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# The Impact of Nursing Factors on the Outcomes of Adult Medicare Surgical Patients With and Without Depression

## Abstract

Depression is common among older surgical patients and increases their risk of adverse events, including complications, readmissions, and even death. Although recent initiatives have focused on the importance of ameliorating the negative effects of depression in hospitalized patients, little attention has focused on the relationship between depression and surgical patient outcomes and the critical role that the Registered Nurse (RN) workforce can play in improving these outcomes. The purpose of this study was to examine the relationship between depression and hospital nursing factors (the work environment, staffing, and education), and 30-day mortality, failure to rescue (FTR), and 30-day readmission. This study was a secondary analysis of observational data from 2006-2007 and employed three linked data sets: 1) The 2006-2007 Multi-State Nursing Care and Patient Safety Survey; 2) The 2006-2007 American Hospital Association (AHA) Annual Survey; and 3) Medicare claims data from 2006-2007, which included claims data for older adult patients, 65-90, who underwent general, orthopedic, or vascular surgery in acute care general hospitals in 2006-2007. The final sample included: 311,679 patients, 24,837 nurses, and 533 hospitals. Logistic regression models controlling for patient, hospital, and hospital nursing characteristics were employed to study the association between depression, hospital nursing factors, and 30-day mortality, FTR, and 30-day readmission. Logistic regression models including interactions between depression and hospital nursing factors were also assessed to analyze this relationship. It was found that an increase of the patient to nurse ratio above the median (5.2) was associated with a 1% increase in mortality in patients without depression and a 15% increase in mortality in patients with depression ( $p < 0.05$ ). Additionally, a 10% increase in the proportion of bachelors prepared nurses in a hospital was associated with a 4% decrease in mortality for patients without depression, but a 9% decrease in patients with depression ( $p < 0.05$ ). The focus on improving mental health care in the general hospital setting continues to grow in the context of the Affordable Care Act (ACA). Decreasing patient to nurse ratios and increasing the proportion of baccalaureate nurses are potential strategies to decrease surgical patient mortality in older adults with and without depression.

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Linda Aiken

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THE IMPACT OF NURSING FACTORS ON THE OUTCOMES OF ADULT MEDICARE SURGICAL  
PATIENTS WITH AND WITHOUT DEPRESSION

**Aparna Kumar**

A DISSERTATION

In

Nursing

Presented to the Faculties of the University of Pennsylvania

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## DEDICATION

To Theo, for not eating the first draft.

To Jonathan, for always knowing the right answer, and for all that you do.

To my parents, because of you, I am here.

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## ABSTRACT

### THE IMPACT OF NURSING FACTORS ON THE OUTCOMES OF ADULT MEDICARE SURGICAL PATIENTS WITH AND WITHOUT DEPRESSION

Aparna Kumar

Matthew McHugh

Depression is common among older surgical patients and increases their risk of adverse events, including complications, readmissions, and even death. Although recent initiatives have focused on the importance of ameliorating the negative effects of depression in hospitalized patients, little attention has focused on the relationship between depression and surgical patient outcomes and the critical role that the Registered Nurse (RN) workforce can play in improving these outcomes. The purpose of this study was to examine the relationship between depression and hospital nursing factors (the work environment, staffing, and education), and 30-day mortality, failure to rescue (FTR), and 30-day readmission. This study was a secondary analysis of observational data from 2006-2007 and employed three linked data sets: 1) The 2006-2007 Multi-State Nursing Care and Patient Safety Survey; 2) The 2006-2007 American Hospital Association (AHA) Annual Survey; and 3) Medicare claims data from 2006-2007, which included claims data for older adult patients, 65-90, who underwent general, orthopedic, or vascular surgery in acute care general hospitals in 2006-2007. The final sample included: 311,679 patients, 24,837 nurses, and 533 hospitals. Logistic regression models controlling for patient, hospital, and hospital nursing characteristics were employed to study the association between depression, hospital nursing factors, and 30-

day mortality, FTR, and 30-day readmission. Logistic regression models including interactions between depression and hospital nursing factors were also assessed to analyze this relationship. It was found that an increase of the patient to nurse ratio above the median (5.2) was associated with a 1% increase in mortality in patients without depression and a 15% increase in mortality in patients with depression ( $p < 0.05$ ). Additionally, a 10% increase in the proportion of bachelors prepared nurses in a hospital was associated with a 4% decrease in mortality for patients without depression, but a 9% decrease in patients with depression ( $p < 0.05$ ). The focus on improving mental health care in the general hospital setting continues to grow in the context of the Affordable Care Act (ACA). Decreasing patient to nurse ratios and increasing the proportion of baccalaureate nurses are potential strategies to decrease surgical patient mortality in older adults with and without depression.

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## Chapter 1: Introduction

### The Issue

Depression is a common, chronic condition among older adults above the age of 65 (CMS, 2012). Annually, 15.7 million adult Americans experience a depressive episode, 6.5 million of whom are older Americans (CBHSQ, 2015; SAMHSA, 2015a). Depressive disorders are defined by the presence of low mood, physical symptoms, and cognitive symptoms, which severely impair day to day function (SAMHSA, 2015b). A diagnosis of depression represents a significant clinical concern, particularly for hospitalizations involving surgery. Half of all elders will undergo a surgical procedure, one in four of whom will have depression (CDC, 2013, 2014; SAMHSA, 2011; Turrentine, Wang, Simpson, & Jones, 2006). Surgery exposes elders to significant risk, increasing the risk of morbidity and mortality to a greater extent than in younger adults (Turrentine et al., 2006). To add to this risk, a significant proportion of the 50 million surgical procedures performed annually in the United States, will result in unintended consequences (CDC, 2010; Zeeshan, Dembe, Seiber, & Lu, 2014).

Surgical complications, including death, represent 45% of all adverse events (Pham et al., 2011). Especially fraught with risk are orthopedic surgical procedures, which represent the most common surgeries reporting adverse events (Zeeshan et al., 2014). Similarly, nearly one in six general or vascular surgeries will result in complications (Ghaferi, Birkmeyer, & Dimick, 2009b). Depression exacerbates the risks of surgery in elders, increasing the risk of longer length of stay (Bourgeois, Kremen,

Servis, Wegelin, & Hales, 2005; Fulop, Strain, & Stettin, 2003), hospital readmission (Ciro et al., 2012), adverse events (Connerney, Shapiro, McLaughlin, Bagiella, & Sloan, 2001) healthcare costs, and additional hospitalizations (Katon, 2011; Sayers et al., 2007). These vulnerabilities make nursing care critical during the post-operative period in this population.

Caring for these complex patients and detecting patient changes in order to prevent potential complications is central to the role of the Registered Nurse (RN). It is theorized that this is achieved through RNs carrying out surveillance. In this context, RNs function as a surveillance system within organizations, gathering, analyzing, and synthesizing patient data for clinical decision making (Clarke & Aiken, 2003; Henneman, Gawlinski, & Giuliano, 2012). Nursing care is intensive during the postoperative period, during which surgical patients require careful monitoring of vital signs, respiratory status, and surgical site (Zeitz, 2005). Nurses may be able to decrease the odds of complications and even death by assessing, recognizing, and preventing complications (Aiken et al., 2011; Diya, Van den Heede, Sermeus, & Lesaffre, 2012; Wadlund, 2006). Nurse led interventions, such as self-care promotion or patient education, can also decrease the odds of readmissions (Leppin et al., 2014). RNs, thus, have the potential to directly influence surgical outcomes for vulnerable patients, including complications, mortality, and failure to rescue (FTR) , defined as a death within 30 days following an unanticipated surgical complication (Aiken, Smith, & Lake, 1994). The organization of nursing, including the hospital nursing factors of the work environment, staffing, and

proportion of bachelor's prepared nurses (BSNs), can facilitate RNs in performing better surveillance, resulting in the potential for improved surgical outcomes such as mortality, readmissions, and FTR (Clarke & Aiken, 2003; Ma, McHugh, & Aiken, 2015; McHugh, Berez, & Small, 2013; McHugh & Ma, 2013).

It is unknown how RN surveillance may influence depression; however, it is known that patients with depression have additional challenges. For example, in the post-operative period, physiological factors predispose patients with depression to an increased risk of delirium, delayed wound healing, complications from anesthesia, lower pain thresholds, and adverse events (Frasure-Smith et al., 2007; Ghoneim & O'Hara, 2016; Kudoh, Takahira, Katagai, & Takazawa, 2002). In addition, lower social support and impairment in activities of daily living (ADLs) in surgical patients with depression can decrease a patient's ability to engage in recovery and rehabilitation (Ciro et al., 2012; Tully & Baker, 2012). Elderly patients with depression have the added complexity of atypical clinical presentation; patients may present with irritability, anxiety, and somatic complaints rather than low mood (Taylor, 2014). If not properly recognized and treated, depression in elderly post-operative patients can further increase the risk of delirium, complications, and post-discharge physical health (Tully & Baker, 2012). These challenges make RN care of elderly surgical patients critical in the post-operative period.

Building upon established research that links the organization of nursing to surgical patient outcomes, the purpose of this study was to increase understanding of the relationship between hospital nursing factors and mortality, FTR and readmission in

surgical patients with and without depression. The hypothesis was that better organization of nursing would be associated with improved surgical outcomes. However, hospital level nursing factors would have a greater impact on outcomes for patients with depression than on those without depression.

### **Study Overview, Specific Aims, and Hypotheses**

This study employed cross-sectional data from patients, nurses, and hospitals to examine the relationship between nursing and patient outcomes. The data were derived from the 2006-2007 American Hospital Association (AHA) Annual Survey, the 2006-2007 Multi-State Nursing Care and Patient Safety Survey, and Medicare beneficiary data for claims years 2006-2007 for older adults age 65 and up. The sample consisted of all general, orthopedic, and vascular surgery patients in California, Florida, New Jersey, and Pennsylvania. The three data sets were combined for analysis at the patient level. The main aim of this research was:

*To examine the relationship between the nurses' work environment, staffing, and education on 30-day all-cause mortality, failure to rescue (FTR), and 30-day unplanned readmission in general, orthopedic, and vascular surgical patients with and without depression.*

**Hypothesis:** Better nurse work environment, lower patient to nurse staffing ratios, and higher proportions of bachelor's prepared nurses (BSNs) will be associated with lower odds of 30-day all-cause mortality, failure to rescue (FTR),



and 30-day unplanned readmission to a greater extent in surgical patients with depression than in surgical patients without depression.

### **Significance and Innovation**

Despite recent initiatives to decrease morbidity and mortality in surgical patients, there remain significant institutional differences in surgical outcomes including: mortality, FTR, and hospital readmission (Ghaferi et al., 2009b; Kohn, Corrigan, & Donaldson, 2000). Still, little emphasis has been placed on the role that nursing care can play in improving patient outcomes. The Centers for Medicare and Medicaid Services (CMS) is focused on improving quality of care, via efforts to decrease infections through the Hospital-Acquired Condition Reduction Program (HACRP), which penalizes hospitals for certain acquired conditions, and the Hospital Value-Based Purchasing Program (HVBPP), which provides payments based on quality (Raso, 2013). Both programs assess patient outcomes directly related to surgical patients. Hospital nursing factors, such as the proportion of BSNs, staffing levels, and the quality of the work environment have the potential to move the needle on these measures as they have been demonstrated to decrease the odds of mortality and FTR in surgical patients (Aiken et al., 2011; Aiken, Clarke, Cheung, Sloane, & Silber, 2003). A great deal of attention has also been focused on improving quality of care by decreasing hospital readmissions. Medicare patients, who have higher risks of readmissions, are of particular interest and the focus of the Hospital Readmissions Reduction Program (HRRP), which applies penalties to hospitals with high rates of readmission for

designated conditions (Jencks, Williams, & Coleman, 2009). Since 2015, CMS has included coronary artery bypass surgery (CABG), percutaneous transluminal angioplasty and other vascular procedures in the HRRP. This is significant because among surgical patients, vascular patients have the highest readmission rates, nearly 24% (Eun, Nehler, Black, & Glebova, 2015).

Improving patient outcomes in an elderly vulnerable surgical population has financial, resource, and policy implications (Siegel, 2013). In patients with chronic conditions, present in nearly all Medicare patients, depression increases health care costs and the risk of morbidity, mortality, functional decline, and poor quality of life (Katon et al., 2005; Lin et al., 2004; Lin et al., 2010; Simon et al., 2005). Yet, few rigorous studies specifically study surgical outcomes in patients with depression. Only one study has examined the effect of hospital nursing factors on mortality and FTR in patients with serious mental illness (SMI) (Kutney-Lee & Aiken, 2008).

This research addressed this gap in the literature. Generating more evidence on the impact and influence of hospital nursing factors on outcomes in surgical patients with depression is of interest to researchers and policy makers. The outcomes of mortality, FTR, and readmissions are indicators of quality of care; hence, decreasing the odds of mortality, FTR, and readmissions is critical as hospitals face increased financial pressures (Chen, Bazzoli, & Hsieh, 2009). In addition, through CMS programs such as the HRRP, the HACRP, and HVBP, hospitals are under mounting pressure to improve patient outcomes. As the Affordable Care Act (ACA) takes effect, more patients with mental

illness will present to the general acute care setting (Golberstein & Gonzales, 2015; Unutzer, Schoenbaum, Druss, & Katon, 2006; Wiechers, Karel, Hoff, & Karlin, 2015). Therefore, addressing quality of care of hospitalized adults, particularly older adults, is a priority for providers, hospital administrators, and policy makers as a strategy to decrease complications, death, and readmissions as well as to decrease cost (Blount et al., 2006; Thorpe, Ogden, & Galactionova, 2010). In this context, the highly skilled nurse workforce is uniquely positioned to improve quality of care in elderly surgical patients with depression.

This research expands understanding of how hospital nursing factors may improve outcomes for elderly, surgical patients with depression. This study builds upon a robust body of research on the impact of nurse practice environment, staffing, and education on patient outcomes. It furthers this program of research by applying established measures and a conceptual framework to the selected population of patients with depression. Although mortality, FTR, and readmissions have been studied in other surgical populations, the application of these measures in surgical patients with depression is novel (Aiken et al., 2011; Aiken et al., 2003; Aiken, Clarke, Sloane, Lake, & Cheney, 2008; Ma et al., 2015).

This study included all surgical patients with depression, including but not exclusive to major depressive disorder (MDD). The organization of nursing has been studied in general, orthopedic, and vascular surgical patients and has been shown to lower the odds of 30 day all-cause mortality, FTR, and 30 day all-cause readmission;

however these relationships have not been studied specifically in patients with depression (Aiken et al., 2003; Aiken, Clarke, Sloane, Sochalski, & Silber, 2002; Ma et al., 2015). Studies on patient outcomes such as readmissions, mortality, and service use for people with mental illness have primarily focused on identifying disparities in outcomes for medical or surgical patients with Serious Mental Illness (SMI) including: schizophrenia, bipolar disorder, and major depressive disorder (Chwastiak et al., 2014; Copeland et al., 2014; Plomondon et al., 2007; Salsberry, Chipps, & Kennedy, 2005). Because depression has a higher prevalence than SMI, this research provides results applicable to a broader hospitalized older adult population.

### **Summary**

Depression is common among surgical patients and increases the risk of poor surgical outcomes as well as increased health care costs (CMS, 2012; Connerney et al., 2001; Katon et al., 2008; Sayers et al., 2007). Depression is especially important in the elderly, who are at a greater risk of morbidity and mortality after surgery (Turrentine et al., 2006). Given their critical role in postoperative care, RNs are uniquely positioned to improve outcomes such as mortality, FTR, and readmissions in surgical patients, particularly in the elderly (Aiken et al., 2003; Aiken et al., 2002; McHugh & Ma, 2013). As quality improvement and cost control measures spread, there is an increased focus on improving surgical outcomes relating to complications, mortality, and readmissions (Raso, 2013). The role of RNs in influencing outcomes for elderly surgical patients with depression has not been directly studied. By increasing evidence on the impact of the

organization of nursing in this population, hospital administrators and policy makers will be better positioned to make decisions on how to improve the outcomes of elderly surgical patients with depression.

## Chapter 2: Background and Significance

### Introduction

Chapter 2 reviews literature related to depression and hospital patient outcomes, describes the relationship between hospital characteristics and patient outcomes, and elucidates the link between RN care and outcomes in surgical patients and patients with depression. The Quality Health Outcomes Model (QHOM) guides this discussion.

### Conceptual Framework

This study was influenced by the QHOM (**Figure 1**) (Mitchell, Ferketich, & Jennings, 1998). The QHOM model builds upon Donabedian's linear structure process outcomes model, but includes a fluid model that allows interactions between the client, the system and the intervention. Donabedian defines structure as the characteristics of the organization that deliver care and its key features, such as the teaching status or bed size of a hospital (Donabedian, 1966). Process, in Donabedian's model, and intervention in the QHOM model, refers to the praxis of healthcare providers within an organization, such as the delivery of antibiotic therapies (Donabedian, 1966; Mitchell et al., 1998). Finally, outcomes are defined as the effect of providers and healthcare entities on the patient's health status (Donabedian, 1966; Mitchell et al., 1998). The inclusion of the client in the QHOM is a novel aspect, which is not included in Donabedian's model (Donabedian, 1966; Mitchell et al., 1998). The client's inclusion acknowledges that the unique features of a patient, such as patient characteristics and

medical comorbidities, contribute to outcomes (Mitchell et al., 1998). The QHOM differs from Donabedian's model in that it proposes that interventions do not directly exert influence on outcomes; rather they work through the system and client features. The QHOM posits that the system and client features, therefore, have the potential to directly influence outcomes (Mitchell et al., 1998; Mitchell & Lang, 2004). The QHOM assumes that the organization of nursing, a system characteristic, can be measured and modified to improve patient, nurse, and organizational outcomes (Aiken & Patrician, 2000). The QHOM, depicted below in **Figure 1**, has served as the conceptual framework for decades of research studying the relationships between nursing factors and patient outcomes (Aiken, Sochalski, & Lake, 1997; Kutney-Lee et al., 2015; Mitchell & Lang, 2004).

In this study, the QHOM acts as a framework to explain the relationships between the nurse work environment, staffing, and education on mortality, FTR, and readmissions in surgical patients with depression. The influence of system, client, and intervention factors on outcomes and one another can be examined through its lens (Mitchell et al., 1998; Mitchell & Lang, 2004). In this study, only the client, system, and outcomes are directly analyzed. The system includes hospital structural characteristics as well as the organization of nursing. Hospital structural characteristics include: teaching status, technology status, bed size, ownership and location. Client factors include: presence of depression, patient characteristics, type of procedure, and medical comorbidities. The organization of nursing includes the hospital nursing factors of the

work environment, staffing, and education. The outcome variables are mortality, failure to rescue (FTR), and readmissions. Although interventions are not measured in this study, both the system and client factors are thought to directly influence nurse surveillance, surgical procedure, and post-surgical care. The effect of the intervention is mediated by the client or the system to influence outcomes.



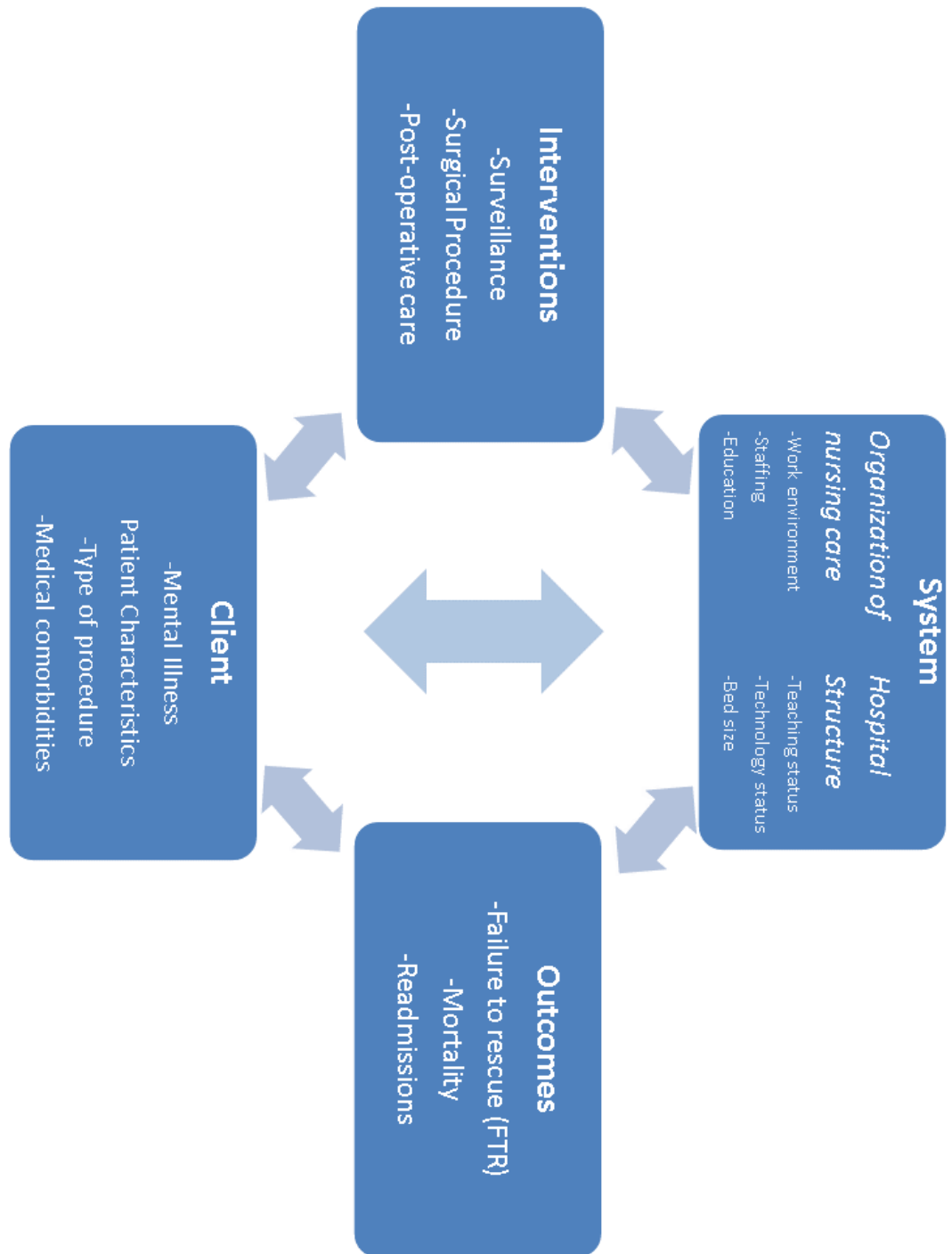


Figure 1. Quality Health Outcomes Model

## Review of the Literature

### Depression and Hospital Patient Outcomes

**Mortality and failure to rescue (FTR).** In hospitalized medical and surgical patients, depression is independently associated with an increased risk of hospitalization, length of stay, and readmissions (Katon, 2011; Prina et al., 2015; Prina et al., 2013). Mortality, defined as death within 30 days of admission to the hospital, is a valid outcome indicator when risk adjustment for patient characteristics is adequately performed (Silber, Williams, Krakauer, & Schwartz, 1992). Despite challenges to its reliability in measurement, especially in low volume hospitals, mortality is often used to benchmark quality of hospital care for surgical patients (Dimick, Welch, & Birkmeyer, 2004; Pitches, Mohammed, & Lilford, 2007; Silber et al., 2002). Depression, for both medical and surgical inpatients, is not consistently linked to differences in mortality. Among medical inpatients, only a few studies have demonstrated that major depressive disorder is associated with an increased risk of in-hospital mortality (Cavanaugh, Furlanetto, Creech, & Powell, 2001; Cullum, Metcalfe, Todd, & Brayne, 2008). On the contrary, a study of older medical inpatients over the age of 65 suggested that depression is not associated with mortality (McCusker et al., 2006). However, the majority of studies on hospitalized medical patients focus on mortality in large time intervals post-discharge. For example, in a study with a national sample of Medicare patients hospitalized for acute myocardial infarction (AMI), while mental illness was associated with a 19% increase in the risk of mortality at 1 year follow up, depression

(classified as an affective disorder) was not associated with mortality (Druss, Bradford, Rosenheck, Radford, & Krumholz, 2001). An additional study demonstrated that mortality and functional status were lower for patients who had increasing severity of depression within one year of hospitalization (Pierluzzi et al., 2012). In another study of coronary heart disease (CHD) patients hospitalized for intracoronary stenting, depression increased the risk of death at 2 year follow up, but this relationship did not predict mortality at 3 year follow up (Meyer, Hussein, Lange, & Hermann-Lingen, 2014).

Still less research exists on outcomes for surgical patients with depression, apart from post-operative cardiac surgery patients. As in medical patients, studies on the link between depression and mortality in surgical patients provide mixed results. A recent study at the Veteran's Administration (VA) showed that mortality in surgical patients with SMI, which includes major depressive disorder, was not associated with mortality (Copeland et al., 2014). However, a systematic review of the association between anxiety and depression and coronary artery bypass graft (CABG) surgery on morbidity and mortality illustrates that several studies have shown an association between depression and increased mortality (Tully & Baker, 2012). For example, one study examined discharge records of patients who had CABG surgery and demonstrated that depression was associated with a 24% higher chance of dying in the hospital (Dao et al., 2010). In the majority of the studies the time frame of measuring mortality varied from 2-10 years (Tully & Baker, 2012). Neither the time interval of death nor inpatient versus outpatient deaths were differentiated (Tully & Baker, 2012). Only one study to date, on

patients undergoing cytoreductive surgery, examines 30-day mortality and has found a significant relationship between depression and higher mortality (Low et al., 2016).

Failure to rescue (FTR), the event of death within 30 days of admission after a complication, is conceptually related to mortality. However, FTR is more directly influenced by hospital characteristics while mortality is influenced by both hospital and patient characteristics (Ghaferi, Birkmeyer, & Dimick, 2009a; Silber et al., 1992). At present, no research literature exists that directly examines the relationship between depression and FTR. However, one study examining the relationship between the organization of nursing, SMI, and FTR, among other outcomes, did find that patients with SMI have similar mortality rates, higher risks of postoperative complications, and lower rates of FTR than patients without SMI (Kutney-Lee & Aiken, 2008). Still, FTR is potentially an important outcome measure as the vulnerabilities of patients with depression, including poor wound healing and increased risk of delirium, may be linked to the risk of complications.

**Readmissions.** A readmission can be defined as an unplanned admission to a hospital within 30 days of discharge from the same or another hospital (Merkow et al., 2015). Among surgery patients, one study shows an association between readmission within 30 days of discharge and complications from a surgical procedure (Merkow et al., 2015). The majority of the literature on depression and readmissions focuses on medically ill patients in the community. However, several studies do examine surgical patient readmissions. In one study of Medicare inpatients, both medical and surgical,

depression was found to nearly triple the odds of readmission (Marcantonio et al., 1999). Depression has been associated with readmissions in CABG patients in one study; however, the study captured all readmissions within 6 months of discharge (Tully, Baker, Turnbull, & Winefield, 2008). In another study of CABG surgery patients, depression was associated with a greater likelihood of readmissions, length of stay, wound infection, poor quality of life, and return of angina and other symptoms within five years of hospitalization (Tully & Baker, 2012). A general study of medical surgical patients showed that serious mental illness (SMI) was associated with a 24% increased risk of readmission within 30 days (Chwastiak et al., 2014). In the above noted study of patients undergoing cytoreductive surgery, patients with depression were nearly six times more likely to be readmitted within 30 days of admission (Low et al., 2016). In another study examining factors associated with 30-day readmission in spinal surgery patients, patients with depression had a 50% higher risk of being readmitted than patients without depression (Akins et al., 2015). A recent study on the effect of psychiatric disease, including depression, on total hip arthroplasty patients, demonstrated that patients with depression were more likely to have medical complications, such as stroke, and surgical complications, such as wound infection, at 30 days post-admission (Klement et al., 2016). Such factors can contribute to risk of readmission (Tully & Baker, 2012). Hence, while research on depression and readmissions appears to demonstrate that depression increases the odds of

readmission, few studies have focused on 30 day readmissions for surgical patients with depression.

**Depression and patient vulnerabilities to poor outcomes.** Patients with depression have multiple risk factors that complicate care and increase the risk of poor outcomes following surgery. Multiple studies demonstrate that patients with depression are at greater risk for poor self-care, readmissions, high utilization, and mortality (Johnson et al., 2012; Rathore, Wang, Druss, Masoudi, & Krumholz, 2008). There are several underlying processes that influence these poor hospital outcomes. Contributing physiological risk factors are: elevated panic-anxiety response due to respiratory threat, hypo-activity of the hypothalamic-pituitary-adrenal (HPA) axis, impairment in the pain transmission system, and depressed cortisol levels, which can diminish the immune response, delay wound healing, require increased pain management, and increase the risk of post-operative delirium (Cerejeira, Batista, Nogueira, Vas-Serra, & Mukaetova-Ladinska, 2013; King et al., 2015; Kudoh, Kudo, Ishihara, & Matsuki, 1997; Liberzon et al., 2006; Reiche, Nunes, & Morimoto, 2004). Higher cortisol levels among patients with depression increase the risk of developing post-operative delirium (Kudoh et al., 2002). One study estimated that approximately 88% of patients with depression develop delirium, or acute post-operative confusion (Kudoh et al., 2002). Antidepressant medication also has the potential to interact with anesthesia and contribute to the risk of delirium (Kudoh et al., 2002). In addition, the stress response to surgery is lower in patients with depression, thus decreasing the expected anti-inflammatory and immune

responses to surgery (Kudoh, Isihara, & Matsuki, 2000). Research has shown a strong association between depression and inflammation, both central and peripheral, which can also increase sensitivity to pain (Walker, Kavelaars, Heijnen, & Dantzer, 2014). Antidepressant medications may modulate this system, decreasing inflammation and decreasing sensitivity to pain in patients treated for depression (Walker et al., 2014). Furthermore, HPA axis dysfunction is associated with greater severity of symptoms in patients with depression and greater risk of developing further psychiatric comorbidity post-operatively (King et al., 2015).

Patients with depression also have more pain symptoms than patients without depression due to dysfunction in the endogenous pain modulation system and systemic inflammation, poor transmission of serotonin and norepinephrine, and poor inhibition of nociceptive signals (Katon, 2011). Therefore, patients with untreated depression often report higher postoperative pain as depression lowers the pain threshold (Caumo et al., 2002; Ghoneim & O'Hara, 2016). The added pain medication needs of patients with depression, specifically for opioids, also increases the risk of opioid related adverse events, which can impact length of stay, cost of care, readmissions, and in-hospital mortality (Kessler, Shah, Gruschkus, & Raju, 2013). While some studies suggest that patients with depression have lower perceptions of pain, or higher pain thresholds, this can potentially be explained by alteration in the dysregulation of the pain transmission system from antidepressant treatment, which partially regulates this pathway (Landa, Peterson, & Fallon, 2012).

## Patient Characteristics and Outcomes

Research has demonstrated that specific patient characteristics can influence the risk of complications, mortality, and readmissions following surgery. Hence, it is critical to adjust for these factors when studying the aforementioned outcomes. A primary risk adjustment variable for surgical patients is diagnosis related groups (DRGs), which classify the patients' diagnoses and procedures (Kominski, 2007). Given that different procedures carry different risks of morbidity and mortality it is intuitive to include this factor. Another related health measure, comorbidities, defined as diagnoses unrelated to the hospital admission, are common and can impact patient outcomes (Iezzoni, 2013). Particularly in the elderly, comorbidities, such as chronic pulmonary disease or chronic kidney failure, can increase the risk of morbidity and mortality (Badheka et al., 2014; Lindman & Patel, 2016; Neumayer et al., 2007; Tisminetzky, Goldberg, & Gurwitz, 2016). Depression is common among elderly patients with multiple chronic illnesses, many of whom will undergo surgery (Albrecht et al., 2015; CMS, 2012; Katon et al., 2010). Furthermore, in patients with chronic illness, such as coronary heart disease (CHD), depression is associated with behaviors that increase the risk of disease exacerbation such as poor adherence, smoking, and decreased physical activity (Blumenthal et al., 2003; Katon, 2011). The more poorly managed the disease, for example diabetes, the greater the risk of complications from surgery such as delayed wound healing, infection, or ulcers in the extremities (Katon, 2011; Wukich, 2015). Therefore, comorbidities can exert influence on the outcomes for surgical patients,



especially those with depression. Finally, transfer of a patient from an outside facility or to an outside facility can be an indicator of clinical severity and is an important risk adjustment factor (Rosenberg et al., 2003).

While several standard methods exist for risk adjustment of comorbidities, the Elixhauser method is applied in this study because it has been employed in studies on administrative data such as Medicare data (Elixhauser, Steiner, Harris, & Coffey, 1998; Mehta et al., 2016). Multiple studies have established that age alone, especially above 80 years of age, is an independent predictor of morbidity and mortality for a diverse range of surgical procedures (Benotti et al., 2014; Hamel, Henderson, Khuri, & Daley, 2005; Turrentine et al., 2006). Advanced age is also a risk factor for 30-day unplanned readmission (Tsai, Joynt, Orav, Gawande, & Jha, 2013). Gender has also been implicated in surgical outcomes, with males having a higher risk of mortality following a surgical procedure (Badheka et al., 2014; Benotti et al., 2014). Males also have a greater likelihood of readmission (Tsai et al., 2013).

### **Hospital Characteristics and Outcomes**

Hospital structural characteristics have not been directly studied in relation to outcomes of surgical patients with depression. However, multiple studies suggest that there are several features that influence surgical patient outcomes (Schultz & Servellen, 2000). Measures that have shown the highest consistency in their link to mortality and complications include: teaching status, technology status, bed size, location (urban or rural), and ownership (public versus private) (Schultz & Servellen, 2000). Patients cared

for in major teaching hospitals may have a lower risk of death and shorter length of stay than minor teaching hospitals (Rosenthal, Harper, Quinn, & Cooper, 1997). Teaching hospitals generally care for sicker patients and may provide better patient care (Hartz et al., 1989). Bed size has been linked to mortality and a larger number of beds (greater than 200) is associated with a decrease in FTR (Ghaferi et al., 2009a; Hartz et al., 1989). While research suggests that risk of readmission is more likely linked to patient characteristics than hospital characteristics, larger teaching hospitals and hospitals that care for economically disadvantaged patients also have higher rates of readmissions (Joynt et al., 2014; Singh et al., 2014; Barnett, Hsu, and McWilliams, 2015). In addition, location of the hospital or geographic variation has also shown to be associated with 30-day mortality, with facilities that have a lower likelihood of death clustering together (Chassin, Park, Lohr, Keeseey, & Brook, 1989). Finally, for-profit and public hospitals have been associated with an increased risk of mortality as compared to private, not-for-profit hospitals (Hartz et al., 1989). This is potentially explained by the idea that higher mortality rates in public hospitals may reflect the low socioeconomic status of the patients receiving care in the hospital (Hartz et al., 1989). These factors are included in the models examining the relationship between depression and mortality, FTR, and readmissions.

### **The Organization of Nursing and Outcomes**

Considerable research has demonstrated that the organization of nursing, including good work environments, high proportions of BSN prepared nurses, and good

staffing ratios, are associated with better surgical patient outcomes and fewer adverse events (Aiken et al., 2011; Aiken et al., 2008; Friese, Lake, Aiken, Silber, & Sochalski, 2008).

Nurse staffing, defined as the number of patients assigned to each nurse on a shift, has been studied in surgical patients and is associated with better patient outcomes. For instance, it has been established that better staffing levels are affiliated with lower odds of mortality and FTR in general, orthopedic, and vascular surgical patients to a greater extent in hospitals with good nurse work environments (Aiken et al., 2011). While research does not exist that examines the impact of staffing on surgical patients with depression, one study looked at the impact of staffing on surgical outcomes for patients with SMI. In this study, staffing ratios are shown to play a significant role in decreasing the odds of 30 day mortality and FTR for surgical patients with SMI (Kutney-Lee & Aiken, 2008). Relating to patients with depression, research in oncology and palliative care demonstrates that despite the presence of depression among many patients, few nurses assess patients for depression or refer for services (Little, Dionne, & Eaton, 2005). In this context, improved staffing levels may allow more time for nurses to screen for depression and follow up with patients in the hospital. Using an alternate measure of staffing, more direct care nursing hours, or the total number of hours a nurse spends on patient care per day, is closely tied to staffing and can also significantly lower the odds of FTR in medical and surgical patients (Needleman, Buerhaus, Mattke, Stewart, & Zelevinsky, 2002). Furthermore, in a retrospective

observational study of multiple units within a hospital, nurse staffing levels that were below standard levels for the patient census, were linked to higher odds of inpatient mortality (Needleman et al., 2011).

Higher proportions of BSN nurses are also linked to lower odds of mortality and FTR in general, orthopedic, and vascular surgical patients (Aiken et al., 2003; Kutney-Lee, Sloane, & Aiken, 2013). While the effects of the organization of hospital nursing on surgical patient outcomes has not been well-studied in patients with depression, several studies shed light on the possible impact that nursing can have. In a study comparing nurses' responses to case studies of patients having a myocardial infarction (MI), nurses were less likely to assess and create an appropriate plan of care for patients on psychotropic medications; however, nurses with a BSN were more likely to detect MI symptoms, even in the presence of psychotropic medication (McDonald et al., 2003). The impact that the BSN prepared nurse can have on outcomes may partially be explained by the nurse's ability to perform better surveillance in the post-operative period (Kutney-Lee, Lake, & Aiken, 2009). Higher proportions of BSNs in hospitals are associated with lower rates of pressure ulcers, fewer infections due to medical care, and fewer instances of deep vein thrombosis or pulmonary embolism (Blegen, Goode, Park, Vaughn, & Spetz, 2013). In addition, research has suggested that BSN nurses are less likely to be the subject of disciplinary action or complete medication errors (Fagin, 2001). Nurses with BSNs are also perceived as having strong critical thinking skills,

decreased focus on nursing tasks, strong leadership skills, and effective nurse-patient communication skills (Goode et al., 2001).

In addition to staffing and education factors, the work environment in which nurses practice has also shown associations with improved patient outcomes. The work environment is defined as the organizational structure that influences nursing practice (Lake, 2002). This is measured through the Practice Environment Scale of the Nurse Work Index (PES-NWI), which measures factors that influence nursing care such as the nurse relationship with physicians or management, staffing and resource adequacy, foundations for quality of care, and nurse participation in hospital affairs (Kramer & Hafner, 1989; Lake, 2002). Evidence exists that nursing may play a role in decreasing the risk of readmission, potentially decreasing variation among hospitals (Ma et al., 2015). For elders, readmission can be especially significant in relation to increasing frailty and the risk for further adverse events (Pugh et al., 2014). Among elder Medicare surgical patients (general, orthopedic, and vascular), better work environments, as well as improved staffing ratios and higher proportions of BSNs are associated with lower odds of readmission (Ma et al., 2015). In addition, for surgical patients in better work environments, improvements in staffing ratios and proportions of BSNs in hospitals decreases mortality and FTR to a greater extent than in hospitals with average work environments (Aiken et al., 2011). Additionally, in cancer patients undergoing surgery, patients in poor work environments had an increased risk of death and FTR (Friese et al., 2008).

## Intervention

While the interventions, including surgical procedures, postoperative care, and nursing surveillance, are not directly studied, it is hypothesized that improved nurse surveillance is influenced by better organization of nursing, including the work environment, the proportion of BSNs, and staffing (Kutney-Lee et al., 2009). Surveillance can be defined as observation, assessment, and application of nursing judgment to a patient's care and is simultaneously influenced by hospital organization and the organization of nursing as well as client characteristics (Kutney-Lee et al., 2009). It is known that patients with SMI require intensive nursing care in order to prevent adverse events such as falls, complications, FTR and mortality (Hanrahan & Aiken, 2008; Hanrahan, Kumar, & Aiken, 2010; Kok, Williams, & Zhao, 2015; Rentala, Fong, Nattala, Chan, & Konduru, 2015; Segre, O'Hara, Arndt, & Beck, 2010). Surveillance, which unfolds at both an individual and an institutional level, has the potential to decrease such adverse events (Kutney-Lee et al., 2009). Greater institutional capacity for nurse surveillance was associated with better outcomes (Kutney-Lee et al., 2009). Individual nurse actions within institutions with high surveillance levels are the mechanism that may drive this. For example, in one study, high intensity of surveillance with 12 or more surveillance acts delivered to the patient per day decreased the frequency of falls in an older, hospitalized adult population (Schever et al., 2008).

Although surveillance is important for all hospitalized patients, it may be even more critical for vulnerable patients with depression. Patients in the postoperative

period face multiple transitions in care and receive intensive nursing care (Zeitz, 2005). Given the physiological vulnerability of surgical patients with depression, nursing care is critical in preventing adverse events such as wound infection, delirium, or inadequate pain control during these transitions. This intrinsic vulnerability also makes good nursing care essential to delivering quality care during the post-operative phase for this population. Due to the elevated pain perception and increased medication demands in this population, nurses require vigilance to monitor and assess pain responses that may be atypical to other post-operative patients. In addition, given the predisposition to poor wound healing, nurses must be able to ensure proper wound care, assessment, and teaching prior to discharge. Furthermore, given the risk of delirium in this population, nurses must not only regularly assess, but also respond appropriately and provide appropriate treatments for delirium. These crucial aspects of nurse surveillance are dependent upon not only understanding the unique needs of patients with depression, but also identifying them among surgical patients. Therefore, it is postulated that nurses working in hospitals with poor staffing ratios, poor work environments, or low proportions of BSNs may not be able to adequately perform surveillance.

### **Summary and Gaps in the Literature**

There is little research on the impact of the organization of nursing on the outcomes of older surgical patients with depression. Few studies exist examining FTR; mortality is the most widely studied outcome measure. Still, the majority of the literature focuses on medical inpatients. Literature on readmissions in surgical patients

does exist, primarily focused on hip and knee replacement patients. However, general, orthopedic, and vascular surgical patients have not been widely studied nor have patients with depression. Patients with depression have specific physiological vulnerabilities that make nursing care in the postoperative period important to improving outcomes. Only one study has employed appropriate risk adjustment and modeling in this surgical population to examine the complex relationships of nursing factors on mortality and FTR in psychiatric patients (Kutney-Lee & Aiken, 2008). However, this analysis was limited to the most severe mental illnesses defined by SMI. The method used in this study builds upon prior research by focusing on depressive disorders, which affect a significant proportion of hospitalized patients. It also examined Medicare data in order to perform analysis on a large sample and applied appropriate risk adjustment models. Although findings from established research on outcomes are mixed, patients with depression often have a higher risk of mortality and poor outcomes. Yet, the mechanism by which their outcomes are impacted is poorly understood. It is hypothesized that nursing may partly explain this variation, given the known impact of the organization of nursing on the care of surgical patients.



## **Chapter 3: Methods and Design**

### **Introduction**

This chapter describes the methods and design of the study. The approach, sample, variables, plan for data analysis, limitations, and human subjects' considerations are detailed. The parent study supporting this research is also presented.

### **Research Design**

This study was a secondary analysis of cross-sectional observational data from 2006-2007. The goal of the study was to examine the relationship between the organization of nursing (hospital nursing factors of nurse education, nurse staffing, and nurse work environment) and outcomes for surgical patients with and without depression. This study builds and expands upon a program of research that has conducted multiple evaluations of the association between these hospital nursing factors and adult surgical patient outcomes (Aiken et al., 2011; Aiken et al., 2010). To address the study's aims, Medicare beneficiary claims data from 2006-2007 for 311,679 beneficiaries undergoing orthopedic, general, or vascular surgery was linked to hospital level data from the American Hospital Association (AHA) Annual Survey and the Multi-State Nursing Care and Patient Safety Study Survey, referred to in this study as the Multi-State Nurse Survey.

### **Parent Study**

The parent study, the Multi-State Nurse Survey, was a mail survey conducted by the Center for Health Outcomes and Policy Research (CHOPR) at the University of

Pennsylvania (R01NR04513; PI: Aiken) between September 2005 and November 2007. On the survey, nurses provided information on hospital nursing factors (nurse work environment, education, staffing) at their institution. Surveyed nurses provided the name of their employer, allowing nurse information to be aggregated to the specific hospital. Using state licensure lists as a sampling frame, a random sample of 272,783 registered nurses from California (40%), New Jersey (50%), Pennsylvania (40%), and Florida (25%) were sent surveys directly by mail. This method helped to avoid bias in hospital selection (Aiken et al., 2011). If surveys were mailed directly to hospitals, those with poor quality could potentially have discouraged nurses from completing the survey (Aiken et al., 2011). This method yielded a 39% nurse response rate from staff nurses working in the study hospitals (39,038 nurses) (Aiken et al., 2011). Nine out of ten hospitals in the study states were represented; or approximately 800 hospitals. A non-response survey of 1,300 original non-respondents was completed, with a 91% response rate, to assess potential response bias. While there were demographic differences between the original and non-responder samples, no differences of hospital nursing factors relevant to the present study were observed (Aiken et al., 2011).

### **Study Sample**

Data came from three linked sources: 1) the 2006-2007 Multi-State Nurse Survey; 2) Medicare claims data from 2006-2007; and 3) the 2006-2007 AHA Annual Survey.

### **Nurses**

The nurse sample came directly from the 2006-2007 Multi-State Nurse Survey and the final sample included responses from 24,837 nurses who identified themselves as staff nurses working in direct patient care in 533 adult acute-care hospitals in California (n=7,102), New Jersey (n=5,639), Pennsylvania (n=6,705), and Florida (n=5,391). The four state approach ensured heterogeneity in the sample of nurses, hospitals, and patients (Aiken et al., 2011; Aiken et al., 2010). Individual nurse survey responses were aggregated to the hospital level for analysis.

### **Hospitals**

Data on structural factors of hospitals were derived from the 2006-2007 AHA annual survey. Five hundred and thirty-three acute care hospitals from CA (n=193), NJ (n=69), PA (n=133), and FL (n=138) were included in the final AHA sample. Hospitals with less than 10 nurse respondents were excluded from the sample to ensure reliability of the organization of nursing measures (Aiken et al., 2011; Aiken et al., 2010). This method has been established in prior studies for this sample of nurse respondents to the Multi-State Nursing Survey (Aiken et al., 2011; Aiken et al., 2002). Psychiatric hospitals were excluded as this study focused on patients with psychiatric illness in the general care setting.

### **Patients**

Patient data were derived from the Medicare Beneficiary Annual Summary (BASF) File and the Medicare Provider Analysis and Review (MedPar) file from 2006-2007. Index surgical admissions were identified for 311,679 Medicare beneficiaries

between the ages of 65 and 90, represented in 533 hospitals. The patients were hospitalized for common surgical procedures (orthopedic, general, and vascular) in 2006-2007 in California (CA), New Jersey (NJ), Pennsylvania (PA), and Florida (FL). Choosing common procedures allows for comparable comparisons across most hospitals in which surgery occurs (Silber et al., 1992). Established risk adjustment also exists for this surgical procedure grouping (Silber et al., 1992). Index admissions were identified as an admission for a designated general, orthopedic, or vascular surgical procedure. For patients with multiple surgical admissions, one was randomly chosen. To ensure that the randomly chosen admission was not a readmission, there could be no other admission in the previous 30 days.

## **Variables**

### **Hospital Nursing Factors**

Hospital nursing factor variables were composed from questions on the 2006-2007 Multi-State Nurse Survey. Nurses reported on their institution of employment and question responses were aggregated for analysis at the hospital level.

**The nurse work environment.** The Practice Environment Scale of the Nursing Work Index (PES-NWI) (Lake, 2002) is a measure endorsed by the National Quality Forum (Forum., 2004) containing 31 items. The PES-NWI, which assesses the institutional features of the hospitals in which the nurses work, is included on the nurse survey and used to measure the work environment (Lake, 2002). This instrument measures the extent to which RN professional nursing practice is limited or fostered

(Lake, 2002). The PES-NWI represents modifiable features of the nurse work environment, for example, resource adequacy and support of nurses (Kutney-Lee et al., 2009; Lake, 2002). The PES-NWI was developed from the 65 questions of the NWI (Lake, 2002). Each item on the PES-NWI is measured using a four point Likert scale, ranging from 1 “strongly disagree” to 4 “strongly agree,” in which nurses are asked to report the degree to which each characteristic is present in their current job (Lake, 2002). The 31 items can be meaningfully represented by five empirically derived subscales: nurse participation in hospital affairs, nursing foundations for quality of care, nurse manager ability, leadership and support, staffing and resource adequacy, and nurse physician relations (Lake, 2002). The nurse level mean of each subscale was aggregated to the hospital level. A hospital level mean of the five subscales was then generated. The PES-NWI total score was examined as a continuous variable at the hospital level. This measure is reliable at the hospital level and has demonstrated predictive validity (Aiken et al., 2008; Friese et al., 2008; Lake, 2002; McHugh & Ma, 2013).

**Nurse education.** On the Multi-State Nurse Survey, nurses were asked to report their highest level of education. A dichotomous variable was created for whether or not the nurse held a bachelor’s of science in nursing (BSN) or higher degree (i.e. Master’s or Doctorate). This measure was aggregated to the hospital level to estimate, as a continuous variable, the percentage of nurses at each hospital with a BSN or higher.

**Nurse staffing.** On the nurse survey, nurses report the number of patients that they cared for on the last worked shift. The responses of all nurses on all shifts were

aggregated for each hospital in order to estimate staffing by hospital. This continuous variable provides an estimate of the average workload of nurses in each institution. Only direct care nurses and nurses reporting care of between one and twenty patients were included in order to avoid including nurses with supervisory or administrative roles.

#### **Proportion of nurses working in medical/surgical and intensive care unit (ICU)**

**settings.** Given that different hospitals could have different proportions of medical-surgical and ICU units, which influences staffing levels, it was important to control for this factor. Nurses reported the location where they worked on their last shift (i.e. medical-surgical unit or ICU). This measure is a continuous variable, representing the proportion of nurses in a hospital working in either a medical-surgical unit or ICU respectively.

#### **Hospital Variables**

The multivariate analysis accounted for other structural characteristics of hospitals that have demonstrated relationships with patient outcomes: size, technology status, teaching status, state, location, and ownership.

**Size.** Hospitals were categorized into three groups: less than 100 beds, between 101-250 beds, and greater than 250 beds.

**Technology status.** Hospitals were categorized as high technology status if they performed open heart surgery and/or major transplants and low technology status if they did not.

**Teaching status.** Hospitals were categorized as major teaching, minor teaching, or non-teaching hospitals. Major teaching hospitals had resident to bed ratios higher than 1:4, minor with resident to bed ratios less than or equal to 1:4, and non-teaching hospitals did not have postgraduate trainees.

**State.** Four dummy variables were created to identify the state in which the hospital was located (CA, PA, NJ, or FL).

**Location.** Hospital location in the AHA annual survey was classified as division, (>2.5 million), metropolitan (50,000-2.5 million), micropolitan (10,000-50,000), or rural (<10,000), based on core based statistical areas (CBSA) as defined by the U.S. Census Bureau.

**Ownership.** Hospitals were classified into one of three categories: government-owned, non-profit, or for-profit.

### **Patient Variables**

Patient level data was derived from the BASF and MedPar files for 2006-2007. Chronic conditions, including depression, were delineated in the BASF file. This allowed for the inclusion of the depression Chronic Condition Warehouse (CCW) flag as an independent variable in the regression model. Demographic information, service utilization, and the data required to create the outcomes of interest were included in the MedPar file. MedPar claims data included the following variables: age, sex, race, admission date, discharge date, death date, diagnostic codes (DRGs and ICD-9 codes)

and procedure codes. These variables were used to derive the independent and outcome variables of interest.

**Demographics.** The analysis included age as a continuous variable and sex as a dichotomous variable (i.e. male/female).

**Surgery type.** Surgery type was classified by one of 48 potential DRGs for surgical admission (**Appendix A**). This method has been previously defined and applied to surgical populations in the four study states of interest (Aiken et al., 2002; Silber et al., 2007).

**Depression.** Patients with depression were identified in the BASF file that includes Medicare Chronic Condition Data Warehouse (CCW) conditions. CCW data comes from the Centers for Medicare and Medicaid Services (CMS) administrative claims data, which includes flags for common chronic conditions listed in **Appendix B**. Traditional approaches to coding depression rely on ICD-9 codes claimed during an inpatient stay. By utilizing Medicare claims data for all settings to analyze outcomes for patients with depression, this approach captures a higher proportion of patients with depression as it includes both inpatient and outpatient sources of data. The presence or absence of depression, identified by International Classification of Diseases (ICD)-9 codes (see **Appendix B**), was indicated with a dichotomous variable. The depression indicator, the CCW flag, was drawn from complete patient claim file records for 2006 and 2007, for patients who received a diagnosis of depression prior to the index



admission. Depression could also be identified on the index surgical admission.

However, employing the CCW flag yielded a higher sample of patients with depression, approximately 15% with the CCW flag and 7% based on the index surgical admission.

**Comorbid conditions.** Medical comorbidities were identified for risk adjustment by the ICD-9 codes listed as secondary diagnoses in the index admission. The Elixhauser method for comorbidity risk adjustment was employed as it has been previously tested in surgical mortality models (Aiken et al., 2002; Elixhauser et al., 1998; Silber et al., 2002). Depression was excluded from the Elixhauser comorbidities as this was defined by the CCW Medicare flag. In addition, coagulopathies and fluid and electrolyte disorders were excluded based on prior research suggesting that these comorbidity categories are more prone to misclassification errors, whereby complications are falsely categorized as preexisting comorbidities (Glance, Dick, Osler, & Mukamel, 2006; Quan et al., 2005). A list of the comorbidities is detailed in **Appendix C**.

**Transfer status.** Transfer status was a dichotomous variable identifying if the patient was either transferred into or out of the hospital. This information was drawn from admission dates and discharge destination and was included in the final regression model.

## **Outcomes**

**30-day all-cause mortality.** 30-day all-cause mortality was derived from patient level MedPar data, which includes deaths recorded in all settings included in the data

set: inpatient, outpatient, and skilled nursing facilities. To create the measure, the number of days between the date of admission and death was calculated. If this number was less than or equal to 30 days, the patient death was considered a 30-day mortality and assigned a value of “1.” If the number was greater than 30 days, the patient death was not considered a 30-day mortality and was assigned a value of “0” (Jencks, Williams, & Kay, 1988).

**Failure to rescue.** Failure to rescue (FTR) represents the occurrence of an unexpected death, following one of 39 possible complications, such as wound infection or unplanned return to surgery (Silber et al., 2000; Silber et al., 2007). Using MedPar files, these complications were identified through ICD-9 codes in the secondary diagnosis or procedure fields of the index admission and were differentiated from comorbidities (Silber et al., 2007; Silber & Rosenbaum, 1997; Silber, Rosenbaum, Schwartz, Ross, & Williams, 1995; Silber et al., 1992). **Appendix D** and **Appendix E** detail the inclusion and exclusion criteria applied to differentiate between comorbidities and complications. A dichotomous variable for FTR was created with the value of “0” (not a FTR case) and “1” (FTR case, with at least one complication present on the index admission and the patient died within 30 days of admission). Multiple studies have utilized FTR to assess its relationship to system level factors (Aiken et al., 2011; Aiken et al., 2002; Silber et al., 2007; Silber et al., 1992).

**Readmissions.** Using the Medicare claims data from the MedPar file, readmissions were defined as an unplanned admission within 30 days of discharge to

the admitting facility or another facility for all causes. The index surgical admission was the point of reference for a readmission within 30 days. Patients with multiple surgeries were randomly assigned one index admission, congruent with the index admission employed in the mortality measure. Hence, as only one surgical admission was included for each patient in the final sample, a readmission could not be a surgical admission. A dichotomous variable was created with “0” representing no readmission and “1” representing a readmission.

## **Data Analysis**

### **Data Linkage**

The three data sources were linked as follows: 1) Nurse survey data variables were identified by hospital, aggregated, and were merged with AHA hospital data for all four states by a unique hospital identifier; 2) Medicare BASF and MedPar files were combined for the years 2006 and 2007 by beneficiary identification number; 3) Medicare combined files were linked to nurse data by a unique hospital identifier. The combined, multilevel data set included nurse survey data aggregated to the hospital level, hospital characteristics, patient characteristics, and patient outcomes measured at the patient level.

### **Analysis Plan**

The **main aim** of this research was:

*To examine the relationship between the nurses' work environment, staffing, and education on 30-day all-cause mortality, failure to rescue (FTR), and 30-day unplanned readmission in general, orthopedic, and vascular surgical patients with and without depression.*

**Hypothesis:** Better nurse work environment, lower patient to nurse staffing ratios, and higher proportions of bachelor's prepared nurses (BSNs) are associated with lower odds of 30-day all-cause mortality, failure to rescue (FTR), and 30-day unplanned readmission, to a greater extent in surgical patients with depression than in surgical patients without depression.

Hospital, nurse, and patient characteristics were described with descriptive statistics. Significant differences between groups were shown with frequency tables and tested with chi square tests for dichotomous and categorical variables. Continuous variables were described with means, standard deviations, and ranges and t-tests were used to test for significance. Patients with depression were identified and group descriptive statistics were calculated separately from patients without depression. Correlations between hospital characteristics and the organization of nursing variables were evaluated with Spearman correlations. Correlation between the PES-NWI and the staffing measure were also assessed with Spearman correlations. These correlations were analyzed in order to assess for potential multi-collinearity. Missing data was examined prior to analysis and while building analytical models. As models included patient and hospital characteristics sequentially, data were assessed for missing

variables. In all models, missing data was not significant, representing less than 1% of the sample for models of the FTR outcome.

Following this preliminary analysis, hierarchical logistic regression models were employed to examine the relationships between hospital nursing factors on 30-day all-cause mortality, FTR, and readmissions in patients with and without depression. Depression was included as an independent variable in order to assess the direct relationship between depression and the patient outcomes studied. The outcomes of mortality, FTR, and readmissions were represented as dichotomous dependent variables and the nurse work environment, staffing, and education as the primary independent variables. Models included the main effects for depression, the nurse work environment, staffing and education and sequentially added the individual nursing characteristics both individually and jointly. Fully adjusted models controlled for the hospital characteristics, patient characteristics, and the proportion of medical-surgical and ICU nurses detailed in the previous section.

To analyze whether the relationship between the nursing factors and patient outcomes differed for patients with and without depression, an interaction term between depression and the organization of nursing factors (depression\*work environment, staffing, or education) was created. Post-estimation tests, the Wald test and the Likelihood Ratio Test, were employed to test the significance of the interactions in each model. Following the full model for logistic regression, logit models were run to obtain beta coefficients to calculate the odds ratio for each level. Robust variance

estimation accounted for clustering of patients at the hospital level (Williams, 2000).

The accuracy of the models was evaluated with receiver operator curves (DeGeest et al., 2004) and corresponding c-statistics. Statistical significance was set at  $p < 0.05$ . All analyses took place in STATA 13/IC.

### **Human Subjects**

All nurse data aggregated to the hospital level and patient level data were de-identified. Hospitals were also de-identified in study reports. Data was stored on a password protected computer on a secure server at the University of Pennsylvania, School of Nursing. This research did not pose any immediate threat to patients, nurses, or hospitals. Still, Institutional Review Board (IRB) approval was sought and obtained prior to data acquisition and analysis. Exemption was authorized by the IRB on May 10, 2016 (**Appendix F**).

## Chapter 4: Results

The main purpose of this study was to examine the relationship between hospital nursing factors (the nurses' work environment, staffing, and education) on 30-day all-cause mortality, failure to rescue (FTR), and 30-day unplanned readmission in general, orthopedic, and vascular surgical patients with and without depression. First, descriptive statistics for patient, nurse, and hospitals are detailed. Then, the analytic models are described and logistic regression models assess the relationship between hospital nursing factors and mortality, FTR, and readmission. Logistic regression models were also used to assess the interaction between hospital nursing factors and depression on mortality, FTR, and readmissions. Finally, a predictive model is employed to understand the additive impact of significant hospital nursing factors (staffing and education) on mortality in patients with and without depression. The final sample included 533 hospitals, 24,837 nurses, and 311,679 older adult surgical patients.

### Hospital, Nurse, and Patient Characteristics

**Table 1** presents the characteristics of the 533 study hospitals. Among the three categories of hospital size, the most common size was greater than 250 beds (45.8%), the second most common was 101-250 beds (43.2%), and the least common was less than 100 beds (11.1%). More than half of study hospitals were non-teaching (51.8%). Among hospitals with medical trainees (48.3%), most were minor teaching (40.2%) with a ratio of 1:4 or less resident to bed ratio. The distribution of hospitals across states was as follows: California (36.2%), then Florida (25.9%), Pennsylvania (24.9%), and New

Jersey (12.9%). The majority of hospitals were located in either division (40.9%) or metropolitan (48.9%) CBSA areas. Most hospitals were non-profit (71.4%) with others designated as either government (9.3%) or for-profit (19.2%). Just over half of hospitals in the sample were categorized as having high technology status (53.1%), indicating that the hospital performed open heart surgery, organ transplantation, or both.

Among the 533 study hospitals, the average patient to nurse ratio was 5.4 with a standard deviation (SD) of 1.3. The average proportion of nurses with a baccalaureate degree or higher in nursing was 39.7% with an SD of 1.3. The average Practice Environment Scale of the Nursing Workforce Index (PES-NWI) score, which measures the work environment, was 2.75 out of 4 with an SD of 0.2. When hospitals were divided into three categories based on their average PES-NWI scores (1 as the poorest rating and 4 as the highest), the PES-NWI was lowest for the lowest tercile of hospitals (2.49 with an SD of 0.11), higher for the middle (2.72 with an SD of 0.05), and highest for the highest tercile hospitals (2.96 with an SD of 0.12).



<b>Table 1. Hospital Characteristics (n=533)</b>	
<b>Hospital Characteristic</b>	<b>n (%)</b>
<u>Size</u>	
≤100 beds	59 (11.1%)
101-250 beds	230 (43.2%)
>250 beds	244 (45.8%)
<u>Teaching Status</u>	
Non-Teaching	276 (51.8%)
Minor Teaching	214 (40.2%)
Major Teaching	43 (8.1%)
<u>Technology Status</u>	
High Technology	283 (53.1%)
Low Technology	250 (46.9%)
<u>Location</u>	
Division	218 (40.9%)
Metro	261 (48.9%)
Micro	43 (8.1%)
Rural	8 (1.5%)
<u>Ownership</u>	
Government	49 (9.3%)
Non-Profit	375 (71.4%)
For-Profit	101 (19.2%)
<u>State</u>	
California	193 (36.2%)
Florida	138 (25.9%)
New Jersey	69 (12.9%)
Pennsylvania	133 (24.9%)
<u>Hospital Nursing Factors, mean (SD)</u>	
PES-NWI, mean (SD)	2.75 (0.20)
Poor (n=178)	2.49 (0.11)
Mixed (n=178)	2.72 (0.05)
Best (n=177)	2.96 (0.12)
Staffing, mean (SD)	5.4 (1.3)
Education (% BSN), mean (SD)	39.7 (1.3)

Note: Practice Environment Scale of the Nurse Work Environment (PES-NWI); PES-NWI excludes Staffing and Resource Adequacy Subscale. Nurse staffing is measured as the ratio of patients to nurses. BSN=Bachelors of Science in Nursing; Education is reported as the proportion of nurses holding a BSN at the hospital level. Location is defined by Core Based Statistics Area (CBSA): Division=>2.5 million, Metro=Metropolitan, 50,000-2.5 million; Micro=Micro-politan, 10,000-50,000; Rural=<10,000. Percentages rounded and may not total 100%; Number totals may not equal 533 due to missing information from the American Hospital Association (AHA).

**Table 2** presents the characteristics of nurses working in the 533 study hospitals of interest. The majority of nurse respondents were female (93.3%) and had a Bachelor of Science (37.6%) or Associates Degree (36.2%) in nursing. The mean age of nurses reporting was 44.7 with an SD of 10.7. The mean years of experience was 16.6 years with an SD of 10.9.

<b>Table 2. Nurse Characteristics (n=24,837)</b>	
Age (years), mean (SD)	44.7 (10.7)
Female, n (%)	23,074 (93.3%)
Level of Education	
Diploma	4,584 (18.5%)
Associates	8,989 (36.2%)
Bachelors	9,335 (37.6%)
Masters	710 (2.9%)
Doctorate	7 (0.03%)
Years of Experience, mean (SD)	16.6 (10.9)

Note: SD=Standard Deviation; Percentages rounded and may not total 100%; Total RNs may be less than 24,837 due to missing values; RNs reporting are direct care RNs.

**Table 3** provides demographic information on all surgical patients included in the sample within the 533 hospitals of interest. Patients ranged in age from 65 to 89 and the average age was 76.7 with an SD of 6.7. Most patients were female (58.6%) and white (88.3%). Black patients represented 5.3% of the sample. Patients who either transferred into or out of the study hospitals of interest represented a small proportion of the sample (0.4%). The majority of patients were general (48.6%) and orthopedic surgery patients (41.7%). A minority of the patients underwent vascular surgery (9.7%).

Surgical patient characteristics were also examined by groups for non-depressed and depressed patients in **Table 3**. All differences noted between groups were

significant at  $p < 0.001$ . Patients with depression had an average age of 77.2 with an SD of 6.8. A greater proportion of patients without depression were male (43.5%) compared to those with depression (28.4%). A slightly higher proportion of patients with depression were white (90.1%) compared to those without depression (88.0%). While transfer patients represented 0.4% of the patient sample for patients without depression, they represented 0.6% for those with depression. Among the types of surgeries that patients underwent, patients with depression had a greater proportion of orthopedic surgeries (48.9%) than patients without depression (40.5%). Among patients without depression, the majority of patients received general surgery (49.5%). Within these three categories of surgery, patients could be further subdivided into major disease categories (MDCs) by systems: MDC 5 Circulatory; MDC 6 Digestive; MDC 7 Hepatobiliary and pancreas; MDC 8 Musculoskeletal and connective tissue; MDC 9 Skin, subcutaneous tissue, and breast; and MDC 10 Endocrine, nutritional and metabolic. These categories are labelled within surgery groups and the most frequent procedures. Among all patients, the most common procedures were hip operations, representing 20.2% of procedures for patients without depression and 34.7% of all procedures for patients with depression. The least frequent surgery for patients without depression was cardiac valve surgery (5.3%) while the least frequent surgery for patients with depression was lower extremity surgery (3.9%).

<b>Table 3. Surgical Patient Characteristics for Non-Depressed (n=266,195) and Depressed Patients (n=45,484)</b>				
	<u>All Patients n(%)</u> n=311,679	<u>Non-Depressed n (%)</u> n=266,195	<u>Depressed n (%)</u> n=45,484	<u>p value</u>
Age (years), mean(SD)	76.7 (6.7)	76.7 (6.7)	77.2 (6.8)	<0.001
Sex				
Male	129,065 (41.4%)	115,857 (43.5%)	12,911 (28.4%)	<0.001
Female	182,911 (58.7%)	150,338 (56.5%)	32,573 (71.6%)	<0.001
Race				
White	275,330 (88.3%)	234,339 (88.0%)	40,991 (90.1%)	<0.001
Black	16,597 (5.3%)	14,700 (5.5%)	1,897 (4.2%)	<0.001
Other	19,752 (6.3%)	17,156 (6.4%)	2,596 (5.7%)	<0.001
Transfer to/from Outside Hospital	1,296 (0.4%)	1,033 (0.4%)	263 (0.6%)	<0.001
Major Surgical Category				
General Surgery (MDC 6, 7, 9, 10)	151,665 (48.6%)	131,875 (49.5%)	19,491 (42.9%)	<0.001
Orthopedic Surgery (MDC 8)	130,271 (41.7%)	107,906 (40.5%)	22,282 (48.9%)	<0.001
Vascular Surgery (MDC 5)	30,183 (9.7%)	26,414 (9.9%)	3,711 (8.3%)	<0.001
Top 10 Procedures				
Major Vessel Operation Except Heart (MDC 5)	14,719 (4.7%)	13,370 (12.4%)	1,349 (7.1%)	<0.001
Major Intestinal Procedures (MDC 6)	17,429 (5.6%)	15,288 (14.2%)	2,141 (11.2%)	<0.001
Hip Operations Except Replacement (MDC 8)	28,396 (9.1%)	21,769 (20.2%)	6,627 (34.7%)	<0.001
Cardiac Valve and Other (MDC 8)	7,168 (2.3%)	5,720 (5.3%)	1,448 (7.6%)	<0.001
Back and Neck Spinal Procedure (MDC 8)	7,718 (2.5%)	6,629 (6.2%)	1,089 (5.7%)	<0.001
Lower Extremity and Humerous Procedure (MDC 7)	15,765 (5.1%)	13,761 (12.8%)	2,004 (10.5%)	<0.001
Lower Extremity Except Foot (MDC 7)	6,973 (2.2%)	6,235 (5.8%)	738 (3.9%)	<0.001
Local Excision and Removal of Int Fix except Hip or Femur w/o CC/MCC (MDC 8)	7,665 (2.5%)	6,355 (5.9%)	1,310 (6.9%)	<0.001
Local Excision and Removal of Int Fix Hip and Femur w/o CC/MCC (MDC 8)	9,491 (3.0%)	8,266 (7.7%)	1,225 (6.4%)	<0.001
Soft Tissue Procedures with MCC (MDC 8)	11,590 (3.7%)	10,412 (9.7%)	1,178 (6.2%)	<0.001

Note: SD=Standard Deviation; Percentages rounded and may not total 100%; CC=complications or comorbidities; MCC=major complications or comorbidities

**Table 4** highlights the comorbidities present in both non-depressed and depressed patients. All comorbidities were significantly different with the exception of: pulmonary circulation disorders ( $p=0.510$ ), complicated hypertension ( $p=0.525$ ), liver disease/dysfunction ( $p=0.224$ ), lymphoma ( $p=0.131$ ), and solid tumor without metastasis ( $p=0.625$ ). Uncomplicated hypertension was the most common condition among non-depressed (50.3%) and depressed patients (48.7%). Chronic pulmonary disease was the second most common comorbidity, present in 19.5% of non-depressed patients and 23.7% of depressed patients. Diabetes was the third most common disease, present in 17.9% of non-depressed patients and 17.5% of depressed patients. For all surgical patients in the sample, the number of comorbidities ranged from 0-7 with 63.8% having a minimum of one comorbidity. Among those with at least one comorbidity, the average number of comorbidities was 1.7 with an SD of 0.9 for non-depressed patients and 1.8 with an SD of 0.9 for depression patients. Of note, psychoses were much more prevalent in the depressed group (4.3%) than the non-depressed group (0.7%).

<b>Table 4. Surgical Patient Comorbidities (n=311,679)</b>			
<u>Elixhauser Comorbidity</u>	<u>Non-Depressed n (%)</u>	<u>Depressed n (%)</u>	<u>p value</u>
Congestive Heart Failure	31,979 (12.0%)	6,434 (14.2%)	<0.001
Valvular Disease	25,534 (9.6%)	4,217 (9.3%)	0.031
Pulmonary Circulation Disorders	3,544 (1.3%)	623 (1.4%)	0.510
Peripheral Vascular Disease	17,514 (6.6%)	2,830 (6.2%)	0.004
Hypertension (complicated)	2,999 (1.1%)	497 (1.1%)	0.525
Hypertension (uncomplicated)	133,917 (50.3%)	22,154 (48.7%)	<0.001
Paralysis	1,234 (0.5%)	276 (0.6%)	<0.001
Neurological Disorders	8,904 (3.3%)	2,940 (6.5%)	<0.001
Chronic Pulmonary Disease	51,836 (19.5%)	10,777 (23.7%)	<0.001
Diabetes (uncomplicated)	47,816 (17.9%)	7,960 (17.5%)	0.017
Diabetes (complicated)	8,506 (3.2%)	1,608 (3.5%)	<0.001
Hypothyroid	28,823 (10.8%)	6,359 (13.9%)	<0.001
Renal Failure	27,084 (10.2%)	4,803 (10.6%)	0.012
Liver Disease/Dysfunction	3,625 (1.4%)	587 (1.3%)	0.224
Peptic Ulcer Disease (not bleeding)	1,514 (0.6%)	336 (0.7%)	<0.001
AIDS	43 (0.02%)	26 (0.06%)	<0.001
Lymphoma	2,737 (1.0%)	503 (1.1%)	0.131
Metastatic Cancer	12,758 (4.8%)	1,406 (3.1%)	<0.001
Solid Tumor without Metastasis	8,997 (3.4%)	1,557 (3.4%)	0.637
RA/Collagen Vascular Diseases	6,875 (2.6%)	1,339 (3.1%)	<0.001
Obesity	11,068 (4.2%)	1,849 (4.1%)	0.359
Weight Loss	5,691 (2.1%)	1,459 (3.2%)	<0.001
Blood Loss Anemia	5,038 (1.9%)	1,014 (2.2%)	<0.001
Deficiency Anemias	3,064 (1.2%)	608 (1.3%)	0.001
Alcohol Abuse	3,162 (1.2%)	617 (1.4%)	0.002
Drug Abuse	315 (0.1%)	136 (0.3%)	<0.001
Psychoses	1,797 (0.7%)	1,942 (4.3%)	<0.001
Mean Number of Comorbidities per Patient, mean (SD)	1.7 (0.9)	1.8 (0.9)	<0.001

Note: SD=Standard Deviation; RA=Rheumatoid Arthritis; Mean number of comorbidities represents the mean for patients with at least one comorbidity.

**Table 5** displays Spearman correlations for the nurse staffing measure (the average number of patients per nurse) and the composite PES-NWI as well as its subscales. Given that there were two measures for staffing within the model, staffing

and resource adequacy as well as the ratio of patients to nurse, it was important to test for correlation between the two variables. Moderate negative correlation (-0.50) was found between the staffing variable and the staffing and resource adequacy subscale. Staffing and resource adequacy was therefore excluded from the analysis because of its significant correlation. The direct staffing measure was retained in the model as staffing has been shown to influence the outcomes of mortality and FTR in previous studies (Aiken et al., 2011). The subscales of the PES-NWI and the composite measure were highly correlated. This was anticipated given that the rating of each feature of the subscale contributes to the composite score and hypothetically corresponds to each individual subscale. Both Pearson and Spearman correlations were consistent; hence only Spearman correlations are displayed. All correlations were significant at  $p < 0.001$ .

<b>Table 5. Spearman Correlation between Staffing and PES Subscales</b>							
	1	2	2a	2b	2c	2d	2e
1. Nurse Staffing	1.00						
2. Practice Environment	-0.35	1.00					
a. Staffing and Resource Adequacy	-0.50	0.78	1.00				
b. Nurse-Physician Relationship	-0.29	0.74	0.60	1.00			
c. Nurse Manager Ability, Leadership, and Support	-0.29	0.87	0.69	0.54	1.00		
d. Foundations for Quality of Care	-0.34	0.93	0.75	0.61	0.76	1.00	
e. Nurse Participation in Hospital Affairs	-0.32	0.92	0.70	0.56	0.71	0.88	1.00

Note: Nurse staffing is measured as the ratio of patients to nurses. Practice Environment Scale of the Nurse Work Environment (PES-NWI); PES-NWI excludes Staffing and Resource Adequacy Subscale. All five subscales are listed separately. All correlations significant at  $p < 0.001$ .



**Table 6** examines the correlations between hospital nursing factors and hospital structural characteristics. All correlations were significant at  $p < 0.001$ . The majority of the study variables were weakly correlated. Correlations between the hospital nursing factors and hospital structural characteristics were weak to moderate at best.

<b>Table 6. Spearman Correlation between Organization of Nursing and Hospital Variables (n=533)</b>													
	1	2	3	4	5	6	7a	7b	7c	7d	8a	8b	8c
1. Nurse Staffing	1.00												
2. Education	-0.39	1.00											
3. PES-NWI	-0.35	0.25	1.00										
4. Teaching Status	-0.10	0.21	0.02	1.00									
5. Technology Status	-0.20	0.20	0.20	0.16	1.00								
6. Size	-0.12	0.33	0.23	0.26	0.52	1.00							
7. CBSA													
a. Division	-0.09	0.36	0.06	0.10	-0.05	0.08	1.00						
b. Metro	0.04	-0.26	0.01	-0.05	0.14	0.06	-0.88	1.00					
c. Micro	0.10	-0.18	-0.12	-0.10	-0.20	-0.27	-0.18	-0.26	1.00				
d. Rural	0.04	-0.05	0.02	-0.05	-0.07	-0.11	-0.05	-0.07	-0.02	1.00			
8. Ownership													
a. Gov.	-0.08	-0.06	0.08	-0.06	0.08	0.12	-0.03	0.06	-0.06	-0.02	1.00		
b. Nonprofit	-0.03	0.17	0.22	0.04	-0.03	0.16	0.06	-0.07	0.07	0.04	-0.50	1.00	
c. For Profit	0.10	-0.14	-0.29	-0.01	-0.02	-0.25	-0.04	0.06	-0.03	-0.03	-0.12	-0.76	1.00

Note: Nurse staffing is measured as the ratio of patients to nurses. Practice Environment Scale of the Nurse Work Environment (PES-NWI); PES-NWI excludes Staffing and Resource Adequacy Subscale. Education is reported as the proportion of nurses holding a BSN at the hospital level, in 10% increments. Core Based Statistics Area (CBSA): Division= $\geq 2.5$  million, Metro=Metropolitan, 50,000-2.5 million; Micro=Micropolitan, 10,000-50,000; Rural= $< 10,000$ . Gov.=Government. All correlations significant at  $p < 0.001$ .

## Risk Adjustment and Outcomes of Interest

Risk-adjusted logistic regression models were employed to study 30-day mortality, FTR, and 30-day readmissions in general, orthopedic, and vascular surgical patients. Nested models were sequentially built, including patient, hospital, and hospital nursing characteristics. Patient characteristics included: age, sex, race, diagnostic code of procedure, and transfer status. Hospital characteristics included: number of beds (size), teaching status, technology status, CBSA location (division, metropolitan, micropolitan, or rural) and ownership status (government, nonprofit, for profit). Hospital nursing characteristics included: the work environment (PES-NWI), the patient to nurse ratio (staffing), and proportion of bachelor's prepared nurses or higher working in the studied hospitals (education). The fully adjusted models including all control variables had an area under the receiver operating characteristic curve C-Statistic of 0.8 for 30-day mortality, 0.8 for FTR, and 0.7 for 30-day readmission. Given that the value of the C-Statistic was 0.7 or higher for all models, the control variables in the model were appropriate and led to adequate model discrimination.

**Table 7** highlights the proportion of patients, both non-depressed and depressed, that experienced mortality, FTR, or readmission 30 days following a surgical procedure. The frequency of mortality was similar in the non-depressed (3.9%) and depressed (3.9%) groups ( $p=0.698$ ). The FTR rate, or percentage, was calculated by dividing the total number of deaths by the total number of complications, including patients that died but did not have an identified complication (Silber et al., 2007). The

FTR rate was lower in the depressed (8.7%) group than the non-depressed (10.2%) group ( $p=0.027$ ). Readmission was more prevalent in the depressed (9.5%) group than the non-depressed (6.2%) group. Vascular surgery had the highest mortality rate (8.8% in the non-depressed and 7.3% in the depressed group), FTR rate (15.1% in the non-depressed and 11.1% in the depressed group), and the highest readmission rate (10.7% in the non-depressed and 14.0% in the depressed group). Of note, the readmission rate for general surgery was 7.2% for patients without depression and 11.1% for patients with depression. The readmission rate for orthopedic surgery patients without depression was 10.7% and 14.0% for patients with depression. Length of stay was not reported in this table; however, clinically significant differences were not seen between groups. The mean length of stay for patients both with and without depression was 6.2 days with a standard deviation of 1.0. By surgical categories, mean length of stay (SD) for general, orthopedic, and vascular surgery was: 6.3 (1.1), 6.1 (1.0), and 6.4 (1.1) respectively. Of note, when stratified by PES-NWI scores into three categories, hospitals with poor, mixed, and best work environments reported similar rates of mortality, FTR, and readmission.

<b>Table 7. 30-Day Mortality, FTR, and 30-Day Readmission among Surgical Patients (n=311,679)</b>				
<u>Outcome Variable</u>	<u>All Patients n (%)</u>	<u>Non-Depressed n(%)</u>	<u>Depressed n(%)</u>	<u>p-value</u>
<b>Mortality</b>	12,148 (3.9%)	10,390 (3.9%)	1,758 (3.9%)	0.698
General	6,662 (4.4%)	5,657 (4.3%)	1,005 (5.2%)	<0.001
Orthopedic	2,878 (2.2%)	2,396 (2.2%)	482 (2.2%)	0.597
Vascular	2,608 (8.7%)	2,337 (8.8%)	271 (7.3%)	0.002
<b>FTR</b>	9,482 (9.9%)	8,173 (10.2%)	1,309 (8.7%)	0.027
General	5,113 (10.9%)	4,360 (10.8%)	753 (11.3%)	<0.001
Orthopedic	1,992 (6.7%)	1,673 (6.9%)	319 (5.5%)	0.189
Vascular	2,377 (14.5%)	2,140 (15.1%)	237 (11.1%)	<0.001
<b>Readmission</b>	20,778 (6.7%)	16,437 (6.2%)	4,341 (9.5%)	<0.001
General	11,645 (7.7%)	9,468 (7.2%)	2,177 (11.1%)	<0.001
Orthopedic	5,779 (4.4%)	4,135 (3.8%)	1,644 (7.4%)	<0.001
Vascular	3,354 (11.1%)	2,834 (10.7%)	520 (14.0%)	<0.001

Note: Percentages may not total 100% due to rounding. The first row for each outcome presents results for all orthopedic, general, and vascular surgery patients. The three surgery groups are defined in Appendix A. Mortality represents a death within 30 days of admission. FTR=Failure to Rescue and represents a death following one of the complications listed in Appendix E. Readmission is defined as a readmission within 30 days of discharge for all causes. % for FTR represents the FTR rate, defined as the [Total number of deaths/(Total number of patients with complications + number of patients who died without complications)]. % for Mortality and Readmission represent the number of deaths or readmissions/total number of patients.

The FTR outcome measure represents a death that occurs following one of 39 complications. **Table 8** shows the distribution of complications among the non-depressed and depressed groups. Significant differences were seen at  $p<0.05$  for the majority of complications with the exception of: pulmonary embolus ( $p=0.678$ ), transient ischemic attack (TIA) ( $p=0.233$ ), nervous system complications ( $p=0.861$ ), pneumothorax ( $p=0.331$ ), respiratory compromise ( $p=0.404$ ), bronchospasm ( $p=0.088$ ), other respiratory complication ( $p=0.361$ ), peritonitis ( $p=0.373$ ), renal dysfunction

( $p=0.063$ ), compartment syndrome ( $p=0.309$ ), bone necrosis ( $p=0.942$ ), disseminated intravascular coagulopathy ( $p=0.777$ ), and pyelonephritis ( $p=0.889$ ). Overall, 119,642 (38.4%) patients experienced at least one complication. Among all patients, 37.5% of non-depressed patients ( $n=99,979$ ) experienced a complication and 43.2% (19,663) of depressed patients experienced a complication. The most common complications among all patients were: GI bleed and blood loss (6.1% for non-depressed patients and 7.3% for depressed patients), renal dysfunction (6.1% for non-depressed patients and 5.9% for depressed patients), and pneumothorax (4.6% for non-depressed patients and 4.7% for depressed patients). The least common complications, representing 0.1% or less in both groups, were: pyelonephritis, nervous system complications, bone necrosis and compartment syndrome. The prevalence of most complications was similar in the non-depressed and depressed groups; however, psychosis was more prevalent in the depressed (7.2%) than in the non-depressed (2.9%). Patients with depression also had a greater frequency of decubitus ulcers (4.1%) compared to non-depressed patients (2.3%). While rates of complications appeared comparable across the non-depressed and depressed groups, it is important to note that significant variation in complications was seen by surgical group with at least one complication experienced by 39.4% of general surgery patients, 32.5% of orthopedic surgery patients, and 58.8% of vascular surgery patients.

<b>Table 8. Surgical Patient Complications (n=311,679)</b>				
<u>Complication Type</u>	<u>All Patients</u> n (%)	<u>Non-Depressed</u>	<u>Depressed</u>	<u>p value</u>
		n (%) (n=99,979)	n (%) (n= 19,663)	
Cardiac Event	4,110 (1.3%)	3,701 (1.4%)	409 (0.9%)	<0.001
Cardiac Emergency	11,658 (3.7%)	10,273 (3.9%)	1,385 (3.1%)	<0.001
Congestive Heart Failure	2,292 (0.7%)	2,006 (0.8%)	286 (0.6%)	0.004
Hypotension/Shock/Hypovolemia	6,794 (2.2%)	5,875 (2.2%)	919 (2.0%)	0.012
Pulmonary Embolus	2,182 (0.7%)	1,872 (0.7%)	310 (0.7%)	0.608
DVT/Arterial Clot	4,266 (1.4%)	3,556 (1.3%)	710 (1.6%)	<0.001
Phlebitis	2,866 (0.9%)	2,381 (0.9%)	485 (1.1%)	<0.001
CVA/Stroke	1,467 (0.5%)	1,215 (0.5%)	252 (0.6%)	0.005
Transient Ischemic Attack (TIA)	678 (0.2%)	590 (0.2%)	88 (0.2%)	0.233
Coma	1,145 (0.4%)	953 (0.4%)	192 (0.4%)	0.037
Seizure	4,343 (1.4%)	3,243 (1.2%)	1,100 (2.4%)	<0.001
Psychosis	11,242 (3.6%)	7,953 (2.9%)	3,289 (7.2%)	<0.001
Nervous System Complications	362 (0.1%)	308 (0.1%)	54 (0.1%)	0.861
Pneumonia-Aspiration	3,651 (1.2%)	2,992 (1.1%)	659 (1.5%)	<0.001
Pneumonia-Other	9,037 (2.9%)	7,558 (2.8%)	1,479 (3.3%)	<0.001
Pneumothorax	14,409 (4.6%)	12,266 (4.6%)	2,143 (4.7%)	0.331
Respiratory Compromise	8,101 (2.6%)	6,945 (2.6%)	1,156 (2.5%)	0.404
Bronchospasm	311 (0.1%)	255 (0.1%)	56 (0.1%)	0.088
Other Respiratory	1,431 (0.5%)	1,210 (0.5%)	221 (0.5%)	0.361
Internal Organ Damage	9,588 (3.1%)	8,261 (3.1%)	1,327 (2.9%)	0.034
Perforation	4,725 (1.5%)	4,086 (1.5%)	639 (1.4%)	0.036
Peritonitis	2,443 (0.8%)	2,071 (0.8%)	372 (0.8%)	0.373
GI Bleed and Blood Loss	19,622 (6.3%)	16,325 (6.1%)	3,297 (7.3%)	<0.001
Sepsis	8,134 (2.6%)	6,723 (2.5%)	1,411 (3.1%)	<0.001
Deep Wound Infection	10,017 (3.2%)	8,276 (3.1%)	1,741 (3.8%)	<0.001
Renal Dysfunction	18,944 (6.1%)	16,267 (6.1%)	2,677 (5.9%)	0.063
Gangrene/Amputation	4,571 (1.5%)	3,751 (1.4%)	820 (1.8%)	<0.001
Obstruction	9,029 (2.9%)	8,110 (3.1%)	919 (2.0%)	<0.001
Return to Surgery	1,721 (0.6%)	1,511 (0.6%)	210 (0.5%)	0.005
Decubitus Ulcer	8,027 (2.6%)	6,150 (2.3%)	1,877 (4.1%)	<0.001
Orthopedic Complication	1,655 (0.5%)	1,269 (0.5%)	386 (0.9%)	<0.001
Compartment Syndrome	17 (0.01%)	16 (0.01%)	1 (0%)	0.309
Hepatitis/Jaundice	299 (0.3%)	714 (0.3%)	85 (0.2%)	0.002
Pancreatitis	2394 (0.8%)	2,124 (0.8%)	270 (0.6%)	<0.001
Necrosis of the Bone	215 (0.1%)	184 (0.1%)	31 (0.1%)	0.942
Osteomyelitis	3,478 (1.1%)	2,877 (1.1%)	601 (1.3%)	<0.001
DIC	5,159 (1.7%)	4,399 (1.7%)	760 (1.7%)	0.777
Pyelonephritis	194 (0.1%)	165 (0.1%)	29 (0.1%)	0.889
Post-Surgical Complication	7,382 (2.4%)	6,441 (2.4%)	941 (2.1%)	<0.001

Note: Percentages may not total 100% due to rounding. DVT=Deep Vein Thrombosis; CVA=Cerebrovascular Attack; DIC=Disseminated Intravascular Coagulation; Necrosis of the Bone includes thermal or aseptic necrosis.

In order to understand reasons for readmission and how these might differ between patients with and without depression, the top 10 reasons for readmission were examined. This is consistent with the approach used by Medicare and other payers to determine which conditions to target to improve quality and reduce costs (Hines, Barrett, Jiang, & Steiner, 2014). **Table 9** displays the ten most frequent reasons for readmission, based on admission diagnoses, among non-depressed and depressed patients. 5,147 patients (3,959 without depression and 1,188 with depression), were readmitted for the ten diagnoses. The most frequent reason for readmission in both groups was congestive heart failure, 22.5% in the non-depressed group and 19.3% in the depressed group. The majority of the reasons for readmission had similar frequencies in the non-depressed and depressed groups. However, in the non-depressed group 10.2% were admitted for abdominal aortic aneurysm compared to 3.5% in the depressed group. In addition, 17.6% of patients with depression were readmitted for a closed hip fracture (closed fracture of the intertrochanteric section of the neck of femur) compared to 7.4% of those without depression.

<b>Table 9. Top 10 Reasons for Readmission (n=5,147)</b>		
<u>Reason for Readmission</u>	<u>Non-Depressed (n=3,959) n (%)</u>	<u>Depressed (n=1,188) n (%)</u>
Congestive heart failure	891 (22.5%)	229 (19.3%)
Abdominal Aortic Aneurysm	403 (10.2%)	42 (3.5%)
Pneumonia	320 (8.1%)	93 (7.8%)
Lumbar Disc Displacement	113 (2.9%)	30 (2.5%)
Lumbar Spinal Stenosis without Neurogenic Claudication	167 (4.2%)	51 (4.3%)
Shortness of Breath	589 (14.9%)	145 (12.2%)
Chest Pain, unspecified	334 (8.4%)	83 (7.0%)
Abdominal Pain, unspecified site	567 (14.3%)	148 (12.5%)
Closed Fracture of the Intertrochanteric Section of Neck of Femur	292 (7.4%)	209 (17.6%)
Closed Fracture of Unspecified Neck of Femur	283 (7.1%)	158 (13.3%)

Note: Percentages may not total 100% due to rounding.

**Table 10** provides the results from logistic regression models that examined the association between depression and hospital nursing factors on the odds of 30-day mortality, FTR, and 30-day readmission in general, orthopedic, and vascular older adult surgical patients. The first column shows results for the unadjusted bivariate relationships between depression, PES-NWI, staffing, and education on mortality, FTR, and readmission. Education was the only variable with a significant relationship with the odds of mortality. Depression, the PES-NWI, and education were significantly associated with the odds of FTR in the unadjusted model. Depression, the PES-NWI, and education were significantly associated with the odds of readmission in the unadjusted model. In the second column, logistic regression models were partially adjusted for patient and



hospital characteristics. Depression, the PES-NWI, and education were significant in their relationship with the odds of mortality. Depression, the PES-NWI, and education were significant in their relationship with the odds of FTR. Depression was the only significant variable in its relationship to the odds of readmission. The third column displays full jointly estimated logistic regression models adjusted for patient, hospital, and nursing characteristics. Hospital nursing characteristics included: the PES-NWI, staffing, and education as well as the proportion of medical-surgical and ICU nurses within hospitals.

In the full model for mortality, the presence of depression was associated with a 7% decrease in the odds of mortality ( $p < 0.05$ ). One increase in standard deviation from the mean PES-NWI score was associated with a 6% decrease in the odds of mortality ( $p < 0.01$ ). A 10% increase in the proportion of bachelors prepared nurses was associated with a 4% decrease in the odds of mortality ( $p < 0.05$ ). In the full model for FTR, the presence of depression was associated with an 11% decrease in the odds of FTR ( $p < 0.01$ ). One increase in standard deviation from the mean PES-NWI score was associated with a 6% decrease in the odds of FTR ( $p < 0.01$ ). A 10% increase in the proportion of bachelors prepared nurses was associated with a 3% decrease in the odds of FTR ( $p < 0.05$ ). In the full model for readmission, the presence of depression was associated with a 58% increase in the odds of readmission ( $p < 0.001$ ). While hospital nursing characteristics have demonstrated significant relationships with readmissions in

previous research (Ma et al., 2015; McHugh et al., 2013; McHugh & Ma, 2013), it is possible that the effects of including depression in the model alters this relationship.

<b>Table 10. Odds Ratio Estimating the Effects of the Organization of Nursing Features on 30-day Mortality, Failure to Rescue, and 30-day Readmission in Adult Surgical Patients with and without Depression (n=311,679)</b>			
<b>Characteristic of Interest OR (95% CI)</b>	<b>Unadjusted (Bivariate)</b>	<b>Partially Adjusted (Patient and Hospital Characteristics)</b>	<b>Fully Adjusted (Patient, Hospital, and Hospital Nursing Characteristics)</b>
<b><u>Mortality</u></b>			
Depression	0.99 (0.94-1.04)	0.93 (0.88-0.99)*	0.93 (0.88-0.99)*
PES-NWI	0.89 (0.86-0.94)	0.93 (0.89-0.97)***	0.94 (0.89-0.98)**
Staffing	1.02 (0.99-1.05)	1.00 (0.99-1.03)	0.99 (0.97-1.03)
Education	0.95 (0.93-0.97)***	0.96 (0.94-0.98)**	0.96 (0.94-0.99)*
<b><u>Failure to Rescue</u></b>			
Depression	0.94 (0.88-0.99)*	0.89 (0.83-0.95)***	0.89 (0.83-0.95)**
PES-NWI	0.90 (0.86-0.95)***	0.93 (0.89-0.98)**	0.94 (0.90-0.99)**
Staffing	1.02 (0.99-1.05)	1.01 (0.99-1.04)	1.00 (0.98-1.03)
Education	0.96 (0.94-0.99)**	0.97 (0.94-0.99)*	0.97 (0.94-0.99)*
<b><u>30-day Readmission</u></b>			
Depression	1.60 (1.55-1.66)***	1.58 (1.53-1.64)***	1.58 (1.53-1.64)***
PES-NWI	0.95 (0.92-0.97)***	0.98 (0.95-1.00)	0.98 (0.95-1.00)
Staffing	1.00 (0.99-1.02)	1.00 (0.99-1.02)	1.01 (0.99-1.02)
Education	1.01 (1.00-1.03)*	1.01 (0.99-1.02)	1.01 (0.99-1.02)

\*\*\* $P < 0.001$  \*\* $p < 0.01$  \* $p < 0.05$

Note: Depression is indicated by the presence of a Chronic Condition Warehouse (CCW) depression flag. The PES-NWI is the Practice Environment Scale of the Nurse Work Index (excludes the Staffing and Resource Adequacy Subscale), measured in 1 standard deviation unit increments. Staffing is the ratio of patients to nurses and is a continuous measure. Education is the proportion of BSNs at the hospital level, measured in 10% increments. Patient characteristics include: age, sex, race, transfer status, Elixhauser comorbidities, and procedure type (DRG). Hospital characteristics include: teaching status, technology status, size, location (CBSA), ownership, and state. Nursing characteristics include: proportion of medical surgical and ICU nurses at the hospital level, the PES-NWI, the patient to nurse ratio, and the proportion of bachelor's prepared nurses at the hospital level. Partially adjusted models include the PES-NWI, staffing, and education separately. Fully adjusted models jointly adjust for the PES-NWI, staffing, and education. OR: Odds Ratio; CI: Confidence Interval

In order to understand the possible relationship between depression and hospital nursing factors and their joint effect on mortality, FTR, and readmissions, interactions between depression and the PES-NWI, staffing, and education were explored. The PES-NWI was a continuous variable in the interaction term. In order to allow for interpretability, the staffing variable was dichotomized with high staffing as a patient to nurse ratio above the median and low staffing as a patient to nurse ratio below the median. High staffing was unfavorable therefore, while low staffing was favorable. Education was a continuous variable in the interaction, representing the proportion of BSNs at the hospital level. **Table 11** presents odds ratios for the interactions.

<b>Table 11. Odds Ratio Estimating the Interactions of the Organization of Nursing Features on 30-day Mortality, Failure to Rescue, and 30-day Readmission in Adult Surgical Patients with and without Depression (n=311,679)</b>		
<b>Characteristic of Interest OR (95% CI)</b>	<b>Fully Adjusted (Patient, Hospital, and Nursing Characteristics)</b>	<b>Fully Adjusted (Patient, Hospital, and Nursing Characteristics) and Interaction Term</b>
<b><u>Mortality</u></b>		
PES-NWI	0.94 (0.89-0.98)***	0.94 (0.90-0.98)**
PES-NWI*Depression		0.96 (0.89-1.03)
Staffing	0.99 (0.98-1.01)	0.99 (0.97-1.02)
Staffing*Depression		1.05 (1.01-1.08)**
Education	0.96 (0.95-0.98)***	0.97 (0.95-0.99)**
Education*Depression		0.96 (0.92-0.99)*
<b><u>Failure to Rescue</u></b>		
PES-NWI	0.94 (0.90-0.99)**	0.94 (0.90-0.99)*
PES-NWI*Depression		0.98 (0.90-0.99)
Staffing	1.00 (0.97-1.03)	0.99 (0.97-1.03)
Staffing*Depression		1.04 (0.99-1.09)
Education	0.97 (0.94-0.99)*	0.97 (0.92-1.01)
Education*Depression		0.97 (0.92-1.01)
<b><u>30-day Readmission</u></b>		
PES-NWI	0.98 (0.96-1.00)	0.98 (0.96-1.01)
PES-NWI*Depression		0.99 (0.94-1.03)
Staffing	1.01 (0.99-1.02)	1.01 (0.98-1.03)
Staffing*Depression		1.00 (0.98-1.03)
Education	1.01 (0.99-1.02)	1.01 (0.99-1.03)
Education*Depression		0.98 (0.96-1.01)

\*\*\* $P < 0.001$  \*\* $p < 0.01$  \*  $p < 0.05$

Note: Depression is indicated by the presence of a Chronic Condition Warehouse (CCW) depression flag. The PES-NWI is the Practice Environment Scale of the Nurse Work Index (excludes the staffing and resource adequacy subscale), measured in 1 standard deviation unit increments. Staffing is the ratio of patients to nurses and is a continuous measure. Education is the proportion of BSNs at the hospital level, measured in 10% increments. Patient characteristics include: age, sex, race, transfer status, Elixhauser comorbidities, and procedure type (DRG). Hospital characteristics include: teaching status, technology status, size, location (CBSA), ownership, and state. Nursing characteristics include: proportion of medical surgical and ICU nurses at the hospital level, the PES-NWI, the patient to nurse ratio, and the proportion of bachelor's prepared nurses at the hospital level. Fully adjusted models are jointly adjusted for PES-NWI, staffing, and education. In the interaction term, staffing was a dichotomous variable, with "0" representing a patient to nurse ratio below the median and "1" representing a patient to nurse ratio above the median. OR: Odds Ratio; CI: Confidence Interval.

Interactions were calculated by using beta coefficients from logit regression to calculate the odds ratio for patients with depression compared to patients without depression. Depression did not have a significant interaction with the PES-NWI for any of the three outcomes. Depression had a significant interaction with staffing in the model examining 30-day mortality ( $p < 0.05$ ), however this interaction was not significant for FTR or readmissions. Similarly, depression had a significant interaction with education in the model examining 30-day mortality ( $p < 0.05$ ), however this interaction was not significant for FTR or readmissions. **Table 12** compares the full, jointly adjusted model with no interaction term to the full, jointly adjusted model with an interaction term for both staffing and education. In patients without depression, a patient to nurse ratio higher than the median (5.2) was associated with a 1% increase in the odds of mortality. However, for patients with depression, a patient to nurse ratio higher than the median was associated with a 15% increase in the odds of mortality. Similarly, for patients without depression, a 10% increase in the proportion of BSNs at the hospital level, was associated with a 4% decrease in the risk of mortality. However, for patients with depression, a 10% increase in the proportion of BSNs at the hospital level, was associated with a 9% decrease in the risk of mortality.

<b>Table 12. Odds Ratio Estimating the Differential Effects of the Organization of Nursing Features on 30-day Mortality in Adult Surgical Patients with and without Depression (n=311,679)</b>		
	<b>Fully Adjusted (Patient, Hospital, and Nursing Characteristics)</b>	<b>Fully Adjusted (Patient, Hospital, and Nursing Characteristics) and Interaction</b>
	<b>Mortality OR (95% CI)</b>	<b>Mortality OR (95% CI)</b>
Staffing*Depression		1.05 (1.01-1.09)*
No Depression	0.99 (0.97-0.98)	1.01*
Depression	1.03 (0.99-1.08)	1.15*
Education*Depression		0.96 (0.92-0.99)*
No Depression	0.97 (0.94-0.99)*	0.96*
Depression	0.94 (0.89-0.98)*	0.91*

\*  $p < 0.05$

Note: Fully adjusted models are jointly adjusted for PES-NWI, staffing, and education. In the interaction term, staffing was a dichotomous variable, with "0" representing a patient to nurse ratio below the median and "1" representing a patient to nurse ratio above the median. Education is the proportion of BSNs at the hospital level, measured in 10% increments. Odds ratios for the interaction between staffing and depression and education and depression come from logistic regression models. The odds ratios for patients without and with depression were derived from logit regression models, calculated for each group level (no depression vs. depression).

Given the interactions between the presence of depression and staffing and education individually, it was also of interest to understand how staffing and education might additively contribute to decreasing the risk of mortality in patients with and without depression. The presence of depression, the patient to nurse ratio, and the proportion of BSNs were tested in eight combinations in order to understand whether depression, staffing, or education might be most influential in lowering the odds of mortality. In order to assess this difference, staffing and education were categorized into two groups, high and low, divided at the median. High staffing was a high patient to nurse ratio, above the median. Low staffing was a low patient to nurse ratio, below the median. Low staffing was therefore favorable. Education, represented as the proportion

of nurses with BSNs at the hospital level, was high if higher than the median and low if lower than the median. Thus, high education was favorable. First, crude mortality rates were calculated as frequencies for each combination of depression, education, and staffing. Then, a predictive model controlling for patient characteristics was generated employing logistic regression to generate the predicted mortality. Residual mortality was then calculated by subtracting the expected mortality from the observed mortality.

**Table 13** presents the results of analysis with a predictive model with presence or absence of depression, two levels of staffing (high/low), and two levels of education (high/low). It can be seen that in hospitals with low staffing ratios (patient to nurse ratios lower than the median), both crude and residual mortality rates are lowered. This relationship holds when the proportion of BSNs is high, even in the presence of depression. However, in hospitals with low, or favorable, staffing, a low percentage of BSNs can attenuate this relationship, increasing mortality rates. Neither levels of BSNs nor presence of depression were clearly linked to crude or residual mortality.



<b>Table 13. Crude and Residual 30-Day Mortality Rate by Presence of Depression, Level of Staffing, and Proportion of Bachelor's Prepared Nurses (BSNs) (n=311, 169)</b>				
<u>Depression</u>	<u>Staffing</u>	<u>Proportion of BSNs</u>	<u>Crude Mortality</u>	<u>Residual Mortality*</u>
Present	High	High	4.20	0.044
Not Present	High	High	3.91	0.013
Present	High	Low	4.21	0.123
Not Present	High	Low	4.09	0.231
Present	Low	High	3.33	-0.726
Not Present	Low	High	3.57	-0.296
Present	Low	Low	3.79	-0.275
Not Present	Low	Low	4.15	0.311

Note: Staffing was a dichotomous variable with “High” representing a high patient to nurse ratio (poor staffing) and “Low” representing a low patient to nurse ratio (favorable staffing), split at the median. Proportion of BSNs was a dichotomous variable with “High” representing a high proportion of BSNs (favorable) and “Low” representing a low proportion of BSNs (poor), split at the median.

\*Residual mortality was calculated by the following procedure: 30-day mortality was predicted in a model including patient characteristics [age, sex, race, transfer status, Elixhauser comorbidity, and procedure type (DRG)]. Then, the expected 30-day mortality rate was subtracted from the observed rate of mortality. A residual mortality below zero is favorable, representing an observed mortality lower than the expected mortality. A residual mortality above zero is unfavorable, representing an observed mortality higher than expected mortality.

## CHAPTER 5: Discussion

The purpose of this study was to examine the relationship between hospital nursing factors (work environment, staffing, and education) and outcomes for older adult general, orthopedic, and vascular surgical patients with and without depression. The results of this study show that patients cared for in hospitals with higher proportions of bachelor's prepared nurses and lower patient to nurse staffing ratios have a lower risk of dying. This is especially true for older adults with depression, for whom education and staffing lowered the risk of dying to an even greater extent. Although depression was associated with lower odds of mortality and failure to rescue (FTR), this effect was reversed when the moderating effects of education and staffing were taken into account. The work environment did not exert a strong effect on patients with depression and hospital nursing factors did not lower the odds of readmission for patients with depression. In models examining predicted patient to nurse ratios and proportions of bachelors prepared nurses (BSNs) in the hospitals of interest, between the independent variables of depression, patient to nurse ratio, and proportion of BSNs, staffing was found to exert the strongest influence in lowering the odds of mortality for patients with and without depression. Low staffing (low patient to nurse ratio) and a high proportion of BSNs had the greatest effect in lowering the odds of mortality, to a greater extent in patients with depression than in those without depression.

This chapter discusses the principal findings of the study examining the relationships between depression and hospital nursing factors and the outcomes of 30-day mortality, failure to rescue (FTR), and 30-day readmissions. Strengths and limitations of the study will be discussed. The chapter concludes with a discussion of policy implications of this study and directions for future research.

### **Principal Findings**

The overall rate of mortality was 3.9% among all patients and the FTR rate was 9.9% among patients who died within 30 days of admission, slightly higher rates than demonstrated in previous studies examining the relationship of hospital nursing factors to outcomes in this surgical population (Aiken et al., 2011; Aiken et al., 2002). However, the rate of mortality is consistent with a study on variation in hospital mortality, which reported 3.5-6.9% mortality (Ghaferi et al., 2009b). The FTR appears consistent with the literature, which suggests that FTR rates for non-elective surgery range from 13-25%, with higher rates in the elderly (Sheetz et al., 2013). In addition, nearly 78% (n=9,482) of all patients in the sample experienced at least one complication. In addition, the odds of FTR had a similar magnitude, direction, and significance to the odds of mortality in comparable models, a phenomena consistent with the literature (Sheetz et al., 2013). For non-depressed patients, readmission occurred in 6.2% of patients compared to 9.5% of patients with depression. The rate of readmissions for patients with depression was comparable to the rate found in a previous study of readmissions in general, orthopedic, and vascular Medicare surgical patients (Ma et al., 2015). This potentially suggests that

depression may be associated with the overall risk of readmission. While rates of complications appeared comparable between the depressed and non-depressed groups, significant differences in complication rates were seen between surgical groups, ranging from a complication rate of 32.5% for orthopedic surgery patients to 58.8% for vascular surgery patients. Prior research demonstrated similar rates in this population (Ghaferi et al., 2009b); however, it is important to note that understanding the driving forces for complications, particularly in patients with depression, warrants attention.

### **Organization of Nursing and Mortality**

This study demonstrated that staffing and education play an important role in lowering the odds of mortality in surgical patients and to a greater extent in patients with depression. A patient to nurse ratio above the median was associated with a 1% increase in the odds of mortality in patients without depression but 15% in patients with depression. This result is consistent with a prior study on the relationship between staffing and mortality in patients with serious mental illness (major depressive disorder, bipolar disorder, or schizophrenia) (Kutney-Lee & Aiken, 2008). In addition, a 10% increase in the proportion of bachelor's prepared nurses was associated with 4% lower odds of mortality in patients without depression and 9% lower odds of mortality in patients with depression. The effects of staffing and education on lowering the odds of mortality have previously been established in the orthopedic, general, and surgical population (Aiken et al., 2011; Aiken et al., 2003). Although this effect has not been previously established in patients with depression, the effect of nurse education has

been associated with decreasing length of stay and lowering the odds of mortality in patients with serious mental illness (SMI) (Kutney-Lee & Aiken, 2008). This study was the first to examine the interaction between depression and nurse education and its influence on mortality.

The work environment, however, did not demonstrate a significant relationship with mortality in patients with depression as compared to those without depression. Independently, depression, the work environment, and education were associated with lower odds of mortality. However, when interactions were tested between the work environment and depression, this relationship did not remain significant. Given that prior research in this hospital population demonstrates that when staffing is examined in light of categories of the work environment its effects are more pronounced, it is possible that the relationship between staffing and depression is more complex (Aiken et al., 2008). In addition, although staffing independently did not significantly lower the odds of mortality, when the moderating effect of depression was taken into account, staffing exerted an effect in decreasing mortality for both groups. Similarly, this relationship has been studied in patients with SMI, for whom lower patient to nurse staffing ratios lower the odds of mortality to a greater extent than in patients without SMI (Kutney-Lee & Aiken, 2008). Therefore, this study was also the first to examine the interaction between depression and staffing and its influence on mortality.

Although it appears that depression is associated with decreasing the odds of mortality in this population, it is possible that there is unexplained variability due to

differential effects in the subgroups. In addition, it is conceivable that patients with depression may have lower odds of mortality due to selection bias. Research demonstrates that Medicare patients with mental illness, including depression, are less likely to receive medical care and elective procedures than patients without depression (Copeland et al., 2015; Li et al., 2011; Li et al., 2013). This suggests that patients who do receive treatment, might be a healthier sample or may have less severe depressive symptoms.

**Influence of staffing and education on mortality.** Based on the findings in this study that depression had interactions with staffing and education, which significantly affected mortality, a predictive model was tested to assess the simultaneous effects of staffing and education on crude and residual mortality rates. The model demonstrated that the effect of staffing (low patient to nurse ratio) was the most significant factor associated with decreasing the odds of mortality. Low staffing and high proportions of BSNs made the greatest impact on lowering mortality, to a greater extent in patients with depression. This finding further supports the promotion of lower patient to nurse staffing ratios and of nurses obtaining BSNs in order to decrease mortality in older surgical patients. This particularly makes a difference for patients with depression.

#### **Organization of Nursing and Failure to Rescue (FTR)**

Prior research demonstrates that the relationship of hospital nursing factors to FTR is similar to that of hospital nursing factors and mortality. Higher patient to nurse ratios, higher proportions of BSNs and better work environments have been linked to

decreased odds of FTR (Aiken et al., 2011; Aiken et al., 2002; Clarke & Aiken, 2003). While the independent effects of depression, the work environment, and education were associated with a decrease in FTR, these effects were not significant when the interactions between depression and the work environment and depression and education were assessed. While it was hypothesized that patients with depression would have a greater number of comorbidities and risk factors for developing complications as suggested in the literature, few clinically significant differences were seen (Bressi, Marcus, & Solomon, 2006). However, it is conceivable that the effects of depression on the likelihood of developing complications cannot be captured in the short term and the deleterious effects are more likely to be pronounced after discharge or follow up (Burg, Benedetto, Rosenberg, & Soufer, 2003; Connerney et al., 2001). It is also possible that the work environment exerts effects equally on all patients, with or without depression. In addition, significant differences were not seen in the majority of complications leading to mortality in this study. Patients with depression also appeared to have lower odds of FTR than patients without depression. Similar to mortality, it is possible that the patients with depression selected for surgery are generally a healthier population than patients with depression in general (Li et al., 2011; Li et al., 2013).

### **Organization of Nursing and Readmissions**

The relationships explored between depression, hospital nursing factors, and readmissions suggest that depression increases the odds of readmission significantly. However, the work environment, staffing, and education were not significantly

associated with readmissions. This finding raises further questions given the findings of previous studies. Prior research in the Medicare general, orthopedic and vascular surgical population suggest that better work environments are associated with decreased odds of readmission (Ma et al., 2015). In addition, lower patient to nurse ratios are also predictive of the likelihood of a hospital receiving a readmission penalty (McHugh et al., 2013). In this study, testing of interactions of depression and the moderating effects of the work environment, staffing, and education were not significant. Although it was hypothesized that patients with depression would have higher rates of complications contributing to readmissions, this study did not support this hypothesis. One plausible explanation for this is that especially in the population of older surgical patients with depression, significant complications that contribute to readmissions may occur post-discharge and are therefore not captured by pre-discharge complications (Dimick & Ghaferi, 2015).

It is of note that the work environment was hypothesized to decrease the odds of mortality and FTR (Aiken et al., 2008; Friese et al., 2008) and readmissions (Ma et al., 2015) as in prior studies. However, it is possible that the effect of depression on patient outcomes is profound and may influence outcomes to a greater extent than the work environment.

### **Policy Implications**

Approximately 1 in 5 older adult Americans will be affected by mental illness in any year, the most common of which is depression (SAMHSA, 2015a). The treatment of



depression has garnered attention in the past decade; as a result of the ACA's inclusion of mental health coverage, promotion of screening for all adults by the U.S. preventive health task force, and recent international research highlighting the return on investment for treating depression (Beronio, Po, Skopee, & Glied, 2013; Chisholm et al., 2016; Siu, 2016). However, understanding the potential interventions, outside of screening, detection, medication, and therapy has not received much focus. The hospital setting serves as a locus of intervention, a contact point with which many older adults will interface. Shifting efforts to care for patients with depression in the hospital setting allows policy makers to leverage the infrastructure and resources available to target a vulnerable population. It also capitalizes on existing infrastructure and resources, a key component of which is the nursing workforce. The potential for the organization of nursing to influence the outcomes of older adult patients with depression hospitalized for surgery has not been previously explored. Hospital administrators may use the evidence generated in this study to support nursing interventions to improve the outcomes of patients with depression. While the value of improving patient care and preventing untoward harm in this vulnerable older adult population is important, cost analyses and return on investment could also provide further support for hospital administrators to guide decisions (Silber et al., 2016).

While initiatives to improve outcomes in patients with depression focus on prescribed treatments, such efforts have historically not included nursing (Katon, 2011). However, a growing body of evidence supports interventions to improve hospital

nursing factors, namely the work environment, staffing, and education, in order to decrease surgical patient mortality, FTR, and readmissions (Aiken et al., 2011; Aiken et al., 2002; Ma et al., 2015). The information generated in this study builds upon this literature by examining the impact of hospital nursing factors on outcomes for patients with depression. The principal findings from this study support the promotion of lower patient to nurse staffing ratios and higher proportions of bachelors prepared nurses in order to decrease the odds of mortality in older adult surgical patients with depression. Through the nurses' role in monitoring, observation, and assessment, or surveillance, nurses provide continuous care at the bedside and are able to intimately know and address the needs of their patients (Kutney-Lee et al., 2009). In surgical patients, this care is particularly critical in decreasing the risk of infection and other adverse events. Given the physiological vulnerability of patients with depression, this is even more important (Katon, 2011). Administrators may consider promoting environments that support, not only lower staffing ratios and higher levels of education, but that foster the importance of integrating mental health assessment into current practice.

While the work environment did not exert a strong influence on the outcomes of patients with depression, it is possible that the work environment alone does not improve patient care. There are potential unmeasured features outside of the hospital nursing factors examined here in relation to work environment. In addition, it is possible that the work environment provides a positive benefit to all patients. Although the hospital nursing factors studied did not moderate the relationship between depression

and FTR and readmission, the relationships warrant further discussion. Patients with depression have physiological vulnerabilities which predispose them to complications (Katon, 2011). Perhaps because patients with depression are underrepresented among surgical patients and may be a healthier sample, this assumption did not hold in the results presented (Copeland et al., 2015). In addition, it is possible that the complications that patients with depression experience are not those captured by FTR. For example, when reasons for readmission were assessed, it was noted that a significant proportion of patients with depression were readmitted for hip fractures while those without depression were not. The adverse event that most likely precipitated this was a fall (Hanrahan et al., 2010), however this would not have been captured by FTR. In addition, it is important to look at the complications that may affect patients with depression disproportionately. Psychoses occurs more frequently in patients with depression, likely related to delirium (Katon, 2011). While delirium can and may result in death, it is likely that delirium is detected in the hospital setting (Kudoh et al., 2002), and therefore is more promptly treated than other complications might be. With regards to readmissions, it is clear that having depression is associated with an increased risk of readmission (Prina et al., 2013). However, nursing factors were not influential in moderating this relationship. While this seems counterintuitive, it is possible that there are unmeasurable nursing factors that influence readmissions. Hence, hospital administrators and policy makers should support lower staffing ratios and a higher educated nurse workforce. But they should also continue to foster nurse

driven efforts to target specific complications such as psychosis and foster efforts to reduce readmissions in this high risk population. Given the emphasis on value based care, both complications and readmissions can be costly for hospitals (Merkow et al., 2015). It is conceivable that through hospital nursing focused interventions, the underlying factors driving readmissions can better be targeted (Ma et al., 2015; McHugh et al., 2013; McHugh & Ma, 2013).

While the majority of present research on the role in treating patients with depression is in primary care, nurses' involvement in the treatment of depression as a part of a team of providers is evident (Katon et al., 2010). In the hospital setting, it can be hypothesized that screening for depression, through commonly available and validated tools, can be a critical role of the nurse (Celano, Suarez, Mastromauro, Januzzi, & Huffman, 2013). In addition, as organizational culture supports a focus on mental health, nurses can potentially be further engaged to assess the specific vulnerabilities of patients with depression. For example, patients with depression undergoing surgery will be exposed to anesthetic agents. Given the higher risk of delirium in patients with depression, it would be important to take preventative measures. For example, fentanyl inhibits cortisol secretion and significantly lowers the risk of confusion in patients with depression (Kudoh et al., 2002). Nurses could screen for patients at risk and organizations could support policies for specific procedures, such as fentanyl administration during surgery. In addition, providing the appropriate staffing and work environment may allow nurses to better target vulnerable patients. It is hypothesized

that, as nurses have fewer patients to care for, they may have more time to attend to the care of vulnerable patients. Recent literature on missed care, tasks not done by nurses because of time constraints, suggests that nurses often omit tasks when they work in sub-optimal environments and when they care for more patients per shift (Carthon, Lasater, Sloane, & Kutney-Lee, 2015; Kalisch, Tschannen, & Lee, 2011). The most frequently listed missed task is “comforting and caring” for patients (Carthon et al., 2015; Lake, Germack, & Viscardi, 2015). This task could be critical to identifying and appropriately applying interventions to vulnerable surgical patients with depression. On a policy level, this research further supports lower patient to nurse ratios. It was found that staffing was the single most important driver of patient mortality among the nursing factors examined. This affected patients with depression to a greater extent. Hence, mandated staffing ratios, such as those applied in California, may be one strategy that policy makers take to address vulnerable populations such as patients with depression.

In addition to promotion of lower patient to nurse ratios, the Institute of Medicine (IOM), in its landmark *Future of Nursing* report, recommends an 80% bachelors prepared workforce (IOM, 2011). Recent evidence supports the promotion of BSN prepared nurses as an effective intervention to decrease mortality, FTR, and readmissions (Aiken, 2014). Yet, the most recent estimates of the U.S. workforce demonstrate that bachelors prepared nurses make up less than 45% of the nursing workforce (HRSA, 2013). Hence, this study builds upon existing research and provides

further evidence to support promotion of higher education for nurses. On an institutional level, hospital administrators can support educational development of nurses and provide incentives for nurses achieving a higher degree.

### **Limitations**

The nature of the cross-sectional data in this study did not allow for causal inference; rather conclusions were drawn on associations between variables. Given the use of secondary data, only measured variables were accounted for in analysis. Variables that could have contributed to outcomes in patients with depression, such as depression severity or other clinical indicators, were not measured. In addition, it was not possible to differentiate between patients that were or were not treated for depression. However, the data employed in this study represents a strong administrative data set for studying patients with depression. In most settings, depression is often under-coded due to clinical presentation, provider bias, and up-coding of other reimbursable diagnoses (Townsend, Walkup, Crystal, & Olfson, 2012). An advantage of employing the CCW depression flag in the Medicare data to identify patients is that this approach increases the sample size by including both inpatient and outpatient data as well as a larger range of diagnostic codes than is typically employed. Still, this data set did not find differences in comorbidities between patients with and without depression, contrary to the literature. This suggests that the sample population was healthier than other non-surgical populations.

Another limitation is the age of the data sources. The Multi-State Nurse Survey data as well as the AHA and Medicare data were collected in 2006 and 2007, nearly 10 years prior to the time of analysis. However, it is unlikely that the fundamental relationships between depression and nursing factors and mortality, FTR, and readmissions have been altered since the time of the study. Furthermore, the Multi-State Nurse Survey represents a unique data set which allows for the examination of the impact of nursing factors on patient outcomes.

### **Future Research**

The results from this study significantly contribute to the literature on the impact of hospital nursing factors on mortality, FTR, and readmissions, particularly for patients with depression. No prior study has examined this vulnerable population in this light. While staffing and education were found to be associated with lower odds of mortality, the drivers behind this relationship are unknown. It was hypothesized that RN surveillance drives this relationship. However, this is difficult to test in a cross-sectional study. Further research can look at the mechanism for this process, such as missed care, examining tasks that nurses do not complete, and differential effects in patients with and without depression. This additional research might help to clarify why fewer patients per nurse may improve outcomes in patients with depression. Similarly, it would be useful to understand the practice differences of nurses with BSN degrees. Why and how they provide better care for patients with depression than nurses without BSN degrees must be elucidated. It is hypothesized that nurses with BSNs may have greater

awareness of depression, are better able to detect it, and can adapt monitoring and assessment to the unique needs of this population. Qualitative work with hospitals with and without high proportions of nurses with BSNs could verify or augment this hypothesis. In addition, given the physiological vulnerabilities of patients with depression, clinical data abstracted from charts might give further information on their vulnerabilities otherwise not detected by complications and FTR. For example, given the vulnerability to poor wound healing, it is conceivable that the patient received additional wound care, but that this was not billed and coded.

Better understanding the process of this improvement in patient outcomes can also provide support for interventions that have the potential to drive costs up. However, the potential cost savings of the additional care that patients with depression would otherwise receive can support this. To date, no study exists on the impact of staffing and education on cost in patients with depression. However, further examination of the readmission rates and length of stay could provide evidence for this. Hospital administrators are facing increased pressure from CMS to decrease readmissions for high risk populations (Barnett, Hsu, & McWilliams, 2015). Examining ways to decrease length of stay, but not at the cost of increased readmissions, can be of interest to administrators.

### **Conclusion**

In conclusion, the results of this study demonstrate that an increase of the patient to nurse ratio above the median (median: 5.2, mean: 5.4, SD: 1.3) was



associated with an increase in 30-day mortality of 1% for patients without depression but 15% for patients with depression. In addition, a 10% increase in the proportion of BSN prepared nurses was associated with a 4% decrease in 30-day mortality for patients without depression and a 9% increase in 30-day mortality for patients with depression. Furthermore, it was found that the most profound effects on mortality were associated with staffing. The optimal combination of hospital nursing factors was low staffing and high proportion of BSNs, which resulted in the greatest predicted reduction in mortality. This effect was most pronounced for those with depression.

Depression is common, costly, and complicates care for hospitalized older adults undergoing surgery. As Medicare continues to focus on decreasing costs, particularly in the care of patients with chronic conditions, managing the ill effects of depression will be a focus of these efforts. Not only does depression increase complexity of care, it also results in worse physical outcomes, functional status, and quality of life for older adult patients, many of whom are already fragile patients. Simple organizational interventions, including decreasing patient to nurse ratios and increasing the proportion of BSNs have the potential to avert mortality in patients with depression. Both administrators and policy makers can use this evidence to guide staffing and education decisions as well as to shape policy on effective interventions to improve outcomes in patients with depression.

**Appendix A: Categorization of common surgical procedures based on Silber designation**

<b>Surgery Type</b>	<b>DRG</b>
General	146-155, 157-162, 164-167, 170, 171, 191-201, 257-268, 285-293, 493, and 494
Orthopedic	209-211, 213, 216-219, 223-234, 471, 491, 496-503
Vascular	110-114, 119, 120

**Appendix B: Centers for Medicare and Medicaid Services (CMS) Chronic Condition Warehouse (CCW) Condition**

1. Acquired hypothyroidism
2. Acute myocardial infarction
3. Alzheimer's disease (including related disorders or senile dementia)
4. Anemia
5. Asthma
6. Atrial fibrillation
7. Benign prostatic hyperplasia
8. Colorectal cancer
9. Endometrial cancer
10. Breast cancer
11. Lung cancer
12. Prostate cancer
13. Cataract
14. Chronic kidney disease
15. Chronic obstructive pulmonary disease
16. Depression
17. Diabetes
18. Glaucoma
19. Heart failure
20. Hip/pelvic fracture
21. Hyperlipidemia
22. Hypertension
23. Ischemic heart disease
24. Osteoporosis
25. Rheumatoid arthritis/osteoarthritis
26. Stroke
27. Transient ischemic attack

**CMS CCW Depression Diagnoses (DRGs) Included in Flag**

Algorithm	ICD-9/CPT/HCPCS Codes	Number/Type of Claims to Qualify
Depression	DX 296.20, 296.21, 296.22, 296.23, 296.24, 296.25, 296.26, 296.30, 296.31, 296.32, 296.33, 296.34, 296.35, 296.36, 296.50, 296.51, 296.52, 296.53, 296.54, 296.55, 296.56, 296.60, 296.61, 296.62, 296.63, 296.64, 296.65, 296.66, 296.89, 298.0, 300.4, 309.1, 311 (any DX on the claim)	At least 1 inpatient, SNF, HHA, HOP or Carrier* claim with DX codes during the 1-yr period

## Appendix C: List of Elixhauser Comorbidities

(Elixhauser et al., 1998)

<b>Elixhauser Comorbidity</b>	<b>ICD-9 CM Codes</b>	<b>Exclusion by Diagnosis Related Group (DRG)</b>
Congestive Heart Failure	398.91, 402.11, 402.91, 404.11, 404.13, 404.91, 404.93, 428.0-428.9	Cardiac
Cardiac Arrhythmia	426.10, 426.11, 426.13, 426.2-426.53, 426.6-426.89, 427.0, 427.2, 427.31, 427.60, 427.9, 785.0, V45.0, V53.3	Cardiac
Valvular Disease	093.20-093.24, 394.0-397.1, 424.0-424.91, 746.3-746.6, V42.2, V43.3	Cardiac
Peripheral Vascular Disorders	440.0-440.9, 441.2, 441.4, 441.7, 441.9, 443.1-443.9, 447.1, 557.1, 557.9, V43.4	Peripheral Vascular (130-131)
Pulmonary Circulation Disorders	416.0-416.9, 417.9	Cardiac or COPD (88)
Hypertension uncomplicated	401.1, 401.9	Hypertension (134)
Hypertension complicated	402.10, 402.90, 404.10, 404.90, 405.11, 405.19, 405.91, 405.99	Hypertension (134) or cardiac or renal
Paralysis	342.0-342.12, 342.9-344.9	Cerebrovascular (5, 14-17)
Other neurological disorders	331.9, 332.0, 333.4, 333.5, 334.0-335.9, 340, 341.1-341.9, 345.00-345.11, 345.40-345.51, 345.80-345.91, 348.1, 348.3, 780.3, 784.3	Nervous system (1-35)
Chronic pulmonary disease	490-492.8, 493.00-493.91, 494, 495.0-505, 506.4	COPD (88) or asthma (96-98)
Diabetes uncomplicated	250.00-250.33	Diabetes (294-295)
Diabetes complicated	250.40-250.73, 250.90-250.93	Diabetes (294-295)
Hypothyroidism	243-244.2, 244.8, 244.9	Thyroid (290) or Endocrine (300-301)

Renal failure	403.11, 403.91, 404.12, 404.92, 585, 586, V42.0, V45.1, V56.0, V56.8	Kidney transplant (302) or renal failure or dialysis (316-317)
Liver Disease	070.32, 070.33, 070.54, 456.0, 456.1, 456.20, 456.21, 571.0, 571.2, 571.3, 571.40-571.49, 571.5, 571.6, 571.8, 571.9, 572.3, 572.8, V42.7	Liver
Peptic ulcer disease excluding bleeding	531.70, 531.90, 532.70, 532.90, 533.70, 533.90, 534.70, 534.90, V12.71	GI hemorrhage or ulcer (174-178)
AIDS	042-044.9	HIV (488-490)
Lymphoma	200.00-202.38, 202.50-203.01, 203.8-203.81, 238.6, 273.3, V10.71, V10.72, V10.79	Leukemia or lymphoma
Metastatic cancer	196.0-199.1	Cancer
Solid tumor without metastasis	140.0-172.9, 174.0-175.9, 179-195.8, V10.00-V10.9	Cancer
Rheumatoid arthritis/collagen vascular disease	701.0, 710.0-710.9, 714.0-714.9, 720.0-720.9, 725	Connective tissue (240-241)
Coagulopathy	2860-2869, 287.1, 287.3-287.5	Coagulation (397)
Obesity	278.0	Obesity procedure (288) or nutrition or metabolic (296-298)
Weight Loss	260-263.9	Nutrition or metabolic (296-298)
Fluid and electrolyte disorders	276.0-276.9	Nutrition or metabolic (296-298)
Blood loss anemia	2800	Anemia (395-396)

Deficiency anemias	280.1-281.9, 285.9	Anemia (395-396)
Alcohol abuse	291.1, 291.2, 291.5, 291.8, 291.9, 303.90-303.93, 305.00-305.03, V113	Alcohol or drug (433-437)
Drug abuse	292.0, 292.82-292.89, 292.9, 304.00-304.93, 305.20-305.93	Alcohol or drug (433-437)
Psychoses	295.00-298.9, 299.10-299.11	Psychoses (430)
Depression*	300.4, 301.12, 309.0, 309.1, 311	Depression (426)

*\*Although listed, depression is not included in risk adjustment in this study*

## Appendix D: Cancer Diagnosis Exclusion

(For Cancer in Peritonitis)

### ***Excluded Cancer Diagnosis Codes (Principal Diagnosis or Comorbidity):***

140, 1400, 1401, 1403, 1404, 1405, 1406, 1408, 1409, 141, 1410, 1411, 1412, 1413, 1414, 1415, 1416, 1418, 1419, 142, 1420, 1421, 1422, 1428, 1429, 143, 1430, 1431, 1438, 1439, 144, 1440, 1441, 1448, 1449, 145, 1450, 1451, 1452, 1453, 1454, 1455, 1456, 1458, 1459, 146, 1460, 1461, 1462, 1463, 1464, 1465, 1466, 1467, 1468, 1469, 147, 1470, 1471, 1472, 1473, 1478, 1479, 148, 1480, 1481, 1482, 1483, 1488, 1489, 149, 1490, 1491, 1498, 1499, 150, 1500, 1501, 1502, 1503, 1504, 1505, 1508, 1509, 151, 1510, 1511, 1512, 1513, 1514, 1515, 1516, 1518, 1519, 152, 1520, 1521, 1522, 1523, 1528, 1529, 153, 1530, 1531, 1532, 1533, 1534, 1535, 1536, 1537, 1538, 1539, 154, 1540, 1541, 1542, 1543, 1548, 155, 1550, 1551, 1552, 156, 1560, 1561, 1562, 1568, 1569, 157, 1570, 1571, 1572, 1573, 1574, 1578, 1579, 158, 1580, 1588, 1589, 159, 1590, 1591, 1598, 1599, 160, 1600, 1601, 1602, 1603, 1604, 1605, 1608, 1609, 161, 1610, 1611, 1612, 1613, 1618, 1619, 162, 1620, 1622, 1623, 1624, 1625, 1628, 1629, 163, 1630, 1631, 1638, 1639, 164, 1640, 1641, 1642, 1643, 1648, 1649, 165, 1650, 1658, 1659, 170, 1700, 1701, 1702, 1703, 1704, 1705, 1706, 1707, 1708, 1709, 171, 1710, 1712, 1713, 1714, 1715, 1716, 1717, 1718, 1719, 172, 1720, 1721, 1722, 1723, 1724, 1725, 1726, 1727, 1728, 1729, 173, 1730, 1731, 1732, 1733, 1734, 1735, 1736, 1737, 1738, 1739, 174, 1740, 1741, 1742, 1743, 1744, 1745, 1746, 1748, 1749, 175, 1750, 1759, 176, 1760, 1761, 1762, 1763, 1764, 1765, 1768, 1769, 179, 180, 1800, 1801, 1808, 1809, 181, 182, 1820, 1821, 1828, 183, 1830, 1832, 1833, 1834, 1835, 1838, 1839, 184, 1840, 1841, 1842, 1843, 1844, 1848, 1849, 185, 186, 1860, 1869, 187, 1871, 1872, 1873, 1874, 1875, 1876, 1877, 1878, 1879, 188, 1880, 1881, 1882, 1883, 1884, 1885, 1886, 1887, 1888, 1889, 189, 1890, 1891, 1892, 1893, 1894, 1898, 1899, 190, 1900, 1901, 1902, 1903, 1904, 1905, 1906, 1907, 1908, 1909, 191, 1910, 1911, 1912, 1913, 1914, 1915, 1916, 1917, 1918, 1919, 192, 1920, 1921, 1922, 1923, 1928, 1929, 193, 194, 1940, 1941, 1943, 1944, 1945, 1946, 1948, 1949, 195, 1950, 1951, 1952, 1953, 1954, 1955, 1958, 196, 1960, 1961, 1962, 1963, 1965, 1966, 1968, 1969, 197, 1970, 1971, 1972, 1973, 1974, 1975, 1976, 1977, 1978, 198, 1980, 1981, 1982, 1983, 1984, 1985, 1986, 1987, 1988, 19881, 19882, 19889, 199, 1990, 1991, 200, 2000, 20000, 20001, 20002, 20003, 20004, 20005, 20006, 20007, 20008, 2001, 20010, 20011, 20012, 20013, 20014, 20015, 20016, 20017, 20018, 2002, 20020, 20021, 20022, 20023, 20024, 20025, 20026, 20027, 20028, 2008, 20080, 20081, 20082, 20083, 20084, 20085, 20086, 20087, 20088, 201, 2010, 20100, 20101, 20102, 20103, 20104, 20105, 20106, 20107, 20108, 2011, 20110, 20111, 20112, 20113, 20114, 20115, 20116, 20117, 20118, 2012, 20120, 20121, 20122, 20123, 20124, 20125, 20126, 20127, 20128, 2014, 20140, 20141, 20142, 20143, 20144, 20145, 20146, 20147, 20148, 2015, 20150, 20151, 20152, 20153, 20154, 20155, 20156, 20157, 20158, 2016, 20160, 20161, 20162, 20163, 20164, 20165, 20166, 20167, 20168, 2017, 20170, 20171, 20172, 20173, 20174, 20175, 20176, 20177, 20178, 2019, 20190, 20191, 20192, 20193, 20194, 20195, 20196, 20197, 20198, 202, 2020, 20200, 20201, 20202, 20203, 20204, 20205, 20206, 20207, 20208, 2021,



20210, 20211, 20212, 20213, 20214, 20215, 20216, 20217, 20218, 2022, 20220, 20221, 20222, 20223, 20224, 20225, 20226, 20227, 20228, 2023, 20230, 20231, 20232, 20233, 20234, 20235, 20236, 20237, 20238, 2024, 20240, 20241, 20242, 20243, 20244, 20245, 20246, 20247, 20248, 2025, 20250, 20251, 20252, 20253, 20254, 20255, 20256, 20257, 20258, 2026, 20260, 20261, 20262, 20263, 20264, 20265, 20266, 20267, 20268, 2028, 20280, 20281, 20282, 20283, 20284, 20285, 20286, 20287, 20288, 2029, 20290, 20291, 20292, 20293, 20294, 20295, 20296, 20297, 2028, 203, 2030, 20300, 20301, 2031, 20310, 20311, 2038, 20380, 20381, 204, 2040, 20400, 20401, 2041, 20410, 20411, 2042, 20420, 20421, 2048, 20480, 20481, 2049, 20490, 20491, 205, 2050, 20500, 20501, 2051, 20510, 20511, 2052, 20520, 20521, 2053, 20530, 20531, 2058, 20580, 20581, 2059, 20590, 20591, 206, 2060, 20600, 20601, 2061, 20610, 20611, 2062, 20620, 20621, 2068, 20680, 20681, 2069, 20690, 20691, 207, 2070, 20700, 20701, 2071, 20710, 20711, 2072, 20720, 20721, 2078, 20780, 20781, 208, 2080, 20800, 20801, 2081, 20810, 20811, 2082, 20820, 20821, 2088, 20880, 20881, 2089, 2386, 2733, V10, V100, V1000, V1001, V1002, V1003, V1004, V1005, V1006, V1007, V1009, V101, V1011, V1012, V102, V1020, V1021, V1022, V1029, V103, V104, V1040, V1041, V1042, V1043, V1044, V1045, V1046, V1047, V1048, V1049, V105, V1050, V1051, V1052, V1053, V1059, V106, V1060, V1061, V1062, V1063, V1069, V107, V1071, V1072, V1079, V108, V1081, V1082, V1083, V1084, V1085, V1086, V1087, V1088, V1089

## Appendix E: Complications Defined for Failure to Rescue Measure

(Silber et al., 2007)

***Included/Excluded Secondary Diagnosis Codes (SDC), Secondary Procedure Codes (SPC), Principal Diagnosis Codes (PDC), and Principal Procedure Codes (PPC)***

General Classification	Specific Complication	Inclusion Criteria	Exclusion Criteria
Cardiac	Cardiac Event	<b>SDC:</b> 9971 and any of (42612-3, 42689, 42731, 42781, 9) or 41189, 99601  <b>SPC:</b> 3778, 3780-3, 3606	
	Congestive Heart Failure (CHF)	<b>SDC:</b> 5184, 42821, 42831, 42841, 42823, 42833, 42843, or 9971 and any of (428, 4280-1, 4289, 42820-1, 42823, 42830-1, 42833, 42840-1, 42843) or 428, 4280-1, 9, 4289, 42820, 1, 3, 42830-1, 3, 42840-1, 3 and exclusion	<i>History of CHF (180-day lookback):</i>  39891, 40201, 40211, 40291, 40401, 3, 40411, 3, 40491, 3, 428, 4280, 4281, 42820-3, 42830-3, 42840-3, 4289, 5184

	Cardiac Emergency	<p><b>SDC:</b> 4100, 41001, 4101, 41011, 4102, 41021, 4103, 41031, 4104, 41041, 4105, 41051, 4106, 41061, 4107, 41071, 4108, 41081, 4109, 41091, 4271, 42741, 7855, 78550-1</p> <p><b>SPC:</b> 3761, 3791, 8964, 9960-4, 9, 9961-2, or if 9363 or 996 and exclusion</p>	<p><b>PDC:</b> 4275, 7855, 78550-1, 9, 7991</p> <p><b>PPC:</b> 9393, 996, 9963</p> <p><b>DRG</b> DRG = 75-145, 475</p> <p><i>1) Principal Diagnosis of Trauma:</i> 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 817, 818, 819, 820, 821, 822, 823, 824, 825, 827, 828, 829, 830, 831, 832, 833, 835, 836, 837, 838, 839, 850, 851, 852, 853, 854, 860, 861, 862, 863, 864, 865, 866, 867, 868, 869, 870, 871, 872, 873, 874, 875, 876, 877, 878, 879, 880, 881, 882, 884, 887, 890, 891, 892, 894, 896, 897, 900, 901,</p>
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			<p>902, 903, 904, 925, 926, 927, 928, 929, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 952, 953, 958</p> <p><i>Trauma DRGs:</i> 002, 027, 028, 029, 031, 032, 072, 083, 084, 235, 236, 237, 440, 441, 442, 443, 444, 445, 446, 456, 457, 458, 459, 460, 484, 485, 486, 487, 491, 504, 505, 506, 507, 508, 509, 510, 511</p> <p>3) <i>Principal Diagnosis is GI Hemorrhage:</i> 456.0, 456.20, 530.7, 531.00, 531.01, 531.20, 531.21, 531.40, 531.41, 531.60, 531.61, 532.00, 532.01, 532.20, 532.21, 532.40, 532.41, 532.60, 532.61, 533.00, 533.01, 533.20, 533.21, 533.40,</p>
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			533.41, 533.60, 533.61, 534.00, 534.01, 534.20, 534.21, 534.40, 534.41, 534.60, 534.61, 535.01, 535.11, 535.21, 535.31, 535.41, 535.51, 535.61, 578.0, 578.1, 578.9
Respiratory	Pneumonia, other	<b>SDC:</b> 481, 4820-3, 48230-2, 9, 4824, 48240-1, 9, 4828, 48281-4, 9, 4829, 485, 486 or 9973, 514 and exclusion	<b>DRG</b> DRG=75-102, 475  <i>All Diagnosis Codes:</i>  1) <i>Viral Pneumonia</i> 480.0, 480.1, 480.2, 480.8, 480.9, 483, 483.0, 483.1, 483.8, 484.1, 484.3, 484.5, 484.6, 484.7, 484.8, 487.0, 487.1, 487.8  2) <i>Immunocompromised State</i> 042, 136.3, 279.00, 279.01, 279.02, 279.03, 279.04, 279.05, 279.06, 279.09, 279.10, 279.11, 279.12, 279.13, 279.19, 279.2, 279.3, 279.4, 279.8, 279.9

	Pneumonia, aspiration	<b>SDC:</b> 5070-1, 5078 or 9973 and any of 4829, 485, or 486	
	Pneumothorax	<b>SDC:</b> 5120, 5128, 5180	
	Bronchospasm	<b>SDC:</b> 5191 <b>SPC:</b> 8938, 9394	
	Respiratory Compromise	<b>DRG</b> = 483 <b>SDC:</b> 5185, 51881, 9, 7991, 9604, 9670-2 <b>SPC:</b> 311, 312, 3121, 9, 390, 9671-2	
	Other Respiratory Complication	<b>SPC:</b> 3321, 3327, 9390	
Fluid and Electrolyte	Hypotension/Shock/Hypovolemia	<b>SDC:</b> 2765, 4589, 78550-2, 78559, 7963, 9950, 9954, 9980	
Neurologic	Cerebrovascular attack/Stroke (CVA)	<b>SDC:</b> 431, 432, 43301, 43311,43321,43331,43381 ,43391,434,4340-1,4341, 43411,4349,43491,436,99701 <b>SDC:</b> 8703, 8891	<i>History of CVA/stroke (180-day lookback):</i> 431, 432, 43301, 43311, 43321, 43331, 43381, 43391, 434, 4340, 43401, 4341, 43411, 4349, 43491, 436, 99702, 438, 4380, 4381, 43810, 43811, 43812, 43819, 4382, 43820, 43821, 43822, 4383, 43830,

			43831, 43832, 4384, 43840, 43841, 43842, 4385, 43850, 43851, 43852, 43853, 4386, 4387, 4388, 43881, 43882, 43883, 43884, 43885, 43889, 4389, V1259
	Transient Ischemic Attack (TIA)	<b>SDC:</b> 4350-3, 4358-9	
	Seizure	<b>SDC:</b> 7803, 78031, 9 <b>SPC:</b> 8914, 8919	<i>History of Seizure (180-day lookback):</i> 345, 3450, 34500, 34501, 3451, 34510, 34511, 3452, 3453, 3454, 34540, 34541, 3455, 34550, 34551, 3456, 34560, 34561, 3457, 34570, 34571, 3458, 34580, 34581, 3459, 34590, 34591, 7803
	Psychosis	<b>SDC:</b> 292, 2920, 2921, 29211-2, 2922, 2928, 29281-4, 9, 2929, 2930, 2939, 2948, 2949	
	Coma	<b>SDC:</b> 3481, 5722, 7800, 78001, 9	
	Nervous System Complications	<b>SDC:</b> 9970 <b>SPC:</b> 0331, 8914, 8919	

Circulatory	Deep Vein Thrombosis/Arterial Clot	<b>SDC:</b> 4440-2, 4420-1, 4448, 44481, 9, 4449, 4538 <b>SPC:</b> 387, 8866, 8877	
	Pulmonary Embolus	<b>SDC:</b> 4151, 41511, 41519, 4539, 9581 <b>SPC:</b> 8843, 9215	
	Phlebitis	<b>SDC:</b> 4510-1, 45111, 9, 4512, 4518, 45181-2, 4, 9, 4519 <b>SPC:</b> 387, 8866, 8877	
Multi-System	Internal Organ Damage	<b>SDC:</b> 9981, 99811-3, 9982 <b>SPC:</b> 3941, 5412, 9 and exclusion	<b>PPC:</b> 444, 4440-2, 4491
	Return to Surgery	<b>SDC:</b> 9984, 9987 <b>SPC:</b> 3403, 3409, 5411-2, 5492	
	Disseminated Intravascular Coagulopathy	<b>SDC:</b> 2866 <b>SPC:</b> 9907	
	Post-surgical Complication	<b>SDC:</b> 99700-1, 9972, 9975, 99851-2, 9988, 99881-2, 9, 9989, 9990-9	
	Deep Wound Infection	<b>SDC:</b> 9983, 99831-2, 9985, 99859, 9986, 99883 <b>SPC:</b> 5461, 8604, 8659, 8622, 8660-3, 8670, 8674	
	Sepsis	<b>SDC:</b> 0380-4, 03810-1, 03840-4, 9, 03819, 0388-9, 78552, 7907	



Infection	Gangrene/Amputation	<p><b>SDC:</b> 72886, 7854</p> <p><b>SPC:</b> 840, 8401-9, 841, 8410-9 and exclusion</p>	<p><i>Renal Failure Comorbidity:</i> 40301, 40311, 40391, 40402, 40403, 40412, 40413, 40492, 40493, 584, 5845, 5846, 5847, 5848, 5849, 585, 586, V420, V451, V560, V561, V562, V563, V5631, V5632, V568</p> <p><i>PPC (180-day lookback):</i> 3995 during 180 day look back period:</p>
Limb/Extremity	Gastrointestinal Bleeding/Blood Loss	<p><b>SDC:</b> 2851 or 5780-1, 9 or 5307 or any of 4560, 45620, 53082, 53100-1, 53120-1, 53130-1, 53190-1, 53200-1, 53210-1, 53220-1, 53230-1, 53290-1, 53300-1, 53310-1, 53320-1, 53330-1, 53390-1, 53400-1, 53410-1, 53420-1, 53430-1, 53490-1, 53501, 53511, 53540-1, 53551, 53561, 53784, 56212-3, 5693, 56985, 5789</p> <p><b>SPC:</b> 4995</p>	<p><i>1) PD Trauma:</i> 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 817, 818, 819, 820, 821, 822, 823, 824, 825, 827, 828, 829, 830, 831, 832, 833, 835, 836, 837, 838, 839, 850, 851, 852, 853, 854, 860, 861, 862, 863, 864, 865, 866, 867, 868, 869, 870, 871, 872,</p>

		<p>873, 874, 875, 876, 877, 878, 879, 880, 881, 882, 884, 887, 890, 891, 892, 894, 896, 897, 900, 901, 902, 903, 904, 925, 926, 927, 928, 929, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 952, 953, 958</p> <p>2) <i>Trauma</i> <i>DRGs:</i> 002, 027, 028, 029, 031, 032, 072, 083, 084, 235, 236, 237, 440, 441, 442, 443, 444, 445, 446, 456, 457, 458, 459, 460, 484, 485, 486, 487, 491, 504, 505, 506, 507, 508, 509, 510, 511</p> <p>3) <b>SDC-</b> <i>Alcoholism:</i> 2910-5, 29181, 29189, 2919, 30300-3, 30390-2,</p>
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			<p>30500-2</p> <p><b>PPC:</b> 444, 4440-2 if secondary diagnoses 5780-1, 9444, 4440-2 and 4491 if secondary procedure = 4995</p> <p><b>DRG:</b> 1) <i>DRG</i> = 146-171 if secondary procedure = 5307 <i>DRG</i> = 146-167, 170184, 188-208 if any of the secondary diagnoses</p>
Internal/External Bleeding	Peritonitis	<p><b>SDC:</b> 5670-2, 8, 9, 5695, 7894</p> <p><b>SPC:</b> 5491 and exclusion</p>	<b>PD:</b> Cancer diagnoses listed in Appendix C
	Intestinal Obstruction	<p><b>SDC:</b> 5570, 56081, 5609, 9974</p>	<p><b>DRG:</b> 148-153</p> <p><b>PDC:</b> 5570, 56081, or 5609</p>
	Perforation	<p><b>SDC:</b> 5304, 56983, 9982</p>	
Abdomen/Renal	Renal Dysfunction	<p><b>SDC:</b> 5845-9, 7885</p> <p><b>SPC:</b> 3995, 5494, 5498, 598, 8607, 8962 and exclusion</p>	<p><i>Renal Failure Comorbidity:</i> 40301, 40311, 40391, 40402, 40403, 40412, 40413, 40492, 40493, 584, 5845, 5846, 5847,</p>

			5848, 5849, 585, 586, V420, V451, V560, V561, V562, V563, V5631, V5632, V568  <b>PPC</b> (180-day lookback): 3995
	Pyelonephritis	<b>SDC:</b> 5901, 59010-1, 5902-3, 8, 59080, 5909	
Hepatic	Hepatitis/Jaundice	<b>SDC:</b> 570, 5733	
Pancreatic	Pancreatitis	<b>SDC:</b> 5770	
Skin	Decubitus Ulcers	<b>SDC:</b> 7070, 70700-7, 9  <b>SPC:</b> 8622	
Bone	Orthopedic Complications	<b>SDC:</b> 9964, 99666, 99677  <b>SPC:</b> 7971, 7975-6, 7860, 7869 and exclusion	<b>PPC:</b> 8153, 8155, 8183
	Compartment Syndrome	<b>SDC:</b> 9588 or 99889 and  <b>SPC:</b> 8314	
	Necrosis of the bone-thermal	<b>SDC:</b> 73340-4, 9	
	Aseptic osteomyelitis	<b>SDC:</b> 7300, 73000-9, 7302, 73020-9, 99667 and exclusion	<b>PDC:</b> 7300, 73000-9, 7302, 73020-9

## Appendix F: Institutional Review Board Exemption

University of Pennsylvania  
Office of Regulatory Affairs  
3624 Market St., Suite 301 S  
Philadelphia, PA 19104-6006  
Ph: 215-573-2540/ Fax: 215-573-9438  
**INSTITUTIONAL REVIEW BOARD**  
(Federalwide Assurance # 00004028)

11-May-2016

Matthew D McHugh  
Attn: Apama Kumar  
[kumarap@nursing.upenn.edu](mailto:kumarap@nursing.upenn.edu)  
[mchughm@nursing.upenn.edu](mailto:mchughm@nursing.upenn.edu)

PRINCIPAL INVESTIGATOR	: Matthew D McHugh
TITLE	: The Impact Of The Organization Of Nursing On The Outcomes Of Adult Medicare Surgical Patients With Depression
SPONSORING AGENCY	: No Sponsor Number
PROTOCOL #	: 825047
REVIEW BOARD	: IRB #8

Dear Dr. Matthew McHugh:

The above-referenced research proposal was reviewed by the Institutional Review Board (IRB) on 5/10/2016. It has been determined that the proposal meets eligibility criteria for IRB review exemption authorized by 45 CFR 46.101, category 4.

**This does not necessarily constitute authorization to initiate the conduct of a human subject research study. You are responsible for assuring other relevant committee approvals.**

Consistent with the federal regulations, ongoing oversight of this proposal is not required. No continuing reviews will be required for this proposal. The proposal can proceed as approved by the IRB. This decision will not affect any funding of your proposal.

Please Note: The IRB must be kept apprised of any and all changes in the research that may have an impact on the IRB review mechanism needed for a specific proposal. You are required to notify the IRB if any changes are proposed in the study that might alter its IRB exempt status or HIPAA compliance status. New procedures that may have an impact on the risk-to-benefit ratio cannot be initiated until Committee approval has been given.

If your study is funded by an external agency, please retain this letter as documentation of the IRB's determination regarding your proposal.

**Please Note: You are responsible for assuring and maintaining other relevant committee approvals.**

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: <http://www.upenn.edu/IRB/directory>.

Thank you for your cooperation.

Sincerely,

**Stephanie Lesage** Digitally signed by Stephanie Lesage  
Date: 2016.05.11 13:05:10 -04'00'

IRB Administrator

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