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Postoperative delirium (PD) affects approximately 25 percent of participants over the age of 60 having major surgery. Long term negative effects include persistent delirium, loss of independence, nursing home placement, and mortality. There is evidence that incidence is related in-part to multifactorial precipitating and predisposing factors; however, none of the studies found evaluated perioperative environmental factors. One environmental factor that may influence the severity of PD is intraoperative noise. A surgical population with an increased incidence of delirium is orthopedic surgery. Orthopedic surgery, such as total hip or knee arthroplasties, involves the use of equipment such as loud drills and saws. The incidence of PD in those having orthopedic procedures is between 41% and 50%. The purposes of this study were to describe the environmental noise in an orthopedic operating room environment during arthroplastic surgery and to explore the relationship operational noise variables to the incidence and severity of PD. The correlational design is a non-experimental method chosen to examine the strength of the relationship between perioperative noise in the orthopedic total knee or hip arthroplasty suite and the incidence of PD. A convenience sample was comprised of participants presenting at their pre-anesthesia assessment visit and ending when the calculated sample size has been reached. This exploratory study demonstrated inconsistent findings in relation to noise loudness and pitch variables and

delirium severity. However, all noise levels exceeded US governmental agencies recommended maximum levels and may put patients and personnel at risk. More research is needed to further investigate hospital noise and outcomes.

ENVIRONMENTAL NOISE AS RISK FACTOR FOR POSTOPERATIVE DELIRIUM IN AN ORTHOPEDIC SAMPLE: AN EXPLORATORY, CORRELATIONAL STUDY

by

Courtney Brown

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Approved by

_____
Committee Chair

I dedicate this dissertation to my family, but especially my beloved husband Travis Brown who is my hero and my beautiful daughter Anisa who is my biggest fan.

APPROVAL PAGE

This dissertation has been approved by the following committee of the Faculty of The Graduate School at The University of North Carolina at Greensboro.

Committee Chair _____
Dr. Beth Barba

Committee Members _____
Dr. Jie Hu

_____
Dr. Anita Tesh

_____
Dr. Janice Wassel

10/21/2013
Date of Acceptance by Committee

10/21/2013
Date of Final Oral Examination

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While I am pleased with my achievement, I humble myself and give all the glory to the Lord. Without prayer and faith, no person could rise from being a homeless, teenage mother to a Doctor of Nursing.

With man this is impossible, but with God all things are possible. Matthew 19:26

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CHAPTER I

INTRODUCTION

The Centers for Disease Control and Prevention (CDC) estimate that by the year 2030, there will be 72 million elder Americans living in the United States accounting for 20% of the overall population (CDC, 2013). The mission statement on the Administration for Community Living (ACL) notes that one of the most important aspects related to elder health is overall functional status and subsequent independence (ACL, 2013). Postoperative delirium (PD) affects approximately 28 % of participants over the age of 60 having elective surgery (Bruce, Ritchie, Lai, Blizzard, & Raven, 2007). Approximately 21% of patient with delirium at discharge demonstrate persistent delirium 6 months later (Cole, Ciampi, Belzile, & Zhong, 2009). Other long term outcomes include loss of independence, nursing home placement, and subsequent mortality (Cole, Ciampi, Belzile, & Zhong, 2009; McAvay et al., 2006). Delirium is costly. Estimates suggest that delirium treatment generates Medicare costs of $6.9 billion (USD) annually (Inouye, 2006). This increases financial and emotional burdens on caregivers and on the overall healthcare system (Inouye, 2006). Research focused on prevention of PD or preservation of mental function is paramount. There is evidence that incidence is related to multifactorial precipitating and predisposing factors; however, none of the studies found evaluated perioperative environmental factors. Therefore, the

purpose of this study was to describe and examine one perioperative environmental factor yet unexplored as a possible precipitating factor: noise.

Background and Significance

Delirium is defined by the American Psychiatric Association (APA, 2000) in the Diagnostic and Statistical Manual IV (DSM-IV-TR) as "a rapidly developing disorder of disturbed attention that fluctuates with time." Other criteria define delirium by the presence of at least two of the following symptoms resulting from a general medical condition (DSM-IV-TR, code 293.0):

- The patient has a reduced level of consciousness and difficulty focusing, shifting or sustaining attention.
- There has been a cognitive change (deficit of language, memory, orientation, perception) that dementia cannot better explain.
- These symptoms develop rapidly (hours to days) and tend to vary during the day.
- History, physical examination or laboratory data suggest that a general medical condition has directly caused the condition

The incidence of delirium is estimated at 10% to 20% in a general medical population (Tabet et al., 2005), but as high as 60% to 80% of intensive care elder patients (Pandharipande et al., 2005; Pratico et al., 2005). Postoperative delirium (PD) is delirium which presents following a surgical procedure. The incidence of delirium ranges from 10% to 60 % in the postoperative population (Inouye, 2006). The incidence of PD varies among types of surgical procedures. Those having orthopedic procedures show an

incidence between 15% and 50% (Inouye, 2006); whereas the incidence in abdominal aneurysm is 35% (Benoit et al., 2005) and in post-open abdominal is 60% (Ganai et al., 2007).

Delirium incidence has been found to have multiple risk factors. Predisposing factors are patient characteristics which are associated with increased incidence of delirium. These include: increasing age, preexisting cognitive impairment, prior episode of delirium, multiple co-morbidities, impaired functional status, and sensory impairment. Precipitating factors are factors which occur in relation to the triggering of the onset of PD. These include: pain and anxiety, use of psychoactive medications, electrolyte disturbances and elevated blood urea nitrogen or elevated serum creatinine (Franco et al., 2001; Francis et al., 1990; Ganai et al., 2007; Gaudreau, Gagnon et al., 2005; Inouye, & Charpentier, 1996; Levkoff et al., 1992; Marcantonio et al., 1994; Morrison et al., 2003; Pisani et al., 2007).

Delirium and PD result from the interplay of multiple predisposing and precipitating factors (Tables 1 and 2). There have been successful multicomponent interventions aimed at screening those predisposed to delirium and ameliorating the precipitating risk factors. Inouye and colleagues (1999) devised the first multicomponent intervention which included orientation and cognitive stimulation, sleep protocol, early mobilization, sensory input, and adequate hydration. This yielded a decrease in incidence from 15 % to 9.9%. This intervention is now a proprietary program termed "Hospital Elder Life Program" (HELP) and has been replicated in a renal unit and other general medical units (Robinson, Rich, Weitzel, Vollmer, & Eden, 2008; Rubin et al., 2006). It

demonstrated a reduction in relative risk by 35% (Rubin et al., 2006). A recent modified version was tested successfully in a surgical population in Taiwan (Chen et al., 2011).

Marcantonio, Flacker, Wright, and Resnick (2001) conducted a multicomponent intervention study in a postoperative hip population. This study was randomized, controlled and blinded. The program included consultation with a geriatrician and tailored interventions including oxygen therapy, pain management, elimination of psychoactive medications, bowel and bladder regimen, poor nutrition, early ambulation, prevention and early treatment of postoperative complications, environmental stimuli, and early delirium treatment. There was a reduction in PD incidence from 50% in the control group to 32% in the intervention group ($p=0.04$). Delirium severity by cumulative episodes was also reduced from 29% to 12% ($p=0.02$). Noise reduction strategies have been utilized in successful delirium prevention interventions in medical and post-surgical settings (Benedict et al, 2009; Cole, McCusker, Bellavance et al., 2002; Gurlit & Mollmann, 2008; Inouye et al., 1999). However, the effect of noise reduction strategies in the operating room on PD has not been studied.

The economic consequences of delirium are daunting. Delirium creates costs to hospitalized individuals, healthcare systems, and society resulting from providing care to those affected. In relation to costs to the individual, delirium is associated with subsequent mortality of 25% to 33% in the hospital (Panharipande, Jackson, & Ely, 2005). Across studies, delirium is also associated with falls, longer length of hospital stay, and pneumonia (Ganai et al., 2007; Harding, Martin, & Holmes, 2008). Delirium persisting beyond hospital discharge can last up to six months, with negative outcomes

(institutionalization, mortality, cognitive decline, functional decline) rising with duration (Cole, Ciampi, Belzile, & Zhong, 2009).

Healthcare systems are affected by direct or indirect costs including consulting expensive medical services, such as psychiatry (Franco et al., 2001; Leslie et al., 2005). The estimated costs per case of delirium per patient in 2008 ranged from $16,303 to $64,421 creating a national burden on the health care system ranging from $38 billion to over $150 billion annually (Leslie, Marcantonio, Zhang, Leo-Summers, & Inouye, 2008). This is just the tip of the iceberg. There are hidden costs passed onto caregivers and loved ones including time spent from work in caregiving, changes in family roles, the emotional burden of caregiving as well as the loss of independent living for those affected with delirium. Any reduction in delirium incidence, given the increase in the elder population, would reap large costs savings to the health care system and the individuals as well as their loved ones.

Statement of the Problem and Assumptions

The World Health Organization (1999) in their Community Noise Guidelines (Table 3) recommended that a noise level in operating rooms deserves "special attention," and noise should not exceed 30 dBA while indoors. Noise is a known environmental stressor and can result in three physiologic responses to noise exposure: voluntary skeletal muscle movement in avoidance or involuntary reflexive action, visceral smooth muscle and glandular response, and activation of the neuroendocrine and sympathetic nervous system (Prashanth & Venugopalacha, 2008). There is a positive association between past chronic noise exposure (> 85 dBA) and the incidence of

cardiovascular morbidity and mortality as well as total overall mortality in industrial workers (Melamed, Kristal-Boneh, & Froom, 1999). Finally, wake-up reactions occur at the threshold of maximum levels of 48 dBA at the position of the ear (Mashke, Hect, & Wolf, 2004). The effect of medications for sedation on the perception of noise in the operating room has not been studied. The effect of intraoperative noise on PD has not been investigated.

The main assumption of this study was that noise can be perceived as stressful. Another assumption was that environment has an effect on mental and physical well-being. A third assumption was that a participant under stress may exhibit changes in mental well-being which may be exhibited through changes in cognition or behavior.

Research Questions

1) What is the description of environmental noise (loudness and pitch) in an orthopedic surgical suite?
2) When controlling for psychological (baseline cognitive status, noise annoyance, and noise sensitivity) and functional (activities of daily living) characteristics of the individual, which characteristics of intraoperative noise (loudness and pitch) explain the severity of PD in an orthopedic surgical sample of elders?
3) Which noise variables (loudness and pitch) collected during this study are the most significant to the severity of PD?

Purposes

The purposes of this study were to describe the environmental noise (loudness and pitch) in the operating room environment of elderly participants having orthopedic

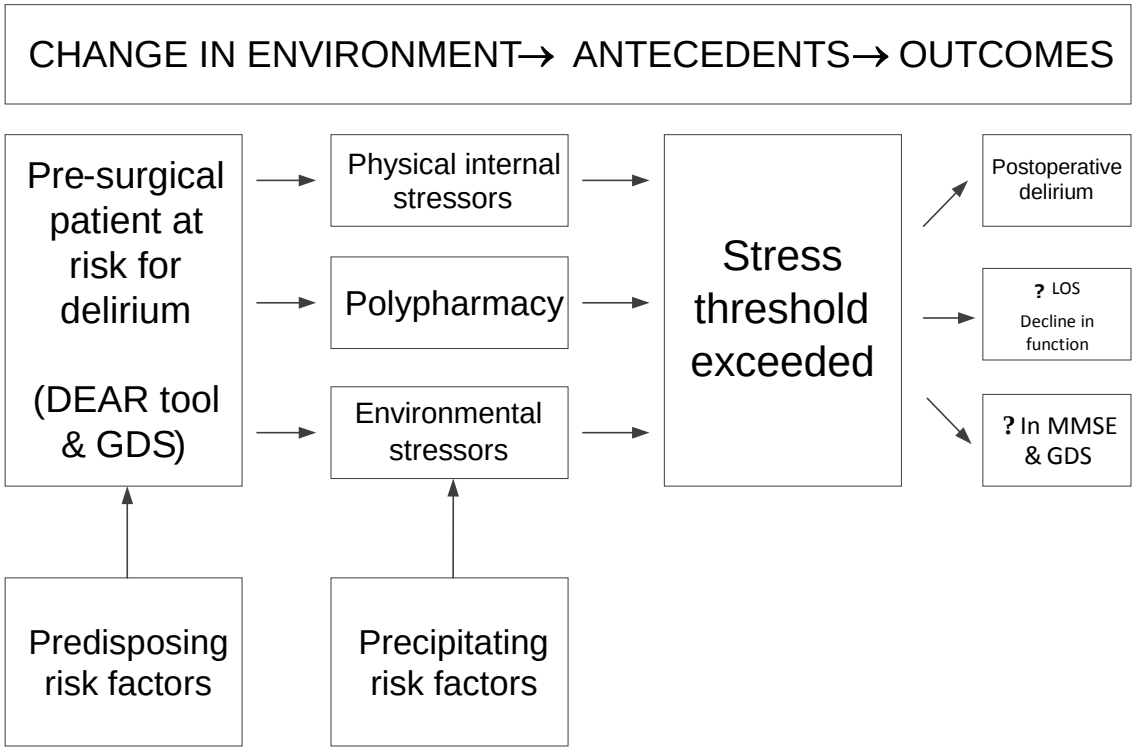
arthroplastic surgeries and to explore the relationship of intraoperative noise (loudness and pitch) to the severity of PD. Arthroplasty procedures involve the replacement of severely damaged knee or hip joint cartilage or bone with metal and plastic prostheses (American Academy of Orthopedic Surgeons, 2007). The outcomes of this study may yield future research regarding environmental milieu of the operating room suite and its effect on delirium.

Theoretical Foundation

The theory chosen to frame this study was the Progressively Lowered Stress Threshold (PLST) as modified by Fick (2011) in her R03 study on delirium superimposed on dementia (PLST-DSD) (Figure 1). Because this study included patients with and without dementia, the beginning construct related to the participant was modified to "Pre-surgical person at risk for delirium." Fick (2011) described that a hospitalized person with dementia may be exposed to "three axes" of stress variables: physical internal, polypharmacy, and environmental. These axes may combine to exceed the stress threshold of the individual to yield delirium as a potential outcome. Because the predisposing risk factors for delirium have been identified, the "Pre-surgical person at risk for PD" is conceptually defined as a person presenting for surgery who will be exposed to physical internal, polypharmacy, and environmental stressors and are at risk for crossing their stress threshold and subsequent development of PD. Because predisposing risk factors increase the risk of PD, baseline cognitive status and baseline functional status was ascertained. These would increase the influence of stressors in crossing the stress threshold. Noise is an environmental stressor; however, the literature

suggested that it is mediated by noise annoyance and noise sensitivity (Lusk et al, 2002; Schreckenberg, Griefahn and Meis 2010).

Figure 1. Progressively Lowered Stress Threshold Model as Organizing Framework for Delirium Superimposed on Dementia



PLST-DSD (Fick, 2011) model as adapted framework for study of environmental noise as stressor for delirium.

Conceptual Definitions

Pre-surgical patient at risk for delirium: Pre-surgical patient at risk for PD theoretically is a person presenting for surgery who will be exposed to physical internal, polypharmacy, and environmental stressors at risk for crossing their stress threshold and subsequent development of PD. Predisposing risk factors were operationally defined by

the predictive tool (DEAR tool) developed by Freter et al. (2005) which quantified risk by ascertaining the following predisposing risk factors in addition to age, substance use, and sensory impairment.

Functional status: Functional status is an individual's ability to perform normal daily activities required to meet basic needs, fulfill usual roles, and maintain health and well-being. Decline in functional status was measured by an individual's loss of independence in activities of daily living (ADLs) over a period of time (Katz, Ford, Moskowitz, Jackson, & Jaffe, 1963). Functional status was operationally measured via the Katz ADL tool whereby a score of 6 indicated full function, a score of 4 indicated moderate impairment, and a score of 2 or less indicated severe functional impairment (Wallace & Shelkey, 2008).

Cognitive impairment: Cognitive impairment was theoretically defined as decreased capacity to utilize an array of tools, such as perception, memory, and sensation, deployed to orient self within the environment (Piaget, 1950). Because the DEAR tool by Freter and colleagues (2005) only assigns positive values to evidence of cognitive impairment (MMSE less than 24), the brief Mini-Cog tool was utilized to distinguish evidence of cognitive impairment rather than the longer MMSE. The Mini-Cog generates scores ranging from 0 to 3. A score of three is non-demented, with intermediate recall evaluated by a clock drawing test (CDT). This tool has a reported sensitivity between 76% and 99% and a specificity of between 89% and 100% (Doerflinger, 2007; Holsinger et al., 2012; Milian et al, 2012).

Depression: Depression was theoretically defined as a disorder of mood characterized as feelings of sadness, loss, or anger which persist for weeks or months (NIH, 2011). Depression was operationalized by the GDS-15 (Sheikh & Yesavage, 1986). The GDS-15 screened and categorized participants for depression. In the literature, sensitivity ranged between 84% to 92%, and specificity ranged from 89% to 95% (Sheikh, Yesavage, Brooks, Friedman, & Gratzinger, 1991).

Physical Internal Stressors

Noise loudness: Noise loudness was theoretically defined as a sound pressure level perceived as stressful or bothersome to the receiver (Lusk, Haggerty, Gillespie, & Caruso, 2002). Noise loudness, in decibels dB and dBA (Lavg) (via sound level meter) and A-weighted average (dBA) (via sound dosimeter), Lpeak, Lmax and by total number of bursts or impacts was measured using a commercially available meter which is OSHA approved for the detection of sound levels within the operating room. The personal sound dosimeter was placed at ear or shoulder level to measure personal noise exposure.

Noise pitch: Noise pitch was theoretically defined as the tonal value in hertz perceived as stressful or bothersome to the receiver (Prashanth & Venugopalacha, 2008). Noise pitch, operationally defined as hertz (Hz) with purposive sampling at stressful levels (30-6,000 Hz) was measured using a commercially available meter which is OSHA approved for the detection of sound levels and hertz within the operating room.

Noise annoyance: Noise annoyance was theorized as the degree to which the individual perceived the noise as “annoying” or “psychologically disturbing” (Lusk et al.,

2002). Noise annoyance was operationalized utilizing a 5 item questionnaire with a Likert scale developed by van Dijk, Souman, and de Vries (1987).

Noise sensitivity: Noise sensitivity moderates the relationship between annoyance and noise (Byers, 1996). Noise sensitivity was theorized as the ability to adapt to noise levels over a period of time (Weinstein, 1978). Noise sensitivity was operationally defined by the Weinstein Noise Sensitivity scale (WNS). This scale contains 20 items scaled for sensitivity.

Pain: Pain was defined as the subjective experience of discomfort and could further be classified as acute or chronic (Guyton & Hall, 2006). Pain was operationalized by the NVAS utilizing a scale from zero to ten.

Stress Threshold: Stress threshold is a theoretical imaginary line in which coping with internal and external stressors is compromised, yielding behavioral changes and/or acute confusion. Stress threshold itself was not operationally defined; however the concept of Postoperative Delirium as a consequence of its breech was defined.

Postoperative Delirium: Postoperative Delirium was theoretically defined as evidence of stressors exceeding the individual's ability to cope or adapt (Hall & Buckwalter, 1987) following a surgical procedure. Delirium was defined by the APA DSM-IV-TR (2000) diagnostic criteria: a) disturbance of consciousness reduced ability to focus, sustain or shift attention; b) a change in cognition or the development of a perceptual disturbance that is not better accounted for by a preexisting, established or evolving dementia; c) the disturbance develops over a short period of time (usually hours to days) and tends to fluctuate during the course of the day; and d) there is evidence from

the history, physical examination or laboratory findings that the disturbance is caused by the direct physiological consequences of a general medical condition (APA, 2000).

Presence of delirium was operationalized as diagnostic positive via the Confusion Assessment Method which included psychomotor disturbances as a diagnostic feature (Inouye et al., 1990).

Independent and Dependent Variables

Pre-surgical Person at Risk for PD

Figure 1 depicts the model for this study. The adapted PLST-DSD categorized variables in a linear fashion commencing with pre-surgical person at risk for PD. This incorporated the predisposing risk factors and constructs of baseline cognitive and functional statuses which are both associated with increased severity of PD. A whisper test was performed to determine the risk factor of sensory impairment generating a point value with this tool. Prior episodes of delirium (Franco et al., 2001) and pain or anxiety (Morrison et al., 2003) are also associated with PD and were measured. Baseline cognitive status was defined as the capacity to use such tools as perception, memory, and sensation to orient self within the environment (Piaget, 1950). Cognitive impairment was screened with the Mini-Cog instrument (Doerflinger, 2007). During screening, prior episodes of delirium were solicited by self-report or found through chart review. Functional status was defined as an individual's ability to perform normal daily activities to meet basic needs, fulfill usual roles, and maintain health and well-being (Katz et al., 1963). This was incorporated in the tool developed by Freter et al. (2005). Decline in functional status was defined as an individual's loss of independence in activities of daily

living (ADLs) over a period of time (Katz et al., 1963), and was operationalized by the Katz ADL tool (Wallace & Shelkey, 2008). Pain was defined as the subjective experience of discomfort classified as acute or chronic (Guyton & Hall, 2006). Pain was measured with the commonly utilized numeric visual analog scale (NVAS). Anxiety was defined as a state of heightened fear or threat (Riskind, Williams, & Joiner, 2006). Anxiety was also measured with the numeric visual analog scale (NVAS).

Physical Internal Stressors

Because the adapted PLST-DSD model incorporated environmental stressors as mediators of PD, noise variables of noise loudness, noise pitch, noise annoyance, and sensitivity were included in the analyses. Noise annoyance was theorized as the degree to which the individual perceived the noise as "annoying" or "psychologically disturbing" (Lusk et al., 2002). Noise annoyance was operationalized utilizing a 5 item questionnaire with a 15 point Likert-type scale (van Dijk et al, 1987). Noise sensitivity was defined as the ability to adapt to noise levels over a period of time (Weinstein, 1978). Research has demonstrated that noise sensitivity moderates the degree of noise annoyance and is associated with greater stress response in addition to physical and mental complaints (Byers, 1996; Schreckenberg et al., 2010). Noise sensitivity was operationally defined by the Weinstein Noise Sensitivity scale (WNS).

Noise variables included in measurement of decibels dB (Lavg) via sound level meter and A-weighted average (dBA) via sound dosimeter, Lpeak, Lmax, hertz (Hz) utilizing both sound dosimeter and sound level meter with purposive sampling at known stressful levels (30-6,000 Hz), total number of bursts, patient arousals, and usual sources

of sound (set-up, saw, drill, music, conversation). Two instruments were utilized to measure these noise variables. The sound dosimeter was the Quest Edge E4, an OSHA approved device for measuring personal sound exposure. This device was placed at ear level of the participant. The second instrument was the Quest 1900 with octave band analysis for sampling sound frequencies. This device was placed in the operative suite within six feet of the patient's ear and not infringing upon the sterile field. In addition, field notes were taken to assist in the correlation of noise variables to the activities occurring at the time of collection.

Postoperative Delirium

The main dependent variables were: a) incidence of PD operationalized as positive confusion assessment method status (CAM) (Inouye et al., 1990); b) severity of delirium utilizing the Delirium Index (DI) (McCusker et al., 1998); and c) presence of psychomotor disturbances (hypoactive, hyperactive, or mixed) through patient observation. As these outcomes may present from the time the study participant has left the recovery area and the 72 hour endpoint, chart reviews were utilized to detect presence of PD (Kudoh et al., 2003; Morrison et al., 2003). Secondary outcomes were the presence of pain or anxiety via NVAS. In addition to the quantitative measures of variables, field notes were collected intraoperatively to assist in the correlation of noise variables to the activities occurring at the time of collection.

Summary

Delirium and PD have negative consequences to the individual, healthcare organizations, and society as a whole. Because multicomponent intervention strategies

demonstrate reductions in PD incidence and subsequent costs, it was paramount to explore all possible risk factors to the development of PD. Noise is a known environmental stressor. There have been no studies found that have evaluated which noise variables (loudness or pitch) had the greatest effect on patient's perception of noise as disturbing in the operative environment. The effect of intraoperative noise on PD has not been investigated.

CHAPTER II

REVIEW OF THE LITERATURE

Introduction

This chapter presents the relevant literature regarding delirium and postoperative delirium (PD), and relationship of noise as a stressor that leads to cognitive and behavioral changes. Researchers continue to examine the etiology, risk factors, pathological processes, as well as interventions to ameliorate PD. Many of the successful interventions are derived from recent and current scientific findings on the precipitating factors which trigger delirium. Prior to commencing a study on intraoperative noise and postoperative delirium, this body of science must be explored to elucidate methodologies employed and any gaps in knowledge in the study of PD.

In considering theoretical frameworks to guide this study, the theory of Progressively Lowered Stress Threshold (PLST) was originally chosen. However, upon further consideration the theory derived from this model termed "PLST model as Organizing Framework for Delirium Superimposed on Dementia (DSD)" (PLST-DSD) by Fick (2011) better delineated antecedents, environmental stressors, and outcomes related to delirium. Because the PLST-DSD was recently developed, the literature regarding the original PLST was reviewed. The risk factors of delirium from the literature were identified and discussed in relation to this theory. In addition, previous intervention studies conducted in elders were evaluated.

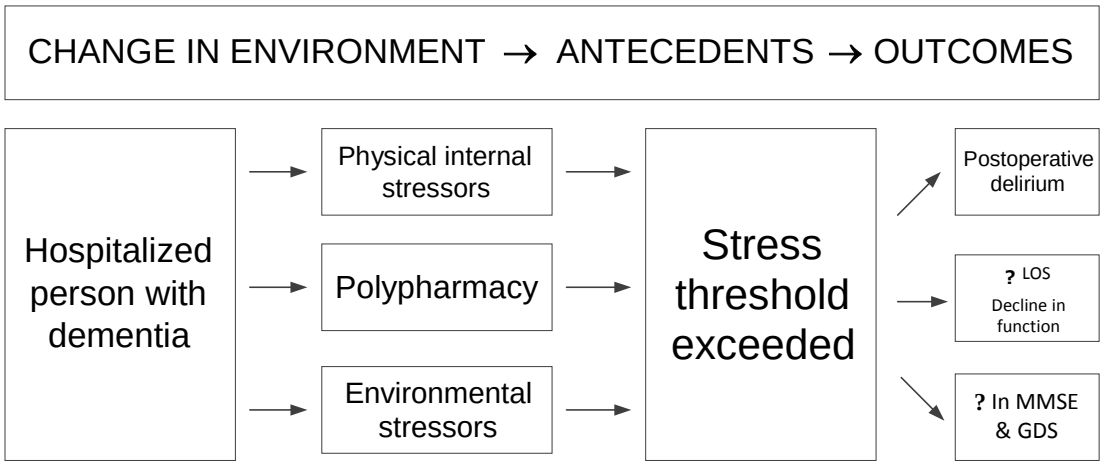
Theoretical Framework

The PLST-DSD (Fick, 2011) (Figure 2) is a nursing middle-range theory derived from the Progressively Lowered Stress Threshold model posited by Hall and Buckwalter (1987) (Figure 2). PLST-DSD served as an appropriate theoretical scaffold of the study of noise and the relationship to PD (Figure 1). The original PLST was "built upon theories of acute confusion, client-centered therapy, anxiety, stress, and coping, as well as key elements of the Ecological Theory of Aging to explain and predict behaviors in dementia" while under stress (Smith et al., 2004, p. 1756).

The original PLST model for the study of abnormal behaviors in person-environment interactions has been applied to interventional research in the care of Alzheimer's Dementia and related disorder (ADRD) patients, community-based research on caregiver burden and depression, and caregivers (Smith et al., 2004). Dissertations utilizing the PLST included the use of music (individualized versus classical) and ADRD (Gerdner, 1998), a test of the PLST model in caregivers (Hall, 1998), calming music and hand massage on agitation (Remmington, 1999), psychoimmunological outcomes in dementia caregivers following interventions (Garand, 2000), predictors of depression among dementia patient caregivers (Cruz, 1997), pain in institutionalized elders (Young, 2001), noise and agitation in dementia (Joose, 2009), and the use of preferred music on traumatic brain injury patients' agitation (Park, 2010). A master's thesis evaluated music's effect on mealtime agitation in dementia with the PLST framework (Hicks, 2001). The original PLST model has shown the most utilization in nursing practice and

research. It provided a theoretical vantage to study the environment of dementia patients (Gerdner, 1998; Hicks, 2001; Joose, 2009; Remmington, 1999) as well as their caregivers (Cruz, 1997; Hall, 1998).

Figure 2. Progressively Lowered Stress Threshold Model as Organizing Framework for Delirium Superimposed on Dementia



PLST model as organizing framework for delirium superimposed on dementia (Fick, 2011)

Antecedents: Predisposing Risk Factors

An adaptation of the PLST-DSD (Figure 1) was utilized to frame this study. The main proposition of PLST-DSD is that the outcomes of delirium, worsening cognitive function or depression, and decrease in physical function are demonstrated when external or environmental demands and/or internal demands exceeds the person's ability to cope thereby surpassing the person's stress threshold. Antecedents of PLST-DSD commence with "Hospitalized person with dementia." As this study included patients with and without cognitive dysfunction, this concept is adapted as "Pre-surgical patient at

risk for delirium." Theoretically, this change could then incorporate all patient-level predisposing factors associated with delirium incidence, such as cognitive impairment and depression.

Predisposing risk factors were defined as those contributing to the baseline vulnerability of a person to develop delirium (Inouye & Charpentier, 1996). Patients with higher predisposing factors such as dementia are more vulnerable at developing more moderate to severe delirium; whereas those who are less predisposed require a greater number of precipitating factors (Voyer, McCusker, Cole, St.-Jacques, & Khomenko, 2007). These findings are congruent with the PLST-DSD model and afford the opportunity to assess risk and attenuate precipitating factors.

Cognitive Impairment

The literature regarding predisposing risk factors evaluated risk factors in the delirium literature and PD literature separately (Tables 1 and 2). Cognitive impairment and dementia are considered to be the greatest predisposing risk factors for the development of delirium and PD (Noimark, 2009). In eight studies of delirium, five utilized non-probability, cohort, and convenience sampling methods (Francis et al., 1990; Inouye & Charpentier, 1996; Inouye et al., 1999; Levkoff et al., 1992; Pisani, Murphy, Van Ness, Arujo & Inouye, 2007; Trzepacz et al., 1998; Voyer et al., 2007). Cognitive impairment was a frequently found co-morbidity and was described as increasing the risk of developing delirium with odds ratios (OR) ranging between 3.42 (Voyer et al., 2007) with mild cognitive impairment and linearly increasing with worsening impairment to OR 6.3 with known dementia (Pisani et al., 2007). Cognitive impairment was not found

to have a relationship with delirium symptoms but cognitive impairment did increase the severity of delirium (Trzepacz et al., 1998; Voyer et al., 2007). Baseline cognitive status was measured with the MMSE in five of the eight delirium studies and with the Informant Questionnaire for Cognitive Decline in the Elderly (IQCODE) in two.

Cognitive impairment yielded greater risk to the development of PD in ten studies. OR ranged from 3.1 (95% CI 1.73, 5.43) (Franco et al., 2001) to 8.42 (p=0.001) (Givens et al., 2008). Baseline cognitive status was measured utilizing the MMSE in five studies, the Telephone Interview for Cognitive Status (TICS) in three studies, and the Dementia Rating Scale (DRS) in two (Benoit et al., 2005; Dolan et al., 2000; Franco et al., 2001; Givens et al., 2008; Lemstra et al., 2008; Lowery, Wesnes, Brewster, & Ballard, 2008; Marcantonio et al., 1994; Priner et al., 2008; Vaurio et al., 2006). Donna Fick, expert on delirium superimposed on dementia and creator of PLST-Delirium, recommends utilizing the CAM in the presence of dementia to determine delirium presence in Try This: Delirium Superimposed on Dementia (Fick & Mion, 2008).

Age

Advanced age has been implicated as an independent risk factor in delirium literature (Levkoff et al., 1992; Pandharipande, Jackson, & Ely, 2005). In an early prospective cohort of community-dwelling hospital admissions ages 65 years and older (n=325), age carried an adjusted OR of 5.4 (95% CI 2.4, 12.3) (Levkoff et al., 1992). However, in combination with cognitive impairment the OR doubled (OR 11.9, 95% 4.1, 34.1) (Levkoff et al., 2005). In a subsequent synthesis of studies conducted in the intensive care units, Pandharipande, Jackson, and Ely (2005) separated the risk factors

into three categories: host factors, acuity of illness, and iatrogenic or environment. This is analogous to the theoretical model. Host factors included age, pre-existing cognitive impairment, and comorbidities. Other delirium research studies did not find significant differences between delirious and non-delirious in relation to age (Francis et al., 1990; Inouye and Charpentier, 1996; Pisani et al., 2007; Voyer, McCusker, Cole & Khomenko, 2006), whether samples were 50 years and older (Pisani et al., 2007) or 70 years and older (Francis et al., 1990).

Table 1. Predisposing and Precipitation Risk Factors Associated with Delirium

Predisposing	**Precipitating**
Increased age Sensory Impairment Multiple co-morbidities • Neurological disorders • Diabetes • Hypertension • Ischemic heart disease • Congestive heart failure • Vascular disease • Stroke • Atrial fibrillation • Smoking Impaired functional status • Resident prior to admission • Dependence in ADLs Psychological conditions • Depression • Cognitive dysfunction • Prior episode of deliuium	Medications • Type of anesthesia • Duration of anesthesia • Addition of 3 or more medications • Discontinuation of antidepressants • Lithium Immobility Surgery • Type and duration • Complications Hypoxia Indwelling catheters Physical restraints Malnutrition Dehydration Infection

Predisposing	Precipitating
Serum chemistries • Increased creatinine • Increased blood urea nitrogen • Ecectrolyte imbalances Malnutrition • Vitamin of thiamine deficiency	Pain • Uncontrolled • Use of morphine Hemodynamic complications • Anemia or blood loss • Hypotension • Blood transfusions Serum chemistries • Increased creatinine • Increased blood urea nitrogen • Electrolyte imbalances Metabolic derangement • Poor glycemic control (> 150mg/dL) • Acidosis or alkalosis Dehydration Abuse or withdrawal from alcohol or substances Psychoactive medications Use of pain medicines

Note: Compiled from Benoit et al., 2005; Cole, 2005; Flinn, Diehl, Seyfried, & Milani, 2009; Ganai et al., 2007; Kudoh, Katagi, & Takazawa, 2002; Pandharipande, Jackson, & Ely (2005); Pratico et al., 2005; Vaurio, Sands, Wang, Mullen, & Leung, 2006

Table 2. Medications Associated with Increased Incidence of Delirium

Anticholinergics

- Atopine
- Scopolamine

Antihistamines

- Cimetidine
- Ranitidine
- Diphenhydramine
- Hydroxyzine
- Chlorpheniramine

Benzodiazepines

- Lorazepam
- Midazolam
- Diazepam

Hypnotics

- Propofol
- Barbiturates

Antidepressants

- Tricyclic antidepressants
- Selective serotonin reuptake inhibitors

Opioids

- Meperedine
- Fentanyl
- Morphine
- Hydromorphone

Non-steroidal, anti-inflammatory

- Indomethacin
- Ibuprofen
- Naproxen

Antiparkinson

- Benztropine
- Levodopa
- Trihexyphenidyl
- Biperiden

Cardiac medications

- Digoxin
- β-blockers
- Calcium channel blockers
- Class 1A antiarrhythmics
- ACE inhibitors
- Methyldopa

Neuroleptics

- Chlorpromazine
- Clozapine
- Thioridazine

Antibiotics

- β- Lattamase
- 3rd generation cephalosporins
- Fluoroquinolones
- Aminoglycosides

Note: Compiled from Cole 2005; Fong, Sands, & Leung, 2006; Pratico et al., 2005

In relation to PD, advanced age emerged as an independent risk factor (Benoit et al., 2005; Franco et al., 2001; Priner et al., 2008; Vaurio et al., 2006). In 2001, Franco, Litaker, Locala and Bronson found the relative risk attributed to age greater than 70 years when compared to ages 50 to 70 years for PD was 3.1 (95% CI, 1.75, 5.55). Their sample of 500 included 148 orthopedic patients, of which 20 developed PD. Benoit and colleagues (2005) did not find statistical differences between groups (delirious vs. non-delirious) in relation to age in their sample (n=102) of abdominal aorta repair participants. However, upon further analysis they noted that the 12 patients with ages 80 years or older demonstrated a statistically higher incidence of PD (75%) than patients less than age 80 years (27.8%) (p=002). In 2007, Vaurio and colleagues also found increased odds associated with age greater than 70 years (OR 3.4; 95% CI, 1.5, 4.2). Their sample consisted of 333 non-cardiac surgical patients of which 53% were orthopedic procedures ages 65 years and older with a mean age of 74 years (± 6 years). While Dolan and colleagues (2000) found a statistical difference in age between their delirious and non-delirious patients ($p<0.004$), the mean age of the non-delirious was 80 years (±7.4 years) and delirious was 83 years (±7.1 years) is not clinically relevant. Priner and others (2008) demonstrated only a modest but significant increase in relative risk of 1.07 (95% CI, 1.07, 1.47, p=0.004)

Other studies did not demonstrate or discuss that advanced age is a significant risk factor for PD (Brauer, Morrison, Silberzweig, & Siu, 2000; Ganai et al., 2007; Gaudreau et al., 2005; Givens, Sanft & Marcantonio, 2008; Kudoh, Katagi, & Takazawa, 2002; Lemstra et al., 2008; Lowery, Wesnes, Brewster, & Ballard, 2008; Marcantonio et al.,

1994; Morrison et al., 2008). This may be due to older, homogenous samples with less variability. Brauer and colleagues (2000) reported a delirious sample with a mean age of 85 years of surgical hip repair patients. Ganai and colleagues (2007) utilized an open abdominal procedure sample with a mean age, 79 years (95% CI, 77 to 80 years). The study by Givens, Sanft, and Marcantonio (2008) also demonstrated an average age of 79 years (± 8 years) in their surgical hip sample. Lowery, Wesnes, Brewster and Ballard (2008) utilized an orthopedic hip and knee sample ages over 70 years and found no significant differences between the group with delirium and the rest of the participants of age (77.2 (±4.3) vs 76.3 (±4.6), t=0.675 (92), p=0.501). In addition, Marcantonio and colleagues (1994) utilized a nested case control study design with mean age of 73 years (± 8 years); however, when matching was complete age did not demonstrate significance (p=0.92). In addition, Morrison (2003) found that age was significant in univariate analyses (p=0.02), but when combined in a multivariate analysis demonstrated a relative risk of 1.0 (95% CI, 0.97, 1.1).

Functional Status

Functional status is the degree to which an individual can provide self-care in activities of daily living (ADL) (Katz et al., 1963), and has been found to be an independent risk factor in delirium and PD. In 1999, Francis, Martin and Kapoor demonstrated that ADL impairment was associated with delirium with an adjusted OR 2.7 (95% CI, 1.2, 5.8). Pisani and colleagues (2007) reported significantly greater ADL impairment on hospital admission in their delirious sample versus their non-delirious ($p<0.001$). Voyer, McCusker and Khomenko (2007) described a decrease in functional

status with cognitive impairment for those with delirium. Other studies did not measure or analyze functional status (Inouye & Charpentier, 1996; Inouye et al., 1999; Levkoff et al., 1999; Pandharipande et al., 2005; Siddiqi, House, & Holmes, 2006; Trzepacz et al., 1998).

Functional status received greater attention in the PD literature. Dolan and colleagues (2000) found that on average PD participants were impaired in approximately one ADL and one instrumental ADL activity beyond those without delirium. These findings are consistent with other literature (Ganai et al., 2007; Givens et al., 2008; Morrison et al., 2003; Vaurio et al., 2006). Franco with colleagues (2001) found impaired functional status demonstrated a relative risk of 1.57 (95% CI, 1.27, 1.94, p=0.001). In 2007, Ganai reported a relative risk of 2.4 (95% CI, 1.6, 3.5, p<0.001 associated with poor functional status defined as 1 or more deficits in ADL independence. However, their multivariate analysis revealed an adjusted OR 11.7 (95% CI, 2.5, 56.1, p=0002). Although this figure is three times that reported by Givens and colleagues (2008) 3.4 (p=0.005). Several studies did not report findings related to functional status (Benoit et al., 2005; Brauer, Morrison, Silberzweig, & Siu, 2000; Kudoh, Katagi, & Takazawa, 2002; Lemstra et al., 2008; Lowery, Wenes, Brewster, & Ballard, 2008; Priner et al., 2008). Functional status was measured in five studies with various measures including the Katz ADL (Ganai et al., 2007; Givens et al., 2008), instrumental ADL (Vaurio et al., 2006), ambulatory status (Givens et al., 2008), specific activity scale (Franco, Litaker, Locala, & Bronson, 2001; Marcantonio et al., 1994), and functional independence measure (Morrison et al., 2003).

Depression

Preoperative depression has been implicated in the development of PD. Givens, Sanft, and Marcantonio (2008) evidenced an adjusted OR for PD with preoperative depression of 3.53 (p=0.03) in an older hip fracture sample. Preoperative depression increases the risk of subsequent PD, and increases the duration of PD (Leung, Sands, Mullen, Wang, & Vaurio, 2005). Stopping antidepressant medications 72 hours prior to surgery revealed increases in PD incidence (30%) versus those who continued their use (13%; P=0.05) (Kudoh, Katagai, & Takazawa, 2003). The severity of delirium increases with the number of depressive symptoms with five or greater demonstrating worsened outcomes (Leung, Sands, Mullen, Wang, & Vaurio, 2005; McAvay et al., 2007). The causal path may be bi-directional as history of delirium also demonstrates significantly greater risk of developing subsequent depression (Davydow, 2009). It has also been demonstrated as a long term outcome of incident PD even up to six months post PD-recovery (Dolan et al., 2000). While a non-significant (p=0.087) increase of depressive symptoms were reported in just one study (Benoit et al., 2005). The Geriatric Depression (GDS) scale has been utilized predominately across study samples (Givens, Sanft, & Marcantonio, 2008; Vaurio, et al., 2006).

Depression and delirium can overlap and is often a confluence of symptoms. In a basic incidence study utilizing the short GDS-15 and the CAM, Givens, Jones and Inouye (2009) found that of 459 elder participants, 23 (5%) had an overlap of depression and delirium, 39 (8.5%) had delirium alone, and 121 (26.3%) had depression. However,

when the overlap was present, there was a greater risk of functional impairment which often resulted in institutionalization as well as mortality.

Sensory Impairment

Sensory impairment has received attention from the delirium and the PD literature. In relation to delirium, Inouye and colleagues (1993) first identified sensory visual impairment (acuity < 20/70) as an independent risk factor for incident delirium (RR 3.51; 95% CI 1.15, 10.71). This study led to a predictive tool that appears throughout delirium literature with which baseline risk is assessed (Inouye, Bogardus, Charpentier & Leo-Summers, 1999; Inouye & Charpentier, 1996).

In relation to PD literature, sensory impairment as a risk factor has received limited attention. Ganai and colleagues (2007) utilized sensory impairment as inclusion criteria to obtain a sample at high risk for in-hospital delirium. In other studies of PD, sensory impairment was either not discussed or measured (Benoit et al., 2005; Brauer et al., 2000; Dolan et al., 2000; Franco, Litaker, Locala & Bronson, 2001; Gaudreau et al., 2005; Givens, Sanft, & Marcantonio, 2008; Kudoh, Katagai, & Takazawa, 2003; Lemstra et al., 2008; Lowery, Westnes, Brewster & Ballard, 2008; Marcantonio et al., 1994; Priner et al., 2008; Vaurio et al., 2006). Therefore, it is uncertain what relationship sensory impairment(vision or hearing) has with PD.

Stressors: Precipitating Risk Factors

The impeteus crossing the stress threshold results from heightened perceived stressors along three axes: physical internal, polypharmacy, and environmental. These axes may combine to exceed the stress threshold of the individual to yield delirium as a

potential outcome. Stressors that can be experienced in the operative setting include anxiety from a surgical procedure, pain, and psychoactive medications which may alter perception which PLST-DSD incorporates. The reciprocal proposition of PLST-DSD is that ameliorating internal stressors, polypharmacy, and environmental stressors would assist in preventing delirium (Fick, 2011). According to the PLST-DSD model, these stressors can have a cumulative effect to push or tip a participant over an imaginary line called the stress threshold whereby the outcomes, such as those that characterize PD can occur (Fick, 2011). Interventions in which participants' precipitating events are minimized would prevent breaching their stress threshold.

During anesthesia, the participant is theoretically unconscious or unaware and relying on the anesthesia provider to manage the stressors being experienced, such as pain, should parameters indicate an unmet need. However, little is known about the operating room environment as imposing stressors aside from the surgical stress which could influence the development of delirium as a result of passing the stress threshold. While many factors are important for a thorough understanding of a person's reaction to his environment, the current study was developed on the postulation that an environmental stressor, noise in the operating room, has a significant effect on the postoperative cognitive and behavioral outcomes of the patient. The stressor of noise is the independent variable, with delirium being the primary dependent variable. Thus, this model provided a theoretical foundation for the study of operating room noise and the development of PD.

Internal Stressors

Comorbidities.

Beginning with the early studies of co-morbidities, severity of illness and accompanying electrolyte abnormalities have been found to increase the risk for delirium. In studies of older general medical patients, comorbidities carried an adjusted OR ranging from 1.1 (95% CI, 1.01, 1.28) (Levkoff et al., 1992) to 5.9 (95% CI, 1.1, 32.2) (Francis et al., 1990). Abnormal sodium was found to have an adjusted OR of 6.2 (95% CI, 2.2, 17.8), which more than doubled that of azotemia adjusted OR of 2.9 (95% CI, 1.3, 6.7) (Francis et al., 1990). Elevated creatinine carries an adjusted OR of 2.1 (95% CI, 1.1-4.0) (Pisani et al., 2007). Severity of illness in one study was measured with the Charleson Comorbidity Index (CCI) (Francis et al., 1990). In subsequent studies of delirium in general medical patients, malnutrition with serum albumin less than 30 g/dL carried a relative risk of 3.9 (95% CI, 2.0-7.5) (Inouye and Charpentier, 1996). Severity of illness has been utilized to match case and controls in clinical trials with the Acute Physiology, Age, and Chronic Health Evaluation (APACHE) tool (Inouye, Bogardus, Charpentier, & Leo-Summers, 1999), or the more recent APACHE II (Pisani et al., 2007). Higher scores indicating more severe illness has been found to be highly associated with delirium ($p<0.001$) in unadjusted analyses (Pisani et al., 2007).

The effect of co-morbidities on the outcome of PD has consistent results. Brauer and colleagues (2000) in their older hip fracture sample identified causes attributable to comorbid cases. The relative risk related to increasing number of comorbidities is 1.75 (95% CI 1.09, 2.79) (Franco, Litaker, Locala, & Bronson, 2001). The most frequent

comorbid causes identified were sensory or environmental, infection, drug use, and fluid or electrolyte disturbances (eg, abnormal serum sodium level or elevated serum urea nitrogen–creatinine ratio). The pathologies listed as the most significant in relation to the association with PD include congestive heart failure ($p<0.003$), stroke ($p<0.001$), and cancer ($p<0.001$) (Dolan et al., 2000). The association between PD and congestive heart failure have been verified in a subsequent study utilizing an older hip fracture sample (adjusted OR 2.9; 95% CI, 1.6, 5.3) (Morrison et al., 2003). In an open abdominal surgical sample, Ganai and colleagues (2007) found that while preoperative poor nutritional status carries a significant relative risk of 2.1 (95% CI, 1.3, 3.4), perioperative fluid and volume status changes did not significantly increase the risk for incident delirium. During multivariable modeling, poor preoperative nutritional status carried an adjusted OR of 7.3 (95% CI, 1.7-31.2). The CCI has also been used in studies of PD to quantify severity of illness (Dolan et al., 2000; Franco, Litaker, Locala, & Bronson, 2001). The APACHE has also been used in studies of PD (Morrison et al., 2003), Society of Anesthesiologists physical status scale (Vaurio et al., 2006).

Pain.

Pain is defined as the subjective experience of discomfort and can further be classified as acute or chronic (Guyton & Hall, 2006). Because pain is associated with surgical procedures, literature regarding PD has provided evidence to its effect. In 2003, Morrison and colleagues evaluated 541 hip fracture patients in a prospective cohort study. Patients who had received less than 10 mg of parenteral morphine demonstrated high relative risk (RR) (RR 5.4, 95% CI 2.4, 12.3) for incident delirium versus those that

had received more (RR 2.4, 95% CI 1.3, 4.5). In the setting of cognitive impairment, undertreated pain yielded even greater risk (RR 9.0, 95% CI 1.8, 45.2). This finding is congruent with the PLST-DSD model as well as the suggested adaptation. Likewise, Vaurio and others (2006) demonstrated that baseline moderate (OR, 2.2; 95% CI 1.2 to 4.0) and severe (OR, 3.7; 95% CI, 1.5, 9.0) preoperative resting pain, and increase in level of pain from baseline to postoperative day one (OR, 1.1; 95% CI, 1.01, 1.2) were independently associated with a greater risk for the development of postoperative delirium. Also, opioid intravenous patient-controlled analgesia pain medication use demonstrated decreases in risk (OR, 0.4; 95% CI, 0.2, 0.7). One study found no increased risk was associated with untreated pain (RR 1.0, 95% CI, 0.7, 1.4) (Ganai et al., 2007).

Environmental Stressors

Noise.

Sound is a mechanical pressure wave of air comprised of the characteristics of wave amplitude, or loudness, and the distance between waves, known as frequency or pitch (Guyton & Hall, 2006). These waves travel through the air from the sound source and are transferred into human hearing through the outer ear and inner ear. Sound vibrations first make contact with the eardrum which conducts the vibrations to the ossicles and finally the cochlea, a fluid-filled, hair-lined, coiled tubular organ. The sound vibrations that are conducted to the cochlea cause the hairs inside to oscillate to generate neural impulses to the brain via the auditory nerve for subsequent interpretation. When sound becomes louder, more hair cells excite the nerve endings more rapidly. Frequency

is transmitted via which hair cells within the cochlea are stimulated. The brain maintains a specialized auditory cortex in the parietal and temporal lobes for sound discrimination (Guyton & Hall, 2006).

The human ear has a wide range of frequencies it can interpret. A young person can hear at frequencies of 20 to 20,000 cycles per second, or hertz (Hz). However, the full range can only be perceived as a function of loudness. Meaning, low levels of sound may limit the perception of sound at the higher and lower ends of this range of frequencies. In addition, in old age, the frequency range decreases to 50 to 8000 Hz or more. As noise perception is both mechanical in the ear and neural in the brain, any damage to these structures would limit sound interpretation (Guyton & Hall, 2006).

According to the United States Department of Labor Occupational Safety and Health Administration (OSHA), excessive occupational noise is a health hazard and should be monitored (OSHA, 2008). Noise is measured in decibels (dB) and in a logarithmic fashion whereby time included in noise exposure via the A-weighted scale (dBA) (Nott & West, 2003; OSHA, 2008). If sound increases by 3 dB, this is experienced as a doubling of the noise exposure, or dose (Nott & West, 2003). Noise is considered continuous if it occurs in bursts occurring in less than 1 second intervals. OSHA mandates protective devices should exposure exceed 80 dB for greater than 2 hours and prohibits continuous exposure greater than 115 dB and impact noise greater than 140 dB (OSHA, 2008). An octave band analyzer or spectrum analysis provides the frequency of sound measured in Hz. El Dib and Matthew (2009) found premature damage to hearing may result from occupational exposure to loud noise between 1000

and 6000 Hz. To put this in perspective, noise levels of 60 dB is present in normal conversation, levels of 80 dB are present in heavy traffic, levels of 100 dB are present with a chainsaw or car horn, and decibels of 120 are associated with a jackhammer (Richardson, et al., 2008).

Noise has been studied at length in industrial and occupational settings, in neighborhoods exposed to heavy aircraft traffic noise, and in neighborhoods exposed to heavy automobile traffic. Hearing protection devices in industrial settings with a noise range of 74.3 to 90.6 dB resulted in a significant reduction in both systolic and diastolic blood pressure when controlling for patient demographic variables (gender, race, age) (Lusk et al., 2002). This study was conducted on hourly workers in an automobile plant. The sample was 8% male with an average age of 46 (± 6.14) years with a range from 31 to 64 years. Noise exposure was measured in dBA via a third party noise survey examining sound pressure. Noise annoyance was measured utilizing the tool for noise annoyance by van Dijk et al. (1987).

Three physiologic responses to noise exposure include voluntary skeletal muscle movement in avoidance or involuntary reflexive action, visceral smooth muscle and glandular response, and activation of the neuroendocrine and sympathetic nervous system (Prashanth & Venugopalacha, 2008). Common symptoms that industrial workers attribute to noise include eyeball pressure, sleep disturbance, neck pain, fatigue, repeated headaches, and irritability (Prashanth & Venugopalacha, 2008, p. 97). These symptoms varied with the sound frequency. For example, eyeball pressure and backache were highly associated at 31.5 Hz, a very low frequency, whereas neck pain was not associated

at this frequency (Prashanth & Venugopalacha, 2008, p. 97). These authors studied industrial workers; however, only one participant was over age 56 years. Noise was measured utilizing a sound level meter in dBA. These researchers also measured noise sensitivity through a questionnaire geared towards industrial noise. Industrial machines produce noise frequencies in the low (>22-500 Hz) and mid (>500-2kHz) octave band frequency ranges. Organs of the human body resonate at low (20-200 Hz) and infrasound (< 20 Hz) frequencies. For example, the chest wall resonates at between 50 and 100 Hz, the head at 20 to 30 Hz, and the thorax at 63 to 160 Hz (Alves-Pereira & Castelo Branco, 2004). There is a positive association between past chronic noise exposure (> 85 dBA) and the incidence of cardiovascular morbidity and mortality as well as total overall mortality in industrial workers (Melamed, Kristal-Boneh, & Froom, 1999). Finally, wake-up reactions occur at the threshold of maximum levels of 48 dBA at the position of the ear (Mashke, Hect, & Wolf, 2004). The pilot study of noise and delirium (Brown, 2010) demonstrated a personal exposure at the ear of 58.4 dBA and average maximum levels of 82.8 dBA. The effect of medications for sedation on the perception of noise has not been studied.

Two studies presented on non-auditory chronic effects of noise exposure on industrial workers. Prashanth and Venugopalacha (2008) conducted a cross-sectional design of six types of industrial workers, such as automotive parts, polymer, dairy products, and plywood. They used a questionnaire and interviews regarding noise annoyance and sensitivity as well as health status. Noise was measured at each industrial setting utilizing a sound level meter. Lusk et al. (2002) focused on automobile plant

workers. They conducted a longitudinal, cohort study over 8 months and evaluated participants for noise exposure effects on the cardiovascular system. The authors found that while chronic noise exposure was not significantly related to blood pressure, the use of hearing protection was significantly predictive of lower blood pressure. Noise exposure was reported in dBA and pressure levels, which were collected utilizing a sound level meter. Noise annoyance and sensitivity were measured utilizing the annoyance scale by van Dijk et al. (1987).

Aircraft noise impairs cognition in school aged children (Matsui, Stansfield, Haines, & Head, 2004; Stansfield et al., 2005). In an examination of children (n=2844) exposed to chronic aircraft or automobile traffic noise, the children exposed to aircraft noise had impaired reading comprehension ($p=0.0097$) and recognition memory ($p=0.141$) (Stansfield et al., 2005). While these cognitive changes were not noted with road traffic noise, both aircraft and road traffic noise generated a positive relationship with annoyance ($p< 0.0001$ and $p=0.0047$, respectively) (Stansfield et al., 2005).

Noise annoyance and sensitivity.

Noise annoyance is defined as the degree to which the individual perceives the noise as "annoying or psychologically disturbing" (Lusk et al., 2002, p 276). Noise annoyance was first described by van Dijk et al. (1987) in a sample of industrial workers. Two thirds of workers were characterized as noise-annoyed, and they described various aspects of annoyance such as irritation, alarm reactions, mental workload and time pressure; however, these aspects increased annoyance to a greater degree than the noise pressure levels, or loudness (van Dijk et al., 1987). This study utilized 539 male workers

with age distribution categorized (< 25 years old was 21%; 25 to 34 years old was 31%; 35 to 49 years old was 33%, 40 to 54 years old was 9%; 55 to 65 years old was 6%). This study generated the five question Likert scale of noise annoyance. Noise annoyance is highly associated with physiological effects (increased heart rate, increased blood pressure, backache, eyeball pressure) (Lusk et al., 2002). Annoyance is not associated with sound pressure levels (Kroesson, Molin, & van Wee, 2010), but is associated with sound characteristics such as: intermittent, irregular, tonal, pulse, and impulse (Prashanth & Venugopalachar, 2011).

Noise sensitivity was first studied by psychologist Weinstein in 1978 in a cohort of dormitory dwelling college students. Noise sensitivity, or the threshold in which sounds are perceived as noise, was correlated with lower scholastic ability, social anxiety, and desire for privacy (Weinstein, 1978). The resulting 21 Likert questionnaire determines degree of noise sensitivity with group means of the original study of 67.9 indicating sensitivity and 39.8 yielding insensitivity. Schreckenberg, Griefahn and Meis (2010) interviewed community-dwellers residing near Frankfurt airport ages 17 to 80 years. Noise was reported in LA-eq which is calculated as an average noise exposure following the collected in dB via a sound level meter. Noise annoyance was measured utilizing a 35 item questionnaire called the noise sensitivity questionnaire (NoiSeQ), a Swedish-language tool on noise sensitivity. The noise annoyance scale utilized was the five point scale created by Fields et al. (2001).

Noise sensitivity is a moderator of noise annoyance and other subjective complaints such as sleep disturbance. Noise sensitivity is associated with physical and

mental complaints as well as introverted personality, neuroticism, and negative affect (Schreckenberg et al., 2010; Shephard, Welch, Dirks, & Mathews, 2010). Noise sensitivity was predicted by age with higher noise sensitivities in older versus younger participants (Schreckenberg et al., 2010). Noise sensitivity is estimated to affect 50 percent of individuals (Shephard et al., 2010), and maintains a genetic heritability (40 %) evidenced in twin studies (Heinonen-Guzejev et al., 2005) as demonstrated with anxiety (Rijsdijk, et al., 2003; Federenko, et al., 2006).

Postoperative auditory recall.

Anesthesia is derived from the Greek word anaisthēsia meaning "insensible," or "unable to perceive" (anesthesia, 2009); and it is an assumption that persons receiving anesthesia will be oblivious to the operating room environment with decreased sense of hearing ("anesthesia," 2009). While anesthesia depresses nerve transmission in the brain and spinal cord, the acoustic nerve remains active during general anesthesia and is often chosen to monitor neurologic integrity (Daunderer & Schwender, 2000; Sigalovsky, 2003; Sloan, 2001). Davis et al. (2007) conducted a functional magnetic resonance imaging scan on 12 healthy volunteers, and even under heavy sedation and limited cortical function, the temporal lobe, responsible for sound recognition, remained active in an anesthetic dose-dependent manner (Davis et al., 2007). During general anesthesia or heavy sedation when people are not actively listening, the cerebral cortex is receiving acoustic input in the form of sound. In short, it is likely that people receiving general anesthesia can hear everything in their environments. In fact, there are cases of recall that frequently occur in the form of auditory recollections and dreaming; although some

patients report delayed psychological disturbances, nightmares, and post-traumatic stress disorders (Errando et al., 2008; Samuelsson, Brudin, & Sandin, 2007).

Alternatively, there is evidence that changing environmental noise under anesthesia effects postoperative outcomes. Leardi et al. (2001) conducted a randomized controlled trial between 3 groups. The groups were randomized to a) new age music, b) patient-selected music, and c) control group with normal intraoperative noise. While plasma cortisol levels dropped in the groups listening to music, they increased in the control group exposed to intraoperative noise. However, between the two music groups, plasma cortisol levels were significantly lower in the group of patients that selected music choice. The mean age of the participants was 65 years and all were undergoing differing types of outpatient procedures and anesthesia.

Intraoperative music was effective in reducing postoperative pain in a cesarean section sample (Ebneshahidi & Mohseni, 2008), in a hysterectomy sample with a mean age of 50 (Nilsson, Rawal, Unestahl, & Unosson, 2001), and in a spinal surgery sample with a mean age of 62 (Lin et al., 2011). Intraoperative music also increased elderly cataract surgical patient satisfaction scores greater than relaxing suggestions, white noise or operating room noise, in descending order (Cruise, Chung, Yogendran, & Little, 1996). All of the studies presented were randomized, controlled trials with findings that highlight differences between control groups exposed to intraoperative, environmental noise and music intervention groups.

Noise in the operating room.

Noise has been described as affecting the operating room environment. The World Health Organization (1999) in their Community Noise Guidelines (Table 3) recommended that a noise level in operating rooms deserves "special attention," and noise should not exceed 30 dBA while indoors. In an evidence-based review of the literature, Hasfeldt, Laerkner, and Birkelund (2010) found that of the eighteen relevant studies regarding operative noise, average noise levels ranged from 51 to 75 dBA with maximum noise levels ranging from 80 to 109 dBA. The main source of noise was attributed to staff-related activities such as conversation, dropping tools, and opening surgical trays. Of the two studies focused on patient perception, the patients who were the most stressed were not those exposed to the highest levels of noise (Hasfeldt, Laerkner, & Birkelund, 2010; Liu & Tan, 2000).

Nott and West (2003) evaluated noise levels in an orthopedic operating room. They sampled 31 operations with a sound level meter involving participants' ages 16 to 92 years. The noisiest procedure was found to be the total knee arthroplasty with a maximum intensity of 101 dBA. Other findings included maximum intensities by sound source. The hammering of the intermedullary femur nail peaked at 107 dBA with the number of impacts reaching 23. This study measured noise with the sound level meter, but did not evaluate a patient's exposure using a sound dosimeter. Other sources with high peak levels included animated conversation (83 dBA), instrument set up (94-104 dBA), the closing of bin lids (101.5-104 DBA), and the detachment of the compressed air line (105 dBA). These findings were replicated in another study by Love (2003), also in

an orthopedic suite. In this small study, the average sound level (Lavg) of 3 total hip arthroplasties was 78.7 dBA and the average of 2 total knee arthroplasties was 80.9 dBA. However, this study was focused on environmental noise exposure as perceived by the surgeon. A personal sound dosimeter was worn by the surgeon in this study to yield the noise variables.

Table 3. World Health Organization Community Noise Guidelines

Specific Environment	**Critical Health Effect(s)**	**L_{Aeq} [dB(A)]**	**Time base [hours]**	**L_{Amax} fast [dB]**
Outdoor living area	Serious annoyance, daytime and evening	55	16	-
	Moderate annoyance, daytime and evening	50	16	-
Dwelling, indoors	Speech intelligibility & moderate annoyance, daytime & evening	35	16	
Inside bedrooms	Sleep disturbance, night-time	30	8	45
Outside bedrooms	Sleep disturbance, window open (outdoor values)	45	8	60
School classrooms & preschools, indoors	Speech intelligibility, disturbance of information extraction, message communication	35	During class	-
Preschool bedrooms, indoors	Sleep disturbance	30	Sleeping time	45
School, playground outdoors	Annoyance (external source)	55	During play	-
Hospitals, ward rooms, indoors	Sleep disturbance, night-time	30	8	40
	Sleep disturbance, daytime and evenings	30	16	-
Hospitals, treatment rooms, indoors	Interference with rest and recovery	#1		

Specific Environment	Critical Health Effect(s)	L_{Aeq} [dB(A)]	Time base [hours]	L_{Amax} fast [dB]
Industrial, commercial shopping and traffic areas, indoors and outdoors	Hearing impairment	70	24	110
Ceremonies, festivals, and entertainment events	Hearing impairment (patrons: <5 times/year)	100	4	110
Public addresses, indoors and outdoors	Hearing impairment	85	1	110
Music and other sounds through headphones or earphones	Hearing impairment (free-field value)	85 #4	1	110
Impulse sounds from toys, fireworks, and firearms	Hearing impairment (adults) Hearing impairment (children)	- -	- -	140 #2 120 #2
Outdoors in parkland and conversation areas	Disruption of tranquility	#3		

#1: As low as possible
#2: Peak sound pressure (not LAF, max) measured 100 mm from the ear
#3: Existing quiet outdoor areas should be preserved and the ratio of intruding noise to natural background sound should be kept low
#4: Under headphones, adapted to field-free values.

Noise affects behavior.

There are two behavioral changes resulting from noise exposure of interest: acoustic shock and startle reflex. Acoustic shock is a clinical syndrome resulting from exposure to an abrupt, intense or unanticipated sound termed the acoustic incident (McFerran & Baguley, 2007). Causative acoustic incidents have been studied and found to have intensities of 56 to 108 dB and frequencies of 100 to 3800 Hz (McFerran &

Baguley, 2007). Early symptoms, occurring immediately or within minutes, include ear pain (81%), neck and jaw pain (11%), tinnitus (50%), and balance problems (48%) (Milhinch, 2002). Late symptoms, occurring within hours, may include anxiety, depression, hypervigilance, and anger and can become chronic (Milhinch, 2002).

The acoustic startle, a primitive reflex, is a cluster of reactions to sudden loud sounds including muscle contractions and increased heart rate. This reflex is enhanced by stressful stimuli such as pain and environmental conditions, such as noise (Osuch et al., 2004). Psychologists utilize noise in fear-conditioned response experiments by exposing animals to painful stimuli while exposing them to unanticipated noise or light as environmental cues. These animals develop a potentiated startle reflex to noise, and fear or behavioral changes (i.e. avoidance behaviors, defensive reflexes, freezing) become the conditioned response (Armario, Escorihuela, & Nadal, 2008; Davis, Falls, Campeau, & Kim, 1993). An exaggerated startle is a diagnostic symptom of post-traumatic stress disorder (Osuch et al., 2004). It is also associated with schizophrenia, anxiety disorders, obsessive-compulsive disorders, and attention deficit disorders and phobias, although prior traumatic noise exposures are not requisite to the heightened response (Braff, Geyer, & Swerdlow, 2001; Lang, Davis, & Ohman, 2000).

The startle reflex is insensitive of acoustic qualities in decibels and hertz. Meaning, it can present at any hertz or decibel range in human hearing. However, the acoustic stimulus must be sudden (Yeomans, Li, Scott, & Frankland, 2002). It is postulated that the acoustic startle is protective of dorsal head and body blows. During the startle reflex, the eyes close, the neck flexes forward and neck muscle contract, the

shoulders move upwards towards the head to limit neck exposure, and the thoracic and abdominal muscles stiffen (Yeomans et al., 2002).

Polypharmacy

Psychoactive medications.

Beginning with the early studies, psychoactive medications have been found to increase the odds or relative risk for delirium. The Beers criteria, derived from "Explicit criteria for determining inappropriate medication use in nursing home residents," was first introduced in 1991 to assist physicians in prescribing medications for the elderly to avoid inappropriate medication use. Many of the guidelines target psychoactive medications such as long-acting benzodiazepines, sedative-hypnotics such as barbiturates, antipsychotics, non-steroidal anti-inflammatory drugs, and analgesics (Beers et al., 1991). The Beer's criteria are updated periodically such as in 1997 (Beers, 1997). In the latest publication update by Fick and colleagues in 2003, the list of medications has grown from 33 inappropriate medications requiring dosing guidance to almost 50.

Beginning with elder medical patient samples, Francis and colleagues in 1990 found psychoactive medications defined as use of narcotics, sedative-hypnotics, "mild tranquilizers," or anticholinergics generated an adjusted OR for delirium of 3.9 (95% CI, 1.4 to 10.8). Inouye and Charpentier (1996) further demonstrated that when 3 or more medications are introduced, the relative risk of delirium almost tripled to 2.9 (95% CI 1.6 to 5.4). In 2005, Pandharipande, Jackson, and Ely reported lorazepam, a long-acting benzodiazepine, as an independent risk factor for delirium in their elder ICU cohort sample with a significant OR 1.2 (95% CI 1.0 to 1.4, $p = 0.02$). The risk increased

exponentially with low dosages, but demonstrated a plateau of 20 milligrams (mg) of lorazepam. Likewise, Pisani and colleagues (2007) evidenced an OR with benzodiazepines use of 3.4 (95% CI, 1.6 to 7.0).

When compared to the literature of delirium, psychoactive medications demonstrated increased risk for PD as well. Marcantonio and colleagues (1994) demonstrated increased risk of PD with both meperidine with an OR 2.7 (95% CI 1.3 to 5.5) and benzodiazepines OR 3.0 (95% CI 1.3 to 6.8), with longer acting benzodiazepines generating greater odds versus short acting (5.4 vs 2.6 respectively). The risk for delirium with meperidine was corroborated with Morrison and colleagues (2008), with a RR of 2.4 (95% CI, 1.3 to 4.5). And the risk was also higher with increasing number of psychoactive medications in abdominal aneurysm patients (Benoit et al., 2005), as in the delirium literature. Psychoactive medications have been found to be the most attributable cause of PD in a retrospective chart analysis of a hip fracture repair sample (n=54) (Brauer, Morrison, Silberzweig, & Siu, 2000). In a knee and hip replacement sample, Priner and others (2008) demonstrated psychotropic medication use as a main predictor of PD with an OR of 7.5 (95% CI 1.7 to 37.4; $p = 0.01$). Psychotropic medication use was defined as a patient currently prescribed and taking neuroleptic, antidepressant or anxiolytic drug.

In a critical meta-analysis of psychoactive medications and delirium, Gaudreau and colleagues (2005) found that studies which grouped psychoactive medications in statistical analyses found positive associations with delirium and PD. However, when medications were evaluated separately conflicting results were generated. In addition,

most of the studies regarding psychoactive medication use lacked a control group utilizing cohort sampling methodology.

Other researchers focused on pre-admission factors aside from psychoactive medication use or outcomes post-discharge from the hospital (Dolan et al., 2000; Franco, Litaker, Locala, & Bronson, 2001; Givens, Sanft, & Marcantonio, 2008; Lemstra et al., 2008; Lowery, Wesnes, Brewster, & Ballard, 2008; Vaurio et al., 2006). One particular study that demonstrated a non-significant increase in delirium relative risk of 1.2 with use of precipitant medications (95% CI 0.8 to 1.6, p=0.38) (Ganai et al., 2007).

Outcomes

Delirium

Delirium is defined by the American Psychiatric Association (APA, 2000) in the Diagnostic and Statistical Manual IV (DSM-IV-TR) as "a rapidly developing disorder of disturbed attention that fluctuates with time." Other criteria defining delirium by the presence of at least two of the following symptoms resulting from a general medical condition (DSM-IV-TR, code 293.0):

- The patient has a reduced level of consciousness and difficulty focusing, shifting or sustaining attention.
- There has been a cognitive change (deficit of language, memory, orientation, perception) that a dementia cannot better explain.
- These symptoms develop rapidly (hours to days) and tend to vary during the day.
- History, physical examination or laboratory data suggest that a general medical condition has directly caused the condition

Delirium has been studied in both medical and surgical populations. Patient populations studied include those undergoing surgery for abdominal aneurysm repair, open abdominal surgery, and orthopedic surgery, and those in intensive care, general medical, and long term care (Benoit et al., 2005; Brauer, Morrison, Silberzweig, & Siu, 2000; Dolan et al., 2000; Francis, Martin, & Kapoor, 1990; Franco et al., 2001; Ganai et al., 2007; Givens, Sanft, & Marcantonio, 2008; Kudoh, Katagi, & Takazawa, 2002; Lowery, Wesnes, Brewster, & Ballard, 2008; Pandharipande, Jackson, & Ely; Pratico et al., 2005; Pretto et al., 2009; Vaurio, Sands, Wang, Mullen, & Leung, 2006; Voyer, McKusker, Cole, St. Jacques, & Khomenko, 2007). The incidence varies among these diverse groups. The incidence of delirium is estimated at 10 to 20 percent in a general medical population (Francis et al., 1990; Tabet et al., 2005), but as high as 60 to 80 percent of intensive care elder patients (Pandharipande et al., 2005; Pratico et al., 2005).

Prevalence was highest at 68.3% among newly hospitalized patients from long term care facilities (Voyer et al., 2007) to as low as 12 % in a general medical population on admission to acute care facilities (Inouye, Rushing, Foreman, Palmer, & Pompei, 1998). Prevalence upon hospital admission following hip fracture has been found between 7 to 13.5 percent (Brauer et al., 2000; Dolan et al, 2000). Outside of these prevalence studies, delirium is often not systematically detected upon admission to the hospital.

Of the eight incidence studies, five utilized non-probability, cohort, and convenience sampling methods (Francis et al., 1990; Inouye & Charpentier, 1996; Inouye et al., 1999; Levkoff et al., 1992; Pisani, Murphy, Van Ness, Arujo & Inouye, 2007;

Trzepacz et al., 1998; Voyer et al., 2007). Cognitive impairment was a frequently found as a co-morbidity and was described as increasing the risk of developing delirium with odds ratios (OR) ranging between 3.42 (Voyer et al., 2007) with mild cognitive impairment and linearly increasing with worsening impairment to OR 6.3 with known dementia (Pisani et al., 2007).

The tools utilized to measure presence of delirium included the diagnostic criteria of the DSM-III, DSM-IIIR, or DSM-IV, as well as the CAM. However, the CAM or the CAM-ICU was utilized in 4 of the eight studies (Inouye & Charpentier, 1996; Inouye et al., 1999; Pisani et al., 2007; Voyer et al., 2007). Other risk factors found consistently among studies and reviews included physical restraints, comorbidities, psychoactive medications, advanced age, sensory impairments, and fluid or electrolyte disturbances (Francis et al., 1990; Inouye & Charpentier, 1996; Inouye et al., 1999; Levkoff et al., 1992; Pandharipande et al., 2005; Pisani et al., 2007; Siddiqi et al., 2006; Trzepacz et al., 1998; Voyer et al., 2007). In addition, four of the eight studies measured functional status utilizing either an activities of daily living (ADL) scale (Francis et al., 1990; Inouye et al., 1999; Pisani et al., 2007) or the Barthel index (Voyer et al., 2007).

Postoperative Delirium

Postoperative delirium (PD) presents following a surgical procedure. Because this study is measuring PD as a primary dependent variable and main outcome of the model as evidence for crossing the stress threshold, the literature related to PD is examined. Six of the PD studies utilized an orthopedic surgical sample (Brauer et al., 2000; Dolan et al., 2000; Franco et al., 2001; Givens et al., 2008; Lowery, Wesnes,

Brewster, & Ballard, 2008; Pretto et al., 2009). The incidence of delirium ranges from 10 to 60 percent in the postoperative population (Franco et al., 2001; Moller et al., 1998). The incidence of PD varies among types of surgical procedures. Those having orthopedic procedures show an incidence between 15 and 50 percent (Brauer et al., 2000; Franco et al., 2001; Lowery, Wesnes, Brewster, & Ballard, 2008; Vaurio et al., 2006) whereas the incidence in abdominal aneurysm is 35 percent (Benoit et al., 2005) and in post-open abdominal is 60 percent (Ganai et al., 2007). Of the fourteen studies determining PD incidence, ten utilized prospective, non-probability, convenience cohort sampling methods (Benoit et al., 2005; Brauer et al., 2000; Dolan et al., 2000; Givens et al., 2008; Kudoh et al., 2002; Lowery, Wesnes, Brewster, & Ballard, 2008; Marcantonio et al., 1994; Morrison et al., 2003; Priner et al., 2008, Vaurio et al., 2006).

Eleven of the fourteen studies utilized the CAM to determine presence of PD (Brauer et al., 2000; Dolan et al., 2000; Gaudreau, Gagnon, Roy, Harel, & Temblay, 2005; Givens et al., 2008; Kudoh et al., 2002; Lemstra, Kalisvaart, Vreeswijk, van Gool, & Eiklenboom, 2008; Lowery, Wesnes, Brewster, & Ballard, 2008; Marcantonio et al., 1994; Morrison et al., 2003; Priner et al., 2008; Vaurio et al., 2006). Other measures used to detect PD in studies not utilizing the CAM measured delirium via diagnostic criteria of the DSM-III, DSM-IIIR, and the DSM-IV (Benoit et al., 2005; Franco et al., 2001; Ganai et al., 2007).

Other risk factors included psychoactive medications, functional impairment, advanced age, comorbidities, infection, sensory impairment, fluid or electrolyte imbalances, substance or alcohol withdrawal, and undertreated pain (Benoit et al., 2005;

Brauer et al., 2000; Dolan et al., 2000; Franco et al., 2001; Ganai et al., 2007; Gaudreau et al., 2005; Givens et al., 2008; Kudoh et al., 2002; Lowery, Wesnes, Brewster, & Ballard, 2008; Marcantonio et al., 1994; Morrison et al., 2003; Vaurio et al., 2006). Operative risk factors demonstrating no effect of the incidence of PD included type of anesthesia, duration of anesthesia, preoperative serum C-reactive protein, serum interleukin-6, and insulin growth factor, excess blood loss, blood transfusion, and excess fluid administration (Ganai et al., 2007; Morrison et al., 2003).

Change in Behavior

Another hallmark of delirium, with or without dementia, is psychomotor changes. In a study of delirium severity following hip fracture repair, Marcantonio, Ta, Duthie, and Resnick (2002) found that the dichotomous outcome of the Confusion Assessment Method (CAM) failed to identify "subsyndromal" delirium. The four psychomotor subtypes identified in delirium include pure hypoactive, pure hyperactive, mixed, and normal (Peterson et al., 2006). The prevalence of the subtypes varies among studies. The pure hypoactive form ranges in prevalence from 43.5% to 71% (Marcantonio et al., 2002; Peterson et al, 2006), the mixed type accounts for a prevalence of 54.9%, and the purely hyperactive subtype is the rarest at 1.6% (Peterson et al., 2006). Hypoactive delirium is characterized by fatigue, lethargy, and decreased alertness or activity (APA, 2000). Hyperactive delirium is characterized by agitation, vigilance, combativeness and hallucinations (APA, 2000). The mixed psychomotor subtype is a combination of hypoactive and hyperactive psychomotor subtypes (APA, 2000).

The outcomes related to these subtypes also vary. The hypoactive form is associated with less severe delirium, is related to older age, and results in less institutionalization (Marcantonio et al., 2002; Peterson et al, 2006); while normal psychomotor activity had the lowest overall mortality (Kiely, Jones, Bergmann, & Marcantonio, 2007). Hyperactive or mixed subtypes are associated with worsening delirium and nursing home placement (Marcantonio et al., 2002; Peterson et al, 2006). All subtypes demonstrate greater mortality than normal psychomotor activity (Kiely et al., 2007; Marcantonio et al., 2002).

Interventions

As risk factors are elucidated, interventions have developed with a focus on predictive tools and detection of those patients at risk. Confounding the identification of delirium are the commonly co-occuring psychopathologies of depression and dementia. Delirium may be present with both of these as underlying conditions or delirium may be assumed to be an exacerbation of these diseases. There have been five review articles highlighting the differences and similarities of these diseases (Arnold, 2004; Gillis & MacDonald, 2006; Gleason, 2003; Henry, 2002; Hoot Martin, & Hoot Haynes, 2000). Donna Fick, expert on delirium superimposed on dementia, recommends utilizing the CAM to determine delirium status in Try This: Delirium Superimposed on Dementia (Fick & Mion, 2008).

Some studies utilized an intervention to prevent delirium. The most successful interventions are multicomponent and are often aimed at screening those predisposed to

delirium and ameliorating the precipitating risk factors. Inouye and colleagues (1999) devised the first multicomponent intervention which included orientation and cognitive stimulation, sleep protocol, early mobilization, sensory input, and adequate hydration. This yielded a decrease in incidence from 15 % to 9.9%. This intervention is now a proprietary program termed "Hospital Elder Life Program" (HELP) and has been utilized in various patient settings (Robinson, Rich, Weitzel, Vollmer, & Eden, 2008; Rubin et al., 2006). This intervention was replicated with similar results, a reduction in relative risk by 35% (Rubin et al., 2006).

Other multicomponent interventions with additional therapies have been applied with varying results. For example, Milisen and colleagues (2001) added systematic cognitive screening, geriatric consulting services, and scheduled pain protocols. However, multicomponent preventive strategies decrease the incidence in decrements ranging from 3% to 24% (Bjorkelund et al., 2008; Inouye et al., 1999; Marcantonio, Flacker, Wright, & Resnick, 2001; Milisen et al., 2001; Robinson, Rich, Weitzel, Vollmer, & Eden, 2008). Other additions have included pain management strategies (Bjorkelund et al., 2008; Marcantonio, Flacker, Wright, & Resnick, 2001; Milisen et al., 2001). Only one multicomponent study failed to find significant differences between the intervention and control groups; although the authors found their study was underpowered as it was a pilot study (Benedict et al., 2009). Also, there was a large difference in number of days delirious between the medical population and the surgical population. Of the seven studies evaluated, four occurred in a surgical hip population which provides further validation of the inclusion of hips in the study sample.

Summary

Delirium and PD are multidimensional disorders of cognition and behavior. The PLST-DSD is a worthy theoretical model to frame research on PD. Furthermore, the PLST-DSD is congruent with research findings on the known predisposing and precipitating risk factors for PD. The predisposing risk factor with the greatest influence on the variability of PD is impaired cognitive status. The three main precipitating risk factors were explored, including internal stressors such as comorbidities, polypharmacy and environment. Noise has been found to be an environmental stressor. Yet, there is limited understanding on its effect on elder arthroplastic patients. As it is unknown which aspects of noise are most stressful during surgery, this was explored and related to a particular poor outcome in this population: PD.

CHAPTER III

METHODS

Noise imparts physiologic stress on the human (Evans et al., 1995; Lusk et al., 2002; Muchnik et al., 1998; Rosenlund et al., 2001; Rylander & Bjorkman, 1988). Scaffolding within PLST-DSD (Fick, 2008) a positive correlation between noise and the severity of PD is theorized. However, it is unknown which aspects of noise (pitch, loudness) have the greatest influence on the variability of PD severity. Therefore, these measures were studied. A correlational design was used to describe the relationship between environmental noise in the operating room environment of elderly participants having orthopedic arthroplastic surgeries and to examine the relationship of intraoperative noise to the severity of PD.

Design

As a correlational design is non-experimental, there is no randomization to treatment group. None of the independent variables were manipulated in this study. However, a correlational approach allowed for the careful examination of relationships between the independent variables and the outcome of PD and for the exploration into the significance of the studied environmental noise variables (Gliner, Morgan, & Leech, 2009).

Study Setting

Data was collected during the first 72 hours of an operative visit of a total knee or hip arthroplasty participant starting in the preoperative anesthesia assessment, the preoperative holding room, the inpatient orthopedic operating room, the recovery room, and ending in the rehabilitation unit. The study setting was a large not-for-profit regional hospital that contains 961 acute care, long-term, rehabilitation, and psychiatric bed capacity. During fiscal year 2009, over 2,000 total knee and total hip arthroplasties were performed (Lambert, 2010). All orthopedic surgeons (n=7) who were approached granted permission to approach and consent their patients in the study.

Sampling Plan

Recruitment for this study began in December of 2011 and ended in March of 2012 when the calculated sample size had been reached. Recruitment technique was convenience sampling of community-dwelling elders presenting for orthopedic joint replacement surgery. The criteria for inclusion of participants:

1. English speaking and understanding
2. Presenting for total knee or hip joint replacement
3. Receiving a spinal or epidural as the primary anesthetic
4. Age greater than or equal to 50 years

The criteria for exclusion of participants:

1. Current inpatient hospitalized status for night prior to data collection
2. Prevalent delirium at screening via Confusion Assessment Method (CAM) (Inouye et al., 1990)

3. Pre-existing sensory loss such as deafness requiring hearing aid or legal blindness
4. Participated in pilot study (Brown, 2010)

Power Analysis

A sample of at least 48 participants was calculated prior to participant recruitment. Statistical power was estimated under a variety of alternative scenarios. The power calculations computed an initial model including risk and depression (denoted as reduced) versus a full model calculation including noise sensitivity, annoyance, and noise measure(s) added would be for the outcome, delirium severity. Incidence was not chosen to explore as the inclusion of logistic regression modeling would double the number of required participants which was not feasible for the projected time and resources allotted for this study.

Table 4. Power Calculations for Multivariable Linear Regression Modeling of Delirium Severity Using DI

N total	No. predictors*	R2 reduced	R2 full	R2 difference	Power (%)
48	5	0.30	0.45	0.15	79.4
48	5	0.50	0.60	0.10	75.7
48	5	0.50	0.65	0.15	93.8
48	5	0.70	0.80	0.10	96.5
48	7	0.30	0.45	0.15	69.9
48	7	0.50	0.60	0.10	65.7
48	7	0.50	0.65	0.15	88.7
48	7	0.70	0.80	0.10	93.0
48	12	0.30	0.45	0.15	51.9
48	12	0.50	0.60	0.10	47.8
48	12	0.50	0.65	0.15	74.7
48	12	0.70	0.80	0.10	81.8

*Risk index and depression score are in the reduced model and are counted among the number of predictors. Noise sensitivity and annoyance are counted among the predictors in every full model.

Power was calculated for varying sizes of the full model, where the number of predictors was varied according to the number of noise measures ultimately included. Because any full model would at least contain risk index, depression score, noise sensitivity, noise annoyance, and at least one noise measure, the calculations were performed starting with the number of predictors at 5 and varied up to 12 (i.e., up to modeling eight different noise measures).

Voyer et al. (2006) reported that similar modeling without noise measures for DI resulted in an R2 = 0.70. From the above table, there is at least 80% power to detect an increase in R2 of 0.15 or more when the sample size is n=48 and the R2 from a reduced model with just risk index and depression is at least 0.50 and the total number of

predictors is 10 or less (i.e., 6 of the up to 16 noise measures are kept in a full model). If the R2 from a reduced model is higher around 0.70, then there is >80% power to detect an increase in R2 of 0.10 or more with 12 predictors. For model parsimony and given the target sample size of n=48 participants, no more than 8 of the up to 16 noise measures would be kept and hence the maximum size of the full model would be no greater than with 12 predictors. Graphical and bivariate analysis initially explored which noise measures should be pursued. Power is greater if fewer predictors are used while the model R2 is higher and thus these estimates are conservative if analysis reveals model fit is improved under such a scenario.

Human Subjects Protection

Approval for this study was obtained from the Institutional Review Board (IRB) of The University of North Carolina at Greensboro. In addition, permission to conduct the study was obtained from the medical center according to hospital policy. All participants were informed regarding the purpose of the study and expectations of participation. A written consent form was explained by the principal investigator (PI) and signed by each participant or legal guardian prior to collecting data and each participant received an exact copy. The consent form was written at a fourth grade reading level in clear, concise statements. The consent explained that participation was voluntary and future withdrawal from the study could be completed at any time without negative repercussions. Assent procedures were utilized in the preoperative room, the postoperative room, and the nursing rehabilitation unit in the event the participant was

under the influence of anxiolytic medications. These forms and procedures were approved by the university IRB.

Confidentiality was assured by utilizing four-digit codes to identify participants instead of names, medical record numbers, social security numbers, or any other personal identifiers. A master list of participant names was kept in hard copy format separate from the data collection forms. All data collection forms and the master list was kept in a locked file in the PI's campus office. Electronic files pertaining to the study only use the four digit participant codes as identifiers, and the computer was password protected. The HIPPA and personal health information rules of the medical center were followed by the PI and RA.

Instruments

There were eleven instruments in addition to the sound meters used during this study: the Mini-Cog (Doerflinger, 2007), the Weinstein (1978) noise sensitivity, and noise annoyance scales, the Katz Activities of Daily Living (ADL) scale (Katz et al., 1963), the Confusion Assessment Method (CAM) (Inouye et al., 1990), the Delirium Index (DI) (McCusker et al., 1998), a numeric visual analog scale (NVAS) for pain and anxiety, a Whisper test and the tool under development by Freter and colleagues (2005) which quantifies risk for PD based upon assessment of predisposing risk factors.

Pre-surgical Patient at Risk for PD

DEAR tool.

Pre-surgical patient at risk for PD theoretically is a person presenting for surgery who will be exposed to physical internal, polypharmacy, and environmental stressors at risk for crossing their stress threshold and subsequent development of PD. This was operationally defined by the predictive DEAR tool developed by Freter and colleagues (2005) (Appendix A). Because the tool by Freter and colleagues (2005) measures risk, it involves the collection of the following predisposing risk factors: baseline cognitive status utilizing the MMSE, advanced age, functional status assessed by the Katz ADL tool, self-reported sensory impairment, and the use of alcohol or benzodiazepines upon admission. However, because the tool by Freter and colleagues (2005) only awards a point for evidence of cognitive impairment (MMSE less than 24 points), the more brief Mini-Cog was utilized to screen for baseline cognitive impairment.

Mini-Cog.

The Mini-Cog was utilized during the pilot during a screening and is a brief dementia screening tool that incorporates the classic clock drawing test (CDT) and a 3 item recall (Doerflinger, 2007) (Appendix B). The scale is scored 0 to 3. If the participant is able to recall all three items, the score is a three and the outcome is non-demented. If there is intermediate recall of 1 to 2 words, the CDT is evaluated. If the CDT is abnormal, the participant is classified as demented. If the participant is unable to recall any of the words, the participant is classified as demented. This tool has a reported sensitivity between 76% and 99% and a specificity of between 89% and 100%

(Doerflinger, 2007; Holsinger et al., 2012; Milian et al, 2012). During the pilot, the test was easily administered with no explanation necessary save the directions of drawing the clock face. All participants recalled the three words of "California," "table," and "horse" with clocks drawn between items given and recall.

Katz Index of Independence.

Functional status was operationalized by the Katz Index of Independence in activities of daily living (ADL) scale (Katz et al., 1963) and was incorporated within the DEAR tool by Freter and colleagues (Appendix A). This scale measures an individual's ability to perform normal daily activities required to meet basic needs, fulfill usual roles, and maintain health and well-being (Katz et al., 1963). Decline in functional status was measured by an individual's loss of independence in activities of daily living (ADLs) over a period of time (Katz et al., 1963). Functional independence is an indicator of intact cognitive function (Katz et al., 1963) and is often used to determine a change from baseline function or functional outcomes in delirium (Inouye et al., 1998; Kiely et al., 2006). Therefore, this instrument was administered preoperatively and correlated to PD. The instrument is scored in activities of daily living (bathing, dressing, toileting, transferring, continence, and feeding) whereby a "1" point indicates independence. A score of 6 indicates full function, a score of 4 indicates moderate impairment, and a score of 2 or less indicates severe functional impairment (Wallace & Shelkey, 2008). The Katz ADL has been used in elder populations and demented populations (Bae et al., 2000; Beloosesky, Grinblat, Epelboym, & Hendel, 2001; Hill, Backman, & Fratiglioni, 1995; de Rooij et al., 2008; Ulander, Jeppsson, & Grahn, 1997; Westergren, Karlsson,

Anderson, Ohlsson, & Halberg, 2000). The Katz has been used to evaluate functional return postoperatively (de Rooij et al., 2008; Ulander et al., 1997), the development of pressure ulcers (Westergren et al., 2000), and as a trend for drugs geared at prevention of cognitive decline (Bae et al., 2000). Functional assessment has been shown to be a marker of cognitive impairment (de Rooij et al., 2008). This tool is non-proprietary and appears in the Try This series which provides geriatric assessment tools for use in research and practice. Katz scores less than fully functional (score < 6) have demonstrated increased risk for development of delirium (Pisani et al., 2007).

Whisper test and Self Report of Visual Acuity.

Sensory impairment was assessed with the DEAR tool posited by Freter and colleagues (2005). The question in this tool is a self-reported sensory impairment: "Do you use a hearing aid or have difficulty seeing the TV without glasses?" Either answered to the positive generates an addition of a point to the risk factor. Participants were excluded if they were diagnosed as legally blind. The addition of a whisper test ensured that the participant is able to perceive low level sound which was also present and measured in the operative environment. Participants were included in the study if they were able to comprehend normal-level conversational English without the use of a hearing aid. The Whisper test consists of the test examiner standing 2 feet away from the participant. A combination of 3 letters and numbers was whispered by the examiner. The participant is asked to repeat the three item combination. If the combination is repeated correctly, hearing is classified as normal. If there is an error, an alternate combination of three letters or numbers is provided in the same way. If the participant is

able to repeat a total of 3 of the 6 letters or numbers, hearing was considered normal (Pirozzo, Papinczak, & Glasziou, 2003). In a systematic review, the Whisper test was found to have sensitivity in four adult studies between 90% or 100% and, specificity between 70% to 87%. The Whisper test was found to be superior screening tool for hearing impairment to self-reported measures in a systematic review by Bagai, Thavendiranathan and Detsky (2006).

Geriatric Depression Scale - 15.

Because depression has been found to be associated with PD, and is incorporated within the PLST-DSD model, this construct was also measured on each participant utilizing the short version of the Geriatric Depression Scale (GDS-15) (Appendix C). The GDS was originally designed as a 30-item instrument designed specifically for the elderly, with scores greater than 11 indicating depression. Each question is binary with a score of "1" demonstrating depression and "0" as not. In the literature, sensitivity ranges between 84% to 92%, and specificity ranges from 89% to 95% (Sheikh, Yesavage, Brooks, Friedman, & Gratzinger, 1991). The GDS-15 version designed by Sheikh and Yesavage (1986), incorporates similar binary coding with a cut score of 5 or greater indicating depression. This shorter version takes approximately 5 to 10 minutes to render complete and was utilized (Sheikh & Yesavage, 1986). The internal consistency of the shorter 15-item version is 0.79 versus the full version of 0.88 (Jongenelis, et al., 2005). The GDS-15 has been utilized with success in mild to moderate cognitively impaired samples (Isella, Villa, & Appollonio, 2002; Lach, Chang, & Edwards, 2010; Watson, Zimmerman, Cohen, & Dominik, 2009). In the setting of cognitive impairment, the

GDS-15 using a cut-off score of 4 performed better than the recommended cut-off score of 5, with a sensitivity of 91.2% and specificity of 59.5% (Lach, Chang, & Edwards, 2010). The psychometrics of the GDS-15 have been found stable with older African Americans (Pedrazza, et al., 2009), in Asians (Nyunt, Fones, Niti, & Ng, 2009), in Portuguese (Pochino, 2009) and in the oldest old (age > 90 years) (Van der Weele et al., 2009). Additionally, an informant GDS-15 is comparable to the self-report GDS-15 (Brown & Schinka, 2005). The GDS-15 version was utilized during the pilot and demonstrated minimal variability with a range of 0 to 3 and a mean of 2.2 points.

Environmental Stressors

Quest EDGE E4 dosimeter and 1900 sound pressure level meter.

Environmental stressors such as noise loudness, noise pitch, noise annoyance and noise sensitivity were also measured. Noise loudness is theoretically defined as a sound pressure level perceived as stressful or bothersome to the receiver (Lusk, Haggerty, Gillespie, & Caruso, 2002). Noise loudness was measured in decibels dB and dBA (Lavg) (via sound level meter) and A-weighted average (dBA) (via sound dosimeter), Lpeak, Lmax and by total number of bursts or impacts. The personal sound dosimeter placed at ear or shoulder level measures personal noise exposure. Noise pitch was defined as the tonal value in hertz perceived as stressful or bothersome to the receiver (Prashanth & Venugopalacha, 2008). The EDGE Quest E4 personal dosimeter and the Quest 1900 sound pressure level meter quantified intraoperative noise. Because sounds below 60 dB are not considered harmful in the occupational setting, this device does not measure below 60 dB. This might have caused an erroneously elevated Lavg as reflected

in the pilot. The benefit of the sound level meter device is the ability to measure a wider range of sounds from 20 dB to 140 dB. However, this device measures the overall qualities of sound of the environment and not necessarily the participant's personal exposure. Octave band analysis analyzes the hertz, or frequencies, of the sounds of the room. The Quest 1900 device sampled these frequencies at the varying octaves of the hertz ranges either automatically or when prompted by the technician.

Weinstein Noise Sensitivity scale (WNS).

Noise annoyance and noise sensitivity was operationalized respectively by van Dijk et al. (1987) and the Weinstein Noise Sensitivity scale (WNS). Weinstein developed and tested the WNS in college students in dormitory living arrangements and found that noise-sensitive individuals demonstrate a greater need for privacy and lower scholastic ability (Weinstein, 1978) (Appendix D). Noise sensitivity moderates the relationship between the environment and noise annoyance (Byers, 1996). The WNS has been used in multiple studies to measure sensitivity to noise (Ljungberg & Neely, 2007; Meister & Donatelle, 2000). In the original study, Weinstein (1978) found a Kuder-Richardson score of 0.84 to 0.87 with a nine-week test-retest of 0.75. The scale generated a range of scores from 25 to 89. Mean scores from those students classified as noise-sensitive were 67.9 and noise-insensitive were 39.8. Good reliability of the WNS was reported in a surgical population (n=150) (Cronbach $\alpha = 0.76$) (Topf, 1985) and hospitalized cardiovascular patients (n=30) (Cronbach $\alpha = 0.89$) (Webb, 1998). One study utilized the scale by selecting the upper and lower quartiles to stratify results to noise sensitive or insensitive but did not provide the actual scores for review (Ljungberg

& Neely, 2007). Another chose the mean noise sensitivity scores to designate the participants as either sensitive, above or at the mean, or insensitive, below the mean score (Byers, 1996). Annoyance is often measured utilizing a visual analog scale (Aniansson, Petersson, & Peterson, 1983; Byers, 1996; Moorby, 1999; Persson & Bjorkman, 1988). However, this is usually measured at the time of the noise event. This is not congruent with the study. A 5 item questionnaire with a Likert scale for noise annoyance (van Dijk et al. 1987) was used to test noise annoyance as a trait and subsequently correlated to workplace stress (Lusk et al., 2002) (Appendix E). While psychometric properties were not reported by the authors, Lusk et al. (2002) reported an internal consistency using this tool of 0.79. Prevalence of noise annoyance and noise sensitivity can be determined during the preoperative screening of individuals. These traits are considered stable over time (Haines, Stansfield, Job, Berglund & Head, 2001; Sandrock, Schutte, & Griehahn, 2010).

Outcomes

PD

The three instruments to be administered following surgery evaluated the presence of the primary dependent variable of PD included the Confusion Assessment Method, the Delirium Index, and the non-verbal assessment scale for anxiety and pain.

The Confusion Assessment Method (CAM).

The CAM was a logical instrument as it was originally derived from the American Psychiatric Association (APA) Diagnostic and Statistical Manual of Mental Disorders (DSM-III-R) (APA, 1987, 2000; Inouye et al., 1990), created for the non-

psychiatrist, and provides an operational definition of delirium. The CAM contains nine criteria and a tool (Appendix F) with four diagnostic components of delirium. To diagnose delirium utilizing CAM, the first two dimensions must be present (acute and fluctuating course, inability to focus), as well as one of the last two features (disorganized thinking, altered level of consciousness) (Inouye et al., 1990). The CAM is easy to administer, does not require extensive training and was developed with an elder population of 65 to 98 years (Inouye et al., 1990). Inouye et al. (1990) first reported a sensitivity of 94% to 100%. In an evaluation of 7 studies (N = 1071), Wei, Fearing, Sternberg and Inouye (2008), specificity was found to be 89% (95% CI, 85% to 94%) and sensitivity to be 94% (95% CI = 91% to 97%). The developers made CAM training available online to users, and it is free and available to public. The CAM is found to be highly sensitive and specific to detect delirium which is important as delirium is the primary outcome variable of interest in the study.

The Delirium Index (DI).

The Delirium Index (DI) (McCusker et al., 1998) was administered to determine severity of delirium. The DI contains seven features present in the CAM and ranks each on a 3 point Likert scale (McCusker, Cole, Dendukuri, & Belzile, 2004) (Appendix G). In initial testing of the DI, inter-rater reliability was 0.78 between research assistants and 0.88 between research assistants and geriatric psychiatrists. Criterion validity, assessed by the correlation between DI and Delirium Rating Scale scores, another popular delirium rating tool, (Spearman's correlation r) was 0.84. Convergent validity was evaluated using correlations of the DI with two measures of current function, the MMSE

and the Barthel index (r = −0.60 and −0.70 respectively) (McCusker et al., 1998). The scale ranges from 0 to 21 points, with higher scores indicating more severe delirium (McCusker et al., 2004). Cronbach's alpha for the DI was 0.74 overall and increased to 0.82 after removing the feature of perceptual disturbances (McCusker et al., 2004). In addition, this tool has been found reliable and valid in those with and without dementia (McCusker et al., 2004), an important consideration in this study. The author of the DI has made this tool free and available to the student researcher.

Non Verbal Assessment Scale.

NVAS for both anxiety and pain was administered to determine if behavior was related to either state anxiety or per the CAM not indicative of delirium (Appendix H). A NVAS was useful for quantifying subjective data and allowing for closed-ended response by the participant (Hulley, Cummings, Browner, Grady, & Newman, 2007). Visual analog scales have been used in clinical research utilizing a 10 centimeter line partitioned from 0 to 10 (none to unbearable) (Hulley et al., 2007). These scales are sensitive to change and offer continuous data (Hulley et al., 2007). The NVAS for anxiety was tested in a post-surgical population which was correlated significantly to the state (0.64, $p<0.001$) and trait (0.46, $p < 0.005$) scales of the State-Trait Anxiety Inventory (Elkins, Staniunas, Rajab, & Snyder, 2004). They were administered both preoperatively and postoperatively to assess for changes.

Data Collection

The study setting is a large not-for-profit regional hospital that contains 961 acute care, long-term, rehabilitation and psychiatric beds. During fiscal year 2009, over 2,000

total knee and total hip arthroplasties were performed (Lambert, 2010). Seven orthopedic surgeons granted permission to enroll their patients into the study and collect data intraoperatively. No surgeons who were approached refused access to their patients.

Each participant was screened and consented at their pre-hospitalization anesthesia visit. An oral explanation regarding the study was provided to each eligible, interested participant by clinic personnel. Clinic personnel attained HIPPA authorization prior to contact by the PI. Contained in the explanation was the purpose of the study and the time allotted for necessary cognitive tests which varied between 20 and 30 minutes. People meeting the inclusion criteria were consented for the study and screened by the PI utilizing both verbal and written cognitive and hearing tests. When a participant was excluded via a cognitive or hearing test, the person was thanked for their donation of time. Once preoperative cognitive tests (CAM); NVAS for pain and anxiety; Katz ADL; Noise annoyance and noise sensitivity; Mini-Cog (Doerflinger, 2007); and Whisper test were completed and the participant deemed for inclusion in the study, demographics were recorded (Appendix I) and the participant was given a four-digit identification code for the database.

Prior to consent, the risks, benefits, and rights of participation were presented orally by the PI. The risks to the participant were minimal, and study participants may experience anxiety or distress from psychological tests or being excluded via cognitive testing. No distress was noted in participants. Should distress have been noted, testing would have been stopped immediately and participants recommended seeing their primary care physician. Participants would not be compensated for psychological

distress. Potential benefits to the participant included earlier detection of PD and subsequent intervention, as CAM administration is not routinely performed. The potential benefits to society included determining if intraoperative noise is a risk factor to the development of PD in the elderly. Interventions may be investigated to reduce or eliminate this stressor. In addition, if noise levels in the orthopedic suites during arthroplasties were determined to be in excess of OSHA acceptable limits, interventions should be considered to protect operating room personnel from occupational hearing impairment. Participants were not compensated for their participation in this study. Participants were informed that they had a right to refuse to participate or to withdraw at any time, without penalty. They were informed that withdrawal would not affect them in any way, and with withdrawal they may request that any of their data which had been collected be destroyed. Consents (Appendix J) were signed in duplicate and each subject was given a written record that explained all rights, risks, benefits, and contact information for this study.

The participant was met the day of surgery in the holding room by the PI, assented, and the CAM and NVAS for pain and anxiety were readministered by the PI. This required five minutes of the participant's time. The participants were accompanied to their scheduled operating room by the intraoperative data collector (PI or research assistant (RA)) so that utilization of sound meters measuring the environmental noise were recorded throughout the procedure and descriptive field notes (Appendix K) were handwritten to correlate sources of sound. The intraoperative data collection occurred over a 2 to 3 hour period of a total knee or hip arthroplasty procedure. Following the

procedure, the person was accompanied to the recovery room by the intraoperative data collector (PI or RA). The CAM was readministered by the PI just prior to discharge from recovery room to the rehabilitation unit. Typical discharge from the post-recovery unit was within 60 minutes of arrival. The CAM, the Delirium Index (DI) and the NVAS for pain and anxiety were administered by the PI to determine severity and to differentiate pain and anxiety. This testing took an additional 5 to 10 minutes. The chart of the participant and nurse report were reviewed by the PI to determine if delirium, as measured by DSM-IV-TR diagnostic criteria, occurred between discharge from the recovery room and the first 72 hours of admission to the nursing unit. This time frame was chosen because PD onset peaks between immediately following surgery through postoperative day 3 (Kudoh et al., 2003; Morrison et al., 2003). Time allotted to this task varied with the operative schedule and data collection utilized evening hours. Each chart review took approximately 5 to 10 minutes.

Pilot Study

A pilot study utilizing a similar protocol was conducted during June of 2010 to October of 2010 at the study setting one (Brown, 2010). The original protocol is available for review (Appendix L). A total of 13 participants were consented and five participants completed the pilot. Of the 48 potential participants, 17 were excluded during the recruitment period for having a total hip arthroplasty. Therefore, the protocol includes total hip arthroplasty participants in order to increase the subject pool (Appendix M). In addition, the original protocol limited the participants to age 65 years or older. By lowering the minimum age to 50 years or older, the potential pool at study setting one

increased by 25%. A minimum age of 50 for inclusion is found in the literature that evaluates risk factors for PD (Litaker et al., 2001; Marcantonio et al., 1994).

The pilot protocol conducted at an academic medical center brought unforeseen challenges. Preoperative patients were brought to the regional anesthesia area the day of surgery to have spinals or epidural regional anesthesia blocks placed two hours prior to their scheduled operation. The protocol required the participants to assent immediately prior to their operative procedure. Participants should be assented prior to psychoactive sedation administration for block placement. Ongoing data collection during the case often prevented successful assent prior to medication use, causing patient drop-outs. Study setting 2 was selected at a large, non-profit hospital with a busy orthopedic surgery schedule with a reported average weekly number of total orthopedic arthroplastic procedures exceeding 40 (Lambert, 2010). Participants often have regional blocks placed in the operative suite which would allow the assent procedure prior to psychoactive medication administration.

The instruments utilized in the pilot that were still present in the study include the CAM, NVAS for pain and anxiety, the Mini-Cog and the noise measuring devices. The CAM was negative in every patient, and the student researcher found it easy to administer. The CAM is diagnostic positive or negative for acute confusion. As none of the participants demonstrated any facet of confusion either at initial screening, preoperative screening, or postoperatively as an outcome, it was not determined how the tool would perform in this population. However, the CAM is reported to have sensitivity greater than 94% and specificity of 89% to 95% (Waszynski, 2007). The author of the

CAM has granted permissions and provided the student researcher with the CAM training manual and coding guide. The NVAS for pain and anxiety and the Mini-Cog were also easily understood by the participants without additional explanation.

The EDGE Quest E4 sound dosimeter was placed at ear or shoulder level. The results from the EDGE are presented in Table 5. Because sounds below 60 dB are not considered harmful in the occupational setting, the floor of the device is represented in the Lmin column of 62.1 dB, which caused an erroneously elevated Lavg. The pilot did not identify necessary changes in regards to the use of this device. The sound level meter utilized was the Quest 1900 with octave band analysis. This device measures the overall qualities of sound of the environment and not necessarily the participant's personal exposure. The software accompanying the octave band analysis creates samples every 1 to 3 seconds. The sound levels from this device are presented in Table 6. OSHA utilizes the A weighted exposure level to determine acceptable noise limits related to duration. While the average sound measured does not meet the level of environmental noise, the Lpeak and Lmax values approach the exposure limits. For example, OSHA recommends that sounds of 109 dB not exceed 1 minute and 53 second duration. Because the EDGE was set to sample every minute, we may have missed the duration of these peak values. Therefore, the study included more frequent sampling to every 5 to 10 seconds for better discrimination of when noise was excessive.

Table 5. Noise Levels from the EDGE Personal Dosimeter

ID	LPeak (dB)	LMax (dB)	Lmin (dB)	Lavg (dB)
1002	104.3	83.7	62.1	62.4
1003	108.9	85.0	62.1	57.8
1009	103.3	84.7	62.5	61.1
1010	109.1	81.2	62.1	55.2
1013	102.8	79.6	62.1	55.5
Mean	105.7	82.8	62.2	58.4

Table 6. Data Retrieved from Sound Level Meter

ID	LPeak (dB)	LMax (dB)	Lmin (dB)	Lavg (dB)
1002	104.3	74.9	**	57.5
1003	103.0	73.2	**	52.8
1009	103.0	74.3	**	55.2
1010	110.0	86.9	53.3	58.4
1013	103.7	89.3	52.5	54.8
Mean	104.8	79.7	52.9	55.7

** This device lacked a minimum measurement on some samples due to lack of researcher familiarity with device settings.

Research Assistants

The research assistants (RA) were trained to collect the intraoperative noise-related data while the PI performed assent procedures and cognitive testing of the postoperative participants. This strategy blinded the PI to the quality of intraoperative noise and reduced the introduction of researcher bias.

Two research assistants, a biology graduate, and a second-year nursing student who were instructed on sterile technique and understand health-related terminology. Both research assistants were required to complete human subjects' research training per the University of North Carolina at Greensboro standards and medical center institutional requirements. Approximately 12 hours of investigator-led training were conducted on the

research protocol, instruments, and data collection tools chosen for the study. While normally 10% of RA cases would be observed by the PI for 15 minutes in duration to ensure inter-rater reliability, this is not feasible in an intraoperative environment where traffic into the rooms is limited to ensure hardware sterility. The PI observed the RA on15 minutes of one case for data entry to ensure compliance with the protocol. The RA collected data for the duration of each operative case. A total knee or hip arthroplasty has an average duration of 2 to 3 hours.

Data Analysis Plan and Procedures

Descriptive statistics were calculated for each variable including mean, standard deviation, range, skew and kurtosis for all interval-level variables and proportions were estimated for each nominal-level variable. All interval-level data that were not normally distributed were analyzed using non-parametric tests.

Data analyses for each research question are outlined below:

Research Q1. What is the description of environmental noise (loudness and pitch) in an orthopedic surgical suite?

To determine the noise level in the operating room, the noise was recorded in dBA in real time via a sound pressure level meter and a personal sound dosimeter. The sound pressure level recorded every minute on the internal digital log. The average (Lavg) noise pressure level was computed as well as the peak level (Lpk) of noise was digitally recorded in each surgical case, along with the maximum and minimum averages (Lmin, Lmax). Any impact noise generated that exceeds 140 dBA was recorded in increments of time and number. Field notes were taken to describe the noise

environment and common sources of noise (set-up, instrumentation, clean-up). These noise sources were found to be present during the pilot study. Descriptive statistics (mean, median, min, max, SD) and graphical analyses were used to describe the collected levels.

Research Q2. When controlling for psychological (baseline cognitive status, noise annoyance, and noise sensitivity) and functional activities of daily living (ADL) characteristics of the individual, which characteristics of intraoperative noise (loudness and pitch) explain the severity of PD in an orthopedic surgical sample of elders?

Delirium severity score and NVAS scores for anxiety and pain were analyzed using multivariable linear regression. Minute-level readings of the dosimeters were summarized to the person-level and considered using mean and coefficient of variation (CV). The four different readings: Lavg-1, Lcpk, Lmax, and Lavg-2 were initially considered independently, and their associations were summarized graphically and with Pearson or Spearman correlations. Reliability measured via internal consistency was estimated using Cronbach's alpha. An alpha of at least 0.70 was deemed adequate.

All predictor variables were entered simultaneously into a multiple regression model to determine how well the participant-related variables—psychological and functional— and the noise variables explained the prevalence of postoperative delirium.

All independent variables were examined for correlation and evaluated for multicollinearity. Severity of confusion (DI) was examined separately in a multivariable linear regression.

In the event that two variables correlated at 0.85 or higher, one variable would be eliminated from the multiple regression analysis or separate models were created. In addition, the tolerance level and variance inflation factor of all independent variables were calculated to further determine multicollinearity when all variables were examined together. A tolerance value less than 0.10 and a variance inflation factor greater than 10 was used to identify multicollinearity for possible elimination of variables (Polit & Beck, 2004).

Research Q3. Which noise variables (loudness and pitch) collected during this study are the most significant to the severity of PD?

Characteristics of the individual were entered into regression modeling. Then, noise measures in dB were entered into the model individually to ascertain their influence on the outcome of delirium severity. This analyzed the specific amount of variance that noise in dB and Hz accounts for on PD above and beyond what was explained by individual variables. Analyses were performed in PASW 18 (SPSS, Inc., Chicago IL), SAS v9.2 (SAS Institute, Cary, NC), and STATA IC-12 (College Station, TX) with a two-sided P-value < 0.05 was considered statistically significant.

Summary

The purposes of this study were to describe the environmental noise in an orthopedic operating room environment during arthroplastic surgery and to explore the

relationship between noise variables (loudness, pitch) to the severity of PD. The correlational design was a non-experimental method chosen to examine the strength of the relationship between perioperative noise in the orthopedic total knee or hip arthroplasty suite and the severity of PD. A convenience sample was comprised of 50 participants presenting at their pre-anesthesia assessment visit and ending when the calculated sample size had been reached. A RA was secured to aid in data collection procedures as outlined, which also improved methodological considerations (i.e. non-introduction of researcher bias).

CHAPTER IV

RESULTS

Recruitment

The original desired recruitment goal was 80 participants with an anticipated target of 50 participants with completed data to ensure adequate power. Participants were recruited at their preanesthesia clinic visit. Each eligible, interested participant was approached. Informed consent was obtained prior to cognitive testing, and demographic information was collected. During concurrent data collection, a low retention rate (34%), necessitated increasing recruitment and enrollment efforts to achieve the minimum target of subjects completing the study. A final sample of 50 participants was yielded from a pool of 134 recruited participants (37% recruitment rate). The poor retention rate resulted from the variability in the operating room schedule, the participants' opting for a general anesthetic on the day of surgery, and the liability of having only one set of recording equipment to record one case at a time resulting in the inability to record concurrent surgeries.

Characteristics of the Sample

Demographic characteristics of those who completed the study are found in Table 7. Participants had a mean age of 70.74 (± 9.17) years with a range in years from 50 to 90 years old. The age group with the greatest representation was 70 to 79 years (40%), followed by 60 to 69 year olds (28%), 80 to 90 year olds (20%) and 50 to 59 year olds

(12%). There were a greater proportion of females (62%) in the sample. The sample was almost exclusively white (94%), with only two African American participants and one Asian-Indian.

Participants demonstrated greater variability in education, marital status, and annual household income when compared to race and ethnicity. A little more than one-third of the sample reported having a high school education (36%). Twenty-six percent of the participants reported attending some college or an associate degree, and 20% reported having a bachelor's degree. Educational attainments with less representation included master's degree completion (6%) and doctoral degree (4%). There were also few with elementary (4%) and middle school (4%) education. The majority of the sample was married at the time of recruitment (70%). One-fifth indicated widow-status (20%). The remaining 10% were divorced (4%) or single (6%). Thirty-four percent of the sample reported an annual household income of greater than $60,000 per year. Other reported incomes were evenly distributed between $10,000 and $60,000 with only one participant reporting an annual household income below $10,000 per year.

Table 7. Demographic Characteristics of Participants (n=50)

Variable	Frequency	%
Age		
50-59	6	12%
60-69	14	28%
70-79	20	40%
80-90	10	20%
Mean ± SD	70.74	±9.17
Gender		
Male	19	38%
Female	31	62%
Race		
White/Caucasian	47	94%
African American	2	4%
Asian-Indian	1	2%
Education		
Elementary	2	4%
Middle School	2	4%
High School	18	36%
Associates/Some college	13	26%
Bachelor's Degree	10	20%
Master's Degree	3	6%
Doctorate	2	4%
Annual Household Income (USD)		
Less than 10,000	1	2%
10,000-20,000	5	10%
20,000-30,000	6	12%
30,000-40,000	5	10%
40,000-50,000	6	12%
50,000-60,000	4	8%
Greater than 60,000	17	34%
Refuse/Don't know	6	12%
Marital Status		
Married	35	70%
Single	3	6%
Divorced	2	4%
Widowed	10	20%
Separated	0	0%
Comorbidities		
Hypertension	33	66%
Coronary Artery Disease	4	8%
Congestive Heart Failure	2	4%
Peripheral Vascular Disease	3	6%
Diabetes	9	18%
Chronic Kidney Disease	1	2%

Variable	Frequency	%
Chronic Liver Disease	1	2%
Current Tobacco use	6	12%
Chronic Obstructive Pulmonary Disease	3	6%
Obstructive Sleep Apnea	7	14%
Psychotropic Medicines		
Currently Taking Psychotropic Meds	20	40%
On multiple psychoactive medications	6	12%
• Opiates	8	16%
• Antidepressants	8	16%
• Hypnotic/sedative	7	14%
• Benzodiazepines	3	6%
• Antispasmotics	2	4%
Obesity		
• Underweight (BMI < 18.5)	1	2%
• Normal (BMI 18.5-24.5)	12	24%
• Overweight (BMI 25-29.5)	16	32%
• Obese (BMI > 30)	9	18%
• Severely Obese (BMI > 35)	10	20%
• Morbidly Obese (BMI > 40)	1	2%
• Super Obese (BMI > 50)	0	0%

Comorbidities.

In relation to physical well-being, many of the participants displayed common comorbidities. Hypertension was the most common comorbidity reported at 66%. This was followed by diabetes (18%), obstructive sleep apnea (14%), and peripheral vascular disease (6%). While 12% of the sample reported smoking, 6% reported chronic obstructive pulmonary disease. Another well-represented comorbidity was in relation to obesity. Only 24% of the sample had a normal body mass index (BMI), with the sample BMI mean of 28.49 (SD=5.80). The majority of the sample was either overweight (32%) or obese (40%) with a BMI greater than 30. Of those classified as obese, half were severely obese with a BMI greater than 35 and one participant was morbidly obese with a BMI greater than 40. Those who developed PD had significantly lower mean BMI

values than those who did not develop PD (23.86 ± 2.55 vs. 29.26 ± 5.85 respectively; p=0.021). BMI was significantly correlated to PD severity (r = -0.327, p = 0.023).

Creatinine.

Serum creatinine information was collected at screening or preoperatively when available. The sample's overall mean was serum creatinine of 0.92 (± 0.268). However, between PD and non-PD groups, PD groups had significantly higher serum creatinine (mean = 0.88 non-PD, mean=1.15 PD; p = 0.022).

Psychoactive medications.

Of the sample, forty percent were currently prescribed a psychoactive medication. Twelve percent of the sample was prescribed multiple psychoactive medications. Opiates (16%) and antidepressants (16%) were the most common with eight participants prescribed in each. These were followed by the hypnotic and sedating classes of drugs (14%). The least commonly prescribed drugs were benzodiazepines (6%) and antispasmodics (4%). The use of psychoactive medications overall was not correlated with delirium severity (r = -0.269; p = 0.061). However those without PD were prescribed more psychoactive medications than their PD counterparts (PD mean 2.27 ± 4.37 versus non-PD mean 0.32 ± 0.82).

There were three varieties of total arthroplastic joint procedures represented in the sample. Ten participants of the sample had a total hip arthroplasty (20%). Two participants (4%) received a revision of a total knee arthroplasty involving replacement of both intra-articular pieces of the knee. The remaining 38 procedures were unilateral total knee arthroplasties (76%). The duration of the procedures varied among six surgeons

spanning from 95 to 214 minutes. Because all participants received a propofol infusion throughout the duration of their procedure, this also affected the total amount of propofol documented. The total amount of propofol administered ranged from 70 mg to 1300 mg with a mean dose of 604 mg. However, there was missing data for total amount of propofol administered on 10 operative records (20%). Midazolam was administered to 80% of participants, with an average dose of 2.25 mg (mode = 2 mg). Fentanyl was administered to 76% of participants with an average dose of 81.75 mcg (mode = 100 mcg).

Cognitive impairment.

Participants were screened for cognitive impairment with the Mini-Cog instrument (Doerflinger, 2007). During screening, prior episodes of delirium were solicited by self-report or found through chart review. Fourteen participants (28%) were found via Mini-Cog to screen positive for a cognitive impairment (95% CI = [17.5%, 41.7%]). Of those screening positive for cognitive impairment, one person had a 3-item recall of zero, while six participants had 3-item recall of one word. The remaining seven participants with intermediate 3-item recall of two words screened positive for cognitive impairment by a clock-drawing test. Only one participant reported a prior episode of PD; however it was reported at the 72 hour end-point. None of the participants were found to have prior PD via chart review.

Pain.

Pain was defined as the subjective experience of discomfort (Guyton & Hall, 2006). Pain was measured with the commonly utilized numeric visual analog scale

(NVAS) on a 0 to 10 continuous rating scale. Pain at the screening had an NVAS average of 2.58 (±3.36). The mode was a level of zero, with participants indicating that at rest there was zero pain. The NVAS did not vary greatly between screening and their preoperative visit. The preoperative NVAS for pain demonstrated a mean of 2.5 (±3.2) with a mode of zero. The pain level after surgery was the lowest value, most often related to the continuation of the spinal anesthetic into the early postoperative period with an average NVAS of pain of 1.64 (±2.87).

Anxiety.

Anxiety was defined as a state of heightened fear or threat (Riskind, Williams, & Joiner, 2006). Anxiety was also measured with a NVAS on a 0 to 10 continuous rating scale. The screening NVAS for anxiety had an average of 2.32 (±2.67) with a mode of zero. The preoperative anxiety NVAS did rise on average to 3.46 (±3.20) with a bimodal distribution with NVAS of zero and five. The postoperative NVAS of anxiety was lowest in the postoperative period with an average of 1.24 (±2.56), again with a mode of zero.

Functional status.

Participants' functional status was operationally measured and screened via the Katz ADL tool (Wallace & Shelkey, 2008). Twelve percent demonstrated evidence of functional impairment in one or more ADL (95% CI = [5.6%, 23.8%]). Of those, 10% reported functional impairment in bathing and 12% reported a functional impairment in dressing. The remaining 44 participants (88%) were functionally intact with a Katz ADL score of 0.

Sensory loss.

The whisper test was utilized to screen individuals with possible sensory impairment. Five individuals screened positive for a possible hearing impairment (10%); although all participants were able to comprehend and respond appropriately during cognitive testing and screening and none of those included utilized hearing assistive devices. In relation to vision impairment, 14 (28%) individuals reported being unable to see the television without corrective lenses. Thus, a total of 19 (38%) participants demonstrated a form of sensory impairment (95% CI = [25.9%, 51.8%]).

Depression.

Depression was measured in the participants utilizing the Geriatric Depression Scale, short version (GDS-15) designed by Sheikh and Yesavage (1986), incorporates similar binary coding with a cut score of 5 or greater indicating possible depression. The mean score was 0.98 (±1.46) with a range from 0 to 6. Two participants (4%; 95% CI = [1.1%, 13.5%]) demonstrated possible depression with GDS-15 scores greater than 5 (scores of 5 and 6 respectively). The mode for GDS-15 score was zero, or screening negative for depression (n=25, 50%). The Cronbach's alpha for the GDS tool was 0.662, which is minimally acceptable. However, Cronbach's alpha would increase to 0.702 if item 9 ("Do you prefer to stay at home, rather than going out and doing new things?") was removed from the scale.

Noise annoyance.

Noise annoyance was theorized as the degree to which the individual perceived the noise as "annoying" or "psychologically disturbing" (Lusk et al., 2002) and was operationalized utilizing a 5 item noise annoyance (NA) questionnaire with 3-point Likert-type scale developed by van Dijk et al. (1987). The mean NA score was 4.78 with a minimum score of zero and a maximum of 13 points of the possible 15 points. Using a low (0-4 points), medium (5-9 points), and high (10-15 points) classification system for noise annoyance, twenty-five participants appeared in the low NA category (50%) with 21 participants in the moderately noise-annoyed category (42%), and the remaining 8 percent high noise-annoyed (n=4). The Cronbach's alpha for NA tool was 0.639. This is also minimally acceptable, but removal of item 1 ("Are you startled by noise?") would improve reliability (Cronbach's alpha = 0.682).

Noise sensitivity.

Noise sensitivity was defined as the ability to adapt to noise levels over a period of time (Weinstein, 1978). Noise sensitivity was operationally defined by the Weinstein Noise Sensitivity scale (WNS). In the original study, mean scores from college students classified as noise-sensitive were 67.9 and noise-insensitive were 39.8. In this study, the overall mean score was 79.2 (SD=1.82) with a range from 53 to 107. Using a noise-sensitive cut-off of 67.9, forty-two of the participants were noise-sensitive (84%; 95% CI = [71.5%, 91.7%]). Eight (16%) of the participants scored below 67; however, as the lowest score was 53, no participant could be deemed noise-insensitive with a score of or below 39.8. The Cronbach's alpha for the WNS was an acceptable 0.743.

Pre-surgical risk.

Pre-surgical risk was operationally defined by the DEAR tool (Freter et al., 2005). This tool assigns a point for each of the following: advanced age, cognitive impairment (Mini-Cog), sensory impairment, and substance abuse (alcohol or benzodiazepines). The mean value among all participants was 1.2 points (± 1.14 points) with a range of 0 to 5. The DEAR total was significantly correlated to delirium severity ($r = 0.399$; $p < 0.01$). The Cronbach's alpha for this tool was minimally acceptable at 0.663. Between non-PD and PD groups, PD groups demonstrated significantly greater number of risk factors via the DEAR tool (1.02 versus 2.29; $p = 0.005$).

Outcome: PD

PD Incidence

Of the 50 participants, 7 people developed PD (14%; 95% CI = [7.0%, 26.2%]). PD was identified by the CAM tool and severity was quantified by the Delirium Index (DI). The CAM tool maintained a negative status (score = 0) for all participants at screening and in the holding area prior to surgery. Following surgery, changes in CAM status and DI were noted. The CAM was readministered postoperatively in the recovery area before the participant's discharge to a nursing unit. In this setting, the CAM generated a positive screening of PD for two participants (4%; 95% CI = [1.1%, 13.5%]). The behavioral subtype identified at this point with those two participants was hypoactive delirium. At the 72 hour end-point, the CAM was administered to all participants. At this time point, seven participants screened positive for PD (14%; 95% CI = [7.0%,

26.2%]). The behavioral subtype identified via CAM included four hypervigilant and three hypovigilant. None of the CAM-positive participants were comatose.

PD Severity

As the DI was administered to all participants, the mean and standard deviation for those with and without delirium will be explained. The DI was administered to all participants at screening, preoperatively, postoperatively, and at the 72 hour end-point. The mean scores for the DI had from screening a DI mean score of 0.88 (±1.08), preoperative DI mean score of 0.32 (±0.65), postoperative DI mean score of 0.78 (±2.01), and the 72 hour end-point DI mean score of 1.51 (±3.57). Between those who developed and those who did not develop PD by the 72 hour end-point (PD = 1.86 ±1.35 vs No PD = 0.72 ±0.96), the screen DI mean varied slightly. This difference in DI scores increased between groups with PD and without PD with the preoperative DI (preop DI 1.29 ±1.11 vs. 0.16 ±0.37 respectively), the postoperative DI (postop DI 4.0 ±3.92 vs. 0.26 ±0.73 respectively), and the 72 hour end-point DI (EP-DI 9.57 ±3.31 vs.0.17 ±0.58 respectively).

Research Questions

Research Question # 1

What is the description of environmental noise (loudness and pitch) in an orthopedic surgical suite?

To answer this question, two sound recording devices yielded intraoperative data: the personal noise dosimeter and the sound pressure level meter (SPL). The personal noise dosimeter (Edge) was placed at ear-level of the participant to collect noise loudness

in decibels (dBA) at one-minute intervals. The SPL device measures noise of the entire operative suite in both loudness and pitch, or hertz (Hz). The SPL recorded every 10th of a minute on the internal digital log. The average noise pressure level was computed (Lavg). The peak decibel (Lcpk) of noise was digitally recorded in each surgical case as well as the maximum and minimum of all sound measures. Any impact noise generated that exceeds 140 dBA was recorded in increments of time and number. Summary statistics are outlined and graphically displayed below.

Table 8. Summary Statistics from Edge Sound Dosimeter in Decibels (dB)

Sound measure	Min	Max	Mean	SD (±)
Lavg-1 mean	64	78	66.84	2.64
Lavg-1_median	64	77	66.35	2.67
Lavg-1 min	63	69	63.71	1.11
Lavg-1 max	68	91	73.88	4
Lcpk-1mean	102	103	102.81	0.2
Lcpk-1 median	102	103	102.76	0.17
Lcpk-1 min	102	103	102.3	0.23
Lcpk-1 max	103	118	105.84	4.03
Lmax mean	65	82	76.1	3.18
Lmax median	65	82	75.93	2.83
Lmax min	63	76	68.07	2.7
Lmax max	73	96	87.35	4.34

Table 9. Summary Statistics from SPL with Octave Band Analysis for All Participants in dBA

Hertz Range	Sound Measure	Min	Max	Mean (± SD)	Sound Measure	Min	Max	Mean (± SD)
16 Hz	Lavg mean	8	64	19.27 (±15.10)	Lavg median	8	64	18.99 (±14.98)
	Lmax mean	12	68	22.60 (±15.01)	Lmax median	11	67	22.14 (± 14.83)
	Lmin mean	3	61	15.08 (±15.47)	Lmin median	3	60	15.07 (±15.44)
	Lpk mean	16	80	28.19 (±17.23)	Lpk median	16	79	27.72 (±16.95)
31.5 Hz	Lavg mean	8	35	24.60 (±5.90)	Lavg median	8	35	24.34 (±5.96)
	Lmax mean	12	36	27.02 (±5.38)	Lmax median	11	36	26.56 (±5.47)
	Lmin mean	4	34	21.74 (±6.58)	Lmin median	4	34	21.74 (±6.60)
	Lpk mean	17	41	32.72 (±5.23)	Lpk median	16	40	32.25 (±5.31)
63 Hz	Lavg mean	20	33	29.05 (±4.0)	Lavg median	20	33	28.66 (±4.02)
	Lmax mean	22	36	31.64 (±3.86)	Lmax median	22	35	31.00 (±3.90)
	Lmin mean	17	31	26.14 (±4.17)	Lmin median	17	31	26.09 (±4.22)
	Lpk mean	28	43	38.86 (±3.99)	Lpk median	28	43	38.24 (±4.01)
125 Hz	Lavg mean	23	46	40.60 (±4.36)	Lavg median	22	46	40.27 (±4.55)
	Lmax mean	26	49	43.17(±4.27)	Lmax median	25	49	42.52 (±4.38)
	Lmin mean	20	44	37.95 (±4.58)	Lmin median	20	44	37.89 (±4.72)
	Lpk mean	33	57	51.38 (±4.52)	Lpk median	33	57	50.74 (±4.62)
250 Hz	Lavg mean	40	53	49.70 (±3.04)	Lavg median	40	54	49.30 (±3.08)
	Lmax mean	42	56	52.46 (±3.17)	Lmax median	41	57	51.82 (±3.21)
	Lmin mean	37	50	46.89 (±2.94)	Lmin median	38	51	46.76 (±3.02)
	Lpk mean	51	65	61.43 (±3.34)	Lpk median	50	65	60.82 (±3.38)

Hertz Range	Sound Measure	Min	Max	Mean (± SD)	Sound Measure	Min	Max	Mean (± SD)
500 Hz	Lavg mean	48	68	55.48 (±2.54)	Lavg median	48	60	54.80 (±2.66)
	Lmax mean	51	64	58.75 (±2.88)	Lmax median	50	65	58.12 (±3.16)
	Lmin mean	45	55	51.89 (± 2.06)	Lmin median	46	55	51.58 (±2.12)
	Lpk mean	60	74	68.68 (± 3.00)	Lpk median	59	74	67.98 (±3.23)
1000 Hz	Lavg mean	53	61	57.29 (±1.40)	Lavg median	52	60	56.50 (±1.51)
	Lmax mean	56	64	60.69 (±1.55)	Lmax median	55	64	59.66 (±1.68)
	Lmin mean	50	57	53.78 (±1.30)	Lmin median	50	57	53.50 (±1.35)
	Lpk mean	66	75	71.42 (±1.69)	Lpk median	65	75	70.22 (±1.84)
2000 Hz	Lavg mean	53	59	56.19 (±1.26)	Lavg median	51	59	55.26 (±1.56)
	Lmax mean	56	63	59.34 (±1.45)	Lmax median	55	62	58.26 (±1.80)
	Lmin mean	50	55	52.99 (±1.15)	Lmin median	49	55	52.63 (±1.81)
	Lpk mean	68	75	71.18 (±1.38)	Lpk median	67	74	69.94 (±1.72)
4000 Hz	Lavg mean	50	58	52.91 (±1.53)	Lavg median	48	57	51.58 (±1.86)
	Lmax mean	53	61	56.08 (±1.50)	Lmax median	51	60	54.39 (±1.83)
	Lmin mean	46	54	49.65 (±1.61)	Lmin median	45	54	49.18 (±1.90)
	Lpk mean	66	73	68.94 (±1.35)	Lpk median	64	72	67.13 (±1.64)
8000 Hz	Lavg mean	44	55	47.27 (±2.23)	Lavg median	42	53	46.08 (±2.45)
	Lmax mean	47	58	50.54 (±2.19)	Lmax median	44	56	48.69 (±2.38)
	Lmin mean	40	51	43.93 (±2.33)	Lmin median	39	51	43.64 (±2.70)
	Lpk mean	61	71	64.41 (±1.93)	Lpk median	58	69	62.38 (±2.12)

Hertz Range	Sound Measure	Min	Max	Mean (± SD)	Sound Measure	Min	Max	Mean (± SD)
16kHz	Lavg mean	31	48	34.9 (±4.17)	Lavg median	29	47	33.67 (±4.29)
	Lmax mean	34	52	38.24 (±4.16)	Lmax median	32	50	36.17 (±4.24)
	Lmin mean	26	44	31.59 (±4.24)	Lmin median	25	44	31.40 (±4.52)
	Lpk mean	49	66	53.25 (± 3.91)	Lpk median	47	64	51.08 (±3.99)

Figure 3. Graphical Display of SPL Mean Lavg by Hz and dB-A with Comparison to SD

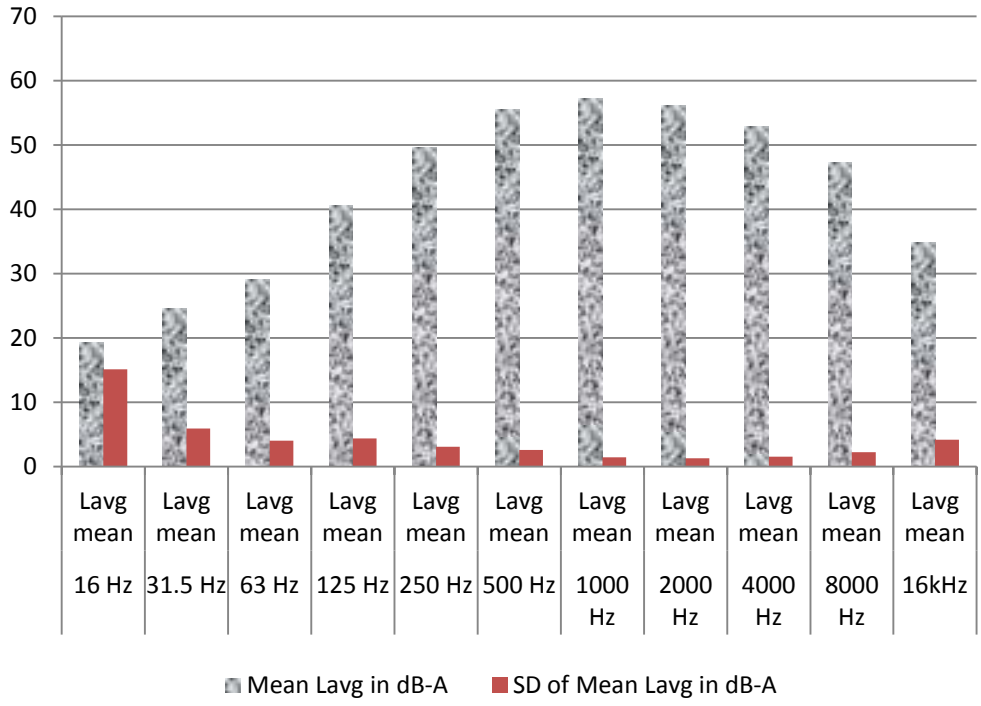


Figure 4. Graphical Display of SPL Mean Lpk by Hz and dB-A with Comparison to SD

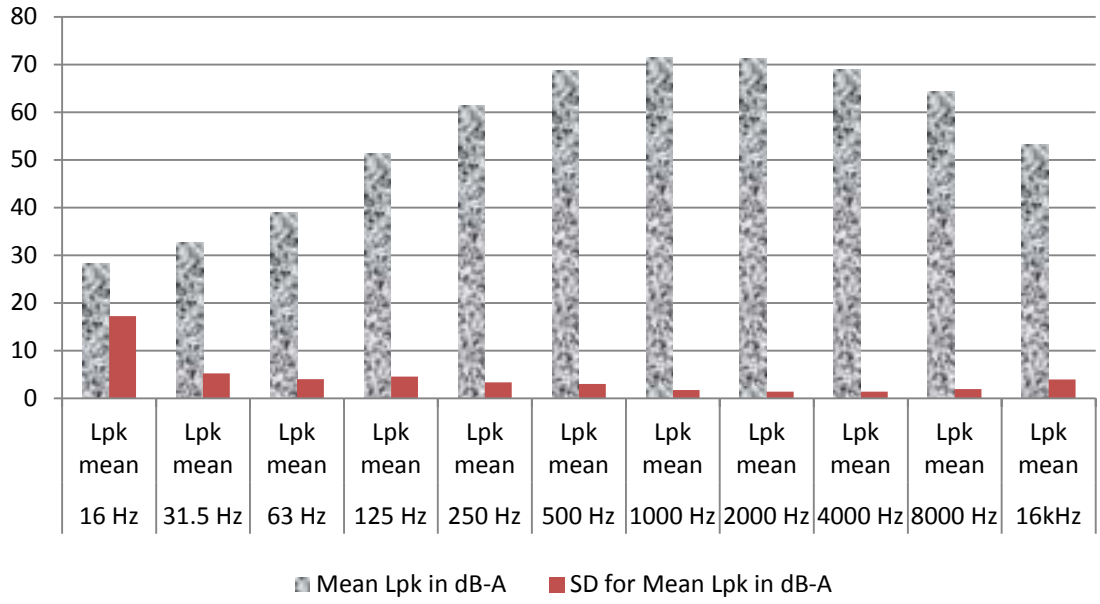
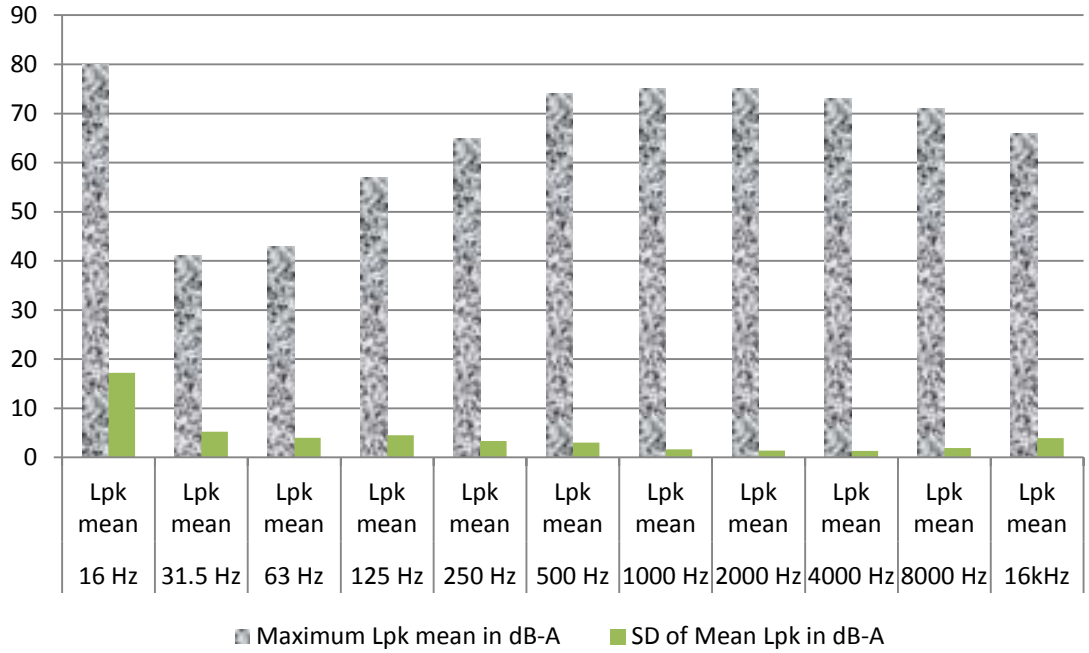


Figure 5. Graphical Display of SPL Max Lpk by Hz and dB-A Comparison to Mean Lpk SD



The frequency with the greatest maximum peak levels were in the lowest frequency of 16 Hz (80 dB). These maximum peak levels dropped to lower levels at 31.5 Hz, 63 Hz, 125 Hz, and 250 Hz (41 dB, 43 dB, 57 dB, 65 dB). The average peak levels are more congruent in the Hz levels of 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz (74 dB, 75 dB, 75 dB, 73 dB) and then decrease slightly in subsequently higher octaves of 8000 Hz and 16000 Hz (71 dB, 66 dB). There is also much greater variability in dB levels in the extremes of frequencies. For example, at 16 Hz the mean average dB level (19.27 dB) ranges from 8 to 64 dB with a standard deviation of 15.1 dB, whereas within the octave of 2000 Hz the mean average level of 56.19 dB with a standard deviation of 1.26 dB and a range of 53 to 59 dB. In addition, the average mean peak levels demonstrated a bell shape with lower dB in the extremes of frequencies (Figures 3-5).

Research Question #2

When controlling for psychological (baseline cognitive status, noise annoyance, and noise sensitivity) and functional (activities of daily living (ADL) characteristics of the individual, which characteristics of intraoperative noise (loudness and pitch) explain the severity of PD in an orthopedic surgical sample of elders?

The following patient characteristics were found to have significant mean differences with respect to the dichotomous outcome of PD: preoperative anxiety ($p = 0.006$), 3-item recall ($p = 0.004$), clock-drawing test ($p<0.001$), DEAR tool total ($p = 0.005$), age ($p=0.004$), BMI ($p=0.021$), and serum creatinine ($p=0.022$). There were not significant mean differences in noise annoyance, noise sensitivity, and ADL status (Table 10).

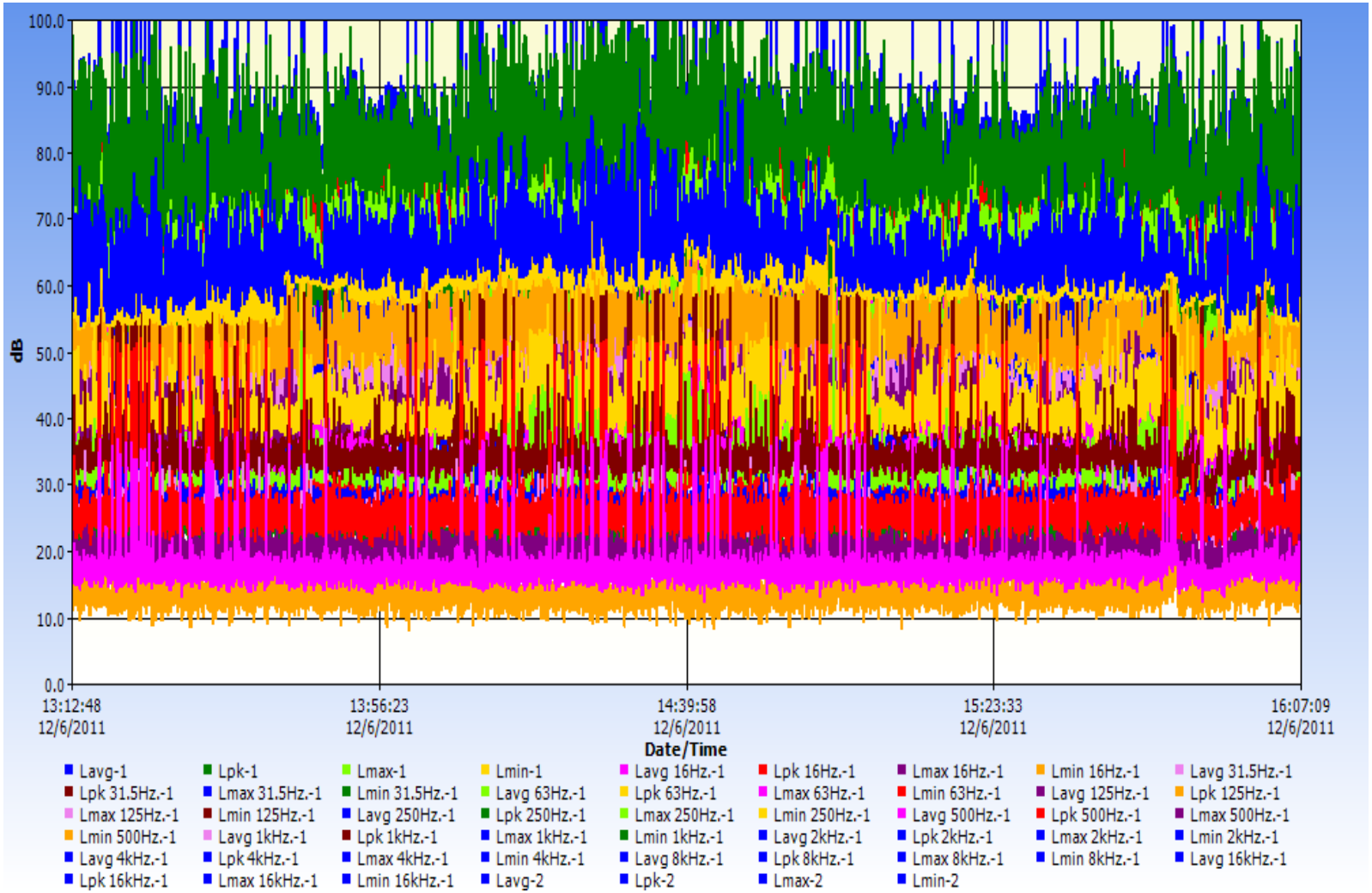
Table 10. ANOVA of Delirium Severity by Patient Level Characteristics

Variable	Sum of Squares	df	Mean Square	F	P
Recall 3-Item	Between Groups	4.561	1	4.561	9.002	**0.004****
	Within Groups	24.319	48	.507		
	Total	28.880	49			
CDT positive	Between Groups	4.220	1	4.220	34.560	< **0.001****
	Within Groups	5.860	48	.122		
	Total	10.080	49			
Preop-anxiety	Between Groups	74.799	1	74.799	8.436	**0.006****
	Within Groups	425.621	48	8.867		
	Total	500.420	49			
DEAR total	Between Groups	9.595	1	9.595	8.465	**0.005****
	Within Groups	54.405	48	1.133		
	Total	64.000	49			
Age	Between Groups	676.577	1	676.577	9.432	**0.004****
	Within Groups	3443.043	48	71.730		
	Total	4119.620	49			
BMI	Between Groups	175.269	1	175.269	5.717	**0.021***
	Within Groups	1440.976	47	30.659		
	Total	1616.245	48			
Creatinine	Between Groups	.365	1	.365	5.753	**0.022***
	Within Groups	2.284	36	.063		
	Total	2.649	37			

**Significant at the 0.01 level (2 tailed)

*Significant at the 0.05 level (2 tailed)

Figure 6. Graphical Display of SPL Data Points in One Procedure



These characteristics were utilized to build a patient-level regression model to evaluate the effects of intraoperative noise (level and pitch). Correlations among these measures are presented in Table 11. All measures correlated significantly with the outcome of EP-DI. All measures had a weak-to-moderate magnitude of correlation ($r < 0.60$); however, the CDT-positive status correlated moderately and was significant at the 0.01 level ($r = 0.651$).

Table 11. Correlation Matrix for Patient Level Characteristics and PD Severity

Variables	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
1 PD severity	-	**-.316***	**.651****	**-.300***	**.399****	**.316***	**-.327***	**.367***
2 Three-Item recall		-	**-.438****	.247	**-.354***	**-.536****	.185	-.233
3 CDT-positive			-	-.048	**.520****	**.464****	**-.353***	0.75
4 Preop anxiety				-	-.098	-.139	.227	-.274
5 DEAR total					-	**.496****	-.249	-.027
6 Age						-	**-.327***	.228
7 BMI							-	.036
8 Creatinine								-

**Correlation significant at the 0.01 level (2 tailed)
*Correlation significant at the 0.05 level (2 tailed)

In response to research question number two, the characteristics of the participant (age, BMI, 3-item recall, CDT-positive, preoperative anxiety, DEAR total, and creatinine) were entered into the regression analysis together in one block. This analysis failed to demonstrate significance with any variable except for the DEAR tool ($p= 0.0031$) with the entire model yielding an R^2 of 0.0790 (Table 12).

Table 12. Robust Regression of PD Severity Using Patient Level Characteristics

Parameter Estimates							
Parameter	**DF**	**Estimate**	**Standard Error**	**95% Confidence Limits**		**Chi-Square**	**P-value**
Intercept	1	1.4466	1.4904	-1.4745	4.3677	0.94	0.3317
age	1	-0.0093	0.0162	-0.0410	0.0223	0.33	0.5638
creatinine	1	-0.3196	0.7446	-1.7789	1.1397	0.18	0.6677
DEAR tool	1	0.3851	0.1303	0.1298	0.6404	8.74	**0.0031**
3-Item recall	1	-0.1421	0.2065	-0.5468	0.2625	0.47	0.4912
CDT	1	0.3868	0.3955	-0.3884	1.1619	0.96	0.3281
Preop anxiety	1	0.0282	0.0401	-0.0504	0.1068	0.49	0.4819
BMI	1	-0.0179	0.0203	-0.0576	0.0219	0.78	0.3778
Scale	0	1.4062					

$R^2 = 0.0790$

Research Question #3

Which noise variables (loudness and pitch) collected during this study are the most significant to the severity of PD?

In response to question three, the Edge noise variables were evaluated using boxplots and error bars for patterns with respect to the outcome of PD. Following this preliminary analysis, noise variables with patterns suggestive of differences were assessed with robust regression modeling. All regression analyses including the Edge sound variables exceeded the R^2 value of the patient-level regression model of 0.0790 (range of 0.421 to 0.964) (Table 13). However, only the models that included Lavg max and Lmax max noise variables demonstrated significance ($p = 0.018$; $p = 0.012$).

Table 13. Robust Regression for EDGE Noise Loudness (dB) and Effect on Delirium Severity Score**

Parameter	Estimate	Standard Error	t	P value	95 % confidence interval	Psuedo R^2
Lavg median	-0.014	0.164	-0.09	0.933	-0.345, 0.317	0.421
Lpk median	0.054	0.056	0.97	0.339	-0.058, 0.165	0.434
Lmax median	-0.076	0.071	-1.08	0.287	-0.219, 0.067	0.437
Lavg min	0.211	0.370	0.57	0.572	-0.537, 0.958	0.425
Lpk min	0.055	0.054	1.02	0.313	-0.054, 0.164	0.435
Lmax min	-0.042	0.057	-0.73	0.471	-0.158, 0.074	0.428
Lavg max	**0.013**	**0.018**	**0.73**	**0.469**	**-0.023, 0.050**	**0.951**
Lpk max	0.038	0.059	0.64	0.528	-0.082, 0.158	0.426
Lmax max	**-0.005**	**0.012**	**-0.43**	**0.673**	**-0.030, 0.019**	**0.964**

**Controlled for 3-item recall, CDT, preop anxiety, age, BMI and DEAR total

Next, the SPL noise variables were evaluated using graphics in exploratory analyses (e.g., boxplots, error bar charts) for patterns with respect to the outcome of PD. The Hz ranges with the greatest mean average dB occurred (500 Hz, 1000 Hz, 2000 Hz, 4000 Hz) in normal range of human hearing. The noise variables within the range of plausible human hearing were chosen (125 Hz to 8000 Hz) to test with the robust regression model methodology. This regression method was utilized to evaluate each noise variable's influence on the model (Table 14).

Table 14. Robust Regression of Delirium Severity Including SPL Median Noise Pitch Characteristics**

	Variable	Coefficients	Standard Error	t	P	95% confidence interval (min, max)	Pseudo R^2
125	Lavg median	0.098	0.096	1.02	0.313	-0.096, 0.292	0.431
	Lmax median	0.093	0.094	0.99	0.331	-0.100, 0.285	0.521
	Lmin median	0.098	0.093	1.05	0.298	-0.090, 0.285	0.431
	Lpk median	0.101	0.094	1.08	0.287	-0.089, 0.291	0.432
250	Lavg median	0.158	0.138	1.15	0.256	-0.120, 0.437	0.438
	Lmax median	0.165	0.132	1.24	0.221	-0.103, 0.432	0.438
	Lmin median	0.151	0.141	1.08	0.289	-0.133, 0.435	0.432
	Lpk median	0.160	0.126	1.26	0.214	-0.096, 0.415	0.524
500	**Lavg median**	**0.315**	**0.153**	**2.05**	**0.047**	**0.005, 0.625**	**0.473**
	Lmax median	0.237	0.131	1.82	0.077	-0.027, 0.502	0.461
	Lmin median	**0.440**	**0.193**	**2.28**	**0.028**	**0.050, 0.830**	**0.484**
	Lpk median	0.233	0.129	1.81	0.078	-0.028, 0.495	0.461
1000	Lavg median	0.387	0.286	1.36	0.183	-0.190, 0.964	0.441
	Lmax median	0.301	0.264	1.14	0.261	-0.233, 0.836	0.434
	Lmin median	0.405	0.310	1.30	0.200	-0.222, 1.031	0.440
	Lpk median	0.285	0.236	1.21	0.234	-0.192, 0.761	0.436
2000	Lavg median	0.216	0.289	0.73	0.468	-0.373, 0.796	0.423
	Lmax median	0.222	0.255	0.87	0.388	-0.293, 0.738	0.426
	Lmin median	0.095	0.324	0.29	0.770	-0.560, 0.750	0.417
	Lpk median	0.364	0.258	1.41	0.166	-0.157, 0.886	0.443
4000	Lavg median	0.031	0.239	0.13	0.897	-0.452, 0.515	0.416
	Lmax median	0.065	0.249	0.26	0.797	-0.440, 0.570	0.417
	Lmin median	-0.130	0.228	-0.57	0.573	-0.591, 0.332	0.420
	Lpk median	0.183	0.279	0.66	0.516	-0.382, 0.748	0.422
8000	Lavg median	-0.053	0.175	-0.30	0.766	-0.407, 0.302	0.417
	Lmax median	-0.072	0.183	-0.40	0.692	-0.443, 0.297	0.418
	Lmin median	-0.103	0.156	-0.66	0.513	-0.419, 0.213	0.422
	Lpk median	0.020	0.210	0.10	0.923	-0.405, 0.045	0.416

** Controlled for 3-item recall, CDT, preop anxiety, age, BMI and DEAR total

The regression models presented included the patient level characteristics and each noise median variable. All regression analyses including the SPL sound variables exceeded the R^2 value of the patient-level model of 0.0790. However, only variables demonstrating significant influence within the model of the median values was Hz range of 500 of Lavg median and Lmin median ($p = 0.047$ and $p = 0.028$ respectively).

Summary

The overall incidence of PD in this sample of community dwelling elders was 14% with a mean delirium score differing between those who developed and those who did not develop PD by the 72 hour end-point (PD = 1.86 ± 1.35 *vs* No PD = 0.72 ± 0.96). There were significant differences between those who had PD and those without in relation to evidence of cognitive impairment, overall risk, BMI, serum creatinine, and preoperative anxiety. Noise in the operating room had mean overall average levels of 66.84 dB (± 2.64), mean peak levels of 102.81 dB (± 0.2), mean maximum levels of 76.1 dB (± 3.18). None of the regression models including noise variables were conclusive in demonstrating noise loudness or pitch as a significant influence on the variability of delirium severity. However, all regression models including noise explained the variability of delirium severity to a greater degree than patient-level regression models.

CHAPTER V

DISCUSSION

The purposes of this study were to describe noise in the operating room during total joint replacement and to explore noise characteristics' influence on the severity of PD in community-dwelling older adult patients. This study examined the relationships between patient-level characteristics and the development of PD. Both noise characteristics for loudness (decibels) and pitch (Hz ranges) were explored for their influence on the model for PD severity (DI). A discussion of the findings will be presented in this chapter and likened to prior research on PD severity. A summary of limitations associated with this study will be presented as well as recommendations for further research and nursing implications.

The sample generated from recruitment differed in racial and gender characteristics when compared to the North Carolina census data in 2010 (United States Census Bureau, 2013). The sample was 94% Caucasian, 4% African American, whereas North Carolina census data of 9,535,483 people demonstrates 72% Caucasian and 22% African American. Women of North Carolina comprise 51% of the population; however female gender was ascribed by 62% of the sample.

Socioeconomic indices (marital status, income, educational attainment) of the sample also differed when compared to the North Carolina census data. While 53% of males and 49% of females over age 15 reported being married in the North Carolina

census, the proportion of the sample that reported being married was 70%. One-fifth of the sample were widowed (20%) versus 2.5% of males and 9.9% of females over age 15 of the North Carolina census data (United States Census Bureau, 2013). The sample declared greater educational attainment than found in the North Carolina census. More than one-third of the sample reported having a high school education (36%), whereas 27% of the North Carolina census ages 25 years and older reported having graduated high school. Twenty percent had obtained at least a bachelor's degree compared with 17% of the population; and 10% had attained either a master's (6%) or doctoral (4%) degree versus 8.9% of the population of North Carolina aged 25 years or older (United States Census Bureau, 2013). The median household income in North Carolina was $46,291 in 2010 (United States Census Bureau, 2013). Thirty-four percent of the sample reported an annual household income of greater than $60,000 per year. Other reported incomes were evenly distributed between $10,000 and $60,000 with only one participant (2%) reporting an annual household income below $10,000 per year. The census data reveals that 16.1% of the population of North Carolina lives below the poverty level (United States Census Bureau, 2013). In sum, the sample was diverse in economic backgrounds and educational attainments despite having similar gender and racial backgrounds. None of these variables were analyzed against the outcome of PD severity.

Environmental Operating Room Noise

The operating rooms during a total hip or knee demonstrated elevated levels of noise throughout the procedure. The average maximum levels approached the OSHA occupational exposure limit of 80 dB. The Environmental Protection Agency

recommends that hospital noise during waking hours not exceed 45 dB and sleeping hours not exceed 35 dB. Both the average and maximum noise levels collected exceeded these limits. The peak dB levels were also elevated. These findings are consistent with prior literature. Hasfeldt, Laerkner, and Birkelund (2010) found that of the eighteen relevant studies regarding operative noise, average noise levels ranged from 51 to 75 dBA with maximum noise levels ranging from 80 to 109 dBA. The main source of noise was attributed to staff-related activities such as conversing, dropping tools, and opening surgical trays. The maximum average peak in this study was 105.8 dB and the minimum average peak was 102.3 dB. OSHA mandates protective devices should be worn if noise exposure exceeds 80 dB for greater than 2 hours and prohibits continuous exposure greater than 115 dB and impact noise greater than 140 dB (OSHA, 2008). Premature damage to hearing may result from occupational exposure to loud noise between 1000 and 6000 Hz (El Dib & Matthew, 2009).

The Quest 1800 sound pressure level (SPL) meter stratified the noise levels in the incremental frequency bands. Beginning with the lower frequencies, the frequency with the greatest maximum peak levels were in the lowest frequency of 16 Hz. These maximum peak levels dropped to lower levels at 31.5 Hz, 63 Hz, 125 Hz, and 250 Hz. The average peak levels are more congruent in the Hz levels of 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz and then decrease slightly in subsequently higher octaves of 8000 Hz and 16000 Hz. There was also greater variability in dB levels in the extremes of frequencies. The Hz ranges with the greatest mean average dB occur (500 Hz, 1000 Hz, 2000 Hz, 4000 Hz) in normal range of human hearing.

Patient-level Characteristics and Delirium Severity

The sample demonstrated differing levels of cognitive impairment. Fourteen participants screened positive for a cognitive impairment. Compared to the literature, the prevalence of cognitive impairment of a community-dwelling cohort aged 68 to 72 years was approximately 10% and increased to 20% by ages 76 to 80 (Anstey et al., 2013). The sample exceeded these prevalence rates with a screening positive for cognitive impairment in 28%.

Because baseline cognitive impairment is a known predisposing risk factor for PD, it was necessary to screen for its presence. In the correlational analyses, participants' three-item recall demonstrated a significant correlation with delirium severity. The clock drawing test demonstrated a strong significant correlation to delirium severity. These findings are consistent with the literature in which cognitive impairment and dementia are considered to be the greatest predisposing risk factors for the development of PD (Noimark, 2009). Cognitive impairment has not been found to have a relationship with delirium symptoms but does increase the severity of delirium (Trzepacz et al., 1998; Voyer et al., 2007). These findings also support the model for deirium superimposed on dementia whereby underlying cognitive impairment increases the risk for delirium (Fick, 2011).

It was important to measure pain, as undertreated pain following surgery has been shown to predict PD (Morrison et al., 2003; Vaurio et al., 2006). Because of the lack of variability of pain scores, the correlations between these three time-point pain variables were not significantly associated with the outcome of PD severity and were not included

in the PD severity regression model. The participants either had their pain under control preoperatively via narcotic or non-narcotic analgesics, or they were still pain-free from the lingering effects of the spinal anesthetic.

Preoperative anxiety did rise on average when compared to screened anxiety levels. Anxiety was lowest in the postoperative period. It was important to test for anxiety, because it is an independent risk factor for PD and is a commonly reported emotion prior to surgery (Morrison et al., 2003). Preoperative anxiety was significantly negatively correlated with the outcome of PD severity. This was an interesting finding as it signifies that those who reported less anxiety immediately preoperatively demonstrated increased delirium severity scores postoperatively. Seignourel and others (2008) found that later stages of dementia report less anxiety. However, the participants in this study were not found demented at screening. It is possible that those who developed PD had dementia despite screening negative. These findings warrant further investigation.

Depression has been shown to be a predisposing risk factor for the development of PD. The incidence of depression was extremely low in this sample. Two participants demonstrated possible depression while half of the participants screened negative for depression. Preoperative depression has been implicated in the development of PD (Givens, Sanft &Marcantonio, 2008), and increases the duration of PD (Leung, Sands, Mullen, Wang, & Vaurio, 2005). The severity of PD increases with the number of depressive symptoms with five or greater demonstrating worsened outcomes (Leung,

Sands, Mullen, Wang, & Vaurio, 2005; McAvay et al., 2007). Since only two participants screened positive for possible depression, analysis on the influence of depression on PD severity was not conducted.

Forty-two of the participants were noise-sensitive; no participant could be deemed noise-insensitive. This finding is consistent with previous findings in which noise sensitivity was positively correlated with age (Schreckenberg et al., 2010). The correlation between age and noise sensitivity was not evidenced in bivariate analyses in this sample, perhaps due to the overall homogenous noise sensitivity scale scores. Noise sensitivity is estimated to affect 50 % of individuals (Shephard et al., 2010); however 84% of this sample demonstrated noise sensitivity. Noise sensitivity has been associated with other sensory sensitivities, such as pain (Schreckenberg et al, 2010). It is possible that there exists a bidirectional relationship between the pain associated with osteoarthritis and sensitivity to other sensory stressors such as noise. This would also be congruent with the PLST-DSD model.

Half of the participants demonstrated low noise annoyance category, 42 percent moderate noise annoyance, and the remaining 8 percent high noise annoyance. The only literature found that evaluated noise annoyance prevalence utilized a sample of industrial workers, a weak comparison. These values were not congruent with this study in which 66% of industrial workers were characterized as noise-annoyed (van Dijk et al., 1987). The industrial workers described various aspects of annoyance such as irritation, alarm reactions, mental workload and time pressure; however, these aspects increased annoyance to a greater degree than the noise pressure levels, or loudness (van Dijk et al.,

1987). It was important to include these variables in the analyses because it has been noted that older people have increased noise sensitivity (Schreckenberg et al., 2010) and noise sensitivity is a moderator of noise annoyance and other subjective complaints such as sleep disturbance. While noise annoyance and noise sensitivity were theorized to have an influence on the degree of PD severity conveyed by noise, the analyses did not demonstrate a correlation. This may be explained by an established noise annoyance prevalence which peaks in middle age (45 years) and diminishes in younger and elder years (Van Gerven et al, 2009). This would impede any attempts to describe noise annoyance in a linear fashion with another variable.

Five individuals screened positive for a possible hearing impairment. In relation to vision impairment, 14 individuals reported being unable to see the television without corrective lenses. Thus, a total of 19 participants demonstrated a sensory impairment. Neither of these sensory impairments showed a significant correlation to PD severity. However, identification of impairment were either patient self-reported (vision) or via a screening tool (whisper test) which may have under identified or misidentified those with a sensory impairment. This finding does not support previous findings from general medical patients. Inouye and colleagues (1993) first identified sensory visual impairment (acuity < 20/70) as an independent risk factor for incident delirium in a sample of medical patients. Sensory impairment was either not discussed or measured in PD literature (Benoit et al., 2005; Brauer et al., 2000; Dolan et al., 2000; Franco, Litaker, Locala & Bronson, 2001; Gaudreau et al., 2005; Givens, Sanft, & Marcantonio, 2008;

Kudoh, Katagai, & Takazawa, 2003; Lemstra et al., 2008; Lowery, Westnes, Brewster & Ballard, 2008; Marcantonio et al., 1994; Priner et al., 2008; Vaurio et al., 2006).

The sample demonstrated near normal or normal functional activities of daily living (ADL) scores despite their osteroarthritic pain and range of motion limitations. Twelve percent demonstrated evidence of functional impairment in one or more ADL. Of those, 10% reported functional impairment in bathing and 12% reported a functional impairment in dressing. The remaining 44 participants were functionally intact with a Katz ADL score of 0. Functional impairment did not demonstrate a significant correlation to delirium severity. ADL scores did not significantly differ between those who developed PD and those who did not. These findings are not consistent with prior literature in which participants with PD demonstrated greater functional impairment than those without delirium (Franco et al., 2001; Dolan et al., 2000; Ganai et al., 2007; Givens et al., 2008; Morrison et al., 2003; Vaurio et al., 2006). Several studies did not report findings related to functional status (Benoit et al., 2005; Brauer, Morrison, Silberzweig, & Siu, 2000; Kudoh, Katagi, & Takazawa, 2002; Lemstra et al., 2008; Lowery, Wenes, Brewster, & Ballard, 2008; Priner et al., 2008).

This study failed to find an association with comorbidities and PD severity. Hypertension was the most common comorbidity reported at 66%. This was followed by diabetes (18%), obstructive sleep apnea (14%), and peripheral vascular disease (6%). While 12% of the sample reported smoking, 6% reported chronic obstructive pulmonary disease. The mean Charleson Comorbidity Index demonstrated no significant differences in means between PD and non-PD participants.

In studies of older general medical patients, comorbidities carried an adjusted OR ranging from 1.1 (95% CI, 1.01, 1.28) (Levkoff et al., 1992) to 5.9 (95% CI, 1.1, 32.2) (Francis et al., 1990). Brauer and colleagues (2000) in their older hip fracture sample identified causes attributable to comorbid cases. The relative risk related to increasing number of comorbidities is 1.75 (95% CI 1.09, 2.79) (Franco, Litaker, Locala, & Bronson, 2001). The pathologies listed as the most significant in relation to the association with PD include congestive heart failure ($p<0.003$), stroke ($p<0.001$), and cancer ($p<0.001$) (Dolan et al., 2000). The association between PD and congestive heart failure have been verified in a subsequent study utilizing an older hip fracture sample (adjusted OR 2.9; 95% CI, 1.6, 5.3) (Morrison et al., 2003). However, with only two participants within the sample having congestive heart failure, three with prior stroke or transient ischemic event, and no patient reporting cancer, analyses could not be performed. The small sample size limited analyses on any underrepresented comorbidity.

Another well-represented comorbidity was in relation to obesity. The height and weight collected on each participant yielded a calculated BMI for each participant. While the CCI failed to yield significant findings, the BMI did demonstrate significant correlations to PD severity and significant differences between PD and non-PD groups. Many of the participants displayed common comorbidities. Only 24% of the sample had a normal body mass index (BMI), with the sample BMI mean of 28.49, or overweight. The majority of the sample was either overweight (32%) or obese (40%) with a BMI greater than 30. Of those classified as obese, half were severely obese with a BMI greater than 35 and one participant was morbidly obese with a BMI greater than 40.

However, those who developed PD had significantly lower mean BMI values than those who did not develop PD. BMI was significantly correlated to PD severity, which also demonstrated that when BMI decreased severity of PD increased. It is possible that this result was generated from the numerous statistical analyses performed as well.

The sample's overall mean was serum creatinine was within normal range. However PD groups had significantly elevated serum creatinine. Creatinine was significantly correlated with PD severity as well but the correlation was weak. These findings are consistent with the literature in which an elevated creatinine carries an adjusted OR of 2.1 (95% CI, 1.1-4.0) (Pisani et al., 2007). In literature on delirium in general medical patients, malnutrition with serum albumin less than 30 g/dL carried a relative risk of 3.9 (95% CI, 2.0-7.5) (Inouye and Charpentier, 1996). Lower BMI may indicate malnutrition which would increase the risk of PD for these patients and generate a negative correlation value.

Almost half of the sample were prescribed and currently taking a psychotropic medication with six participants taking multiple psychotropic medicines. The most commonly prescribed medicine was opiates, which are also utilized to treat the pain associated with osteoarthritis. An equally commonly prescribed medicine was antidepressants. Three participants were prescribed a benzodiazepine, which is listed as a drug to be avoided in the elderly (Beers et al., 1991; Fick et al., 2003). Psychotropic medicine utilization was less in the PD than the non-PD group. The use of psychoactive medications overall was not positively correlated with delirium severity.

Overall risk was significantly positively correlated to the incidence and severity of delirium and was the only patient-level variable that was significant under robust regression of PD severity using patient-level characteristics. The DEAR tool which quantifies overall risk has a sensitivity of 71% with a specificity of 49% (likelihood ratio positive 1.4) (Freter et al., 2005). While it was expected that overall risk would be positively correlated to incident PD, it was not expected that overall risk would be positively correlated to delirium severity. All of the patient level factors included in risk score were analyzed independently. The DEAR tool included some of the risk factors (benzodiazepine use, sensory impairment, use of alcohol, functional status) that did not demonstrate significance within this study. However, this could also be due in part to the small sample size.

Noise Variables and Delirium Severity

Because the Edge dosimeter only measures noise levels in loudness, and not in pitch, this dosimeter data was chosen to explore the effects of noise loudness on the model for delirium severity. Within this model all noise loudness variables were entered individually and controlled for the patient-level characteristics. Each derived model explained more in the variance of delirium severity than patient-level characteristics. The models that demonstrated significance included the calculated maximum median noise variables of average loudness and maximum loudness levels. This is consistent with prior noise literature in which noise conveys stress (Evans et al., 1995; Lusk et al., 2002; Muchnik et al., 1998; Rosenlund et al., 2001; Rylander & Bjorkman, 1988). A positive correlation between noise and the incidence of PD was theorized utilizing the PLST-DSD

model (Fick, 2008). While these two parameters demonstrated significance, several other increased noise loudness variables did not. Therefore, more research is needed to verify these findings.

The next model which stratified noise by pitch in the various hertz ranges was evaluated against the patient-level model. Again, all variables were explored and included individually controlling for patient characteristics. Each model was weak in explaining the variance in delirium severity, but still better explained than the patient-level model. The models that demonstrated significance included the of the average and minimum median noise loudness values at 500 Hz. This was an unexpected finding, as these loudness variables do not represent the loudest overall values (as the loudness maximum values of the Edge), but specific loudness parameters of minimum and average assigned within the 500 Hz range. However, of the two studies focused on patient perception, the patients who were the most stressed were not those exposed to the highest levels of noise (Hasfeldt, Laerkner, & Birkelund, 2010; Liu & Tan, 2000). Neither study collected hertz-range data. This may be the missing factor in affecting stress. More research is needed to discern which noise pitches in the hospital setting are the most stressful regardless of noise loudness. These findings should be weighed against previous findings for reliability. To date, studies relating noise Hz ranges to outcomes are found in basic physiological research. There are no studies found assessing patient responses to pitch noise characteristics. In addition, the noise loudness and noise pitch models explained the variance in delirium severity to a much greater degree than the

patient level model. This could have significance to future researchers studying noise. If the deleterious effects of noise are generated separately from both noise loudness and from noise pitch as demonstrated in this study and in prior literature (Prashanth & Venugopalacha, 2008, p. 97), then use of octave band analysis pressure level meters should be included.

Theoretical Framework Utility

The PLST-DSD (Fick, 2011) was deemed an excellent framework in the conduct of this study. The theory framed both predisposing nad precipitating risk factors while allowing for the inclusion of the general environment, such as noise. The modifications made to the theory to incorporate the hospitalized person at risk for PD was necessary and useful. It also allowed for the use of the DEAR tool which quantified that risk in this sample to a greater degree than anticipated.

Limitations

Several limitations to this prospective, exploratory correlational study design are acknowledged. First, this method of study design is observational and lacks control or randomization. Therefore, causality cannot be determined (Polit & Beck, 2004); only the strength of any relationships between variables chosen to study were examined. The methodology of convenience sampling is weak. As this study was exploratory, multiple statistical analyses and t-tests can generate a spurious finding. This particular sample was slightly better educated, greater socioeconomic status, more functional, and demonstrated treated pain and depression than the literature and census data suggested. These factors may have influenced the overall incidence and severity of delirium. The low incidence

and delirium severity may have resulted from the procedures at the study setting already in place to reduce PD. For example, patient rooms had orientation clues such as calendars and clocks. Patients received physical therapy and early mobilization. These interventions may have served to reduce the overall incidence and severity of PD at the end point of 72 hours. The results may not be representative of all participants presenting for total knee or hip arthroplasty and therefore are not generalizable and external validity is threatened. It is difficult to quantify conceptual terms as depression, anxiety, cognition, and delirium as these are operationally defined and rely on instrumentation which may have introduced error and threats to internal validity. Some of the tests were not designed for the elderly (i.e. noise sensitivity and noise annoyance). Therefore, the construct of noise annoyance and noise sensitivity may not have been measured effectively. Some psychological tests demonstrated a low Cronbach's alpha (i.e. depression, noise annoyance) which would indicate that the reliability of the measured construct is threatened. The sound level meter may be another threat to internal validity as it requires recalibration to prevent drift and may have introduced error. Other variables that are self-reported such as age and education may have introduced threats to internal validity if participants did not truthfully or accurately answer. Finally, the study design of using repeated measured could limit findings if maturation or history were introduced.

Nursing Implications

Noise imparts physiological stress on humans (Lusk et al, 2002; Melamed, Kristal-Boneh, & Froom, 1999; Prashanth & Venugopalacha, 2008). Noise was found in

this study to exceed OSHA limits within every surgical case and across the study in summary statistics. According to the United States Department of Labor Occupational Safety and Health Administration (OSHA), excessive occupational noise is a health hazard and should be monitored (OSHA, 2008). OSHA mandates protective devices should exposure exceed 80 dB for greater than 2 hours and prohibits continuous exposure greater than 115 dB and impact noise greater than 140 dB (OSHA, 2008). The Environmental Protection Agency recommends that hospital noise during waking hours not exceed 45 dB and sleeping hours not exceed 35 dB. The average, maximum, and peak noise loudness values consistently exceeded these limits.

Excessive noise exposure may necessitate the patient to wear protective devices (see Figure 3). The hospital staff including the physicians, the nurses and the scrub technicians are all exposed to excessive noise levels as an occupational hazard and may need hearing protection to prevent occupation noise-induced hearing loss. Excessive noise exposure within the Hz range of 1000 and 6000 Hz can lead to premature hearing damage (El Dib and Matthew, 2009). The noise environment of the hospital should have additional safeguards and more routine monitoring to protect its human resources from occupational hearing loss as in other industries.

Interventions have been conducted to reduce noise within the hospital environment; however most have focused on noise reduction on nursing units (Montague, Blietz, & Kachur, 2009; Richardson et al, 2008). Many interventions have been conducted and include: 1) architectural design for sound reduction including barriers and design for maintaining main hospital traffic away from care environments; 2) electronic

design including personal pagers rather than hospital overhead paging, patient-use televisions in close proximity to avoid use of high speaker volume or altering the call bell system for less intrusive sounds; 3) staff behavioral changes such as responding to infusion alarms and ventilator alarms in a timely fashion or restocking supplies during waking hours (Montague, Blietz, & Kachur, 2009; Richardson et al, 2008; Zamberlan-Amorim et al, 2012).

Interventions have demonstrated efficacy in reducing noise levels. Participatory discussions and action plans have been developed by multidisciplinary teams in neonatal intensive care that reduced noise effectively. Strategies included decreased vocal intensity, reduced intensity of phone rings, reminders on devices that make noise, anti-impact guards in cabinets; team reports and questionnaires on noise (Zamberlan-Amorim et al, 2012).

A recommendation following this study would be increased education of operating room personnel on patient and personal safety as it relates to noise exposure. Operating room nurses should be made aware of the current recommended WHO guidelines as well as the excessive noise evidenced by this small study. Nurses, as advocates, should educate patients to the common noise hazards in the operating room. Protective hearing devices such as ear plugs could be made available upon patient request. In addition, new innovations can be designed by nurse entrepreneurs such as new electronic communication tools between surgeons and nurses that would allow the surgeon to listen to his music selections without polluting the noise environment of the operating room and increasing staff and patient exposure.

While this study failed to yield significant findings, the clinical findings merit increased surveillance of environmental noise within the operating room. Surveillance may demonstrate common noise sources, as in this study. For example, the use of physician music selections over the stereo during patient procedures could be discontinued. It was noted via field notes that conversation and communication between staff increased in volume to supersede music being played. Innovations in sound deafening equipment and would decrease the sources of noise attributed to instruments such as saws, drills, and hammers. The shutting of operating room doors is amplified by the use of wooden doors with negative pressure rooms. However, architectural innovations would include the use of doors that incorporate a silent-close function via padding or weighted hinges. Education, surveillance and future research would delineate which of these interventions would prove most useful in the operative setting.

Recommendations for Future Research

This study highlighted an important area in health care that deserves a greater amount of research: noise in hospital environments and particularly surgical suites. Additional research is needed to identify the common sources of noise in each hospital environment and the effects of noise on health outcomes in hospital wards for both patients and personnel. Additional research is needed to determine safe, practical and effective interventions to reduce noise in hospitals. Which interventions offer the greatest benefit? Which interventions are transferrable to the operative environment?

Finally, additional research needs to explore hospital environments and architectural design that would reduce noise levels, including in procedural areas such as the operating room.

Conclusion

The current status quo of hospital operating rooms is putting patients and personnel at risk for noise induced hearing loss and noise-related stress which is unacceptable. This study fully described the environmental noise experienced by elderly patients and hospital personnel during total knee or total hip arthroplasty in one hospital. The noise levels exceeded acceptable limits and guidelines set by EPA, WHO and OSHA. While the study failed to substantiate increasing noise levels yielding worsened delirium severity, it did demonstrate: 1) elderly had greater noise sensitivity; 2) pre-existing cognitive impairment was strongly and significantly correlated to delirium severity in the elderly; 3) age and creatinine were significantly correlated to delirium severity; 4) BMI and self-reported preoperative anxiety were negatively correlated to delirium severity; 5) overall risk via the DEAR tool was significantly correlated to delirium severity to a greater degree than its components: advanced age, sensory impairment, psychoactive medication use, and functional impairment; and 6) the operating room noise levels sampled exceeded governmental and agency-recommended limits. The DEAR tool was found to be useful in identifying elderly at-risk for developing delirium postoperatively. In addition, the literature review identified gaps in the research as to which interventions would be best to reduce noise exposure within the operative environment. Further research in this area is greatly needed.

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APPENDIX A

DEAR TOOL

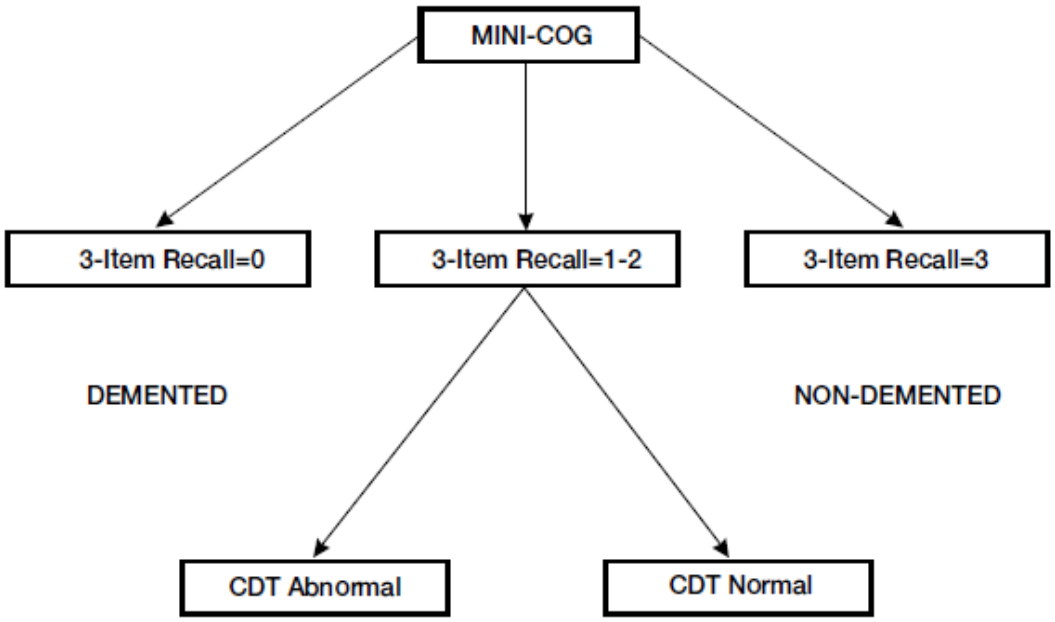
	Risk Factors	
Age: _____ (years)	80 years or older ☐	79 years or younger ☐
Do you use a **hearing aid** or have **difficulty seeing the TV without glasses?**	Yes ☐ Circle: Hearing aid Poor vision	No ☐
ADL Needs assistance with (circle) Bathing yes/no Dressing yes/no Toileting yes/no Grooming yes/no Feeding yes/no	Impairment in *any* ADL ☐	Independent in *all* ADL ☐
Cognition (MMSE questions on back) **MMSE** score: _____/30	MMSE < 24 ☐	MMSE ≥ 24 ☐
Substance use (1) Number of **alcohol**-containing drinks per week: _____ (2) **Benzodiazepine** use: number of times per week: _____	ethanol >3 drinks per week *or* benzodiazepines >3 times per week ☐	ethanol ≤ 3 drinks per week *and* benzodiazepines ≤ 3 times per week ☐
Number of risk factors:		

APPENDIX B

MINI-COG

SCORING
Give 1 point for each recalled word after the CDT distractor.
Patients recalling none of the three words are classified as demented (Score = 0).
Patients recalling all three words are classified as non-demented (Score = 3)
Patients with intermediate word recall of 1-2 words are classified based on the CDT (Abnormal = demented;
Normal = non-demented)
Note: The CDT is considered normal if all numbers are present in the correct sequence and position, and the hands readably display the requested time.

Figure 7. Mini-Cog



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APPENDIX C

GERIATRIC DEPRESSION SCALE-15

Choose the best answer for how you have felt over the past week:

1. Are you basically satisfied with your life? YES / **NO**

2. Have you dropped many of your activities and interests? **YES** / NO

3. Do you feel that your life is empty? **YES** / NO

4. Do you often get bored? **YES** / NO

5. Are you in good spirits most of the time? YES / **NO**

6. Are you afraid that something bad is going to happen to you? **YES** / NO

7. Do you feel happy most of the time? YES / **NO**

8. Do you often feel helpless? **YES** / NO

9. Do you prefer to stay at home, rather than going out and doing new things? **YES** / NO

10. Do you feel you have more problems with memory than most? **YES** / NO

11. Do you think it is wonderful to be alive now? YES / **NO**

12. Do you feel pretty worthless the way you are now? **YES** / NO

13. Do you feel full of energy? YES / **NO**

14. Do you feel that your situation is hopeless? **YES** / NO

15. Do you think that most people are better off than you are? **YES** / NO

Answers in bold indicate depression. Score 1 point for each bolded answer.
A score > 5 points is suggestive of depression.
A score ≥ 10 points is almost always indicative of depression.
A score > 5 points should warrant a follow-up comprehensive assessment.

Kurlowicz, & Greenburg. (2007). The Geriatric Depression Scale. *Try This Series* [Online], 4, 1-2.

APPENDIX D

WEINSTEIN NOISE SENSITIVITY SCALE

1. I would not mind living on a noisy street if the apartment I had was nice.
2. I am more aware of noise than I used to be. (reverse scoring)
3. No one should mind much if someone turns up his stereo full blast once in awhile.
4. At movies, whispering and crinkling candy wrappers disturbs me. (reverse scoring)
5. I am easily awakened by noise. (reverse scoring)
6. If it's noisy where I am studying (substitute reading), I try to close the door or window or move somewhere else. (reverse scoring)
7. I get annoyed when my neighbors are noisy (reverse scoring)
8. I get used to most noises without much difficulty.
9. It would matter to you if an apartment you were interested. (reverse scoring)
10. Sometimes noises get on my nerves and get me irritated. (reverse scoring)
11. Even music I normally like will bother me if I am trying to concentrate. (reverse scoring)
12. It would not bother me to hear the sounds of everyday living from neighbors (footsteps, running water, etc.).
13. When I want to be alone, it disturbs me to hear outside noises. (reverse scoring)
14. I'm able to concentrate no matter what is going on around me.
15. In a library, I don't mind if people carry on a conversation if they do it quietly.
16. There are often times when I want complete silence. (reverse scoring)
17. Motorcycles should be required to have larger mufflers. (reverse scoring)
18. I find it hard to relax in a place that is noisy. (reverse scoring)
19. I get mad at people who make noise that keeps me from falling asleep or getting work done. (reverse scoring)
20. I would not mind living in an apartment with thin walls.
21. I am sensitive to noise. (reverse scoring)

6 point Likert scale: 1-agree strongly, 2- agree, 3-agree a little, 4-disagree a little, 5-disagree, 6-disagree strongly.

Weinstein. (1978). Individual differences in reactions to noise: A longitudinal study in a college dormitory. *Journal of Applied Psychology,* 63 (4), 458-466.

APPENDIX E

NOISE ANNOYANCE SCALE

Q1. Are you startled by noise?

Q2. Conversation problems related to noise?

Q3. Necessity of using gesture-language related to noise?

Q4. Perception of signals impeded by noise?

Q5. Particularly disturbed by certain noisy sources?

Likert scale options: 0-Never/seldom 1-Sometimes 3-Often/always

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Lusk, et al. (2002). Chronic effects of workplace noise on blood pressure and heart rate. *Archives of Environmental Health, 57 (4),* 273-281.

APPENDIX F

CONFUSION ASSESSMENT METHOD

Nine criteria:

1. Acute Onset (Is there evidence of acute change in mental status from baseline?)
2. Inattention (Is patient having difficulty focusing/easily distracted? If present, is it fluctuating?)
3. Disorganized thinking (Any incoherence? Rambling speech? Illogical?)
4. Altered level of consciousness (Anything other than alert is abnormal, including vigilance/hyperalert, lethargy, stupor or comatose.)?
5. Disorientation (Aware of person, place or time?)
6. Memory impairment (Difficulty remembering hospital events since admission or instructions?)
7. Perceptual disturbances (Hallucinations, illusions, misinterpretations?)
8. Psychomotor disturbances (Restlessness or sluggishness?)
9. Altered sleep-wake cycle (Daytime sleepiness or insomnia?)

Diagnostic Features:

Feature 1. Acute onset and fluctuating course

This feature is usually obtained from a family member or nurse and is shown by positive responses to the following questions: Is there evidence of an acute change in mental status from the patient's baseline? Did the (abnormal) behavior fluctuate during the day, that is, tend to come and go, or increase and decrease in severity?

Feature 2. Inattention

This feature is shown by positive response to the following question: Did the patient have difficulty focusing attention, for example, being easily distracted, or having difficulty keeping track of what was being said?

Feature 3. Disorganized thinking

This feature is shown by a positive response to the following question: Was the patient's thinking disorganized or incoherent, such as rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching from subject to subject?

Feature 4. Altered level of consciousness

This feature is shown by any answer other than "alert" to the following question: Overall, how would you rate this patient's level of consciousness? (alert [normal], vigilant [hyperalert], lethargic [drowsy, easily aroused], stupor [difficult to arouse], or coma [unarouseable]).

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* The diagnosis of delirium by CAM requires the presence of features 1 and 2 and either 3/4
Inouye et al., (1990). Clarifying confusion: the confusion assessment method. A new method for the detection of delirium. *Annals of Internal Medicine, 113:* 941- 948.

APPENDIX G

DELIRIUM SEVERITY INDEX

1) Inattention
   0. Attentive;
   1. Generally attentive but makes at least one error in spelling 'WORLD' backwards;
   2. Can generally answer questions, but subject is distractible and at times has difficulty keeping track of questions. May have some difficulty shifting attention to new questions, or questions may have to be repeated several times;
   3. Unresponsive or totally unable to keep track of or answer questions. Has great difficulty in focusing attention and is often distracted by irrelevant stimuli;
   9. Cannot assess.

2) Disorganized thinking
   0. Responses are logical, coherent, and relevant
   1. Responses are vague or unclear
   2. Thought is occasionally illogical, incoherent, or irrelevant
   3. Unresponsive or thought is fragmented, illogical, incoherent, and irrelevant;
   9. Cannot assess (Refuse)

3) Altered level of consciousness
   0. Normal level of consciousness
   1. a) Hypervigilant, b) hypovigilant; (glassy-eyed, decreased reaction to questions);
   2. Drowsy/sleepy; Responds only to loud questions;
   3. Unresponsive **or** comatose.

4) Disorientation in time and place [See 3 MS "Temporal orientation". Additional questions on age, birth date, and birth place may be used].
   0. Knows today's date (± 1 day) **and** the name of the hospital;
   1. Does not know today's date (± 1 day) **or** does not know the name of the hospital;
   2. Does not know the month or year **or** does not know that is in the hospital;
   3. Unresponsive **or** does not know name or birth date; 9. Cannot assess

5) Memory impairment

0. Recalls three words **or** details of hospitalization;
1. Cannot recall one of the words, **or** has difficulty recalling details of the hospitalization;
2. Cannot recall two of the three words **or** recalls few details of the hospitalization;
3. Unresponsive or cannot recall any of the three words **or** details of the hospitalization;
9. Refuse

6) Perceptual disturbances

0. Unresponsive or no perceptual disturbances observed,
1. Misinterprets stimuli (for example, interpreting a door closing as a gunshot);
2. Has occasional non-threatening hallucinations;
3. Has frequent, threatening hallucinations.

7a) Psychomotor agitation

0. No psychomotor agitation;
1. Responds well to questions but moves frequently;
2. Moves continuously (and may be restrained);
3. Agitated, difficult to control (restraints are required)

7b) Psychomotor retardation

0. No psychomotor retardation;
1. Lethargic/sluggish
2. Moves slowly and little spontaneous movement
3. No voluntary movement

Scoring:
1. Total score is sum of 7 item scores.
2. If questions 1, 2, 4 or 5 are checked "9" replace 9 by the score of item 3.

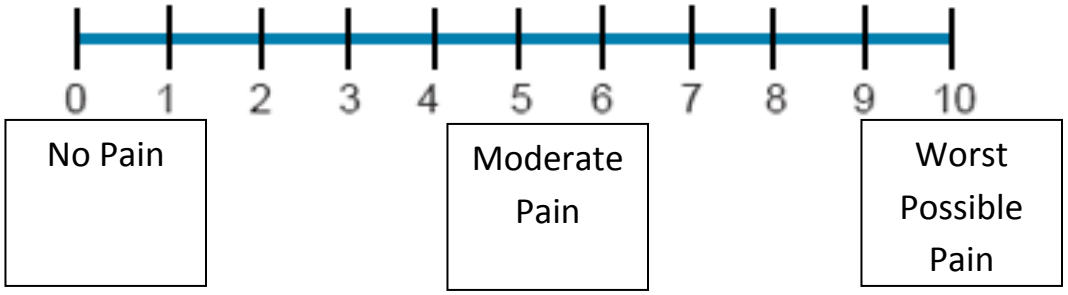
McCusker J, Cole M, Bellavance F, Primeau F. (1998). The reliability and validity of a new measure of severity of delirium. *International Psychogeriatrics*, 10(4): 421-433.

McCusker J, Cole M, Dendukuri N, Belzile E. (2004). The Delirium Index, a measure of the severity of delirium: New findings on reliability, validity, and responsiveness. *Journal of the American Geriatrics Society*, 52(10).

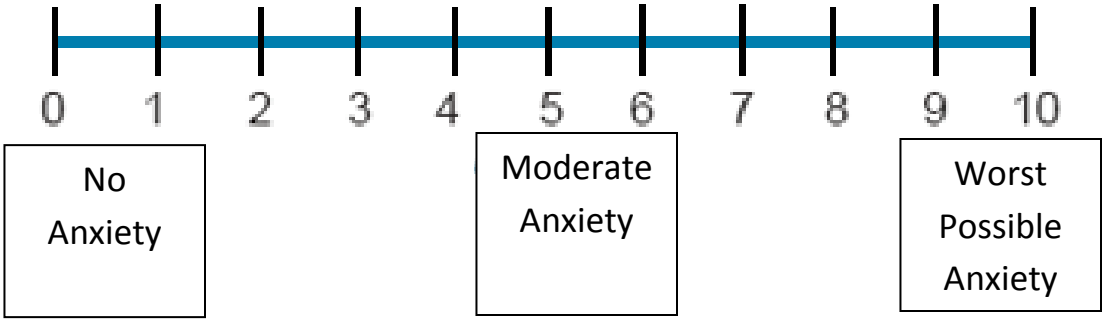
APPENDIX H

NUMERIC VISUAL ANALOG OF ANXIETY AND PAIN

Pain



Anxiety



APPENDIX I

DEMOGRAPHIC DATA TOOL

☐ How old are you today (years):_____

☐ What is your sex?

- ☐ Male
- ☐ Female
- ☐ Other:_____

☐ Please list your marital status:

- ☐ Married or co-habiting
- ☐ Single (never married)
- ☐ Divorced
- ☐ Widowed
- ☐ Separated
- ☐ Other: _____

☐ Please list the highest grade completed in school and any degrees earned:

- ☐ Elementary (grades 1-5)
- ☐ Middle (grades 6-8)
- ☐ High (grades 9-12) or GED equivalent
- ☐ Some College/Associate Degree (1-3 years after high school)
- ☐ Bachelors (4-5 years after high school)
- ☐ Masters (5-7 years after high school)
- ☐ Doctoral (greater than 7 years after high school)

☐ You have been told you had these conditions by a healthcare provider (to be completed by PI):

Weight	Clinical condition
1	Myocardial infarct
	Congestive cardiac insufficiency
	Peripheral vascular disease
	Dementia
	Cerebrovascular disease
	Chronic pulmonary disease
	Conjunctive tissue disease
	Slight diabetes, without complications
	Ulcers
	Chronic diseases of the liver or cirrhosis
2	Hemiplegia
	Moderate or severe kidney disease
	Diabetes with complications
	Tumors
	Leukemia
	Lymphoma
3	Moderate or severe liver disease
6	Malignant tumor, metastasis
	Aids

Figure 1 - Charlson comorbidity index – weighting of the clinical conditions present among secondary diagnoses.

Source: http://www.scielo.br/img/revistas/rsp/v38n6/en_05f1.gif.

Score: _____

☐ Medications and dosages listed on medical record:

- Please list your race:

  - ☐ White
  - ☐ African American or black
  - ☐ Asian American
  - ☐ Native Hawaiian or Other Pacific Islander
  - ☐ Other or Multiracial (please indicate):_____

- Are you of Hispanic origin?

  - ☐ Yes
  - ☐ No

- Are you of Latino origin?

  - ☐ Yes
  - ☐ No

☐ What is your annual income in dollars from 2008:

  - ☐ Less than $10,000 a year
  - ☐ $10,001 - $20,000 a year
  - ☐ $20,001 - $30,000 a year
  - ☐ $30,001 - $40,000 a year
  - ☐ $40,001 - $50,000 a year
  - ☐ $50,001 - $60,000 a year
  - ☐ Greater than $60,001 a year
  - ☐ Don't know
  - ☐ Refuse

Variables: Preanesthesia visit:

- ☐ Results from screening Noise annoyance:_____
- ☐ Results from screening Noise sensitivity:_____
- ☐ Results from screening DEAR risk:_____
- ☐ Results from screening NVAS-Anxiety:_____
- ☐ Results from screening NVAS-Pain:_____
- ☐ Results from screening Mini-Cog:_____
- ☐ Results from GDS-15: _____
- ☐ Results from Whisper test:_____

Day of surgery preoperative:

- ☐ Results from NVAS-Anxiety:_____
- ☐ Results from NVAS-Pain:_____
- ☐ CAM: positive or negative (circle)
- ☐ DI:_____

Day of surgery postoperative:

- ☐ Results from NVAS-Anxiety:_____
- ☐ Results from NVAS-Pain:_____
- ☐ CAM: positive or negative (circle)
- ☐ DI:_____

72 hour review:

- ☐ Results DSM-IV chart review:_____
- ☐ Results DI:_____

APPENDIX J

CONSENT FORM

EXPLORATORY STUDY: INTRAOPERATIVE SOUND AND CONFUSION

Informed Consent Form to Participate in Research

Courtney Brown, MSN, CRNA, Student Investigator

Beth Barba, PhD, RN, FAGHE, FAAN, Principle Investigator

Introduction

This is a research project. You have been chosen for this study because you are having a total knee or hip replacement, you are older than 50 years and less than 90 years, and you are not currently confused. Please take your time in making your decision as to whether or not you wish to participate. Your participation is voluntary. Ask your study nurse or to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

Why Is This Study Being Done?

The purposes of this study are to find how whether sound in the operating room has an effect on confusion in the elderly.

How Many People Will Take Part in the Study?

A maximum of eighty people will take part in this study at this and another research site.

What Is Involved in the Study?

You will be asked to take verbal tests by the research nurse. These tests look for nervousness, depression, and confusion. These will take approximately 10 minutes this first testing period. Prior to surgery, you will be given verbal tests again looking for confusion and nervousness. These will take about 5 minutes. While you are in surgery, the level of sound in the operating room will be recorded using a special machine that measures sound levels. The research nurse is not involved in your care and she will not be interacting with you. After waking up from surgery, you will take the confusion and anxiety tests again. These tests will take an additional 10 minutes. The research nurse will visit you at 72 hours after your surgery for you to take the confusion and anxiety tests for the last time. This time, tests will take about 10 minutes. If you have questions about this study, please let the researcher know before signing the consent. If you were discharged before 72 hours after surgery, the research nurse will be looking in your record to see if you were confused at some point between the recovery room and discharge.

How Long Will I Be in the Study?

You will be in the study for a maximum of 72 hours. You have the right to refuse to participate or to withdraw at any time, without penalty. If you do withdraw, it will not affect you in any way. If you choose to withdraw, you may request that any of your data which has been collected about you be destroyed.

What Are the Risks of the Study?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff. Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be: earlier detection of confusion and care.

What Other Choices Are There?

This is not a treatment study. Your alternative is to not participate in this study.

What about the Use, Disclosure and Confidentiality of Health Information?

By taking part in this research study, your personal health information, as well as information that directly identifies you, may be used and disclosed. Information that identifies you includes, but is not limited to, such things as your name, address, telephone number, and date of birth. Your personal health information includes all information about you which is collected or created during the study for research purposes. It also includes your personal health information that is related to this study and that is maintained in your medical records at this institution and at other places such as other hospitals and clinics where you may have received medical care. Examples of your personal health information include your health history, your family health history, how you respond to study activities or procedures, laboratory and other test results, medical images, photographs/videotapes/audiotapes and information from study visits, phone calls, surveys, and physical or mental examinations.

Your personal health information and information that identifies you ("your health

information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study.

If this research study finds you to be confused, then information collected or created as part of the study may be placed in your medical record and discussed with individuals caring for you who are not part of the study. This will help in providing you with appropriate medical care. In addition, all or part of your research related health information may be used or disclosed for treatment, payment, or healthcare operations purposes related to providing you with medical care.

When you sign this consent and authorization form you authorize or give permission for the use of your health information as described in the consent form. You can revoke or take away your authorization to use and disclose your health information at any time. You do this by sending a written notice to the investigators in charge of the study at the following address:

Courtney Brown, MSN, CRNA
Wake Forest University Baptist Medical Center
PCU 3rd Floor
Medical Center BLVD

Winston Salem, NC 27157

Beth Barba, PhD, RN, FAGHE, FAAN
University of North Carolina at Greensboro
101 McIver House
PO Box 26170
Greensboro, NC 27402-6170
Office 336-334-4785 Fax 336-334-3223

If you withdraw your authorization you will not be able to be in this study. If you withdraw your authorization, no new health information that identifies you will be gathered after that date. Your health information that has already been gathered may still be used and disclosed to others. This would be done if it were necessary for the research to be reliable. You will not have access to your health information that is included in the research study records until the end of the study

What Are the Costs? Will You Be Paid for Participating?

There are no costs to you for taking part in this study. You will not be paid to participate in this study.

What Are My Rights as a Research Study Participant?

You have the right to refuse to participate or to withdraw at any time, without penalty. If you do withdraw, it will not affect you in any way. If you choose to withdraw, you may request that any of your data which has been collected about you be destroyed. If new information relating to the study becomes available, this information will be provided to you.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, you may contact the study investigator, Courtney Brown, MSN, CRNA at (336) 716-1415 or (336) 577-2874 (after hours).

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant at Wake Forest Baptist Health, you should contact the Chairman of the IRB at (336) 716-4542 or Eric Allen of the Office of Research and Compliance at the University of North Carolina at Greensboro at (855)-251-2351. If you have a question about your rights as a research participant at Forsyth Medical Center, you

should contact the Director of Nursing Research Daria Kring at (336)-718-2120 or Eric Allen of the Office of Research and Compliance at the University of North Carolina at Greensboro at (855)-251-2351. Medical Center, You will be given a copy of this signed consent form.

Signatures

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

_____
Subject Name (Printed)

_____ _____
Subject Signature Date

_____ _____
Person Obtaining Consent Date

APPENDIX K

DATA COLLECTION TOOL

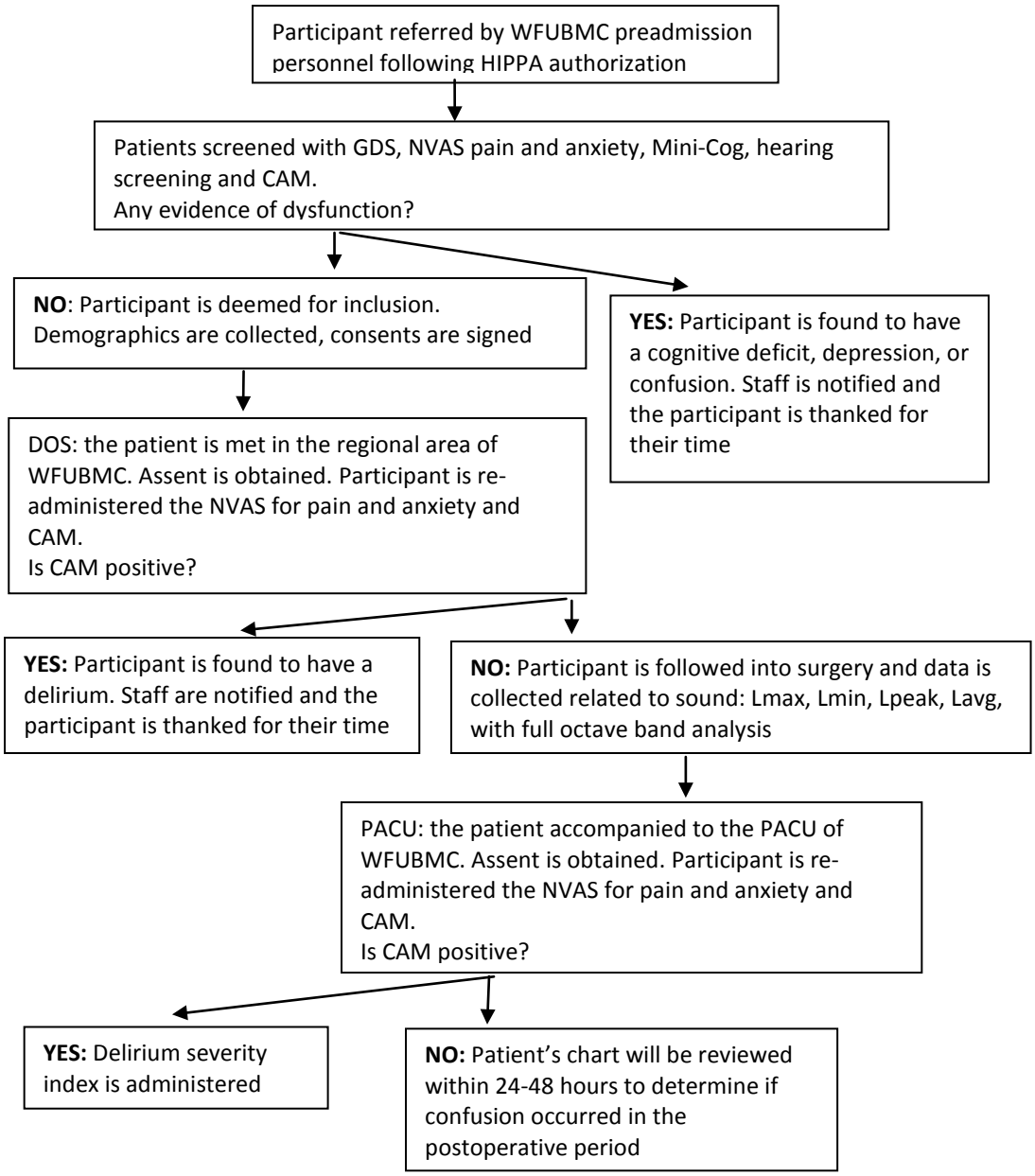
Day of Surgery

RAAPM	PACU
1. Time met PREOP:_____ 2. Assent given: o Yes o No 3. Time tests administered:_____ 4. Results of NVAS anxiety:_____ 5. Results of NVAS pain:_____ 6. Results of CAM:_____ 7. Time entered OR:_____ 8. Time SAB:_____ 9. Time left OR:_____	10. Time entered PACU:_____ 11. Assent given in PACU: o Yes o No 12. Time tests administered:_____ 13. Results of NVAS anxiety:_____ 14. Results of NVAS pain:_____ 15. Results of CAM:_____ 16. Results of DI:_____ 17. Time discharged to nursing unit:_____

18. 72 hour chart review (Date/time):_____
    Evidence of delirium:_____
    DI:_____

APPENDIX L

PILOT PROTOCOL



APPENDIX M

STUDY PROTOCOL