fracture Rate
- PSI #9 - Perioperative Hemorrhage or Hematoma Rate
- PSI #10 - Postoperative Acute Kidney Injury Requiring Dialysis Rate
- PSI #11 - Postoperative Respiratory Failure Rate
- PSI #12 - Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate
- PSI #13 - Postoperative Sepsis Rate
- PSI #14 - Postoperative Wound Dehiscence Rate

- PSI #15 - Unrecognized Abdominopelvic Accidental Puncture or Laceration Rate
- PSI #17 - Birth Trauma Rate – Injury to Neonate
- PSI #18 - Obstetric Trauma Rate – Vaginal Delivery With Instrument
- PSI #19 - Obstetric Trauma Rate – Vaginal Delivery Without Instrument.

The primary study during the development phase of the patient safety indicators was done by Miller, Elixhauser, Zahn, and Meyer (2001). Miller et al (2001) found the following variables to have positive associations with patient safety events: increasing age (risk for elderly above 65 years two times the risk for patients aged less than 18 years), male gender (90 events per 10,000 discharges vs. 86 for female; p-value <0.001), white race (1.7 times the risk for Blacks or Hispanics), not-for-profit hospital status(1.4 times the risk for public or for-profit hospitals), Medicare insurance (2.9 times the risk for uninsured) (Miller et al., 2001). However, this study was done in 2001 when the PSIs were still being developed and with 1996-1997 Healthcare Cost and Utilization Project (HCUP) New York State Inpatient Database (NY SID).

A follow-up study was done by Romano, Geppert, Davies, Miller, Elixhauser and McDonald (2003) using data from the 1995 – 2000 Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample (NIS). In that study, Romano et al (2003) found that the incidence of non-obstetric patient safety events increased with age and was higher for Blacks (1.3-1.6 times the risk for Whites). The study found that while White patients had a higher

risk for most surgical-related patient safety events, Black patients had a higher risk for medical-related events. Hispanic patients were found to have much lower risks than either White or Black patients. It also found that incidence of patient safety events was higher in urban teaching hospitals. These two studies used HCUP data at different levels (state vs national) and their findings on racial disparities were contradictory.

Furthermore, using data from the 2000 HCUP database, Coffey et al (2005) found that non-Hispanic Blacks and Hispanics had higher rates for patient safety events (vs non-Hispanic Whites). When adjusted for income, the disparities disappeared for Hispanics while they remained for non-Hispanic Blacks (Coffey et al, 2005). Shimada et al (2008) found that when compared to White patients, Black patients only had increased odds of experiencing the following patient safety events: decubitus ulcers (OR = 1.35, P < 0.0001) and postoperative deep venous thrombosis/pulmonary embolism (OR = 1.23, P < 0.0001). This study was done using Veterans Health Administration (VHA) hospitals discharge data from 2001–2005. Spencer et al (2013) examined differences in rates PSEs by insurance status of patients within the same hospital using pooled 2006-08 discharge records data from hospitals in eleven states. The study found that Medicaid and Medicare patients experienced significantly more adverse safety events than private pay patients for some PSEs. It also found that Medicaid patients had significantly lower event rates than private payers on other PSEs.

All these studies are more than 10 years old. No study has attempted to look at disparities in patient safety events using more recent HCUP data or any other nationally representative dataset. As such it is unclear if disparities still exist in patient safety events and the magnitude of such disparities if they still exist. Therefore, it is important to explore patient safety events using more recent data.

Public Health Significance

The importance of this study is underscored by the effect of patient safety events on the individual patients, health facilities and the society. Such effects include increased length of hospital stay, tripling of hospital charges, high utilization of hospital resources for acute/intensive care, increased total healthcare expenditure (Kalish et al., 1995). Patient safety events are estimated to result in 251,000 deaths each year in the United States, making it the third leading cause of death in the country (Anderson & Abrahamson, 2017). This figure is likely an understatement as it is based solely on events due to medication errors.

Findings from this study will contribute to body of knowledge on patient safety by updating the information on rates of patient safety events, while highlighting the magnitude and direction of disparities that exist in reported patient safety events. The findings could also inform evidence-based policymaking to address socioeconomic disparities in patient safety events.

Specific Aims

The objective of this study is to examine the racial and socioeconomic disparities in reported patient safety events among hospitalized individuals. The specific aims of this study are:

- i. To examine differences in the rate of patient safety events across racial/ethnic groups among hospitalized patients
- ii. To examine the rate of patient safety events stratified by income level, insurance type, hospital bed size, location, and geographical region among hospitalized patients
- iii. To determine the specific types of patient safety events that are most often reported for racial/ethnic minority inpatients (i.e. Blacks, Asians, and Hispanics).

METHODS**Design and Data**

This is a cross-sectional study of patient safety events among inpatients using hospital discharge data. The study examined disparities in reported patient safety events among inpatients using discharge data from the 2016 National Inpatient Sample (NIS) from the

Healthcare Cost and Utilization Project (HCUP) conducted by the Agency for Healthcare Research and Quality (AHRQ, 2018a). The National Inpatient Sample (NIS) is the largest publicly available all-payer inpatient care database in the United States, with data from approximately 8 million hospital stays each year (AHRQ, 2018a).

As at the time of conceptualizing this study, the 2016 NIS was the most recent year of NIS data available. It contains discharge data from community hospitals located in 46 States and the District of Columbia, approximating a 20-percent stratified sample of community hospitals in the US (AHRQ, 2018a). It covers more than 97 percent of the population of the United States. The NIS defines community hospitals as "all non-Federal, short-term, general, and other specialty hospitals, excluding hospital units of institutions." This definition includes specialty hospitals, public hospitals, and academic medical centers. The data excludes discharges from rehabilitation and long-term acute care hospitals. The NIS includes charge information for all patients, regardless of payer, including persons covered by Medicare, Medicaid, private insurance, and the uninsured. It also includes information on diagnoses, procedures, admission and discharge status, gender, age, race, income (median for ZIP Code), total charges, length of stay, and hospital characteristics (e.g., ownership, size, teaching status) (AHRQ, 2018a). The data is limited in the clinical context that it can provide, compared to chart reviews of clinical records. However, it has the advantages of being readily available, computer readable, inexpensive, and covers a large population sample (Miller et al., 2001; Zhan & Miller, 2003).

Study Population

The study population will include all hospitalized patients in the NIS database with discharge for the year 2016 for whom a bill was submitted. The 2016 HCUP has data for approximately 7 million hospital discharges.

Measures

The main outcome variable is patient safety event (PSE), a binary variable indicating the presence or absence of at least one patient safety indicator (PSI) amongst patients at risk for patient safety events. PSE flags were generated using the AHRQ Quality Indicators Windows Software Version v2019.0.1 (AHRQ, 2019b) and are reported as number of events per 100,000 discharges. The independent and control variables were chosen based on review of literature (Battles & Lilford, 2003; Colla, Bracken, Kinney, & Weeks, 2005; Cooper et al., 2000; Flores, 2000; Flores et al., 2002; Miller et al., 2001; Murff, Patel, Hripcsak, & Bates, 2003; Romano et al., 2003; Shojania, Duncan, McDonald, Wachter, & Markowitz, 2001; Weingart et al., 2000; Zhan & Miller, 2003). These include patient and hospital-level variables (Table 1).

- **Patient-level variables:** age, sex, race/ethnicity (White, Black, Asian, Hispanic, Others), income, insurance type (Medicare, Private, Medicaid, Other), length of stay, discharge disposition (died in hospital, transferred to another facility, discharged home, other)
- **Hospital-level variables:** ownership (government, nonfederal; private, non-profit; private, investor-owned), geographical region (Northeast, Midwest,

West, and South), location/teaching status (rural, urban non-teaching, urban teaching), and hospital bed size.

Age is coded as continuous variable in the HCUP NIS dataset; however, it will be recoded as a categorical variable (0-4, 5-17, 18-44, 45-64, 65+) for the analysis. Race and insurance type are coded as categorical variables. Race and ethnicity is one variable in all HCUP dataset. Irrespective of how the data was collected at the primary source, HCUP combines them into one variable that includes the following values: (1) white, (2) black, (3) Hispanic, (4) Asian, (5) Native American, and (6) others. Some data sources do not provide HCUP with information on race and/or ethnicity. Length of stay is coded as a continuous variable. Hospital bed size is coded as a categorical variable: small, medium, and large using guidelines in the dataset (AHRQ, 2018a), see appendix for more details. Comorbidity information was added to the data using the *Elixhauser* module of the statistical software, STATA (Stagg, 2015). The module generated 31 indicator variables (see appendix), each representing a category on the Elixhauser Comorbidity Index. The Elixhauser Comorbidity Index is a method of categorizing comorbidities of patients based on the International Classification of Diseases (ICD) diagnosis codes found in administrative data, such as HCUP NIS data (Elixhauser, Steiner, Harris, & Coffey, 1998; AHRQ, 2018b). The comorbidity measures, which are used for risk adjusting, are coded as binary variables (0/1), however for the purposes of this study they were recoded as categorical variables indicating the total number of Elixhauser comorbidity categories in a discharge (0, 1, 2, 3, 4, 5+).

Table 1: Measures

Variable Name	Variable Code	Notes
Patient Safety Event	PSE	Composite Binary variable indicating the presence or absence of at least one PSI. The PSIs are generated using the AHRQ software
Age	AGE	Categorical variable (0-4, 5-17, 18-44, 45-64, 65+)
Sex	FEMALE	Binary variable (0) male, (1) female
Race	RACE	Categorical variable (1) white, (2) black, (3) Hispanic, (4) Asian, (5) Native American, and (6) others
Median household income for patient's ZIP Code	ZIPINC_QRTL	Categorical variable. Median household income quartiles for patient's ZIP Code defined as: (4) \$1 - \$42,999; (3) \$43,000 - \$53,999; (2) \$54,000 - 70,999; and (1) \$71,000 or more.
Insurance Type	PAY1	Categorical variable. Primary expected payer: (1) private including HMO, (2) Medicare, (3) Medicaid, (4) Uninsured, (5) other
Length of stay	LOS	Number of days on admission. Continuous variable
Discharge disposition	DISPUNIFORM	(1) routine, (2) transfer to short-term hospital, (5) other transfers, including skilled nursing facility, intermediate care, and another type of facility, (6) home health care, (7) against medical advice, (20) died in hospital, (99) discharged alive, destination unknown
Hospital Geographic Region (See Appendix for more details)	HOSP_REGION	(1) Northeast, (2) Midwest, (3) South, (4) West
Location/Teaching status of hospital (See Appendix for more details)	HOSP_LOCTEACH	(1) rural, (2) urban non-teaching, (3) urban teaching
Bed size of hospital	HOSP_BEDSIZE	(1) small, (2) medium, (3) large
Hospital Ownership Structure	H_CONTRL	(1) government, nonfederal (2) private, non-profit (3) private, investor-owned

Data Collection and Management

HCUP data are initially collected at state level and then voluntarily transmitted to HCUP by participating states. These state-level data contain all inpatient hospital discharge data from community hospitals. The state-level data do not all contain same data elements nor are they

in same format. HCUP converts submitted data from the states into a uniform format to address differences in coding of variables (Figure 1). The uniform data from all participating states is initially stored as the State Inpatient Databases (SID).

The National Inpatient Sample (NIS) is a stratified probability sample of hospitals in this frame (SID), with sampling probabilities calculated to select 20% of the universe of U.S. community, non-rehabilitation hospitals. Sampling strata were created based on five hospital characteristics: Geographic Region (Northeast, Midwest, West, and South), Control (government non-Federal, private not-for-profit, and private investor-owned), Location (urban or rural), Teaching Status (teaching or non-teaching), and Bed Size (small, medium, and large). After strata were defined, hospitals were sorted by stratum, three-digit ZIP Code within each stratum, and by a random number within each three-digit ZIP Code. This was done to improve the generalizability of the sample. Then a systematic random sample of up to 20% of the total number of U.S. hospitals within each stratum was drawn. Prior to 2012, the NIS was a sample of hospitals from which all discharges were retained. However, it was redesigned in 2012 to become a sample of discharges from all hospitals participating in HCUP. The NIS data includes discharge weights to allow for national estimates to be extrapolated from the data.

$$DW_s(\text{universe}) = DN_s(\text{universe}) \div DN_s(\text{sample})$$

where:

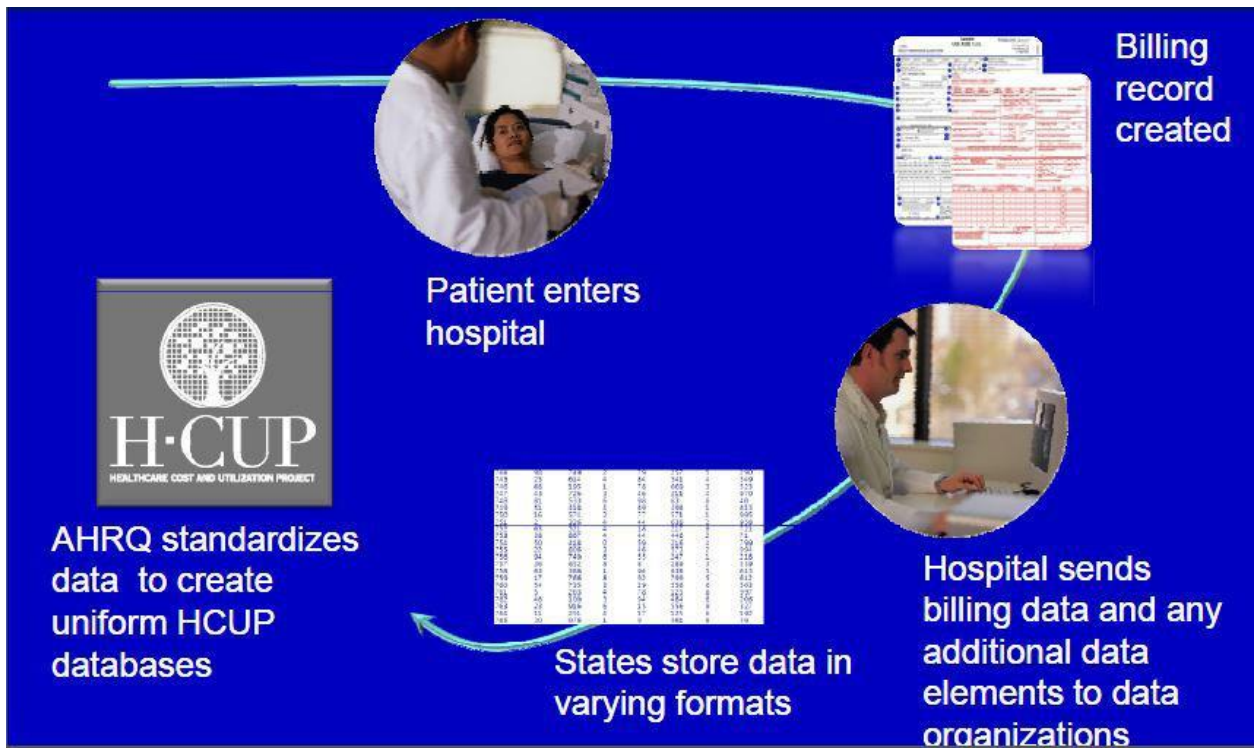
$DW_s(\text{universe})$ = discharge weight

$DN_s(\text{universe})$ = number of discharges from community hospitals in the universe within stratum s ; and

DN_s(sample) = number of discharges selected for the NIS.

Data management and analysis was done using AHRQ Quality Indicators Windows® software version v2019.0.1, September 2019 and STATA statistical software version 14.2. The AHRQ QI Windows® Software contains the algorithm necessary to produce these PSI rates from the NIS data, while the STATA software has an Elixhauser module that contains the algorithm for identification of comorbidity measures.

Figure 1: HCUP Data Collection Process



Source: AHRQ presentation at AcademyHealth March 2006 Meeting (AHRQ, 2006)

Limitations

The NIS database was assembled from billing data and as such, some diagnostic procedures or conditions may be underreported. By design, billing data is optimized for obtaining reimbursement from payers. Procedures or conditions that are deemed not necessary for reimbursement are excluded from the bill and in some cases, several procedures/conditions may be bundled into a higher level class if that would improve opportunities for reimbursement (Ferver, Burton, & Jesilow, 2009). Also, the data is limited in the clinical context that it can provide, compared to chart reviews of clinical records. However, this limitation is also applicable to other administrative databases.

The database does not capture other systemic factors like provider bias that might influence the observed racial disparities. Also, the measure of patient safety events used in this study will only capture PSEs that were included in the billing data. As such the study will be unable to identify PSEs that occurred but were not billable. This might bias the directionality of any observed disparity.

The primary record unit for the HCUP NIS dataset is a single discharge and the data does not contain any patient identifiers or other markers to track multiple admissions or readmissions. As such, it is not possible to discern the number of discharges contributed by an individual patient to the overall discharges reported for the year.

Finally, measuring PSEs via an algorithm that uses diagnostic codes (i.e. the PSI methodology) means that only PSEs that result in an injury will be captured. PSIs do not capture near misses/close calls, dangerous or unsafe conditions, and errors and deviations.

Strengths

Despite the limitations of the HCUP database, it is readily available, computer readable, inexpensive, and covers a large population sample (Miller et al., 2001; Zhan & Miller, 2003). The measure of patient safety events being using in the study, PSI, was specifically designed for administrative databases. It has also been validated using different databases. Also, demographic data such as age, race, and sex included in administrative databases are considered to be reliable and valid.

NIS is the largest all-payer inpatient care database in the United States and is representative of the population of hospitalized patients across the United States. As such the findings will be generalizable to all hospitalized patients across the United States

Ethical Considerations

This study is limited to secondary analysis of existing data. All data had been previously collected by states participating in the Agency for Healthcare Research and Quality's (AHRQ) Healthcare Cost and Utilization Project (HCUP). The data will be obtained in de-identified format, with the NIS data set excluding elements that could directly or indirectly identify individuals. The 2016 NIS data includes the following additional measures: removal of hospital

and state identifiers, and aggregation of all ages above 89 into a single age category. Together, all these measures make the possibility of identifying any of the subjects to be remote. Though the risk was minimal, the dataset was stored and analyzed using a password protected computer.

The proposal for the study was submitted for review and was approved in the “exempt” category by the University of Texas Health Science Center Institutional Review Board (IRB).

Data Analysis

Since NIS data is primarily from discharge summaries, the unit of analysis for this study is hospital discharge. The NIS data was loaded to the AHRQ QI Windows® Software for determine and add PSI flags (0/1) to each discharge. The software adds PSI flags to discharge data using algorithms developed by AHRQ. The output from this initial process was then exported to STATA for further analysis. All further data manipulation, management, and statistical analysis was done using STATA statistical software version 14.

Using STATA version 14, a composite patient safety event (PSE) binary variable was created to indicate the presence or absence of at least one PSI/PSE in the each discharge. Overall descriptive analysis and descriptive analysis by PSE was performed to examine the range of values, including the number of missing cases. Frequency distributions, of all variable of interest in the study population, was produced. Next, bivariate analyses was done to examine differences in the rate of PSI across race, age, income level, insurance type, hospital bed size, location, and geographical region. Chi-square test (categorical variables) and T-test

(continuous variables) were to assess differences in characteristics of discharges with a PSE and those without a PSE.

Differences in PSI rates across racial/ethnic groups, payer groups and income groups were further examined using logistic regression analyses with adjustments for age, sex, and number of comorbidities, payer type, and other variables that were significant in bivariate analysis. The significance level was set at 5 percent. The relationship between racial groups and specific types of patient safety events was also examined using logistic regression.

RESULTS

Select characteristics of the study population are summarized in Table 2. There were 7,120,526 discharges in the study population, of which about 95% were identified as being at risk for patient safety events (PSE) using the AHRQ's WinQI v2019.0.1 ICD-10-CM/PCS software. Among the population at risk for patient safety events, about 87,696 discharges had one or more patient safety events. The mean age of the population at risk for patient safety event is higher than that of the general study population (51.17 vs. 48.99). Those with a patient safety event had an even higher mean age (58.97). About 15% of the study population were less than 18-years old, about 24.42% were aged 18-44 years, 24.59% were 45-64 years, and 35.62%. Majority (62.91%) of the overall study population identify as Non-

Hispanic Whites, 14.39% were Non-Hispanic Blacks/African Americans, 11.63% were Hispanics, and 2.91% were Asians/Pacific Islanders. About 56.74% of the population were females and 43.26% males. Approximately 30% of the population were covered by private insurance, 23.07% by Medicaid, 39.59% by Medicare, and 4.18% were uninsured. About 26.32% of the population had no comorbidity, 50.85% had less than five comorbidities, and 22.84% had five or more comorbidities. The average length of stay on admission was 4.62 days. 30.20% lived in neighborhoods with median household income of less than \$43,000. In terms of hospital characteristics, about 52.26% of the discharges were from large bed size hospitals, 73.60% were private non-profit hospitals, 65.38% were urban teaching hospitals, while 39.33% were in a hospital located in the south.

Among the population at risk for patient safety events (PSE), about 1.30% (87,696 discharges) were identified to have experienced at least one or more patient safety events during their hospitalization. Compared to those with no PSE, those with least one PSE were older (mean age: 58.97 years vs. 51.07 years). About 75% of these discharges were for individuals aged 45-years and older; 60.97% were White Non-Hispanic, 17.91% Black, 9.08% Asian, 45.71% male, 72.18% on some form of public coverage (Medicare and Medicaid), approximately 31% live in a household with median income less than \$43,000, and more than 45% have at least five or more comorbidities during their admission.

Table 2: Selected Characteristics of Study Population by Patient Safety Event (PSE)

Variable	Overall		PSE at-risk Population		No PSE		PSE		p Value
	n	%	n	%	n	%	n	%	
n	7,120,526		6,753,100		6,665,404		87,696		
Age [years]									<0.001**
Mean	48.99		51.17		51.07		58.97		
Age [n(%)]									<0.001*
<5yrs	914,469	12.84%	736359	10.90%	732,991	11.00%	3,368	3.84%	
5-17yrs	180,403	2.53%	12482	0.18%	12,262	0.18%	220	0.25%	
18-44yrs	1,738,488	24.42%	1730657	25.63%	1,711,628	25.68%	19,029	21.70%	
45-64yrs	1,751,039	24.59%	1745666	25.85%	1,723,822	25.86%	21,844	24.91%	
65yrs +	2,536,127	35.62%	2528939	37.43%	2,484,701	37.28%	43,235	49.30%	
Race [n(%)]									<0.001*
White	4,419,985	62.07%	4,248,660	62.91%	4,195,189	62.94%	53,471	60.97%	
Black	1,024,893	14.39%	965,217	14.29%	949,509	14.25%	15,708	17.91%	
Hispanic	828,218	11.63%	757,956	11.22%	749,994	11.25%	7,962	9.08%	
Asians	207,190	2.91%	195,473	2.89%	192,278	2.88%	3,195	3.64%	
Native Americans	43,892	0.62%	40,540	0.60%	40,022	0.60%	518	0.59%	
Others	230,074	3.23%	212,007	3.14%	209,309	3.14%	2,698	3.08%	
Missing	366,274	5.14%	333,247	4.93%	329,103	4.94%	4,144	4.73%	
Gender									<0.001*
Male	3,080,087	43.26%	2,887,631	42.76%	2,847,531	42.72%	40,100	45.73%	
Female	4,040,439	56.74%	3,865,469	57.24%	3,817,873	57.28%	47,596	54.27%	
Payer									<0.001*
Private	2,140,742	30.06%	1,998,693	29.60%	1,978,193	29.68%	20,500	23.38%	
Medicaid	1,642,926	23.07%	1,452,536	21.51%	1,438,596	21.58%	13,940	15.90%	
Medicare	2,818,936	39.59%	2,809,364	41.60%	2,760,005	41.41%	49,359	56.28%	
Uninsured	297,405	4.18%	287,347	4.26%	285,606	4.28%	1,741	1.99%	
Others	211,086	2.96%	196,335	2.91%	194,292	2.91%	2,043	2.33%	
Missing	9,431	0.13%	8,825	0.13%	8,712	0.13%	113	0.13%	
Household Income									<0.001*
\$1-\$42,999	2,150,426	30.20%	2,034,386	30.13%	2,007,368	30.12%	27,018	30.81%	
\$43,000-\$53,999	1,781,084	25.01%	1,692,742	25.07%	1,671,204	25.07%	21,538	24.56%	
\$54,000-70,999	1,675,915	23.54%	1,590,884	23.56%	1,570,734	23.57%	20,150	22.98%	
\$71,000+	1,398,512	19.64%	1,325,730	19.63%	1,308,066	19.62%	17,664	20.14%	
Missing	114,589	1.61%	109,358	1.62%	108,032	1.62%	1,326	1.51%	
Length of stay (days)									<0.001**
Mean	4.62		4.51		4.42		10.94		
Elixhauser Comorbidity									<0.001*
0	1,873,952	26.32%	1,705,625	25.26%	1,691,659	25.38%	13,966	15.93%	
1	932,720	13.10%	814,149	12.06%	809,238	12.14%	4,911	5.60%	
2	951,765	13.37%	904,141	13.39%	897,334	13.46%	6,807	7.76%	
3	926,944	13.02%	908,898	13.46%	898,764	13.48%	10,134	11.56%	
4	808,727	11.36%	801,113	11.86%	788,748	11.83%	12,365	14.10%	
5+	1,626,418	22.84%	1,619,174	23.98%	1,579,661	23.70%	39,513	45.06%	

Bed size of hospital										<0.001*
Small	1,332,158	18.71%	1,271,820	18.83%	1,257,357	18.86%	14,463	16.49%		
Medium	2,067,243	29.03%	1,974,278	29.24%	1,949,745	29.25%	24,533	27.98%		
Large	3,721,125	52.26%	3,507,002	51.93%	3,458,302	51.88%	48,700	55.53%		
Ownership of hospital										<0.001*
government-nonfederal	814,633	11.44%	769,380	11.39%	758,998	11.39%	10,382	11.84%		
private-non-profit	5,241,010	73.60%	4,953,908	73.36%	4,888,320	73.34%	65,588	74.79%		
private-investor-own	1,064,883	14.96%	1,029,812	15.25%	1,018,086	15.27%	11,726	13.37%		
Hospital Location/Teaching Status										<0.001*
rural	645,795	9.07%	629,172	9.32%	623,016	9.35%	6,156	7.02%		
urban-non-teaching	1,819,661	25.56%	1,778,289	26.33%	1,757,875	26.37%	20,414	23.28%		
urban-teaching	4,655,070	65.38%	4,345,639	64.35%	4,284,513	64.28%	61,126	69.70%		
Hospital Region										<0.001*
Northeast	1,312,554	18.43%	1,246,094	18.45%	1,229,232	18.44%	16,862	19.23%		
Midwest	1,584,730	22.26%	1,504,678	22.28%	1,485,299	22.28%	19,379	22.10%		
South	2,800,261	39.33%	2,659,715	39.39%	2,625,792	39.39%	33,923	38.68%		
West	1,422,981	19.98%	1,342,613	19.88%	1,325,081	19.88%	17,532	19.99%		

*A chi-square test was performed

**A t-test was performed

Table 3 lists the different types of patient safety events observed in this study, the numerator, denominator, and rate for each one. None of the discharges in this study had a documentation for PSI-10, PSI-11, or PSI-13. The overall rate for patient safety events for the study population is 1,299 per 100,000 discharges. This rate represents the proportion of discharges with at least one patient safety event reported. PSEs with the highest populations at risk (i.e. denominator) were Iatrogenic Pneumothorax Rate -PSI-6 (n=4,870,981), In Hospital Fall with Hip Fracture Rate -PSI-8 (n=4,116,141), and Central Venous Catheter-Related Blood Stream Infection Rate -PSI-7 (n=3,941,208), while PSEs with the lowest populations at risk include Obstetric Trauma Rate - Vaginal Delivery With Instrument -PSI-18 (n=32,687), Death Rate among Surgical Inpatients with Serious Treatable Conditions -PSI-4 (n=49,524), and Postoperative Wound Dehiscence Rate -PSI-14 (n=390,354). PSI-4

(i.e. death rate among surgical inpatients with serious treatable conditions) had the highest PSE rate of 14,732 per 100,000 discharges, followed by PSI-18 (i.e. obstetric trauma rate - vaginal delivery with instrument) with PSE rate of 11,167 per 100,000 discharges, and PSI-19 (i.e. obstetric trauma rate - vaginal delivery without instrument) with PSE rate of 1,738 per 100,000 discharges. The lowest PSE rate (21 per 100,000 discharges) was observed for PSI-02 (i.e. death rate in low-mortality diagnosis related groups).

Table 3: Rate of Patient Safety Events (PSE) by Type in the Study Population

Indicator	Description	Numerator	Denominator	Rate**
PSI 2	Death Rate in Low-Mortality Diagnosis Related Groups (DRGs)	256	1239365	21
PSI 3	Pressure Ulcer Rate	44403	3367780	1318
PSI 4	Death Rate among Surgical Inpatients with Serious Treatable Conditions	7296	49524	14732
PSI 5	Retained Surgical Item or Unretrieved Device Fragment Count	302	***	***
PSI 6	Iatrogenic Pneumothorax Rate	1396	4870981	29
PSI 7	Central Venous Catheter-Related Blood Stream Infection Rate	867	3941208	22
PSI 8	In Hospital Fall with Hip Fracture Rate	2680	4116141	65
PSI 9	Perioperative Hemorrhage or Hematoma Rate	3870	1369969	282
PSI 10	Postoperative Acute Kidney Injury Requiring Dialysis Rate	***	***	***
PSI 11	Postoperative Respiratory Failure Rate	***	***	***
PSI 12	Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate	11949	1473868	811
PSI 13	Postoperative Sepsis Rate	***	***	***
PSI 14	Postoperative Wound Dehiscence Rate	303	390354	78
PSI 15	Unrecognized Abdominopelvic Accidental Puncture or Laceration Rate	1102	924954	119
PSI 17	Birth Trauma Rate - Injury to Neonate	3368	736359	457
PSI 18	Obstetric Trauma Rate - Vaginal Delivery With Instrument	3650	32687	11167
PSI 19	Obstetric Trauma Rate - Vaginal Delivery Without Instrument	8016	461116	1738
PSE*	Patient Safety Event	87696	6753100	1299

* PSE - Composite binary variable indicating presence or absence of at least one PSI for patients in eligible population.

** Reported as rate per 100,000 discharges.

*** Data not available

Tables 4, 5, and 6 display the results of the bivariate analysis of the relationships between PSES and each of the following variables: race, insurance coverage type, and household income. Compared to those who identify as White non-Hispanic, Blacks (OR: 1.30, 95% CI: 1.27-1.32) and Asians (OR: 1.30, 95% CI: 1.26-1.35) were more likely to experience PSEs. Discharges with Medicare coverage (OR: 1.73, 95% CI: 1.70-1.75) were more likely to have experienced PSE when compared to those with private coverage. However, those with Medicaid (OR: 0.94, 95% CI: 0.92-0.96) and those with no coverage (OR: 0.59, 95% CI: 0.56-0.62) appear to be less likely to experience a patient safety event. Those in households with median income of \$43,000-\$53,999 and \$54,000-70,999 (OR: 0.95, 95% CI: 0.93-0.97) were more likely to experience a patient safety event when compared to those in households with median income of \$71,000 or more.

Table 4: Differences in PSEs across Racial Groups

Race	n	Rate	Bivariate Logistic Regression		
			OR	95% CI	P-value
White	4,248,660	1259	Reference	Reference	Reference
Black	965,217	1627	1.30	1.27-1.32	<0.001
Hispanic	757,956	1050	0.83	0.81-0.85	<0.001
Asians	195,473	1634	1.30	1.26-1.35	<0.001
Native Americans	40,540	1278	1.02	0.93-1.11	0.730
Others	212,007	1273	1.01	0.97-1.05	0.571

n - number of discharges in eligible population.

Rate - PSE rate reported per 100,000 discharges.

OR - Unadjusted odds ratio from logistic regression with Race as the sole predictor

Table 5: Differences in PSEs by Insurance Type

Payer	n	Rate	Bivariate Logistic Regression		
			OR	95% CI	P-value
Private	1,998,693	1026	Reference	Reference	Reference

Medicaid	1,452,536	960	0.94	0.92-0.96	<0.001
Medicare	2,809,364	1757	1.73	1.70-1.75	<0.001
Uninsured	287,347	606	0.59	0.56-0.62	<0.001
Others	196,335	1041	1.01	0.97-1.06	0.532

n - number of discharges in eligible population.

Rate - PSE rate reported per 100,000 discharges.

OR - Unadjusted odds ratio from logistic regression with Insurance as the sole predictor

Table 6: Differences in PSEs by Household Income

Household Income	n	Rate	Bivariate Logistic Regression		
			OR	95% CI	P-value
\$1-\$42,999	2,034,386	1328	0.99	0.98-1.02	0.735
\$43,000-\$53,999	1,692,742	1272	0.95	0.94-0.97	<0.001
\$54,000-70,999	1,590,884	1267	0.95	0.93-0.97	<0.001
\$71,000+	1,325,730	1332	Reference	Reference	Reference

n - number of discharges in eligible population.

Rate - PSE rate reported per 100,000 discharges.

OR - Unadjusted odds ratio from logistic regression with Household Income as the sole predictor

The results of the multivariate logistic regression estimating the adjusted odds of the occurrence of at least one PSE during admission is displayed in Table 7. From the results, racial and ethnic minority groups (Black – AOR 1.33, Asian – AOR 1.51, Hispanic – AOR 1.06, and Native American – AOR 1.13) were significantly more likely to experience at least one or more PSEs when compared to White non-Hispanic group. Additional multivariate regression analyses were done with modified versions of the outcome variable – patient safety events (pse). This was done to examine the impact of the different types of PSEs on the observed AORs for the different racial and ethnic groups in the original model. In each successive model, one or more PSE that racial minority groups have a higher odd of experiencing was dropped from the composite PSE variable. Results of these additional analysis are not

shown. In the first model, pressure ulcer (PSI-3) was dropped from the composite PSE variable. For this model, only the Asian ethnic group had a significantly higher odds (AOR – 1.60) of experiencing at least one or more PSEs when compared to White non-Hispanic group. Blacks and Hispanics had a significantly lower odd of experiencing at least one PSE. In the second model, obstetric trauma rate – vaginal delivery with instrument (PSI-18) and – vaginal delivery without instruments (PSI-19) were dropped from the composite PSE variable. For this model, Blacks (AOR – 1.46) and Hispanics (AOR – 1.09) had a significantly higher odds of experiencing at least one PSE when compared to White non-Hispanic group. In contrast, the odds for Asians was not significantly different from that for the White non-Hispanic group. Other models have nothing significant to report.

For insurance coverage, patients with Medicaid insurance coverage and those without coverage appear to be less likely to experience a PSE when compared to those on private insurance coverage. In contrast, patients with Medicare insurance coverage were more likely to experience at least one or more PSEs when compared to those on private insurance coverage. The adjusted odds of experiencing at least one PSE seemed to be greatest for those aged between five-years old and seventeen-years old, when compared to those aged less than five-years old (AOR: 4.87, 95% CI: 4.21-5.63).

Table 7: Multivariate Logistic Regression predicting the occurrence of at least one PSE

Variables	AOR	95% Conf. Interval	p Value
Race			
White	Reference	Reference	Reference

Black	1.33	1.31 - 1.36	0.000
Hispanic	1.06	1.03 - 1.08	0.000
Asian or Pacific Islander	1.51	1.45 - 1.56	0.000
Native American	1.13	1.03 - 1.24	0.009
Other	1.20	1.16 - 1.25	0.000
Payer			
Private	Reference	Reference	Reference
Medicaid	0.81	0.79 - 0.83	0.000
Medicare	1.09	1.06 - 1.11	0.000
Uninsured	0.58	0.55 - 0.61	0.000
Other	0.81	0.77 - 0.85	0.000
Household Income			
\$71,000+	Reference	Reference	Reference
\$54,000-70,999	0.97	0.95 - 0.99	0.007
\$43,000-\$53,999	0.97	0.95 - 0.99	0.022
\$1-\$42,999	0.97	0.95 - 0.99	0.017
Age			
<5yrs	Reference	Reference	Reference
5-17yrs	4.87	4.21 - 5.63	0.000
18-44yrs	2.38	2.28 - 2.49	0.000
45-64yrs	1.40	1.33 - 1.46	0.000
65yrs +	1.11	1.06 - 1.17	0.000
Gender			
Male	Reference	Reference	Reference
Female	0.92	0.91 - 0.94	0.000
Length of stay	1.03	1.03 - 1.03	0.000
Elixhauser Comorbidity			
0	Reference	Reference	Reference
1	0.47	0.45 0.48	0.000
2	0.51	0.50 0.53	0.000
3	0.67	0.65 0.69	0.000
4	0.80	0.78 0.83	0.000
5+	0.97	0.95 1.01	0.108
Bed size of hospital			
Small	Reference	Reference	Reference
medium	1.07	1.04 - 1.09	0.000
Large	1.13	1.10 - 1.15	0.000
Ownership of hospital			
government-nonfederal	Reference	Reference	Reference
private-non-profit	0.97	0.95 - 0.99	0.017
private-investor-own	0.91	0.89 - 0.94	0.000
Hospital Location/Teaching Status			
rural	Reference	Reference	Reference
urban-non-teaching	1.12	1.09 - 1.16	0.000
urban-teaching	1.29	1.25 - 1.33	0.000
Hospital Region			

Northeast	Reference	Reference	Reference
Midwest	1.04	1.02 - 1.07	0.000
South	1.07	1.05 - 1.10	0.000
West	1.13	1.10 - 1.15	0.000

The analysis also controlled for admission type (elective vs non-elective) and discharge status.

All the other age-groups were also significantly more likely to experience at least one PSEs compared to patients under five-years old. Female patients were slightly less likely to experience a PSE when compared to male patients (AOR: 0.92, 95% CI: 0.91-0.94). For each additional day of admission, the adjusted odds of experiencing at least one or more PSEs increases by a factor of 1.03. Patients in medium and large bed-size hospital were more likely to experience a PSE when compared to those in small bed-size hospitals. Patients in private hospitals (private and investor-owned) were less likely to experience a PSE when compared to those in government non-federal hospitals. In addition, patients in urban hospitals (teaching and non-teaching) were more likely to experience a patient safety event when compared to those in rural hospitals. Patients in all other hospital regions were more likely to experience a patient safety event compared to those admitted to hospitals in the Northeast hospital region.

Table 8 displays results from bivariate and multivariate analysis examining the relationships between different types of patient safety events and race. The table summarizes the rates and adjusted odds of occurrence of each type of patient safety event by racial group. The top three patient safety events reported for Black patients were *Death Rate among Surgical*

Inpatients with Serious Treatable Complications (PSI 4; Rate 14,815 per 100,000 discharges), *Obstetric Trauma Rate-Vaginal Delivery With Instrument* (PSI 18; Rate 6,740 per 100,000 discharges), and *Pressure Ulcer* (PSI 3; Rate 2,117 per 100,000 discharges). Compared to the White non-Hispanic racial group, Blacks were more likely to experience *Pressure Ulcer* (PSI 03, AOR: 1.92, 95% CI: 1.90-1.97), *Central Venous Catheter-Related Blood Stream Infection* (PSI 07, AOR: 1.29, 95% CI: 1.09-1.53), and *Perioperative Pulmonary Embolism or Deep Vein Thrombosis* (PSI 12, AOR: 1.19, 95% CI: 1.13-1.26). However, they were also less likely to experience PSIs 06, 08, 14, 15, 17, 18, and 19 compared to White non-Hispanic. For Hispanics, the top three reported patient safety events were *Death Rate among Surgical Inpatients with Serious Treatable Complications* (PSI 04; Rate 15,054 per 100,000 discharges), *Obstetric Trauma Rate-Vaginal Delivery With Instrument* (PSI 18; Rate 8,707 per 100,000 discharges), and *Obstetric Trauma Rate-Vaginal Delivery Without Instrument* (PSI 19; Rate 1,264 per 100,000 discharges). Hispanics were more likely to experience *Pressure Ulcer* (PSI 03, AOR: 1.25, 95% CI: 1.20-1.29) and less likely to experience PSIs 07, 08, 12, 17, and 19 when compared to White non-Hispanic group. The top three patient safety events reported for Asians were *Obstetric Trauma Rate-Vaginal Delivery With Instrument* (PSI 18; Rate 17,670 per 100,000 discharges), *Death Rate among Surgical Inpatients with Serious Treatable Complications* (PSI 04; Rate 16,885 per 100,000 discharges), and *Obstetric Trauma Rate-Vaginal Delivery Without Instrument* (PSI 19; Rate 3,724 per 100,000 discharges). When compared to White non-Hispanics, Asians were more likely to experience the

following patient safety events: *Death Rate in Low-Mortality Diagnosis Related Groups* (PSI 02, AOR: 2.14, 95% CI: 1.10-4.18), *Death Rate among Surgical Inpatients with Serious Treatable Complications* (PSI 04, AOR: 1.27, 95% CI: 1.08-1.48), *Perioperative Hemorrhage or Hematoma Rate* (PSI 09, AOR: 1.35, 95% CI: 1.10-1.66), *Obstetric Trauma Rate-Vaginal Delivery With Instrument* (PSI 18, AOR: 1.8, 95% CI: 1.61-2.01), and *Obstetric Trauma Rate-Vaginal Delivery Without Instrument* (PSI 19, AOR: 2.02, 95% CI: 1.88-2.18). They were less likely to experience PSIs 8 and 12.

Table 8: Race by type of Patient Safety Event (PSE)

Indicator	n	White		Black			Hispanic			Asian					
		Rate	(n)	Rate	AOR	95% CI	Rate	AOR	95% CI	Rate	AOR				
PSI 2	1,173,794	22	(12)	22	(12)	1.15	0.79-1.67	14	(13)	1.28	0.83-1.96	22	(12)	2.14	1.10-4.18
PSI 3	3,233,843	1165	(4)	2117	(3)	1.92***	1.90-1.97	1212	(4)	1.25***	1.20-1.29	1228	(4)	1.27	1.08-1.48
PSI 4	47,216	14383	(1)	14815	(1)	1.08	0.99-1.17	15054	(1)	1.07	0.97-1.17	16885	(2)	1.35	1.10-1.66
PSI 6	4,674,896	31	(11)	19	(13)	0.59***	0.49-0.72	27	(11)	0.88	0.72-1.08	35	(11)	1.8	1.61-2.01
PSI 7	3,770,483	19	(13)	39	(10)	1.29**	1.09-1.53	16	(12)	0.74*	0.56-0.97	16	(13)	2.02	1.88-2.18
PSI 8	3,953,788	77	(10)	31	(11)	0.51***	0.44-0.60	41	(10)	0.65***	0.55-0.77	50	(10)		
PSI 9	1,306,386	270	(7)	351	(7)	1.08	0.98-1.20	254	(7)	0.95	0.84-1.08	362	(7)	1.3	1.10-1.66
PSI 12	1,405,281	758	(5)	1195	(4)	1.19***	1.13-1.26	713	(5)	0.85***	0.79-0.92	653	(5)	0.71	0.60-0.79
PSI 14	373,912	85	(9)	55	(9)	0.65*	0.42-0.99	60	(9)	0.85	0.55-1.31	53	(9)		
PSI 15	887,628	118	(8)	101	(8)	0.81*	0.66-0.99	128	(8)	1.1	0.90-1.35	160	(8)		
PSI 17	660,884	506	(6)	355	(6)	0.68***	0.60-0.77	406	(6)	0.79***	0.71-0.88	453	(6)		
PSI 18	30,649	11226	(2)	6740	(2)	0.69***	0.60-0.79	8707	(2)	0.93	0.83-1.04	17670	(1)	1.8	1.61-2.01
PSI 19	432,984	1876	(3)	913	(5)	0.59***	0.54-0.65	1264	(3)	0.83***	0.77-0.89	3724	(3)	2.02	1.88-2.18
PSE	6419853	1258		1627		1.33***	1.31-1.36	1050		1.06***	1.03-1.08	1634		1.51	

* p Value <0.05, ** p Value <0.01, *** p Value <0.001

Rate is reported per 100,000 discharges. (X) denotes the rank of the PSE within the racial group
n represents the population at risk for the patient safety event(s).

DISCUSSION

This study examined the current rates of patient safety events (PSE) among hospitalized individuals and possible disparities in reported PSE rates by socioeconomic characteristics (race/ethnicity, income level, and insurance type). This is the first study to use nationally representative data to examine PSEs in the last decade. This study observed a PSE rate of 1,299 PSEs per 100,000 discharges, with the figure representing discharges with at least one patient safety event documented. No prior studies have reported a composite PSE rate in the way it is being reported in this study. Rather they have reported an aggregate number of PSE rates, which is simply a summation of the rates of all the PSEs (Downey et al, 2012). To put this study in context with previous finding in literature, the aggregate number of PSE rates found in this study is 30,839 PSEs per 100,000 discharges. This is lower than a previous rate of 35,815 PSEs per 100,000 discharges reported in 2007 (Downey et al, 2012). Downey et al (2012) observed a decrease in the aggregate PSE rate from 45,401 per 100,000 discharges in 1998 to 35,815 PSEs per 100,000 discharges reported in 2007. Thus, it appears that occurrence of PSEs decreased much more rapidly in the previous decade compared to the current one. While it might be plausible that the PSE rate has decreased, considering greater awareness and several patient safety improvement initiatives across the country in the last decade, there could be alternative explanations for the lower rate that we observed

for 2016. First, a lot has changed with the PSIs since the time of the Downey study. There have been several changes in the definitions of the different PSIs. These revisions have progressively made the PSI definitions more restrictive, which could have resulted in an artificial decline in rates (Bahl et al. 2008). Changes in PSI definitions are in line with AHRQ's goal to keep the indicators relevant (AHRQ, 2019; Romano, Mull, and Rivard 2009). Also, the revisions have led to variation in the number of indicators across the years. At the time of the Downey et al study, there were 20 PSI, however there are currently 17 PSIs in existence. The rate reported by the Downey et al study included 15 indicators, while the rate in the current study includes only 14 indicators. Finally, the transition from ICD-9-CM to ICD-10-CM for PSE case definition might have also impacted the reported rates.

Reporting an aggregate number of PSE rates may lead to an incorrect estimation of the burden of PSEs. Some records may also have several types of PSEs documented, leading to duplicate counts. While it may good to estimate the number of PSEs experienced for each hospitalization episode, the most important PSE is the first one. Each successive PSEs increases the risk of another occurring, thus the focus should be on preventing the first PSE. In order to address the highlighted concerns, this study utilized the composite PSE rate which is reported here. Despite the apparent improvement in patient safety, the rate found in this study is still too high as any number of accidents/incidents that reach individuals as a result of their interaction with the healthcare system is unacceptable.

PSI-3 (Pressure Ulcer Rate) was by far the PSE most observed among the at-risk population in this study, accounting for about half of all PSEs. This was followed by PSI-12 (Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate) and PSI-19 (Obstetric Trauma Rate - Vaginal Delivery Without Instrument). While these three were experienced by more people in the PSE at-risk population, only PSI-19 (with the third highest rate) was among the top 3 PSEs (PSI-4, PSI-18, and PSI-19) when you examine PSEs in relation to their respective at-risk populations. The top three PSE rates as observed in this study are consistent with previous finding using NIS (Downey et al, 2010), albeit with a different order. Although PSI-4 (Death Rate Among Surgical Inpatients With Serious Treatable Conditions,) and PSI-18 (Obstetric Trauma Rate - Vaginal Delivery With Instrument) had among the smallest populations at risk (denominators), they were responsible for the two highest PSE rates respectively. Both PSEs involve procedures on the body with surgical or other equipment, pointing to the need to improve training and expertise in surgical skills and obstetric procedures. Furthermore, two of the three highest PSE rates were observed in obstetric events (PSI-18 and PSI-19), indicating persisting high levels of PSEs during childbirth.

None of the discharges in this study had a flag for PSI-10, PSI-11, or PSI-13. It is possible that none of discharges included in this study had a documentation for the ICD-10 codes in the case definition for the PSEs. It is also possible that the AHRQ WinQI software did not generate flags for these PSEs for the following reasons: inability to risk-adjust

indicator, and/or small sample size (Downey et al, 2012). No rates were reported for PSI-5 as the current AHRQ case definition for this measure does not include an at-risk population or any other denominator description (AHRQ, 2019). However, 302 discharges in our study had a documentation for retained surgical item or unretrieved device fragment count (PSI-5). This PSE is considered a grave but preventable PSE that should never happen (Asiyanbola, Etienne-Cummings, & Lewi, 2012; Norton, Martin, & Micheli, 2012). Like all sentinel events, it is reportable to the Joint Commission and is prioritized for elimination (FencI, 2016). The Association of periOperative Registered Nurses (AORN) guidelines for prevention of retained surgical items has been a reliable guide for addressing this PSE, including such recommendations as addressing prevention of this PSE using a team approach; minimizing distractions, noise, and interruptions during surgical counts; adopting a consistent counting method; ensuring that discrepancies are resolved when observed; and taking a system-approach to performance-improvement to reduce the occurrence of this PSE (FencI 2016). The number of cases for PSI-5 reported in this study is much lower than the 2000 cases reported by Coffey et al (2005) but higher than the 269 cases reported by Shimada et al (2008). The data set and population in both studies are different from the current study. The Coffey et al study used data from HCUP's State Inpatient Databases for year 2000. The data was limited to 16 states that had race/ethnicity documented for a least 90% of their discharge records for year 2000. The Shimada et al study used pooled 2001 – 2005 discharge data from the Veterans Health Administration's administrative databases.

Though the populations in the prior study differ, the current study has a much broader population and a large number should have been observed.

A major goal for this study was to assess if there are socioeconomic disparities in PSEs among hospitalized patients in the US. We observed that racial and ethnic minority groups were significantly more likely to experience at least one or more PSEs when compared to the White non-Hispanic group (Black – AOR, 1.33, Asian – AOR 1.51, and Hispanic – AOR 1.06). Almost two decades after the Institute of Medicine Report highlighting the differences in the quality of care received by racial and ethnic minority groups, this observation confirms findings in literature that disparities in care persist (Nelson, 2002; Shen et al, 2016; Coffey et al, 2005; Shimada et al, 2008).

This study also explored the racial disparities that were reported for the different types of PSEs. There were slight differences in the type of PSE most common for various racial/ethnic groups (i.e. Blacks, Asians, and Hispanics). Among Asians and Hispanics, the top five reported PSEs were the same as for the general population (i.e. PSI-4, PSI-18, and PSI-19), although PSI-18 ranked highest among Asians. However, the top three PSEs reported for Black patients were PSI 4 (Death Rate among Surgical Inpatients with Serious Treatable Complications), PSI 18 (Obstetric Trauma Rate-Vaginal Delivery with Instrument), and PSI 3 (Pressure Ulcer). Notably, Blacks had nearly twice the odds of experiencing pressure ulcers compared to Non-Hispanic Whites and other populations. The findings for

the relationship between racial/ethnic minorities and different PSEs is consistent with prior studies in some areas and different in others. Coffey et al (2005), Shimada et al (2008) and Shen et al (2016) found that higher pressure ulcer rates were reported for racial and ethnic minority groups, with Blacks having the highest rates. While the Coffey et al study did not report on the odds of experiencing pressure ulcer, the Shimada et al study found odds that were similar to this study, and the Shen et al study reported odds that were different from what was found in this study. This study and the Shen study found that Blacks had a significantly higher odds of experiencing pressure ulcer compared to White non-Hispanic group. In this study, Hispanics were observed to have a significantly higher odds of experiencing pressure ulcer, while odds for Asians were not significantly different from White non-Hispanic. In contrast, the Shen Study found Asians to have a significantly higher odds while the odds for Hispanics was not significant. The findings in this study also suggest that the disparities in pressure ulcer appears to be worsening for the Black ethnic group (cf. Shimada Study AOR 1.35 vs Shen Study AOR 1.61 vs Current Study AOR 1.92). Some studies have suggested that disparities in PSEs such as pressure ulcer are not due to differences in care provided to minority racial/ethnic groups, but that patients from minority groups are more likely to seek care in facilities that are less safe i.e. provide poorer quality of care to all patients irrespective of race (Cai, Mukamel, & Temkin-Greener, 2010; Metersky, Hunt, Kliman et al, 2011).

Though all the racial and ethnic minority groups have high rates for obstetric-related PSEs (PSI-18 & PSI-19), only the Asian racial group has a higher odds of experiencing these PSEs when compared to the White non-Hispanic group. Hispanics and Blacks had lower odds of experiencing obstetric-related PSEs. Just like the case of pressure ulcers for the Black racial group, the obstetric trauma (PSI 18 & 19) rate for Asians is 2 – 3 times the rate for other populations. This observation is consistent with findings by Coffey et al (2005), Grobman et al (2015) and Shen et al (2016) in their respective studies. The theory about minorities seeking care in facilities that are less safe does not fully explain this finding as the experience appears unique for the Asian group. A possible explanation could be that Asians have a much higher exposure for obstetric related procedures hence the higher risk. However, this theory is unlikely as findings in literature suggest a lower utilization of obstetric services by Asians. While fertility rate has been declining for all minority groups, the decline has been highest for the Asian group. The group currently has the lowest birth rate among the minority groups in this study (Martin, Hamilton, Osterman, & Driscoll, 2019). The only plausible explanation for this observation limitation in English proficiency. The rise in Asian population in the United states is driven mainly by immigration and most of these immigrants have limited English proficiency which may increase their risk of experiencing PSEs when hospitalized (Betancourt et al, 2012; Flores, 2000; Flores et al., 2002).

A review of the different types of PSEs reported for the different racial and minority groups (outlined above) and the results of the additional regression models (Models 1 & 2) in this study provide possible explanation for the PSEs driving the racial disparities noted in the composite PSE variable used in this study (Black – AOR, 1.33, Asian – AOR 1.51, and Hispanic – AOR 1.06). Put together, these findings indicate that pressure ulcer rates (PSI-3) is primarily responsible for the disparities found in the composite PSE for the Black and Hispanic groups. When pressure ulcer rate is dropped from the composite PSE, the disparities disappear for Blacks and Hispanics, after adjusting for other covariates. For Asians, the disparities disappear only when the two obstetric trauma PSEs (PSI-18 and PSI-19) are dropped from the composite PSE variable. The disparities remain if only one of the obstetric trauma PSEs (or any individual PSE) is dropped. It follows that disparities for Asians are driven by a combination of the obstetric trauma PSEs.

Differences in PSE rates were observed for insurance coverage. The highest PSE rate was observed for patients covered by Medicare while the uninsured had the least rates. The observation for these two groups might be explained by their respective levels of exposure in the at-risk population (2,809,364 vs 287,347 discharges). This study also found that compared to the patients covered by private/employer-based insurance, only the group covered by Medicare had a higher odd of experiencing at least one patient safety event. Other groups had a lower odd of experiencing a PSE. This finding is similar in some ways to prior findings by Spencer et al (2013) and Shen et al (2016). The Spencer et al study found a

higher odds for Medicare patients in 8 of the 15 PSEs they examined. While the Shen et al study did not report their findings for Medicare patients. Patients covered by Medicare are often elderly and may have other comorbidities which could ultimately lead to higher exposure to the healthcare providers. In contrast to this study both prior studies found higher odds for Medicaid.

CONCLUSION

This study assessed PSE rates using nationally representative hospital discharge data in the US. It assessed for socioeconomic disparities in PSEs and identified the specific types of PSEs that are most often reported for racial/ethnic minority inpatients. The study found that PSEs rates in 2016 were lower compared to reported national rates in 2007. Although the rate was lower, a PSE rate of 1,299 PSEs per 100,000 discharges is still too high considering that these are accidents or incidents that reached patients, not including near misses and other indicators of underlying lapses in patient safety environment. Racial/ethnic minorities and patients on Medicare were found to have higher odds of experiencing PSEs. While greater healthcare utilization could be driving the higher rates for the Medicare population, the persisting disparities for racial/ethnic minorities need to be addressed. Finally, Blacks

had nearly twice the odds of experiencing pressure ulcers compared to Non-Hispanic Whites and other populations. Pressure ulcers was found to be the primary driver for disparities in PSEs for Blacks and Hispanics, while obstetric trauma drives the disparities observed in Asians.

This study recommends that health systems should adopt heightened surveillance and specific nursing interventions to proactively prevent the development of pressure ulcers among hospitalized patients, especially those from racial/ethnic minority groups. All members of the inpatient care team should be trained on appropriate skin care for patients on admission, especially for patients who are restricted to their bed while on admission. Where possible, hospitals should utilize beds that are designed to relieve pressure and prevent ulcers. Hospitals should utilize professional medical interpreter services when providing care to patients with limited English proficiency. In addition, providers need to be trained on cultural sensitivity and the specific risk factors faced by different racial/ethnic minority patient groups. A good understanding of the cultural nuances and the PSE risks will help guide providers in their clinical interaction with patients and possibly lead to a reduction in the risk of occurrence of patient safety events. To help reduce the incidence of obstetric trauma experienced by Asians and other minority groups as observed in this study, there is need for improved prenatal care for these groups. Obstetric services should be classified as primary care services and be available, with no copay or co-insurance, at all healthcare facilities including safety net hospitals. Clinicians involved in obstetric care

should spend time getting to know their patients before the delivery. This process should include a comprehensive history of prior pregnancies and obstetric examination at each prenatal visit. Health systems should adopt the medical home model for obstetric care and should ensure that all members of a patient's care team are conversant with the history. Except in exceptional cases, only providers who have been part of a patient's care should lead the delivery team.

Further research is needed to understand the factors that predispose minority patients, especially black patients, to a disproportionately high risk of pressure ulcers. In addition, research is needed to understand what factors in the obstetric care of Asians that predispose them to obstetric trauma.

There are some limitations to bear in mind when interpreting the findings of this study. First is that PSIs by definition only capture inpatient medical, surgical, and obstetric patient safety events. They do not capture medication errors, which tends to occur at a higher frequency than the PSIs (Kohn, Corrigan, & Donaldson, 2000; Bates, Cullen, Laird et al, 1995). Second, PSIs capture only PSEs that reach the patient (i.e accidents/incidents) but do not capture near misses/close calls, dangerous or unsafe conditions, and errors and deviations. Failure to address these other patient safety risks point to underlying lapses in the process of healthcare delivery that ultimately could lead to patient harm. Third, the nature of the HCUP NIS dataset are such that the unit of analysis are

hospitalizations/discharges and not individuals, so if an individual were to experience multiple hospitalizations/discharges in a given year they would be counted multiple times in the dataset. This is of concern since frequent inpatient care utilization could increase one's risk of experiencing a PSE.

Despite the limitations, the HCUP NIS data used in this study covers a large population sample that is representative of the population of hospitalized patients across the United States. Also the measure of patient safety events being using in the study, PSI, was specifically designed for administrative databases

APPENDICES

Appendix A-1: Patient Safety Indicators

INDICATOR	LABEL	NUMERATOR	DENOMINATOR	EXCLUSIONS
PSI #2	Death Rate in Low-Mortality Diagnosis Related Groups (DRGs)	Number of deaths among cases meeting the inclusion and exclusion rules for the denominator.	Discharges, for patients ages 18 years and older or MDC 14 (pregnancy, childbirth, and puerperium), with a low mortality (less than 0.5% mortality)	cases with trauma, cases with cancer, cases with an immunocompromised state, and transfers to an acute care facility.
PSI #3	Pressure Ulcer Rate	Discharges, among cases meeting the inclusion and exclusion rules for the denominator, with any secondary ICD-10-CM diagnosis codes for pressure ulcer stage III or IV (or unstageable)	Surgical or medical discharges, for patients ages 18 years and older	Stays less than 3 days; cases with a principal stage III or IV (or unstageable) pressure ulcer diagnosis; cases with a secondary diagnosis of stage III or IV pressure ulcer (or unstageable) that is present on admission; obstetric cases; severe burns; exfoliative skin disorders.
PSI #4	Death Rate among Surgical Inpatients with Serious Treatable Conditions	Number of deaths among cases meeting the inclusion and exclusion rules for the denominator	Surgical discharges for patients ages 18 through 89 years or MDC 14 (pregnancy, childbirth, and puerperium)	Excludes cases transferred to an acute care facility and cases in hospice care at admission.
PSI #5	Retained Surgical Item or Unretrieved Device Fragment Count	Number of patients in the denominator with any secondary ICD-10-CM diagnosis codes for retained surgical item or unretrieved device fragment		Excludes cases with principal diagnosis of retained surgical item or unretrieved device fragment and cases with a secondary diagnosis of retained surgical item or unretrieved device fragment present on admission
PSI #6	Iatrogenic Pneumothorax Rate	Discharges, among cases meeting the inclusion and exclusion rules for the denominator, with any secondary ICD-10-CM diagnosis codes for iatrogenic pneumothorax	Surgical and medical discharges for patients ages 18 years and older	Cases with chest trauma, pleural effusion, thoracic surgery, lung or pleural biopsy, diaphragmatic repair, or cardiac procedures; cases with a principal diagnosis of iatrogenic pneumothorax; cases with a secondary diagnosis of iatrogenic pneumothorax present on admission; and obstetric cases.

Source: AHRQ Patient Safety Indicators Technical Specifications Updates - Version v2018 and v2018.0.1 (ICD 10), June 2018

Appendix A-2: Patient Safety Indicators

INDICATOR	LABEL	NUMERATOR	DENOMINATOR	EXCLUSIONS
PSI #7	Central Venous Catheter-Related Blood Stream Infection Rate	Discharges, among cases meeting the inclusion and exclusion rules for the denominator, with any secondary ICD-10-CM diagnosis codes for central venous catheter-related bloodstream infections	Surgical and medical discharges for patients ages 18 years and older or MDC 14 (pregnancy, childbirth, and puerperium)	Cases with a principal diagnosis of a central venous catheter-related bloodstream infection, cases with a secondary diagnosis of a central venous catheter-related bloodstream infection present on admission, cases with stays less than 2 days, cases with an immunocompromised state, and cases with cancer
PSI #8	In Hospital Fall with Hip Fracture Rate	Discharges, among cases meeting the inclusion and exclusion rules for the denominator, with any secondary ICD-10-CM diagnosis codes for hip fracture	Discharges, ages 18 years and older, in a medical DRG or in a surgical DRG	Discharges with principal diagnosis of a condition with high susceptibility to falls (seizure disorder, syncope, stroke, occlusion of arteries, coma, cardiac arrest, poisoning, trauma, delirium or other psychoses, anoxic brain injury), diagnoses associated with fragile bone (metastatic cancer, lymphoid malignancy, bone malignancy), a principal diagnosis of hip fracture, a secondary diagnosis of hip fracture present on admission, and obstetric cases.
PSI #9	Perioperative Hemorrhage or Hematoma Rate	Discharges, among cases meeting the inclusion and exclusion rules for the denominator, with any secondary ICD-10-CM diagnosis codes for perioperative hemorrhage or hematoma and any ICD-10-PCS procedure codes for treatment of hemorrhage or hematoma	Surgical and medical discharges for patients ages 18 years and older	Cases with a diagnosis of coagulation disorder; cases with a principal diagnosis of perioperative hemorrhage or hematoma; cases with a secondary diagnosis of perioperative hemorrhage or hematoma present on admission; cases where the only operating room procedure is for treatment of perioperative hemorrhage or hematoma; obstetric cases.
PSI #10	Postoperative Acute Kidney Injury Requiring Dialysis	Discharges, among cases meeting the inclusion and exclusion rules for the denominator, with any secondary ICD-10-CM diagnosis codes for acute kidney failure and any ICD-10-PCS procedure codes for dialysis	Elective surgical discharges, for patients ages 18 years and older, with any ICD-10-PCS procedure codes for an operating room procedure	Cases with principal diagnosis of acute kidney failure; cases with secondary diagnosis of acute kidney failure present on admission; cases with secondary diagnosis of acute kidney failure and dialysis procedure before or on the same day as the first operating room procedure; cases with acute kidney failure, cardiac arrest, severe cardiac dysrhythmia, cardiac shock, chronic kidney failure; a principal diagnosis of urinary tract obstruction and obstetric cases.

Source: AHRQ Patient Safety Indicators Technical Specifications Updates - Version v2018 and v2018.0.1 (ICD 10), June 2018

Appendix A-3: Patient Safety Indicators

INDICATOR	LABEL	NUMERATOR	DENOMINATOR	EXCLUSIONS
PSI #11	Postoperative Respiratory Failure Rate	Discharges, among cases meeting the inclusion and exclusion rules for the denominator, with either: <ul style="list-style-type: none"> • any secondary ICD-10-CM diagnosis code for acute respiratory failure • any secondary ICD-10-PCS procedure codes for a mechanical ventilation for 96 consecutive hours or more that occurs zero or more days after the first major operating room procedure code (based on days from admission to procedure); • any secondary ICD-10-PCS procedure codes for a mechanical ventilation for less than 96 consecutive hours (or undetermined) that occurs two or more days after the first major operating room procedure code (based on days from admission to procedure); • any secondary ICD-10-PCS procedure codes for a reintubation that occurs one or more days after the first major operating room procedure code (based on days from admission to procedure) 	Elective surgical discharges for patients ages 18 years and older, with any ICD-10-PCS procedure codes for an operating room procedure	Cases with principal diagnosis for acute respiratory failure; cases with secondary diagnosis for acute respiratory failure present on admission; cases in which tracheostomy is the only operating room procedure or in which tracheostomy occurs before the first operating room procedure; cases with neuromuscular disorders; cases with laryngeal, oropharyngeal or craniofacial surgery involving significant risk of airway compromise; esophageal resection, lung cancer, lung transplant or degenerative neurological disorders; cases with respiratory or circulatory diseases; and obstetric discharges
PSI #12	Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate	Discharges, among cases meeting the inclusion and exclusion rules for the denominator, with a secondary ICD10-CM diagnosis code for proximal deep vein thrombosis or a secondary ICD-10-CM diagnosis code for pulmonary embolism	Surgical discharges, for patients ages 18 years and older, with any ICD-10-PCS procedure codes for an operating room procedure.	Discharges with a principal diagnosis of pulmonary embolism or proximal deep vein thrombosis; with a secondary diagnosis of pulmonary embolism or proximal deep vein thrombosis present on admission; in which interruption of the vena cava or a pulmonary arterial thromboectomy occurs before or on the same day as the first operating room procedure; with extracorporeal membrane oxygenation; with acute brain or spinal injury present on admission; and obstetric cases.

Source: AHRQ Patient Safety Indicators Technical Specifications Updates - Version v2018 and v2018.0.1 (ICD 10), June 2018

Appendix A-4: Patient Safety Indicators

INDICATOR	LABEL	NUMERATOR	DENOMINATOR	EXCLUSIONS
PSI #13	Postoperative Sepsis Rate	Discharges, among cases meeting the inclusion and exclusion rules for the denominator, with any secondary ICD-10-CM diagnosis codes for sepsis	Elective surgical discharges for patients ages 18 years and older, with anylisted ICD-10-PCS procedure codes for an operating room procedure.	Cases with a principal diagnosis of sepsis, cases with a secondary diagnosis of sepsis present on admission, cases with a principal diagnosis of infection, cases with a secondary diagnosis of infection present on admission (only if they also have a secondary diagnosis of sepsis), obstetric discharges.
PSI #14	Postoperative Wound Dehiscence Rate	Discharges, among cases meeting the inclusion and exclusion rules for the denominator, with anylisted ICD-10-PCS procedure code for repair of abdominal wall and with any ICD-10-CM diagnosis code for disruption of internal surgical wound.	Discharges, for patients ages 18 years and older, with any ICD-10-PCS procedure codes for abdominopelvic surgery, open approach, or with any ICD-10-PCS procedure codes for abdominopelvic surgery, other than open approach	Cases in which the abdominal wall reclosure occurs on or before the day of the first abdominopelvic surgery, cases with an immunocompromised state, cases with stays less than two (2) days, and obstetric cases.
PSI #15	Unrecognized Abdominopelvic Accidental Puncture/Laceration Rate	Discharges, among cases meeting the inclusion and exclusion rules for the denominator, with: <ul style="list-style-type: none"> • Any secondary ICD-10CM diagnosis codes for accidental puncture or laceration during a procedures; and • A second abdominopelvic procedure (ABDOMI15P) =>1 day after an index abdominopelvic procedure. 	Surgical and medical discharges, for patients ages 18 years and older with any ICD-10-PCS procedure code for an abdominopelvic procedure	Cases with accidental puncture or laceration as a principal diagnosis, cases with accidental puncture or laceration as a secondary diagnosis that is present on admission, and obstetric cases.
PSI #16	Transfusion Reaction Count	Surgical and medical discharges for patients ages 18 years and older or MDC 14 (pregnancy, childbirth, and puerperium), with any secondary ICD-10-CM diagnosis codes for transfusion reaction.	Surgical and medical discharges for patients ages 18 years and older or MDC 14 (pregnancy, childbirth, and puerperium)	Cases with a principal diagnosis of transfusion reaction or cases with a secondary diagnosis of transfusion reaction that is present on admission. Also exclude cases: <ul style="list-style-type: none"> • with a principal ICD-10-CM diagnosis code (or secondary diagnosis present on admission) for transfusion reaction • with missing gender, age, quarter, year, or principal diagnosis

Source: AHRQ Patient Safety Indicators Technical Specifications Updates - Version v2018 and v2018.0.1 (ICD 10), June 2018

Appendix A-5: Patient Safety Indicators

INDICATOR	LABEL	NUMERATOR	DENOMINATOR	EXCLUSIONS
PROVIDER-LEVEL INDICATORS				
PSI #17	Birth Trauma Rate – Injury to Neonate	Discharges, among cases meeting the inclusion and exclusion rules for the denominator, with any ICD-10-CM diagnosis codes for birth trauma	All newborns	Preterm infants with a birth weight less than 2,000 grams, and cases with osteogenesis imperfecta.
PSI #18	Obstetric Trauma Rate – Vaginal Delivery with Instrument	Discharges, among cases meeting the inclusion and exclusion rules for the denominator, with any-listed ICD-10-CM diagnosis codes for third- and fourth-degree obstetric trauma	Vaginal deliveries, with any-listed ICD-10-CM diagnosis code for outcome of delivery with any-listed ICD-10-PCS code for vaginal delivery and any-listed ICD-10-PCS procedure codes for instrument-assisted deliveries	Cases with missing gender, age, quarter, year, or principal diagnosis
PSI #19	Obstetric Trauma Rate - Vaginal Delivery Without Instrument	Discharges, among cases meeting the inclusion and exclusion rules for the denominator, with any ICD10-CM diagnosis codes for third- and fourth-degree obstetric trauma	Vaginal deliveries, identified by any listed ICD-10-CM diagnosis code for outcome of delivery with any-listed ICD-10-PCS code for vaginal delivery	Cases: <ul style="list-style-type: none"> • with any listed ICD-10-PCS procedure codes for instrument-assisted delivery • with missing gender, age, quarter, year, or principal diagnosis

Source: AHRQ Patient Safety Indicators Technical Specifications Updates - Version v2018 and v2018.0.1 (ICD 10), June 2018

Appendix B: All States, by U.S Census Bureau Region

Region	States*
Northeast	Connecticut, Maine, Massachusetts, New Hampshire†, New Jersey, New York, Pennsylvania, Rhode Island, Vermont.
Midwest	Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, Wisconsin.
South	<i>Alabama, Arkansas, Delaware, District of Columbia</i> , Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, West Virginia.
West	Alaska, Arizona, California, Colorado, Hawaii, <i>Idaho</i> , Montana, Nevada, New Mexico, Oregon, Utah, Washington, Wyoming.

*States/areas in italics do not participate in HCUP.

Appendix C: Hospital Size Categories (in Number of Beds), by Region

	Location and Teaching Status	Hospital Bed Size		
		Small	Medium	Large
NORTHEAST	Rural	1 - 49	50 - 99	100+
	Urban, non-teaching	1 - 124	125 - 199	200+
	Urban, teaching	1 - 249	250 - 424	425+
MIDWEST	Rural	1 - 29	30 - 49	50+
	Urban, non-teaching	1 - 74	75 - 174	175+
	Urban, teaching	1 - 249	250 - 374	375+
SOUTH	Rural	1 - 39	40 - 74	75+
	Urban, non-teaching	1 - 99	100 - 199	200+
	Urban, teaching	1 - 249	250 - 449	450+
WEST	Rural	1 - 24	25 - 44	45+
	Urban, non-teaching	1 - 99	100 - 174	175+
	Urban, teaching	1 - 199	200 - 324	325+

Appendix D-1: Elixhauser Comorbidity Coding Algorithms

Comorbidities	Elixhauser's original ICD-9-CM	ICD-10-CM
Congestive Heart Failure	398.91, 402.11, 402.91, 404.11, 404.13, 404.91, 404.93, 428.x	I09.9, I11.0, I13.0, I13.2, I25.5, I42.0, 142.5-I42.9, I43.x, I50.x, P29.0
Cardiac Arrhythmias	426.10, 426.11, 426.13, 426.2-426.53, 426.6-426.8, 427.0, 427.2, 427.31, 427.60, 427.9, 785.0, V45.0, V53.3	I44.1-I44.3, I45.6, I45.9, I47.x-I49.x, ROO.O, ROO.1, ROO.8, T82.1, Z45.0, Z95.0
Valvular disease	093.2, 394.0-397.1, 424.0-424.91, 746.3-746.6, V42.2, V43.3	A52.0, I05.x-I08.x, I09.1, I09.8, I34.x-I39.x, Q23.0-Q23.3, Z95.2, Z95.4
Pulmonary Circulation Disorders	416.x, 417.9	I26.x, I27.x, I28.0, I28.8, I28.9
Peripheral vascular disorders	440.x, 441.2, 441.4, 441.7, 441.9, 443.1-443.9, 447.1, 557.1, 557.9, V43.4	I70.x, I71.x, I73.1, I73.8, I73.9, I77.1, I79.0, I79.2, K55.1, K55.8, K55.9, Z95.8, Z95.9
Hypertension, uncomplicated	401.1, 401.9	I10.x
Hypertension, complicated	402.10, 402.90, 404.10, 404.90, 405.1, 405.9	I11.x-I13.x, I15.x
Paralysis	342.0, 342.1, 342.9-344.x	G04.1, G11.4, G80.1, G80.2, G81.x, G82.x, G83.0-G83.4, G83.9
Other neurological disorders	331.9, 332.0, 333.4, 333.5, 334.x, 335.x, 340.x, 341.1-341.9, 345.0, 345.1, 345.4, 345.5, 345.8, 345.9, 348.1, 348.3, 780.3, 784.3	G10.x-G13.x, G20.x-G22.x, G25.4, G25.5, G31.2, G31.8, G31.9, G32.x, G35.x-G37.x, G40.x, G41.x, G93.1, G93.4, R47.0, R56.x
Chronic pulmonary disease	490-492.8, 493.00-493.91, 494.x-505.x, 506.4	I27.8, I27.9, J40.x-J47.x, J60.x-J67.x, J68.4, J70.1, J70.3
Diabetes, uncomplicated	250.0-250.3	E10.0, E10.1, E10.9, E11.0, E11.1, E11.9, E12.0, E12.1, E12.9, E13.0, E13.1, E13.9, E14.0, E14.1, E14.9
Diabetes, complicated	250.4-250.7, 250.9	E10.2-E10.8, E11.2-E11.8, E12.2-E12.8, E13.2-E13.8, E14.2-E14.8
Hypothyroidism	243-244.2, 244.8, 244.9	E00.x-E03.x, E89.0
Renal failure	403.11, 403.91, 404.12, 404.92, 585.x, 586.x, V42.0, V45.1, V56.0, V56.8	I12.0, I13.1, N18.x, N19.x, N25.0, Z49.0-Z49.2, Z94.0, Z99.2

Appendix D-2: Elixhauser Comorbidity Coding Algorithms

Comorbidities	Elixhauser's original ICD-9-CM	ICD-10-CM
Liver disease	070.32, 070.33, 070.54, 456.0, 456.1, 456.2, 571.0, 571.2-571.9, 572.3, 572.8, V42.7	B18.x, I85.x, I86.4, I98.2, K70.x, K71.1, K71.3-K71.5, K71.7, K72.x-K74.x, K76.0, K76.2-K76.9, Z94.4
Peptic ulcer disease excluding bleeding	531.70, 531.90, 532.70, 532.90, 533.70, 533.90, 534.70, 534.90, V12.71	K25.7, K25.9, K26.7, K26.9, K27.7, K27.9, K28.7, K28.9
AIDS/H1V	042.x-044.x	B20.x-B22.x, B24.x
Lymphoma	200.x-202.3x, 202.5-203.0, 203.8, 238.6, 273.3, V10.71, V10.72, V10.79	C81.x-C85.x, C88.x, C96.x, C90.0, C90.2
Metastatic cancer	196.x-199.x	C77.x-C80.x
Solid tumor without metastasis	140.x-172.x, 174.x, 175.x, 179.x-195.x, V10.x	C00.x-C26.x, C30.x-C34.x, C37.x-C41.x, C43.x, C45.x-C58.x, C60.x-C76.x, C97.x
Rheumatoid arthritis/Collagen vascular diseases	701.0, 710.x, 714.x, 720.x, 725.x	L94.0, L94.1, L94.3, M05.x, M06.x, M08.x, M12.0, M12.3, M30.x, M31.0-M31.3, M32.x-M35.x, M45.x, M46.1, M46.8, M46.9
Coagulopathy	286.x, 287.1, 287.3-287.5	D65-D68.x, D69.1, D69.3-D69.6
Obesity	278	E66.x
Weight loss	260.x-263.x	E40.x-E46.x, R63.4, R64
Fluid and electrolyte disorders	276.x	E22.2, E86.x, E87.x
Blood loss anemia	280	D50.0
Deficiency anemia	280.1-281.9, 285.9	D50.8, D50.9, D51.x-D53.x
Alcohol abuse	291.1, 291.2, 291.5-291.9, 303.9, 305.0, V113	F10, E52, G62.1, I42.6, K29.2, K70.0, K70.3, K70.9, T51.x, Z50.2, Z71.4, Z72.1
Drug abuse	292.0, 292.82-292.89, 292.9, 304.0, 305.2, 305.9	F11.x-F16.x, F18.x, F19.x, Z71.5, Z72.2
Psychoses	295.x-298.x, 299.1	F20.x, F22.x-F25.x, F28.x, F29.x, F30.2, F31.2, F31.5
Depression	300.4, 301.12, 309.0, 309.1, 311	F20.4, F31.3-F31.5, F32.x, F33.x, F34.1, F41.2, F43.2

Appendix E: Differences in PSEs by Bed size of Hospital

Bed Size of Hospital	n	Rate	Bivariate Logistic Regression		
			OR	95% CI	P-value
Small	1,271,820	1137	Reference	Reference	Reference
Medium	1,974,278	1243	1.09	1.07-1.12	<0.001
Large	3,507,002	1389	1.22	1.20-1.25	<0.001

n - number of discharges in eligible population.

Rate - PSE rate reported per 100,000 discharges.

OR - Unadjusted odds ratio from logistic regression with Bed size of Hospital as the sole predictor

Appendix F: Differences in PSEs by Location/Teaching Status of Hospital

Location/Teaching Status	n	Rate	Bivariate Logistic Regression		
			OR	95% CI	P-value
rural	629,172	978	Reference	Reference	Reference
urban-non-teaching	1,778,289	1148	1.18	1.14-1.21	<0.001
urban-teaching	4,345,639	1407	1.44	1.41-1.48	<0.001

n - number of discharges in eligible population.

Rate - PSE rate reported per 100,000 discharges.

OR - Unadjusted odds ratio from logistic regression with location/teaching status as the sole predictor

Appendix G: Differences in PSEs by Geographical Region of Hospital

Geographical Region	n	Rate	Bivariate Logistic Regression		
			OR	95% CI	P-value
Northeast	1,246,094	1353	Reference	Reference	Reference
Midwest	1,504,678	1288	0.95	0.93-0.97	<0.001
South	2,659,715	1275	0.94	0.92-0.96	<0.001
West	1,342,613	1306	0.96	0.94-0.99	<0.01

n - number of discharges in eligible population.

Rate - PSE rate reported per 100,000 discharges.

OR - Unadjusted odds ratio from logistic regression with geographical region as the sole predictor

Appendix H: Differences in PSEs by Ownership of Hospital

Hospital Ownership	n	Rate	Bivariate Logistic Regression		
			OR	95% CI	P-value
government-nonfederal	769,380	1349	Reference	Reference	Reference
private-non-profit	4,953,908	1324	0.98	0.96-1.00	0.07
private-investor-own	1,029,812	1139	0.84	0.82-0.86	<0.001

n - number of discharges in eligible population.

Rate - PSE rate reported per 100,000 discharges.

OR - Unadjusted odds ratio from logistic regression with Hospital ownership as the sole predictor

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