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Predicting Arterial Oxygen Desaturation Events Via Patient Journal and Pulse Oximetry Data in Postoperative Ambulatory Surgery Patients

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A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University

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Abstract

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Associations between patient and procedural factors on the nature and quality of the immediate in-home recovery from anesthesia following ambulatory orthopedic surgery are unknown. Further, there is a paucity of outcomes research quantitatively categorizing in-home patient recovery and safety following discharge from same-day orthopedic procedures. Tools are available, however, to shed light on outcomes in this population, and integration of such available measures is critical.

Ambulatory orthopedic surgery is a burgeoning specialty, with growth expected over the foreseeable future. The expected increased patient caseload subsequent to implementation of the Affordable Care Act and aging Baby Boom generation suggests greater morbidity and mortality is on the horizon unless aggressive measures are taken at mitigating risk. Similarly, as the

obesity epidemic expands, obesity-related comorbid conditions including obstructive sleep apnea (OSA) are likely to grow.

The purpose of this research was to explore the relationship between ambulatory orthopedic patient-reported activities (quality of life metrics) and diagnostic factors (physical and perioperative care data) in the immediate postoperative period that are predictive of arterial oxygen desaturation. Data was obtained using a novel patient journal exploring sleep, pain, nausea, tobacco use, alcohol use, and appetite in conjunction with a valid and reliable portable, wrist-worn pulse oximeter. Additional assessment data was taken from the preanesthetic assessment. All participants were scored according to the STOP-Bang questionnaire, an accepted survey of OSA risk.

Patients were recruited from a busy metropolitan ambulatory surgery center in Richmond, Virginia that sees approximately 500 cases monthly, and a 309-bed tertiary care hospital in West Burlington, Iowa. The target sample included 52 individual patients with data collected over the first two post-operative nights following discharge. Two patients were excluded.

Negative binomial regression, $\log_{10}$ transformation, and least-squares regression examined the relationships the STOP-Bang questionnaire, quality of life data, and physical perioperative data had on postoperative desaturation events. Results suggested the STOP-Bang score predicted desaturation events and that age and BMI were significant individual predictors. Opiate pain medication treatment, a happy mood, and home CPAP use were associated with decreased events.

This study provided a unique perspective in patient safety research, relating human behaviors and experiences with postoperative oxygen desaturation. Future research projects

aligned with postoperative monitoring, pulse oximetry, patient safety, and obstructive sleep apnea are potential following the findings of this study.

Chapter 1 – Introduction

Overview

The purpose of this research was to explore the relationship between ambulatory orthopedic patient-reported activities (quality of life metrics) and diagnostic factors (physical and perioperative care data) in the immediate post-operative period that are predictive of arterial oxygen desaturation. Data obtained from a novel patient journal completed during the first 48 hours following discharge from ambulatory orthopedic surgical intervention was used in concert with physiologic and diagnostic data obtained from the preoperative anesthesia history and physical evaluation to determine the combination of factors placing a patient at risk for arterial oxygen desaturation evidenced by postoperative pulse oximetry thresholds of <90% and <88%. The theoretical framework used for this research is novel and based on Avedis Donabedian's structure-process-outcomes theory of quality. The results of this study address the paucity of evidence in what happens to ambulatory orthopedic patients following discharge from surgery and lays the foundation for improved patient safety, practice, and discharge criteria for this burgeoning surgical specialty.

Chapter 1 introduces the problem, its significance, and current gaps in the literature. This is followed by a discussion of the need for aggressive identification of patients and risk factors in the postoperative period, a summary of the purpose for the research, and an introduction of the

theoretical framework developed for the purpose of this study. Finally, the data sources will be introduced.

Background

What happens to same-day orthopedic surgical patients after discharge? Moreover, are there significant changes in the respiratory status of the same-day orthopedic surgical patient that are unknown and go undetected or untreated? These questions are largely unanswered in anesthesia research; providers simply do not know what occurs in the first 48 hours subsequent to same-day (ambulatory) orthopedic surgery. Specific identifiable factors inherent in and unique to each patient that contribute to postoperative deterioration are also poorly understood, especially following discharge from same-day orthopedic surgery. Intensive risk stratification is necessary for patients undergoing same-day orthopedic surgery. These measures include a comprehensive preoperative anesthesia history and physical of all major organ systems. Standardized anesthesia preoperative evaluations include cardiovascular risk factors (heart failure, coronary disease, rhythm disturbances), respiratory morbidities (including OSA diagnosis and smoking history), conditions of the gastrointestinal track, neurologic/psychiatric conditions, metabolic diseases (obesity, diabetes mellitus), musculoskeletal conditions, and renal disease.

As of 2018, orthopedic surgery is one of the highest volume specialties in America. A 2005 survey of all surgeries performed in the U.S. reported over 63% of surgical procedures did not require overnight hospitalization (Russo, Elixhauser, Steiner, & Wier, 2010). There are a total of 5,600 ambulatory surgery visits per 100,000 people compared to 4,100 inpatient surgical visits per 100,000 people annually (Russo et al., 2010). The Healthcare Cost and Utilization

Project (HCUP) notes that four of the highest volume outpatient surgical procedures are orthopedic (Russo et al., 2010).

As the obesity epidemic continues its burgeoning pace, the incidence and prevalence of OSA is also expected to rise (Chau, Mokhlesi, & Chung, 2013). Evidence of the in-hospital management and monitoring of obstructive sleep apnea is well-reported, though literature describing post-discharge monitoring and follow-up is sparse. Pulse oximetry, the "gold standard" of monitoring the oxygenation status of patients in the inpatient environment, has demonstrated a reduction in rescue events and intensive care unit (ICU) transfers in the post-anesthesia care setting (Taenzer, Pyke, McGrath, & Blike, 2010). Further, evidence suggests home pulse oximetry in surgical patients is sensitive and specific for detecting sleep disordered breathing, including OSA (Chung et al., 2012).

Obstructive sleep apnea (OSA) is the most prevalent sleep disorder afflicting the American adult population; up to 11.4% of men and 4.7% of women have moderately severe OSA, and 80%-90% of them are undiagnosed (University of California, San Diego, 2011; Stearns & Stierer, 2007), despite rapid and reliable diagnosis using a preoperative STOP-Bang OSA questionnaire. As more Americans living with obstructive sleep apnea (OSA) receive ambulatory orthopedic surgery, the likelihood of increased postoperative morbidity and mortality is real. Additional risks in the OSA patient population are myriad; cardiopulmonary, metabolic, and psychological complications are the major risk considerations published in the literature ("Practice guidelines," 2014). Correlating post-operative oxygen desaturation using pulse oximetry with patient-reported experiences offers a novel means of discerning which patient antecedents and contributors place patients at risk after discharge home. Pulse oximetry use in the patient's home during sleep demonstrates both sensitive and specific diagnostic capabilities

for OSA and oxygen desaturation incidence and prevalence (Chung et al., 2012). The long-term goal of this research is improvement in postoperative orthopedic surgical patient safety through examining the relationship of: patient-related characteristics; physiologic, surgical, and anesthetic antecedents; and postoperative pulse oximetry.

Purpose of the Study

The purpose of this research was to explore the relationship between ambulatory orthopedic patient-reported activities (quality of life metrics) and diagnostic factors (physical and perioperative care data) in the immediate postoperative period that are predictive of arterial oxygen desaturation. Results of this study are intended to fill gaps in the domains of anesthesia patient outcomes, quality, and safety. The following specific aims, objectives, and hypotheses support this purpose:

Specific Aim 1: Explore the incidence and characteristics of arterial hemoglobin oxygen desaturation events in a postoperative ambulatory orthopedic surgery patient population sample across STOP-Bang scores.

Objective 1: To identify trends in postoperative desaturation events by using data obtained from a portable in-home pulse oximeter

Hypothesis 1 (H_1): Postoperative arterial hemoglobin oxygen desaturation events occur in ambulatory orthopedic surgery patients in positive correlation to STOP-Bang scores.

Specific Aim 2: Identify quality of life and physical/perioperative metrics predictive of postoperative arterial hemoglobin oxygen desaturation events.

Objective 2: To classify journal and assessment data predictive of postoperative desaturation events

Hypothesis 2 (H_2): There are quality of life and physical/perioperative data predictive of postoperative arterial oxygen hemoglobin desaturation events at mild (SpO_2 <90%) and critical (SpO_2 <88%) thresholds.

Specific Aim 3: Investigate the relationship of baseline (basal) arterial hemoglobin oxygen saturation in predicting severe postoperative desaturation events.

Objective 3: To determine if postoperative in-home basal arterial hemoglobin oxygen saturation levels are predictive of desaturation events at the SpO_2 <88% threshold

Hypothesis 3 (H_3): Basal arterial hemoglobin oxygen saturation will negatively predict postoperative desaturation events at the SpO_2 <88% threshold.

Post-discharge, patients resume many of their normal activities of daily living; the interaction of these functions and how they impact their postoperative safety is poorly understood. Patients will self-report their experiences in a form-based journal for the first 48 hours following surgery, including: sleep quality and duration; mood; nausea and pain (and measures taken to provide relief); and alcohol and nicotine use. Correlating these data with stored pulse oximetry readings taken during sleep from a wrist worn oximeter provides associations identifiable for risk mitigation in anesthesia care. It is hypothesized that specific quality of life experiences will positively correlate with post-operative pulse oximetry desaturation, including: alcohol ingestion, nicotine use, antiemetics, narcotic analgesics, and increasing sleep duration or poor sleep quality.

Evidence suggests many predisposing conditions placing patients at higher risk for development of OSA and postoperative desaturation, though their interrelatedness and additive risk effects are poorly understood. These include smoking, alcohol use, obesity, and post-operative narcotic use (Bailey, 1996; Chau et al., 2013; Kim et al., 2012; Lin, Li, & Zhang, 2012; Peppard, Austin, & Brown, 2007; Ramachandran, 2013; Tsutsumi, Miyazaki, Itasaka, & Togawa, 2000; Wetter, Young, Badr, & Palta, 1994; Wolfson, Wong, Veloso, & Wu, 2007). Additional data pulled from a preoperative anesthesia history and physical, including height, weight, standardized physical status, anesthetic modality, and standardized OSA risk classification, offer added facets for consideration. Examining these multifactorial diagnostic characteristics in concert with quality of life experiences support the second specific aim.

Understanding potential contributors to OSA diagnosis is key. Linking comorbid and diagnostic conditions such as gender, body mass index (BMI), OSA diagnosis, American Society of Anesthesiologists (ASA) risk classification, and anesthesia modality with quality of life journal data, and further correlating it with post-operative pulse oximetry data obtained following discharge provides greater depth in determining risk for arterial oxygen desaturation in the first 48 hours after surgery.

Significance of the Study

Though studies exist demonstrating respiratory deterioration in the home following ambulatory surgery (Bowdle, 2004), and beyond consideration of patient history and physical data, no evidence has compared the aggregate effects patient comorbidities and patient activities and experiences have on postoperative arterial oxygen desaturation through quantitative and qualitative analyses. Postoperative symptoms are highly variable and subjective and often include pain, nausea/vomiting, drowsiness, headache, and fever (Chung, Un, & Su, 1996), which

often require pharmacologic treatment. Medications such as narcotic analgesics and antiemetics used to treat postoperative sequelae each carry their own risks, potentially exacerbating postoperative respiratory deterioration risk in both obstructive sleep apnea (OSA)-identified and non OSA-identified populations. These include respiratory depression and increased episodes of apnea and hypoventilation (Bailey, 1996; Lockhart et al., 2013; Momeni, Crucittim, & De Kock, 2006; Yadeau, Liu, Rade, Marcello, & Liguori, 2011).

Clear guidelines for discharge from an inpatient, monitored setting to the unmonitored home environment are nebulous and inconclusive for OSA patients ("Practice guidelines," 2014). Indeed, respiratory deterioration resulting from obstructive sleep apnea is cited as a major antecedent for unanticipated hospital readmission following outpatient surgery (Sabers, Plevak, Schroeder, & Warner, 2003). Further, patients without identifiable risk factors for sleep apnea are also at risk following discharge (Morris et al., 1988).

As patients with increasing complexity and comorbidities seek and receive same-day orthopedic surgical services, aggressive measures to improve anesthesia safety throughout the care continuum must accommodate this flux. This study considered both quality of life and pulse oximeter indicated factors following discharge from same-day orthopedic surgery and drew statistically supported conclusions of patient factors that may collectively indicate a higher risk of respiratory desaturation in the post-operative/post-discharge period. The intent was to produce a study that bridges the gaps in device-reported and quality of life data so that future consideration for discharge home and in-home monitoring following ambulatory surgery will be evidence-supported. Ultimately, combinations of risk factors identified in this research will be clinically useful for flagging patients who will require additional respiratory monitoring in the immediate post-operative recovery period.

Though much research has been devoted to anesthesia outcomes (morbidity and mortality) related to OSA, there is a lack of research describing patient-centered experiences and characteristics (quality of life data) as they relate to OSA following orthopedic surgery, specifically, how the patient slept, his or her pain rating, the measures he or she took to alleviate pain, what/how much he or she drank/ate/smoked, whether a nerve catheter was placed, how many narcotics were taken, and how he or she felt related to mood. Though each factor seems innocuous singly, there may be a set of factors that predispose a patient to postoperative hypoventilation or apnea.

There are no exploratory studies correlating qualitative and quantitative metrics for postoperative ambulatory surgery orthopedic patients. The Anesthesia Patient Safety Foundation (APSF) has led the call for further scholarly insight, stating that postoperative respiratory depression "remains a serious patient safety risk that continues to be associated with significant morbidity and mortality" (Stoelting & Overdyk, 2011). The APSF has also indicated a need for increased postoperative oxygen saturation monitoring (pulse oximetry), a universally available instrument that has a long-established record for sensitivity and specificity in detecting hypoxia and hypoventilatory/apnea states. Correlating patient factors described earlier with pulse oximetry measurements could yield life-saving and disaster-averting data necessary for risk aversion and patient outcome improvement. This seminal study considered the patient as a whole, examining factors that collectively suggested an increased risk of arterial hemoglobin oxygen desaturation states in the home following discharge. The theoretical framework presented in the next section melds current available theory and research with the intent of the study: consider the patient as a whole and determine which factors or combinations of factors may negatively affect outcomes. This research holds the potential of determining holistic risk

factors warranting pause of the anesthesia provider prior to discharge home from ambulatory surgery.

Introduction to the Theoretical Framework

Avedis Donabedian's structure-process-outcomes theory of quality provides the theoretical framework for this research. Donabedian's theory posited that quality is based on a continuum of the constructs of structures, processes, and resulting outcomes; that is, the structures of care areas affect the processes of care, which, in turn, affect outcomes as shown in Figure 1 (Donabedian, 2005).

Figure 1. Donabedian's structure-process-outcomes theory.

Though "quality" is often described in terms of cost savings or length of stay in the hospital, Donabedian (2005) links quality indicators to "recovery, restoration of function and of survival," each of which bears significance with this study's outcomes-based interest in postoperative oxygen saturation (p. 692-693). Donabedian also described the importance of structure in quality of care. The structure of care broadly applies to the physical infrastructure and setting in which care is delivered, and is the basic, foundational level of quality (Donabedian, 1988). For the purpose of this research, the home environment where the patient is discharged to represents the structure of care. Linking structure and outcomes is the process by which care is delivered. Donabedian (1988) described process as what is being done to and what the patient

does for his or her own care. For this research, process describes both patient-reported quality of life characteristics reported in the participant journal (what the patient does) and care delivered to the patient (i.e., surgery). An in-depth discussion of Donabedian's theory, constructs, and application to this study occurs in Chapter 3.

Summary of Data Sources

This study used primary data obtained from three sources. The first source consisted of diagnostic data obtained from the preoperative anesthesia history and physical (noted as physical/perioperative data henceforth). This included an assessment of major organ systems and preoperative diagnoses and comorbidities. Next, a quality of life patient journal of experiences and activities completed on the first- and second-nights following surgery provided subjective data pertinent to this research. These data encompass the patient's reported sleep, mood, pain, and nausea experiences, as well as activities inclusive of smoking, alcohol ingestion, and appetite. Lastly, pulse oximetry data captured using a portable pulse oximeter provides a comprehensive series of arterial hemoglobin oxygen saturation data points for consideration as dependent variables in the analysis.

Chapter Summary and Overview of Remaining Chapters

This chapter has demonstrated the need for aggressive postoperative risk mitigation in the ambulatory orthopedic patient population. The increase in ambulatory surgical cases, together with an anticipated influx of patients living with insidious OSA, point to the real potential for greater morbidity and mortality in the postoperative, post-discharge phase of anesthesia and surgery. Also introduced was Donabedian's theoretical framework of structure-process-outcome.

Chapter 2 provides a comprehensive review of the literature, demonstrating a preponderance of research looking at parts of the postoperative patient's experience and outcomes. Comprehensive evidence supporting the use of postoperative pulse oximetry, both in the hospital and home environments, will be demonstrated. Last, Chapter 2 concludes with a synthesis of the gaps in knowledge warranting this research endeavor, illustrating the need for a comprehensive understanding of the postoperative patient as a whole of many lesser parts. Chapter 3 describes the study methodology, including: study design; data sources and instruments; variables and measures; reliability and validity; and statistical analysis. Statistical results, interpretations, and implications of the results are described in Chapters 4 and 5, respectively. This dissertation concludes with supporting appendices, references, and vita.

Chapter 2 – Literature Review

Introduction

This section will review the current growth in ambulatory orthopedic surgery, and the move from inpatient surgery to surgery occurring on a same-day, outpatient basis. Additionally, obstructive sleep apnea (OSA), the discriminating factor dividing this study's sample, will be introduced. Discussion of OSA prevalence and evidence of OSA-related morbidity and mortality will be presented. Additional patient factors used as metrics for this research, such as tobacco and alcohol use, pain, and nausea, will add depth to the discussion, demonstrating their utility in the patient journal instrument. The utility and use of pulse oximetry will be demonstrated, especially in the home environment for detection of OSA. Donabedian's theory of structure-process-outcome for measuring quality is expanded upon, with applications of his theory to this research and descriptions of applicable constructs.

Growing Demand for Ambulatory Orthopedic Surgery

As of 2018, ambulatory (outpatient) orthopedic surgery exceeds inpatient orthopedic surgery, signaling a move of postoperative recovery from within the hospital environment into the home environment. Ambulatory surgical procedures outnumber inpatient surgical procedures by 130% (Russo et al., 2010). Koenig, Doherty, Dreyfus, and Xanthopoulos (2009) reported that, in 2006, there were 1.7 ambulatory surgery centers (ASCs) per 100,000 people compared to 1.2 ASCs per 100,000 people in 2000, demonstrating substantial growth. The growth in ASC surgeries parallels a shift from inpatient procedures to outpatient procedures in

hospitals. Koenig et al. (2009) also noted that the American health care system has seen a 30% expansion in ambulatory surgical services across both hospital and ASC institutions, reflective of a growing patient population. Similarly, there has been a 70% growth in ambulatory surgery services per Medicare beneficiary between 2000-2007, which is attributable to both ASC market capture from hospitals and the growing size of the Baby Boomer generation (Koenig et al., 2009).

The Obstructive Sleep Apnea Epidemic

Obstructive sleep apnea (OSA) is the most common sleep disorder affecting American adult men and women (Raveendran & Chung, 2014). OSA is characterized by repetitive upper airway obstruction during periods of sleep, often with resultant reduction in hemoglobin oxygen saturation. Epidemiological prevalence is varied in the literature. A seminal study conducted in 1993 asserted 9% of women and 24% of men demonstrated strong predictors for obstructive sleep apnea as demonstrated by polysomnography, the gold standard of OSA diagnosis, albeit expensive and time consuming (Young et al., 1993). The researchers also noted that 2% of women and 4% of men met minimal diagnostic criteria for OSA diagnosis. Similarly, Davies and Stradling (1996) estimated a sleep apnea prevalence of between 1% and 5% of men, with women slightly less. Contemporary research supports historic references and the belief the OSA epidemic is growing; between 2% and 10% of adults are living with obstructive sleep apnea (Alattar, Harrington, Mitchell, & Sloane, 2007; Durán, Esnaola, Rubio, & Iztueta, 2001; Léger, Poursain, Neubauer, & Uchiyama, 2008; Punjabi, 2008).

The determination of true community prevalence of OSA is difficult, likely due to differences in diagnostic procedures and capture of suspected vulnerable individuals (Davies & Stradling, 1996). Many individuals living with OSA are unaware of their condition. Young, Evans, Finn, and Palta (1997) linked questionnaire data with polysomnography data among

1,090 adults aged 30-60 years. Their results concluded 82% of men and 93% of women with moderate or severe OSA were undiagnosed, despite having access to sleep disorder clinics. They also concluded that subclinical OSA, that is, OSA without gross symptomology, may be present in 20%-30% of the middle-aged adult population.

Obstructive Sleep Apnea: Postoperative Risk

A diagnosis of obstructive sleep apnea constitutes increased postoperative morbidity, mortality, and unanticipated hospital admission following surgery. In hospital, the incidence of postoperative hemoglobin desaturation, respiratory failure, cardiac events, and ICU transfers was higher in patients with OSA (Kaw et al., 2012). The effects of OSA on major organ systems are diverse, placing patient at multifaceted risk in the postoperative period (Stearns & Stierer, 2007). Ramachandran (2013) reported patients diagnosed with OSA at risk for cardiac conduction abnormalities (including heart rate variability), sympathetic activation, systemic inflammation, metabolic dysfunction, and post-operative respiratory depression. He also noted inexplicable chemosensitivity changes along pain pathways. This is supported by the research of Blake, Yew, Donnan, and Williams (2009), who noted patients with OSA received an average of three times the dose of morphine than a non-OSA patient cohort. Khalid, Roehrs, Hudgel, and Roth (2011) agreed; they published evidence that OSA patients are prone to chronic pain states, often resulting in higher provider-prescribed opiate dosages. Patients receiving opiates in the postoperative period experience greater centrally mediated apneas than patients who do not receive opiates, placing OSA-risk patients at a distinct morbidity in the postoperative period (Blake et al., 2009).

Airway changes following anesthesia also place patients with OSA at risk in the postoperative period. In a prospective cohort study recently published, both nonobstructive sleep

apnea (n = 20) and obstructive sleep apnea (n = 38), patients suffered sleep disturbance particularly on postoperative night 1 and significantly increased frequencies of sleep-disordered breathing particularly on postoperative night 3 (Frances Chung, Liao, Yegneswaran, Shapiro, & Kang, 2014). The authors contend that following anesthesia, sleep architecture of the airway changes in both OSA-risk and non-risk individuals, placing patients with OSA at a distinct risk to respiratory compromise.

Despite compelling evidence that obstructive sleep apnea places patients at a direct risk of respiratory compromise in the postoperative period, the evidence is not unanimous. In a retrospective analysis of polysomnographically OSA-confirmed patients compared to control (non-OSA) patients, there was no difference in the rate of unplanned hospitalizations or adverse events following ambulatory surgery (Sabers et al., 2003). The authors also discovered unplanned admissions were generally unrelated to cardiac or respiratory compromise. The study was limited, however, only to patients with OSA confirmed by polysomnography and not by other accepted methods and did not include overnight monitoring for hypoxic episodes (thereby using the endpoint of hospital readmission only). Liu et al. (2010) utilized a retrospective chart review of patients with diagnosed OSA to ascertain the risk of postoperative respiratory complications following ambulatory orthopedic surgery. They were unable to demonstrate increased risk of adverse outcomes or unplanned hospital admissions among the sample subset that received regional anesthesia, though patients with concomitant chronic obstructive pulmonary disease (COPD) and upper extremity surgery demonstrated increased risk. The authors noted incidences of hypoxemia ranged 22% to 78% and varied among combinations of risk factors. This supports the need for additional insight into the combined effects of multiple risk factors and patient antecedents for determination of postoperative respiratory risk.

Obstructive Sleep Apnea Diagnosis

Obstructive sleep apnea (OSA) is a disorder characterized by hypoventilatory or apneic episodes during sleep, often hundreds of times throughout the night (Spicuzza, Caruso, & Di Maria, 2015). Respiratory inductive polysomnography (PSG) remains the gold standard for conformational diagnosis of obstructive sleep apnea (Badran, Ayas, & Laher, 2014; Blake, Chia, Donnan, & Williams, 2008; Chau et al., 2013; F Chung et al., 2012; Frances Chung et al., 2012; Farney, Snow, & Walker, 2011; Kaw et al., 2012; Mannarino, Di Filippo, & Pirro, 2012; C. A. Nigro, Aimaretti, Gonzalez, & Rhodius, 2008; Peppard et al., 2007; Porhomayon, Nader, Leissner, & El-Solh, 2014; Qaseem et al., 2014; Sabers et al., 2003; Vana, Silva, & Goldberg, 2013; Wetter et al., 1994). Other less invasive, costly, or time-consuming tools assessing OSA risk are available with impressive sensitivity and specificity.

The STOP-Bang questionnaire, a combination of the STOP questionnaire and the Berlin questionnaire (validated for primary care use), assesses a patient's risk using the following metrics: snoring; tiredness; observed apnea; presence of hypertension; body mass index (BMI) greater than 35 kg/m^2; age older than 50 years; neck circumference greater than 40 centimeters; and gender of male. Answering 'yes' to three or more items indicates a higher likelihood of OSA diagnosis, with sensitivity reported between 76% and 96% (Chung et al., 2008). A prospective cohort study of 47 patients were administered PSG and both the Epworth Sleepiness Scale (ESS) and STOP-Bang questionnaires to explore sensitivity and specificity of the two latter instruments compared to PSG (Vana et al., 2013). The results suggested that the STOP-Bang 30 (BMI cutoff of 30 kg/m^2) correctly identified more patients with OSA and sleep disordered breathing than the ESS alone. Silva, Vana, Goodwin, Sherrill, & Quan (2011) support the sensitivity of the STOP-Bang questionnaire. A total of 4,770 patients with baseline

PSGs completed the STOP-Bang questionnaire, examining its sensitivity for detecting moderate and severe obstructive sleep apnea. Sensitivity for detecting moderate-to-severe OSA was found to be 87% and 70.4% for severe OSA.

Though the STOP-Bang questionnaire is a sensitive predictor in detecting and categorizing OSA severity (Farney et al., 2011), its specificity is not as rigorous in ruling out other sleep disordered breathing morbidities. Chung et al. (2008) cite specificity between 13% and 54%, potentially risking false positives. Silva, Vana, Goodwin, Sherrill, and Quan (2011) contended, however, that the STOP-Bang questionnaire's high sensitivity and modest specificity demonstrates utility in avoiding missing cases that could result in morbidity and mortality. The STOP-Bang questionnaire's inability to determine mortality likelihood over time is also reported. Lockhart et al. (2013) were unable to prove increased 30-day and 1-year mortality after a positive screen for OSA by STOP-Bang questionnaire following surgical intervention. However, the authors noted improved specificity of the STOP-Bang questionnaire (with the added risk factors of BMI, age, neck circumference, and gender) over the STOP questionnaire (omitting the aforementioned risk factors) for detecting certain perioperative complications and intermediate postoperative morbidity.

Quality of Life Factors: Alcohol Use

Alcohol ingestion is a well-researched patient-controlled aggravator of obstructive sleep apnea. It is estimated that as many as 17% of Americans living with OSA are considered heavy alcohol users or abusers (Chung et al., 2011). Anatomically, it is thought that alcohol exacerbates pharyngeal collapse through interfering with and inhibiting upper airway motor output (Punjabi, 2008). Tsutsumi et al. (2000) conducted a study of 37 men with confirmed OSA and aged an average of 46.9 years where the participants ingested ethanol and slept.

Seventy-six percent of the participants demonstrated significant arterial oxygen desaturation detected by pulse oximetry. Though the authors were not able to demonstrate a statistically significant relationship between quantity of alcohol and hemoglobin desaturation, the data suggested alcohol ingestion as a predisposing factor to respiratory depression during sleep. A similar study of men and women using polysomnography (PSG) and alcohol-use questionnaire resulted that, for each additional alcoholic drink consumed, men experience a 25% greater odds of mild or worse sleep disordered breathing (OR = 1.25, 95% CI = 1.07-1.46, p = 0.006) (Peppard et al., 2007). Among women, mild to moderate alcohol ingestion did not demonstrate significant risk exacerbation, reinforcing that male gender is a strong predictor of OSA. Despite convincing evidence linking alcohol consumption and OSA, discrepancies exist, which can be attributed to unreliable instruments measuring alcohol use (e.g., quantity, frequency, alcohol dose per volume) (Lindberg & Gislason, 2000).

Quality of Life Factors: Tobacco Use

Smoking tobacco products, including cigarettes, cigars, and pipes, proves to be a multi-faceted risk factor for obstructive sleep apnea, especially within the perioperative period. First, it is thought that tobacco use potentiates uvular collapse through histological changes mediated by substance P and calcitonin gene-related peptide (CGRP), thereby promoting neurogenic upper airway inflammation and airway collapse (Kim et al., 2012). These changes are demonstrated in both chronic and casual smokers; even secondhand smoke exposure has demonstrated inflammatory changes in the mucociliary clearance of the upper airways (Bascom, Kesavanathan, Fitzgerald, Cheng, & Swift, 1995). Additionally, smoking causes hyperplastic endothelial changes in the nasal mucosa, impairing nasal ciliary function, and promoting nasal mucosal

obstruction- hallmarks of obstructive sleep apnea and heavy snoring (Cohen et al., 2009; Hadar, Yaniv, Shvili, Koren, & Shvero, 2009; Young, Finn, & Kim, 1997).

The direct effect of nicotine on muscles of the upper airway is unclear; it is thought that nicotine may, at first, stimulate the genioglossus and respiratory muscles, but with a subsequent rebound effect during nicotine withdrawal or periods of tobacco abstention (Lin et al., 2012). The stimulant effects and resulting sleeplessness of chronic nicotine use suggest a contributory relationship to daytime sleepiness described by smoking OSA patients, aggravating frequencies of overnight obstructive episodes (Wetter et al., 1994). Additional research clarifying the direct effects of nicotine and nicotine withdrawal on the upper airway and mechanics of obstructive sleep apnea is warranted.

Smokers are more prone to hypoxia during both periods of wakefulness and sleep (Bonsignore et al., 2006). Hypoxia results in a "shift to the left" in the oxyhemoglobin dissociation curve (demonstrating increased oxygen affinity of hemoglobin) due to increases in carboxyhemoglobin and decreased affinity for oxygen binding with hemoglobin (Casasola et al., 2002). Human and animal models confirm that smoking reduces central hypoxia sensitivity, reduces arousal reflexes, and may negatively impact the automatic ability to regain respiratory drive during prolonged periods of apnea (Fewell et al., 1998; Hafström, Milerad, & Sundell, 2002; Lewis & Bosque, 1995). This vicious cycle in the smoking OSA patient is confounded by airways already prone to collapse and obstruction. Interestingly, Wetter and colleagues (1994) concluded that, although active smoking aggravates obstructive sleep apnea, a history of smoking does not place an individual at increased risk for obstructive sleep apnea.

Quality of Life Factors: Pain and Analgesia

Khalid and colleagues (2011) described that patients diagnosed with obstructive sleep apnea are at a higher likelihood of living with chronic pain and greater pain sensitivity. The precise mechanism responsible for this relationship is unclear, but pain-induced sleeplessness is evidence supported (Khalid et al., 2011). Pain is one of the most common symptoms following surgery, placing the OSA patient at a higher likelihood of nighttime sleeplessness, daytime somnolence, and receiving opiate analgesics (Chung et al., 1996). Opioid analgesics are known to depress respiratory drive via opioid receptors in the brainstem, leading to direct inhibition of the ventral and dorsal respiratory control centers (Bailey, 1996). Opioid inhibition of the respiratory control center inhibits motor signals to the diaphragm, thereby potentiating apneic states. Further, Bailey (1996) describes chemoreceptor inhibition in the presence of opioids, reducing medullary response to rising dissolved arterial carbon dioxide ($PaCO_2$) to trigger breathing. This cycle can prove disastrous in the OSA patient; during periods of obstruction and apnea, hypercapnia and hypoxia fail to trigger increased ventilatory drive, minute ventilation decreases, $PaCO_2$ increases, and carbon dioxide narcosis ensues (Bailey, 1996).

Post-operative opioid analgesic use in the OSA patient leads to increased respiratory depression, increased morbidity and mortality, and nausea and vomiting, among other adverse effects (Yadeau et al., 2011). Yadeau and colleagues (2011) found that high symptom-specific scores of opioid side effects (using the Opioid-Related Symptom Distress Scale, or ORSDS) were associated with clinically meaningful adverse events, including drowsiness. In some cases, relevant ORSDS scores were related to activity level, patient satisfaction, and nausea and vomiting measures. Based on responsiveness analysis, nausea and vomiting demonstrated the

highest likelihood in the postoperative period, which in an OSA patient, may lead to increased nighttime sleeplessness, daytime somnolence, and OSA symptom exacerbation.

Though accepted practice recommends minimizing postoperative use of opioids and in favor of non-opioid analgesics in OSA-diagnosed or suspected individuals, there is a lack of rigorous evidence to support this practice (Wolfson et al., 2007). Supporting the findings of Wolfson and colleagues, the American Society of Anesthesiologists' Practice Guidelines for the Perioperative Management of Patients with Obstructive Sleep Apnea (2014) notes little evidence comparing systemic versus regional analgesia modalities, despite recommended against routine systemic opioid administration. Further outcomes-based research in opioid and non-opioid analgesia in the OSA population is warranted.

Pulse Oximetry

Pulse oximetry-reported arterial hemoglobin oxygen saturation is the objective, quantitative outcome metric in this study. Pulse oximetry use is well-researched, and the literature demonstrates high reliability, validity, and sensitivity for detecting obstructive sleep apnea and apneic states. It is a mathematically derived assessment of the percent oxygen saturation of arterial hemoglobin. A classic study by Morris et al. (1988) used pulse oximetry for detection of hypoxic states ($SpO_2 < 90\%$) among 149 patients in the immediate postoperative phase of care. Both inpatient and outpatient strata were considered. Among inpatients, 14% (21) experienced periods of hypoxia during postoperative recovery. The outpatients fared better; just 1% (1) experienced hypoxia prior to discharge from recovery. Morris and colleagues (1988) discovered several patient factors associated with a significantly higher prevalence of hypoxemia, including: obesity (22%); body cavity surgical procedures (24%); age over 40 years (18%); American Society of Anesthesiologists physical status (I, 7%; II, 17%; III, 18%; IV, 100%);

duration of anesthesia longer than 90 minutes (18%); and intraoperative administration of greater than 1,500 ml of fluid (20%).

The ability of pulse oximetry to detect critical hemoglobin oxygen desaturation and avert respiratory collapse has been further demonstrated by a before-and-after concurrence study conducted by Taenzer et al. (2010). Here, a patient surveillance system utilizing wireless nursing notification of critical pulse oximetry-indicated hemoglobin oxygen desaturation was implemented, with the authors comparing pre- and post-implementation rescue events. Rescue events were defined as unanticipated transfers to the intensive care unit (ICU) or activation of a rapid response/Code Blue team. The experimental group with routine monitoring (an orthopedic surgical ward) was compared to two control groups without routine monitoring (urological/gynecological and vascular/general surgical wards). Rescue events decreased from 3.4 (CI 1.89–4.85) to 1.2 (CI 0.53–1.88) per 1,000 patient discharges and intensive care unit transfers from 5.6 (CI 3.7–7.4) to 2.9 (CI 1.4–4.3) per 1,000 patient days when a patient surveillance system using pulse oximetry was employed, whereas the comparison units had no change. The results concluded that patient surveillance monitoring results in a reduced need for rescues and intensive care unit transfers.

This study utilized pulse oximetry in the home post-discharge from ambulatory orthopedic surgery; therefore, it was critical to appraise evidence for pulse oximeter use outside of the inpatient setting. Bowdle (2004) examined nocturnal breathing before and after ambulatory surgery to determine the extent of nocturnal arterial oxygen desaturation and airway obstruction. Forty-five patients aged 10-79 years receiving various ambulatory surgical interventions were included in the study. Recordings both before and after surgery occurred within the participant's home and comprised of an airflow sensor and pulse oximeter. A subset

of nine patients experienced airflow disturbances and/or greater than 1% of pulse oximetry recording time at a hemoglobin oxygen saturation less than 90% on at least one study night, suggestive of obstructive or apneic states. The subset demonstrated greater airflow disturbance and/or oxygen desaturation on postoperative nights compared to the preoperative control (p = 0.042 and p = 0.010, respectively). Interestingly, the median percentage of time with a hemoglobin oxygen saturation less than 90% was greater on the second postoperative night than the first postoperative night in the subset: 2.7% and 1.2%, respectively. This phenomenon has been confirmed in previous research and supports examining the first two postoperative nights in this study.

Other studies have examined the use, reliability, and validity of portable devices for detecting obstructive sleep apnea, supporting use in the home. A seminal study by Emsellem and colleagues (1990) compared the tentative diagnostic capacity of a portable monitor for detecting OSA and comparing it to polysomnography (PSG). The portable monitor included measurements for airflow, chest movement, cardiac rhythm, and pulse oximetry. With a sensitivity of 95% and specificity of 96%, the portable device demonstrated no significant difference in its diagnostic capacity for apneas and hypopneas with simultaneous PSG. Oxygen saturation readings between the two devices correlated well. The authors contend that, although in-laboratory PSG remains the gold standard, portable home monitors demonstrate high negative diagnostic capability (Emsellem et al., 1990). Redline, Tosteson, Boucher, and Millman later reproduced the study in 1991. Thirty-one heterogeneous patients were recruited. Validity of the portable monitor was established by comparisons of in-hospital PSG. Reproducibility of the portable monitor was assessed in two subsequent in-home measures. Redline and colleagues noted high agreement in the number of apnea/hypopnea events per hour of sleep (reported as

respiratory disturbance index, RDI) recorded by both devices (r = 0.96). Their findings led to the conclusion that portable, in-home monitoring demonstrates promising reliability and reproducibility for detecting obstructive sleep apnea when compared to PSG.

Modern pulse oximetry devices have improved upon technology used in the aforementioned classical studies. Newer, high-resolution pulse oximeters have replaced those used in seminal pulse oximetry research and have yielded exceptional results. Similar to the studies conducted by Emsellem et al. (1990) and Redline et al. (1991), Chung et al. (2012) compared a high-resolution wristwatch-style pulse oximeter with standard polysomnography among preoperative surgical patients. The prospective cohort study comprised 475 patients (217 male, 258 female) aged 49 to 71 years. Body mass index (BMI) of the sample ranged 24 to 38 kg/m^2. Patients received both polysomnographic evaluation and wore the portable pulse oximeter simultaneously. The pulse oximeter reported oxygen desaturation index (ODI), cumulative time percentage with SpO_2 less than 90% (CT90), and lowest/average SpO_2 readings. ODI was calculated automatically by the device and reflects the hourly average number of desaturation episodes (at least a 4% decrease in saturation from preceding 20-second average, lasting at least 10 seconds). Chung and colleagues found a high correlation between portable pulse oximeter-reported ODI and PSG metrics, suggesting good inter-instrument reliability, sensitivity, and specificity. ODI reliably predicted apnea-hypopnea indices recorded by polysomnography. The authors noted an oxygen desaturation index greater than 10 demonstrated the highest sensitivity (93%) and specificity (75%) for detecting moderate-to-severe obstructive sleep apnea with PSG confirmation.

Other wrist-worn pulse oximeters have been evaluated with similar reliability and validity. Nigro, Aimaretti, Gonzalez, and Rhodius (2008) evaluated the diagnostic accuracy of

the wristwatch-style Nonin WristOx™ Model 3100 pulse oximeter and nVision® 5.0 software, the predecessor device and software to this study's WristOx2™ Model 3150 pulse oximeter and nVision® 6.4, respectively. Much like studies described earlier, the control measurement was simultaneous polysomnography. Instead of calculating oxygen desaturation index (ODI), the nVision® software reported adjusted oxygen desaturation index (ADI), that is, the mean number of oxygen desaturation episodes per hour of recorded time at or greater than 2%, 3%, 4%, 5%, and 6% (ADI2, ADI3, and so on). Further, the software extracted the accumulated time at oxygen saturations less than 90% (AT90). The apnea/hypopnea index (AHI) was the comparison measurement computed by PSG. The severity of obstructive sleep apnea according to AHI is generally accepted as: slight, AHI≥5 to 15; moderate, AHI≥15 to 30; severe, AHI≥30 (Sala, Nigro, Rabec, Guardia, & Smurra, 2001). One hundred fifty-four sleep laboratory patients completed the study and were considered in the analysis. All patients were referred to the laboratory on suspicion of OSA. The results concluded that an ADI2 of less than 12.2 excluded OSA (defined as an AHI≥5 or AHI≥10) with a sensitivity of 100% and negative likelihood ratio of 0 in the WristOx™ 3100 with PSG control. A positive diagnosis (AHI≥15) was confirmed with an ADI3 greater than 32 at a specificity of 100%. Nigro and colleagues assert the portable pulse oximeter offers an alternative to costly PSG, though the need for additional research and replication in the home was addressed.

Pulse oximeter data capture and quality are affected by several factors. Averaging time, that is, the ability of the device to filter and average readings over prescribed time windows, is one mechanism modern pulse oximeters utilize to adjust data capture frequencies and data quality to optimize accuracy. The data storage rate, measured in Hertz (Hz) or cycles per second, is the frequency in which the device measures and records data. Both averaging time and data

storage rate affect pulse oximetry signals in measuring and recording SpO_2 (Nigro, Dibur, & Rhodius, 2011). Previous studies have demonstrated that adjusting the averaging times with the same pulse oximeter produces different results across measurements, impacting diagnostic capabilities (Davila et al., 2002; Farré et al., 1998). One study by Zafar et al. (2005) demonstrated that even using the same averaging time across different devices produced differing results. It can be inferred that inconsistencies across devices are related to manufacturer-related resolution differences. Controlled testing of data capture rates, data quality, and diagnostic capacity using polysomnography comparison offers an evidence-based solution to determine a device's resolution.

Nigro and colleagues (2011) examined whether the memory capacity and data capture rates of the WristOx™ Model 3100 affected its diagnostic accuracy for obstructive sleep apnea. Again, simultaneous PSG offered a reference control for determining accuracy. A total of 101 sleep laboratory patients participated in the study. Each pulse oximeter was set to one of three manufacturer-programmed recording settings: 0.25, 0.5, and 1 Hz. The nVision® software (version 5.1) calculated the adjusted oxygen desaturation index (ADI), which was determined as the mean number of oxygen desaturation episodes per hour recorded at ≥2, 3, and 4% of baseline SpO_2 (ADI2, 3, and 4). The PSG-determined respiratory disturbance index (RDI) was confirmatory for obstructive sleep apnea when ≥5. The results concluded no statistically significant differences in ADIs across the various data storage rates, confirming the device's reliability.

Basal arterial hemoglobin oxygen saturation is a measure of portable pulse oximeters that carries utility in this research. Rasmussen, Kjaer, Vogt, and Moller (2002) examined 20 participants at home and in-hospital prior to undergoing surgery. They found that preoperative,

in-hospital oxygen saturation values were reliable baseline predictors of at-home arterial hemoglobin oxygen saturation in the elderly. Additionally, a retrospective analysis of 100 participants with chronic obstructive pulmonary diseases showed a relationship between pre-exercise baseline arterial hemoglobin oxygen saturation and post-exercise hypoxemia, suggesting spot-checking pulse oximetry has predictive power in susceptible population samples (Knower, Dunagan, Adair, & Chin, 2001). Though meta-analysis shows continuous pulse oximetry reliably predicts postoperative respiratory depression compared to intermittent pulse oximetry checks (Lam et al., 2017), there is a paucity of research exploring if postoperative pulse oximetry basal spot-checks significantly predict desaturation events in the home. This study attempted to address such a gap.

Theory Application

Avedis Donabedian developed a theory of quality dependent on the linearity of structure, process, and outcomes. Though quality today often refers to the metrics of hospital length of stay or cost containment, Donabedian described quality in much broader terms. Simplistically, he stated quality is "a reflection of values and goals current in the medical care system and in the larger society of which it is a part" (Donabedian, 2005). He noted quality to have both "implicit" and "explicit" criteria. Implicit criteria of quality involve an expert knowing all particular details about a case and recreating the precise sequence of factors and events leading to an outcome so that "what did happen" and "what should happen" are reconciled (Donabedian, 1978). He asserted that such quality measurement is costly, time-consuming, and of questionable reliability given diverse provider-specific practices (Donabedian, 1978).

More broadly, explicit criteria generalize outcomes based on best practices across a healthcare profession (Donabedian, 1978). Such broad considerations apply along the care

continuum, from the moment the patient enters a health care facility, through the care process, the desired result or complication, and beyond. Indeed, Donabedian's theory of quality does not simply conclude at a particular endpoint (the outcome), rather feeds linearly; one outcome leads to another, and so on (Donabedian, 2005).

To arrive at a measurable endpoint, Donabedian describes three constructs of quality, each of which feeds into the next in a contributory manner. The first necessary component of quality measurement is the structure in which care is delivered. Donabedian describes structure as the setting in which care is delivered, inclusive of people, expertise, equipment, buildings, and financials (Donabedian, 1988). As the foundation for quality assessment, Donabedian noted that solely considering structure as a predictor of some outcome is impossible. Structure, he asserted, is the "blunt instrument" of an outcome, and its direct linearity and contribution to processes, though necessary, is likely weak and of little validity (Donabedian, 1988; Donabedian, 2005).

The next construct in Donabedian's theory is process, or the actual care delivered to the patient to produce some effect. Building on structure, process encompasses both what is done to the patient and what the patient does for him or herself (Donabedian, 1988). Though studying structure alone is of little utility, Donabedian described the ability to individually assess processes. Such activities as direct observation of practices, treatments, patient compliance, and behaviors are among several categories of process appraisal (Donabedian, 1978). Process and subsequent outcomes can be measured in the absence of structure considerations, as is the case in "trajectory" or "tracer" studies (Donabedian, 1978).

The final category in quality assessment is the outcome. Donabedian (1988) described the outcome as the effect of care delivered to an individual or a population. Morbidity, mortality,

disability, and longevity are several of the metrics used in measuring outcomes, among others (Donabedian, 1978). Donabedian stated that outcomes can either be predefined on the outset of quality research or without prior understanding or clear definition. He cautioned that the cause-and-effect relationship between processes and outcomes in quality research is not possible; the nuances of processes restrict quality studies to making associations rather than definitive conclusions (Donabedian, 1988).

Donabedian's theory applies for this dissertation. In describing the constructs of his theory, Donabedian notes structure, or the physical structures, as the foundation in the continuum of quality patient outcomes (Donabedian, 1988). Though it does not demonstrate reliability or validity when considered on its own, structure plays a key role in this study. For this research, participants were followed at home in the first 48 hours following ambulatory surgery. The home environment represents the primary structure construct in this dissertation. Since little is reported on at-home patient outcomes following surgery, the home as a construct of Donabedian's structure is a novel consideration.

Donabedian's process construct, which comprises the independent variables of this dissertation, provides the next level in this paper's theoretical framework continuum. Donabedian described process as having three potential measurable components: descriptive (something as it happened); prescriptive (something that should be done); and proscriptive (something that should be avoided) (Donabedian, 2003). The participant's quality of life experiences and the physical/perioperative factors represent this study's process constructs. The purvey of this research rests in descriptive processes; the data were gathered based on something that happened without predilection of whether it should or should not have occurred, the latter being beyond this dissertation's purpose.

Lastly, this dissertation presents pulse oximetry (i.e., arterial hemoglobin oxygen desaturation) as the outcomes construct. Donabedian's (1988) research initially focused on outcomes as a positive effect of quality and care and by recent research as the "gold standard" of quality patient outcomes assessment (Nicolescu, 2017). For this study, the outcome construct was open-ended. This is in line with Donabedian's assertion that processes can be descriptive, prescriptive, or proscriptive: just as a process can be what was done, what should be done, or what should not be done, so too can the outcome be a "positive" or "negative" patient outcome of these process construct. Figure 2 illustrates the theoretical framework used for this dissertation as it is adapted from Donabedian's structure-process-outcome of quality theory.

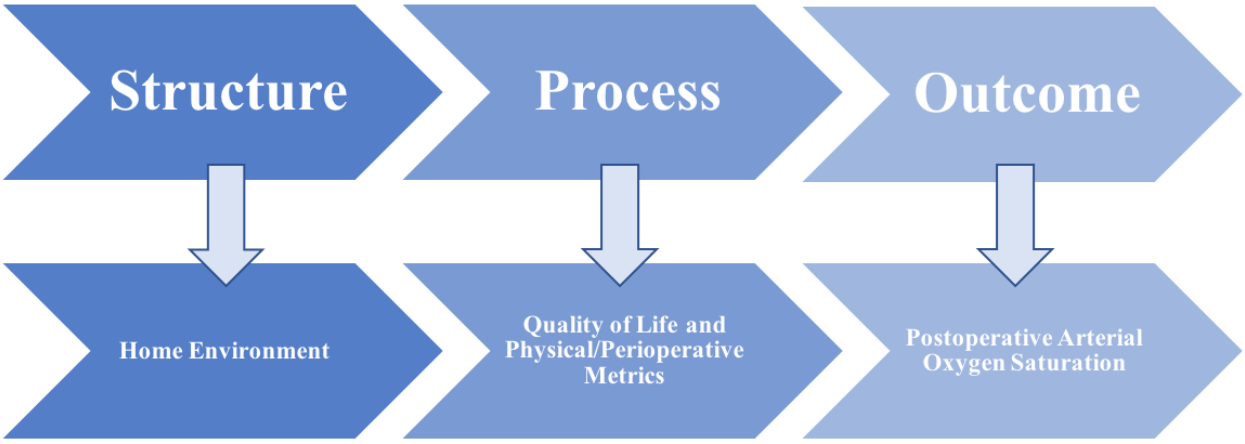


Figure 2. Adapted Donabedian theoretical framework (Elam, 2018).

Chapter Summary

This chapter provided evidence describing the growth of ambulatory surgery, and the shift from inpatient surgical procedures to outpatient, same-day procedures. With the growth in surgical procedures, more patients receive outpatient surgery. Many of these patients are either diagnosed or living with insidious obstructive sleep apnea (OSA), the most common sleep disorder in America. The effects of OSA on postoperative recovery are varied and place the postoperative patient at inherent risk. Concomitant alcohol and tobacco use have largely shown to aggravate postoperative apnea in OSA-susceptible patients. OSA patients are also likely to experience greater sensitivity to pain, and in the presence of opiate analgesics, may experience exacerbation of OSA symptoms. Pulse oximetry remains a reliable and valid instrument for assessing postoperative respiratory function. High-resolution devices have yielded promising results in detecting OSA, performing well against polysomnography. Insight is warranted in the relationship of the combined experiences of a patient in the postoperative phase following ambulatory orthopedic surgery, OSA status, and in-home overnight pulse oximetry readings. This study seeks to address that need. Lastly, Donabedian's structure-process-outcome theory of

quality offers utility in researching gaps in the literature and provides the theoretical framework for this research.

Chapter 3 – Methodology

Introduction

This section provides a description of the methodology and research design used for this study. The purpose of this research was to explore the relationship between ambulatory orthopedic patient-reported activities (quality of life metrics) and diagnostic factors (physical and perioperative care data) in the immediate postoperative period that are predictive of arterial oxygen desaturation.

Included is a description of recruitment and sampling of participants and steps taken to minimize risk to human subjects. The independent quality of life and physical/perioperative variables are identified, and variable measures discussed. Additionally, the author introduces the outcome/dependent variables gathered from pulse oximetry data. In-depth discussion of the study instruments, specifically, the quality of life journal, and the pulse oximeter is provided, as well as a discussion of the reliability and validity of the measures and instruments based on prior research. Lastly, the author discusses assumptions and limitations of the methodology used in this study.

Research Design

The methodology used for this study was a prospective, exploratory, mixed-methods approach utilizing quantitative and qualitative data collected from a convenience sample using an adaptation of Donabedian's structure-process-outcome theory as the framework for research. Through a prospective cross-sectional design, the results of this study are intended to define the

demographic and clinical characteristics of the study group, thereby yielding cross-sectional associations of interest. Causation and sequence of events could not be determined and were not studied as there was no manipulation of variables (the design was non-experimental) (Hulley, Cummings, Browner, Grady, & Newman, 2007). Additionally, the cross-sectional design methodology enabled the researcher to determine prevalence of multiple predictors and outcomes, which was imperative given the breadth of quality of life, physical, and perioperative predictor data, and pulse oximeter outcome measures.

Each participant received a complete preoperative anesthesia history and physical, the standard of care. Items in the anesthesia history and physical include: planned surgical procedure; height; weight; age; gender; known allergies; surgical history; history of anesthesia complications; gross airway and dental exam; assessment of comorbidities of all organ systems; current medications and supplements; and occasionally included hematologic, radiographic, and electrocardiographic tests completed prior to the day of surgery. Finally, an assignment of physical status class according to the American Society of Anesthesiologists (ASA) was determined based on the following criteria: ASA 1 assigned to healthy patients with no comorbidities; ASA 2 assigned to patients with mild systemic disease (i.e., controlled hypertension); ASA 3 assigned to patients with severe systemic disease (i.e., poorly controlled hypertension or diabetes mellitus); ASA 4 assigned to patients with life threatening systemic disease (i.e., decompensated congestive heart failure); ASA 5 assigned to moribund patients who will not survive without surgery (i.e., patients with a ruptured aneurysm); ASA 6 assigned to patients who are declared brain dead and whose organs will be harvested. Only ASA classes 1, 2, and 3 were enrolled for this study to address confounding comorbidities placing them at a higher post-operative risk.

Each participant completed a journal of qualitative, quality of life findings on postoperative day zero and one (the first 48 hours, or night 1 and night 2). Each day comprised three printed pages, for a total of six bound pages, a cover page, and a back page. Participants answered questions in the journal using a pen or pencil. Subjective items in the journal were "choose the best response" formatting by circling or writing a number that corresponded to a labeled descriptor. Subjective, quality of life data in the journal related to the patient's activities and feelings: sleep duration and quality; pain rating and measures taken to alleviate discomfort (pharmacologic and non-pharmacologic); nausea (and measures taken to treat); alcohol intake; nicotine intake; mood/emotional feeling (narrative theme); and diet (appetite and intake). At the Ambulatory Surgery Center at Virginia Commonwealth University, participants were introduced to the study and shown the journal during a preoperative clinic visit. These participants presented at approximately one to two weeks prior to the date of surgery and provided informed consent during their clinic visit. Participants at Great River Medical Center first saw the journal in the preoperative surgical unit the day of surgery approximately two hours prior to the time of surgery, which was also when the participant provided informed consent. The quality of life journal, pulse oximeter, a copy of their executed informed consent, and a writing utensil was placed in a manila envelope and given to the participant and/or a significant other the morning of surgery. In most cases, the study protocol was locked with the participant's personal belongings during surgery. No participant left or misplaced their study materials prior to discharge from the postoperative care area.

After discharge from the postoperative care area, participants wore a portable, wrist-worn pulse oximeter each night during sleep and during periods of daytime napping for the first 48 hours after surgery. The pulse oximeters were noninvasive, painless, and small (like a

wristwatch) and automatically recorded and stored data from the patient. The pulse oximeters were fully automated, activating and recording data when the patient's finger (any finger) was placed inside the soft silicone probe. Data were recorded on the device's internal hard drive and, upon return of the device, were electronically transmitted to a secured, password-encrypted personal computer for compilation and analysis by a manufacturer proprietary software suite (NONIN nVision® data management suite). The software provided hard data on the participant's heart rate (beats per minute) and arterial hemoglobin oxygen saturation (percent oxygen saturation, or SpO2%) whenever the device was worn. The pulse oximeter serial numbers and participant's date of surgery linked both the pulse oximeter and journal data for analysis and linked the participant's personal information (stored in REDCap) for stipend payment. Both the pulse oximeter and patient journal were returned to the research team via a postage-paid United States Postal Service first class padded and insured return envelope provided at the morning of surgery. Participant contact information was stored in the event of loss of the envelope to ensure return of the study instruments, as well as to provide payment of a participatory stipend ($50 Visa® prepaid gift card). All participants returned the study instruments, and none required personal contact from the research team.

Between participant uses, the hard drives of the pulse oximeters were erased, ensuring each participant's readings were unique to him or her. The devices were cleaned using either mild soap and water or a 10% bleach solution according to manufacturer recommendations. Each time a device was returned, new batteries were installed, and the device was tested for proper functionality. Pulse oximetry data (various measures of arterial hemoglobin oxygen saturation) were treated as dependent variables. Patient journal quality of life data and anesthesia history and physical data were treated as independent variables.

Study Sample and Recruitment

Participants received study instructions and materials and provided informed consent at the Ambulatory Surgery Center at Virginia Commonwealth University Health System (VCUHS) and the Same Day Surgery Center at Great River Medical Center (GRMC). Study participants were identified based on convenience sampling, that is, the author, committee members, and research staff worked at either of the facilities. All participant history and physical data were obtained in the preoperative clinic or preoperative care areas of VCUHS and GRMC, respectively, and by review of the patient's electronic and printed medical records. No inpatient follow-up was required. Data analysis occurred in a locked office in the Department of Nurse Anesthesia in the College of Health Professions at Virginia Commonwealth University, and a locked office in West Burlington, Iowa. Computers used for data entry and participant information were password-protected, and identifying data stored in the security encrypted, HIPAA-compliant REDCap software program.

Participants were identified for inclusion initially if they were: (a) receiving orthopedic surgery and (b) planned for discharge same-day. The author, committee members, and research staff identified participants either presenting in the preoperative clinic at VCUHS or in the preoperative care area on the day of surgery at GRMC. Potential participants were flagged based on the previously described inclusion criteria, and subsequently approached in person by the research staff. Initial communication included the general purpose of the study and participant responsibilities.

Participants were also flagged based on obstructive sleep apnea risk and/or diagnosis. Participants were flagged based on the STOP-Bang analysis score, a preoperative non-invasive assessment of sleep apnea risk. Though polysomnography remains the "gold standard" for

definitive diagnosis of OSA, the STOP-Bang score has demonstrated high sensitivity and construct validity to detect OSA status in several studies and is an accepted survey for preoperative OSA-risk evaluation (Chung et al., 2012; Farney et al., 2011; Silva et al., 2011). The STOP-Bang questionnaire is presented in Table 1. Note there are questions asked of the patient and data obtained from a healthcare assessment:

Table 1

STOP-Bang Questionnaire

Patient Questions	Assessment Data
Do you snore loudly?	Body Mass Index >35 kg/m^2
Do you often feel tired or sleepy?	Age greater than 50 years
Has anyone observed you stop breathing when asleep?	Neck circumference >16 inches
Do you have high blood pressure?	Male gender

Note. High Risk = Answering 'Yes' to 3 or more items.

Sampling was based on the demographic of the greater population of interest, that is, all postoperative patients following ambulatory orthopedic surgery. The sample was convenience derived; those who presented at the preoperative clinic or perioperative care area for orthopedic ambulatory surgery were considered for inclusion. Because both institutions are higher-volume orthopedic surgical centers, the author did not experience recruitment difficulties. Participants were generally included if they were able to understand and comply with the study protocol, were undergoing ambulatory orthopedic surgery, were of the age of majority, and were ASA physical status classifications of 1, 2, or 3. General exclusion criteria included minor status, pregnancy, inability to comprehend or comply with the protocol, or incarcerated individuals, with the latter purely based on ability to complete and return the study protocol. Complete participant inclusion and exclusion criteria are presented in Table 2.

Table 2

Inclusion and Exclusion Criteria

Inclusion	Exclusion
Ambulatory orthopedic surgery	Refusal to participate in study
Ability to comply with protocol; basic reading/writing aptitude	Inability to comply with protocol; unable to read/write
Age >/= 18 years	Age < 18 years and pregnancy
Discharged home on same day of surgery	Postoperative hospital admission
ASA Risk Class I-III	ASA Risk Class IV or greater
Ability to give informed consent	Incarcerated/pregnant individuals

Note. ASA = American Society of Anesthesiologists

Power Analysis and Sample Size

Using a-priori sampling methods for studies using regression analysis, 61 participants were necessary for recruitment. This is based on Cohen's f^2 of 0.35 (a large anticipated effect size), power of 0.8, the number of predictors (independent variables), and desired *p*-value of 0.05. Due to unanticipated constraints at both facilities, 52 participants were successfully enrolled in the study. Two participants were disqualified for incomplete return of data. Therefore, 50 participants were included in the analysis.

Data Sources and Data Management

Participant physical and perioperative data was obtained via electronic and printed medical records, and direct patient interviews conducted by anesthesia care providers. The preoperative anesthesia history and physical contained protected health information (PHI) such as surgical and medical histories, major organ system assessments and comorbidities, current medications and supplements, drug allergies, height, weight, age, BMI, STOP-Bang score, radiographic/electrocardiographic/laboratory results (when performed), and access to the

participant's full printed or electronic medical record. Participant name, address, and telephone contact information were linked to physical/perioperative data, the completed journal, and pulse oximeter data by serial number and date of surgery to ensure unique data values. Name and contact information ensured (a) return of research tools and (b) remuneration of the participant stipend.

REDCap was used to store data using password-protected, encrypted personal computers. Only the research team with HIPAA-compliance and human subjects protection training had access to the data set. Data were coded according to the serial number of the pulse oximeter, using date of surgical procedure to maintain unique data sets while pulse oximeters were reused across different participants. Participant contact information was linked to devices serial numbers and used solely for contact purposes and payment of the stipend. Case numbers were assigned using the pulse oximeter's nine-digit serial number. Because pulse oximeters were reused multiple occasions over the course of data collection, the date of surgery was recorded to ensure uniqueness of data sets. For example, if the serial number is 123456789 and the date of surgery was October 31, 2014, the identity code was 1234567891031. The combined serial number/date combination linked participant personal contact information for contact purposes and payment only. The case number also linked the quality of life journal with the pulse oximeter and physical/perioperative data sheet.

Once returned to the research team, the deidentified data were entered into Microsoft Excel, including the physical/preoperative data, quality of life entries from the journal, and readings extracted from the pulse oximeters. Data from the pulse oximeters had previously been extracted by the pulse oximeter's NONIN nVision® data management suite.

Variables and Measurement Reliability and Validity

Independent and dependent variables are described in Tables 3, 4, and 5 below, respectively. All physical/perioperative independent variables reported in Table 3 were recorded by the investigator providing the protocol education and obtaining informed consent. Participants self-reported if they used in-home CPAP therapy for obstructive sleep apnea. Quality of life independent variables were self-reported by study participants and are reported in Table 4. Arterial hemoglobin oxygen saturation (SpO_2) is a derived function of percent hemoglobin saturated in the blood, which was automatically calculated by the pulse oximeter. The dependent variable of arterial hemoglobin oxygen saturation was divided into levels based on frequency, event duration, and independent SpO_2 measurements. Temporal changes in arterial hemoglobin oxygen saturation across the two days of data collection were calculated by the NONIN nVision® data management suite using various metrics listed in Table 5.

Table 3

Physical/Perioperative Independent Variables and Measures

Variable	Measurement
Age	Years
ASA Class	ASA Physical Status Classification: I, II, or III
Anesthesia Modality	General anesthesia, regional anesthesia, monitored anesthesia care, neuraxial anesthesia
Nerve Block	Participant received a peripheral nerve block
Extremity	Site of surgery: right upper/lower extremity, left upper/lower extremity
STOP-Bang	Score based on STOP-Bang questionnaire
Home CPAP Use	Yes or No

Table 4

Quality of Life Independent Variables

Variable	Measurement
Sleep Time	Duration of sleep in minutes
Duration Awake	Duration of mid-sleep awakening in minutes
Times Awakened	Number of times of mid-sleep awakening
Sleepiness	Sleepy Faces Visual Analog Scale: 1 through 5
Mood	Happy, Sad, Angry, Frustrated, Other
Pain	Pain Faces Visual Analog Scale: 0 through 10
Pain Treatment	Narcotic Pain Pill, Non-Narcotic Pain Pill, Ice, Heat, Rest, None
Nausea	Yes or No
Alcohol	Ounces of alcohol
Alcohol Type	Beer, Wine, Liquor
Smoke Times	Number of times a smoking product was used
Smoke Type	Cigarette, Pipe, Cigar
Chew Times	Number of times smokeless tobacco, snuff, or chewing tobacco was used
Appetite	Yes or No for three meals of the day
Portion Consumed	Full, Partial, None for three meals of the day

Table 5

Dependent Variables and Measures

Arterial Hemoglobin Oxygen Saturation	
DV Levels	DV Measures
Total Number of Desaturation Events	Frequency
Time of Desaturation Events	Minutes
Average Desaturation Event Duration (seconds)	Seconds
Baseline SpO_2	% arterial hemoglobin oxygen saturation
Total Time of SpO_2 < 88%	Minutes
Total Number of Desaturation Events of SpO_2 < 88%	% arterial hemoglobin oxygen saturation
Longest Event Duration of SpO_2 < 88%	Seconds
Lowest Recorded SpO_2	% arterial hemoglobin oxygen saturation

Note. SpO_2 is arterial hemoglobin oxygen saturation

The primary measurement tools used for data collection were the patient journal and pulse oximeter. The patient journal comprised largely of quantitative data subjective to the patient's experiences (quality of life) with qualitative themes, a first in research exploring

postoperative OSA-related outcomes. Per Table 4 (above), many variables were nominal in nature and were coded numerically for statistical analysis. The first data item included in the patient journal was a comprehensive sleep journal whereby participants recorded when they laid down, whether to rest, nap, or sleep. Participants recorded duration of rest, the frequency and duration awakened mid-sleep, and quality indicators described later. Participants were encouraged to record occasions of rest or sleep as they occurred, when they occurred, and as many times as they occurred; no limitations on recorded sleep items were imposed in the analysis.

The ordinal measure for pain in this study, the Visual Analog Scale (VAS), has well-described construct and contrast validity and reliability (90% reproducibility) demonstrated in the literature (Bijur et al., 2001). The VAS for pain assessment also correlates well with the verbal pain scale frequently used in clinical settings (DeLoach, Higgins, Caplan, & Stiff, 1998). Figure 3 shows the pain visual analog scale used in this study.

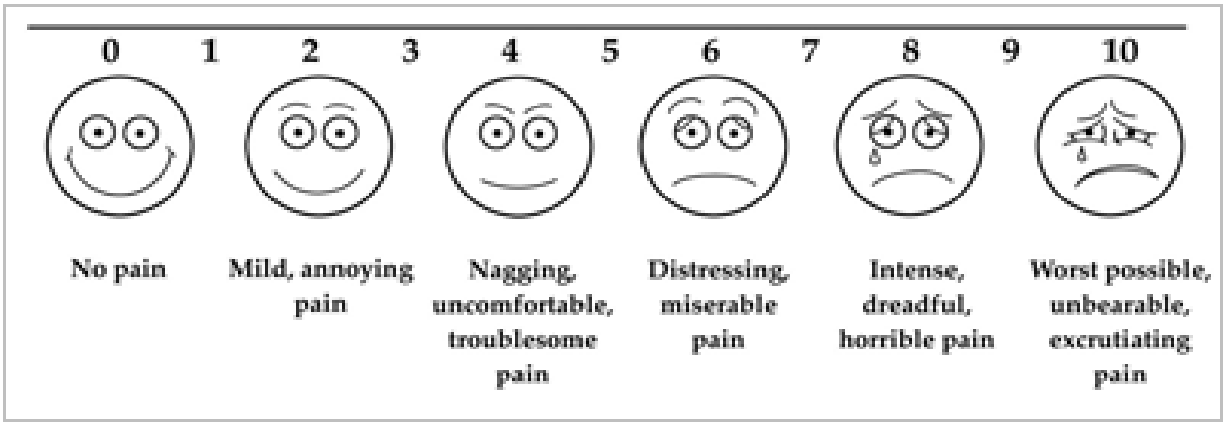


Figure 3. Pain visual analog scale.

Similarly, the VAS has demonstrated validity and reliability in assessment both sleep quality and sleepiness when compared with the Epworth Sleepiness Scale, the "gold standard"

(Maldonado et al., 2004; Tsapakis et al., 2009; Zisapel & Nir, 2003; Zisapel, Tarrasch, & Laudon,, 2006). Therefore, a visual analog scale was employed to measure sleep quality and overall sleepiness (Figure 4).

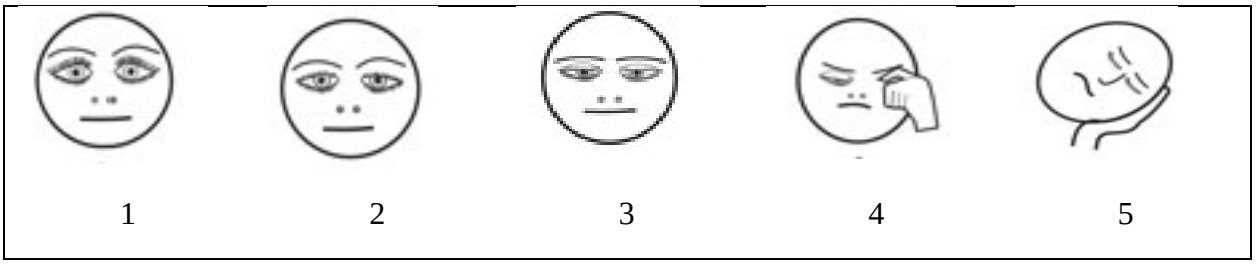


Figure 4. Sleepiness visual analog scale.

Recording mood/feeling as associated with sleep and restfulness presented difficulties. Traditional tests of a patient's mood are characteristically lengthy, time-consuming, and used to assist in the diagnosis of psychiatric conditions. Patient mood for this research was expressed by self-reported narrative using single word adjectives (e.g. sad, happy, angry, etc.). Because these modifiers have not been demonstrated to be reliable or valid in previous health-related research, their inclusion was for theme identification for potential future research. Participants recorded their pain level up to every 4 hours (a generally accepted frequency of post-operative pain assessment).

Additional items considered in the patient journal included nausea, tobacco use, and alcohol use. Nausea assessment frequency mirrored pain assessment and was recorded up to every four hours. Additionally, participants indicated what measures, if any, were taken to alleviate nausea using pre-selected activities (i.e. medication, fluids, food, none). If a participant used tobacco products, he or she specified the number of times engaged in smoking activities. Alcohol use was reported as number of ounces with options to specify beer, wine, or spirits.

Participants received education on measuring ounces of ingestion if they consumed alcohol. A sample of the full patient journal is presented in Appendix A, including the instruction form used to educate participants of the study protocol.

The participants' body mass index (BMI) was manually calculated on the basis of reliable digital scales present in the preoperative clinic to the nearest tenth decimal. Derivation tables of BMI was not utilized due to internal consistency and reliability concerns across various tables. Some variability could be present due to variations in patient attire; therefore, weighing all patients on the same scale in only a hospital gown only ensured external validity.

The pulse oximeter comprises the major measurement tool employed in this study, and the largest expense. The Respironics NONIN WristOx2® Model 3150 (Appendix B) is an FDA-approved device designed for portability and in-home use. It is wrist-mounted with a probe placed over the index finger for data collection. The processor component has a visual display of the heart rate and oxygen saturation and contains a hard drive for compiling data over time. Its cost varies between $500 and $800 per unit, is battery-driven (the sole maintenance necessary), and links to a computer-based software suite for compiling data. Based on the determined sample size and expected average ambulatory orthopedic surgical schedule at the study facility, 20 units were required. Data were pulled from devices using USB connection, encoded, and password protected for HIPAA compliance. A comprehensive software suite from the pulse oximeter manufacturer will be used to compile and organize data for statistical analysis.

When studied for its diagnostic capability of sleep apnea (using data from the like-designed outgoing 3100 model), the device demonstrated a sensitivity and negative likelihood ratio of 100% and 0%, respectively, and a specificity of 100% ("NONIN Wrist Ox® 3100 Operator's Manual," 2005, "Pulse Oximetry: Wearable Digital Pulse Oximeter for the

Ambulatory Patient," 2006). In peer-reviewed research, the Wrist Ox® portable pulse oximeter demonstrates similar sensitivity and specificity (Nigro et al., 2008). Accuracy is reported by the manufacturer to be 70-100% SpO_2 ± 2% SD and +3% for pulse rate. Battery life is estimated at a minimum of 24 hours of continuous measurement, and recordings can be calibrated for every 4 seconds, 2 seconds, or 1 second providing 33 hours, 16 hours, and 8 hours of data stored to the internal memory, respectively. Battery life exceeds each participant's 2-day recording requirement, as the device is only powered on during rest periods, and instructions explaining such will be provided to participants. The device automatically powers on when worn on the wrist, minimizing confusion of device operation. Independent research concludes that the sampling rates and memory capacity of home pulse oximeters do not affect the accuracy of data collection (Nigro, Dibur, & Rhodius, 2011). The Wrist Ox® records oxygen saturation ranging 0%-100% (% SpO_2) and pulse rate ranging 18 to 300 beats per minute. The manufacturer reports bias at +0.03 and precision at ±2.08 standard deviations ("Tested in Motion : See the Nonin Difference," 2012).

Data Entry and Analysis

Data was received by mail from study participants, including the participant quality of life journal and pulse oximeter. Initial physical and perioperative data were previously entered in a Microsoft® Excel spreadsheet. These included: the pulse oximeter serial number and date of surgery; participant age, gender, anesthesia modality, and surgical extremity; the results of the STOP-Bang questionnaire according to each of the eight items; and whether the participant used home CPAP device. Participant contact information was included strictly for compensation purposes as required by the United States Internal Revenue Service and for contacting a participant if the study materials were not received. These identifying data were entered into an

encrypted database and reported to the VCU Business Office as required by law. This form is found in Appendix C.

As materials were received, research assistants extracted data from the pulse oximeter using the manufacturer's software program and entered study-related items into a spreadsheet. A sample of the extraction program's output is found in Appendix D. Items from the quality of life journal and initial physical and perioperative data sheet were entered into the same data set as the pulse oximeter according to unique, deidentified participant identification numbers. Nominal items in the master data set were coded for analysis. There was a total of 5276 unique data entries.

Descriptive statistics (mean and standard deviation) were calculated for continuous variables and frequencies for categorial variables. Negative binomial regression was used to examine the relationship of the independent variables within the quality of life journal and physical/perioperative date and the dependent variables of the duration of desaturation events, specifically at the <90% and <88% thresholds (representing "mild" and "critical" events). Using the "mild" and "critical" desaturation events categories improved the interpretability and utility of the results. The relationship of basal arterial hemoglobin oxygen saturation on various desaturation events was also analyzed using negative binomial regression given variance in the models exceeded means. Least-squares regression ascertained the best fit model for the data based on the large degree of variance in the data. A *p*-value of 0.05 was deemed significant. The predictive capacity of basal/baseline oxygen saturation for critical desaturation events was analyzed using multiple regression analysis. The analyses were completed using IBM® SPSS.

Human Subjects

Institutional Review Board (IRB) approval was received at both institutions where participants were recruited. Risk to human subjects was approached with the premise that the study enhanced monitoring in the post-operative/post-discharge phase of care. The anticipated risks to participants included discomfort wearing the portable pulse oximeters (addressed by using adjustable straps) and collection of protected health information (which was minimized through use of REDCap for data management). Women and minorities were given equal consideration pursuant to the inclusion and exclusion criteria presented earlier, and patients aged younger than 18 years at the time of recruitment were excluded from research, protecting minors. Pregnant patients and prisoners were excluded from research due to confounding risk and logistical concerns for retrieval of study instruments, respectively, and for avoidance of risk of vulnerable populations. A comprehensive informed consent form was developed in accordance with IRB regulations, and all participants were provided full informed consent by anesthesia care providers of the risks and benefits (Appendix E). In compliance with the Health Insurance Portability and Privacy Act of 1996 (HIPAA), patient identifiers were masked and maintained confidential. Protected health information for each participant was linked to study data via unique coding comprising the last four digits of the pulse oximeter serial number and date of surgery. Participant contact information was maintained via REDCap software for remuneration of stipend only, reported to the university business office per IRS requirements, and destroyed upon study completion.

Participant Risk and Stipend

There was minimal risk to participants enrolled in this study. Risk of the disclosure of protected health information was minimized through use of the REDCap data management

system discussed earlier. There was a negligible risk of participant discomfort associated with wearing the pulse oximeter. This was mitigated through the use of an adjustable wrist strap and soft silicone finger probe. Participants will be encouraged to wear the device on whichever wrist and finger was more comfortable, which followed manufacturer guidelines. No participant reported any physical discomfort or deprivation as a result of wearing the pulse oximeter. The only cost incurred by participants was their time in completing the two-night data collection. Return postage-paid envelopes were provided for the participant to send the instruments to research staff after completing the second night's data. Upon return of the instruments, participants received a $50 Visa gift card as a stipend sent by United States Postal Service. Contact information obtained for remuneration was destroyed following completion of the study, submission to the university for tax purposes, and remittance of the stipend. Coercion was minimized through reinforcement that participation in the study did not affect the anesthetic or surgical course. All participants received education that participation in the study could be terminated at any point for any reason without any adverse effect to their care trajectory. The author's research chairperson was the point of contact for study participants. All participants returned the study protocol in a timely manner.

Assumptions

Several assumptions apply for this dissertation. First, all instruments and measures were assumed valid based on evidence in the literature or manufacturer reported testing. The research team received extensive training by the author and committee chair, therefore, it was assumed that all participants received accurate education of the study protocol. Lastly, results from the participant quality of life were assumed to be truthful, accurate, and valid, and having been completed by only the participant consented.

Study Limitations

The primary limitation of this study was the inability to infer causation between independent and dependent variables. Because the study was neither randomized nor exerted any experimental control, causation was beyond the purvey of this dissertation (Polit & Beck., 2012). Though power analysis suggested a sample size of 62 participants, external factors restricted the sample size to 50 cases. Though this increases the likelihood of Type II error, this study's findings provide a foundation for further research. Lastly, interrater reliability was not assessed across research participants, restricting the generalizability of this study's findings; attempts were made to ensure each participant received equal operationalization, but definitive cross-participant aptitude and veracity could not be assessed.

Chapter Summary

This was a prospective mixed-methods quasi-experimental study involving the collection of subjective quality of life data from a printed patient quality of life journal and recorded objective quantitative data from a portable pulse oximeter. The purpose of this research was to explore the relationship between ambulatory orthopedic patient-reported activities (quality of life metrics) and diagnostic factors (physical and perioperative care data) in the immediate post-operative period that are predictive of arterial oxygen desaturation. Participants were sampled based on convenience; recruitment occurred at a preoperative surgical clinic before or on the day of surgery pursuant to the inclusion and exclusion criteria. Participants completed a 2-day journal and wore a reliable, valid portable pulse oximeter during periods of rest or sleep. Journal data, pulse oximetry data, and preoperative, diagnostic data gathered from the preoperative anesthesia history and physical were analyzed using negative binomial regression and least-squares regression analyses. The risks to participants were negligible, and patients who

completed the study received a $50 participatory stipend. Finally, the limitations of this dissertation were introduced.

Chapter 4 – Results

Introduction

This dissertation reports the findings of a prospective, exploratory, mixed-methods study of postoperative ambulatory orthopedic surgical patients, arterial hemoglobin oxygen desaturation events, and the relationship quality of life and physical/perioperative metrics have on said events. The study used Donabedian's structure-process-outcome theory of quality as a framework for research, where the home environment represented the construct for structure, quality of life and physical/perioperative metrics represented the constructs for process, and arterial hemoglobin oxygen desaturation events represented the constructs for outcome. The specific aims of this study were: (a) to explore the incidence and characteristics of arterial hemoglobin oxygen desaturation events in a postoperative ambulatory orthopedic surgery patient population sample; (b) to identify quality of life and physical/perioperative metrics predictive of postoperative arterial hemoglobin oxygen desaturation events; and (c) to synthesize the combined synergistic relationships quality of life and physical/perioperative data in Aim 2 in predicting postoperative desaturation events. The purpose of this research was to explore the relationship between ambulatory orthopedic patient-reported activities (quality of life metrics) and diagnostic factors (physical and perioperative care data) in the immediate postoperative period that are predictive of arterial oxygen desaturation.

Chapter 4 of this dissertation reviews sample recruitment and introduces coding of

variables. Results of descriptive statistics, negative binomial regression, and least-squares regression are then presented pertinent to study hypotheses. The chapter concludes with a summary.

Recruitment and Sample Size

Fifty-two participants met inclusion criteria and were successfully recruited for this study. This study used convenience sampling, thus sample selection was not randomized. Fifty-two participants were initially enrolled in the study. Two participants were excluded from the final data analysis: one for absent quality of life journal data; one for an unanticipated malfunction in the portable pulse oximeter. Both participants returned the protocol and were remunerated accordingly. No participants were excluded for illegible quality of life journal entries. All included pulse oximeter data files appeared complete and without aberration. The sample size studied in this dissertation was, therefore, 50 participants.

Data Analysis

Following data entry by research assistants, the data was inspected by the author, verifying accuracy. During descriptive analysis, the variance exceeded the means of the outcomes variables. Because the data was over-dispersed and outcomes were discreet continuous counts (rather than binary), negative binomial regression was used to test hypotheses 1 and 2 (Polit & Beck, 2012). The original data was not normally distributed. Log_{10} transformation reduced skew in the analysis, accounted for differences in the responses, and made the data approximately normally distributed for least-squares regression (Field, 2009). For hypothesis 3, multiple regression was used to analyze the interaction of basal oxygen saturation on critical desaturation event frequency and time metrics at the SpO_2 <88% threshold.

Data Coding and Descriptive Statistics

Though data collected in the quality of life journal and physical/perioperative data sheet contained narrative themes, much of the data was interval, ordinal, or continuous in measurement. Some nominal data required coding.

First, American Society of Anesthesiologist (ASA) physical status (PS) classification maintained its appropriate numerical classification. Though the study exclusion requirements listed ASA PS classification 4 participants as excluded (severe, poorly controlled systemic disease), one ASA 4 participant was accepted into the study and included in the data set after completion of data collection. The variable was treated as a single, interval variable in the analysis. Table 6 illustrates the frequencies of participant ASA classifications:

Table 6

ASA PS Frequencies

ASA PS Classification	N
1	9
2	29
3	11
4	1

Note. ASA PS is American Society of Anesthesiologist Physical Status

Next, the total score of the STOP-Bang questionnaire is presented. Scores of '3' or greater were considered at high risk for obstructive sleep apnea (OSA) according to prior research and represented the threshold of probable obstructive sleep apnea for this study. The

variable was treated as a single, interval variable in the analysis. Table 7 shows frequencies of STOP-Bang questionnaire total scores:

Table 7

STOP-Bang Questionnaire Total Score Frequencies

STOP-Bang Total Score	N
0	3
1	7
2	9
3	10
4	6
5	8
6	2
7	3
8	2

Anesthesia modality was divided into three categories based on participant response: general anesthesia; general anesthesia with regional anesthesia; and regional anesthesia with monitored anesthesia care (MAC). The variables were each coded 0, 1, and 2, respectively, and treated as single, interval level variables. A summary of their frequencies is in Table 8:

Table 8

Anesthesia Modality Frequencies

Anesthesia Modality	N
General Anesthesia	21

Anesthesia Modality	N
General and Regional Anesthesia	25
Regional and MAC	4

The site of surgery was coded for laterality as either 0 or 1- anatomical left or right, respectively- and 0 or 1 for lower or upper extremity, respectively. These nominal variables (originally four) were assigned as two dummy variables and an interaction variable. Frequencies of the surgical site are presented in Table 9:

Table 9

Surgical Site Frequencies

	Left Side	Right Side
Lower Extremity	10	10
Upper Extremity	16	14

Note. Values are N

Table 10 presents frequencies of the remaining categorial variables. Of note, only two participants confirmed there were on home continuous positive airway pressure (CPAP) therapy.

Table 10:

Categorial Variable Frequencies

Variable	Category	N
Gender	Male	20

Variable	Category	N
	Female	30
Peripheral Nerve Block	Yes	29
	No	21
Home CPAP Use	Yes	2
	No	48

Means and standard deviation for remaining journal data were calculated. Pain level, an ordinal scale variable, was ranked from 0 through 10 according to the visual analog scale (VAS) included in the journal. For a given participant, mean and standard deviation were calculated across all responses; if one participant logged four responses and another eight responses, the means and standard deviations were calculated individually and then as an aggregate. Similarly, nausea mean and standard deviation were calculated individually and collectively based on the sums of those who reported experiencing postoperative nausea, though only 26 participants experienced nausea. The sum of minutes slept was calculated for each participant and a combined mean and standard deviation for the study sample calculated. Mood descriptive statistics were based on the sum reported of each of four categories. The 'Other' mood category was omitted from analysis due to poor response rate. Alcohol and cigarette descriptives were based on the number of ounces and cigarettes smoked, respectively. Smokeless tobacco was omitted as no participants reported its use. Additionally, appetite and meal consumption were omitted from the analysis due to poor response. A summary of remaining journal descriptive statistics is provided in Table 11:

Table 11

Journal Data Descriptive Statistics

Variable	Mean	Standard Deviation
Age	50.46	11.19
Pain Level	4.01	1.98
Pain RX	4.62	3.05
Pain OTC	0.72	1.39
Nausea	0.199	0.28
Sleep Duration	1092.14	384.16
Happy Mood	2.08	1.99
Sad Mood	0.18	0.63
Angry Mood	0.18	0.89
Frustrated Mood	1.44	2.21
Alcohol Use	4.32	22.58
Tobacco Use	3.26	9.13

Note. RX is prescription narcotic/opioid analgesic; OTC is over-the-counter analgesic

Mean and standard deviation were calculated for each of the pulse oximetry data values. Chapter 3 describes the measurement scales for each of the variables. Though the sample size was 50, average low SpO_2 less than 88% resulted in 43 responses. Because the value represented

the average value of all arterial hemoglobin oxygen saturation data points less than 88%, the "critical" desaturation threshold, seven participants never experienced desaturation events below this threshold. Table 12 displays descriptive statistics for pulse oximeter data:

Table 12

Pulse Oximeter Descriptive Statistics

Variable	Mean	Standard Deviation	N
BasalSpO2	92.67	2.63	50
Time88	64.97	145.66	50
Events88	48.76	82.26	50
MaxTime88	725.80	1738.74	50
MinSpO2	69.20	15.22	50
AvgLowSpO2	89.32	2.73	50
AvgLowSpO288	84.09	4.07	43

Hypothesis Testing

Hypothesis 1 (H_1) tested the predictive capacity of the STOP-Bang questionnaire for postoperative arterial hemoglobin oxygen saturation (SpO_2 %) at mild (<90%) and critical (<88%) desaturation thresholds:

H_1: Postoperative arterial hemoglobin oxygen desaturation events occur in ambulatory orthopedic surgery patients with: (a) diagnosed obstructive sleep apnea (according to use

of CPAP); (b) risk of obstructive sleep apnea according to the STOP-Bang questionnaire; and (c) no diagnosis or risk of obstructive sleep apnea in the first 48 hours following discharge.

To test this hypothesis, the STOP-Bang score (0 through 8, with 3 being the cutoff for probably obstructive sleep apnea) was treated as the independent variable and two oxygen desaturation thresholds were treated as the dependent variables: SpO_2 <90 % (mild desaturation) and SpO_2 <88% (critical desaturation). Negative binomial (NB) regression showed that, as the STOP-Bang questionnaire total score increases, the number of desaturation evens (SpO_2 <90 % and SpO_2 <88%) also increases. In the appended graph (Figure 5), predicted values of the regression equation are plotted with the solid lines. Hatched areas adjacent to the solid lines comprise the confidence intervals. Note the two outliers of the graph: two participants had STOP-Bang scores of 8, but both participants used home continuous positive airway pressure devices (CPAP), thus their observed desaturation events fell much lower than the predicted values of the regression equation. Noteworthy, most of the remaining observed means fell within the confidence intervals for both the SpO_2 <90 % and SpO_2 <88% dependent variable thresholds.

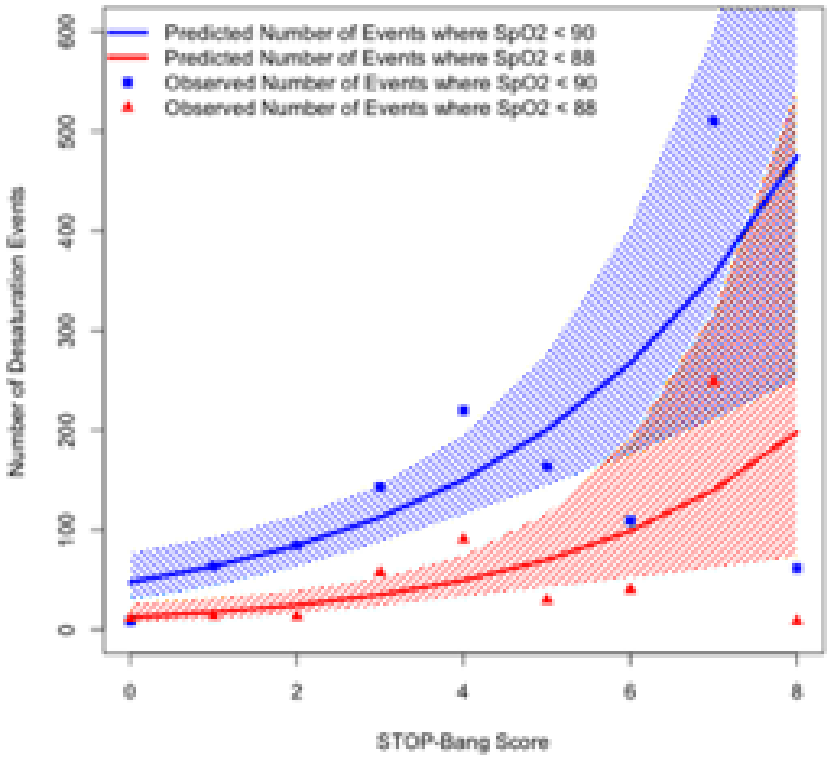


Figure 5. Number of SpO_2 events for each STOP-Bang score.

Parameter estimates of the above model for SpO_2 <90 % and SpO_2 <88% are presented in Tables 13 and 14, respectively.

Table 13

STOP-Bang Prediction of Desaturation Events at SpO_2 <90%

	Estimate	Standard Error	z Value	p-value
Intercept	3.86	0.25	15.143	$<2x10^{-16}$***
STOP-Bang	0.29	0.07	4.46	$8.22x10^{-06}$***

Note. *** denotes significance at p <0.05

Table 14

STOP-Bang Prediction of Desaturation Events at SpO_2 <88%

	Estimate	Standard Error	z Value	p-value
Intercept	2.51	0.40	6.22	$4.86x10^{-10}$***
STOP-Bang	0.35	0.10	3.41	0.0005***

Note. *** denotes significance at p <0.05

The next regression examined the relationship STOP-Bang scores of 0 through 8 had on the total time (in minutes) of arterial hemoglobin oxygen desaturation events at both the SpO_2 <90 % and SpO_2 <88% thresholds. The intercept row represented a STOP-Bang score of 0, while the STOP-Bang predictor row (Duration.STOP.Bang) was the predicted increased duration of desaturation events (in minutes) for every STOP-Bang score increase of one level. The model was predictive of desaturation events at the SpO_2 <90 % threshold, yet was not at the SpO_2 <88% threshold (Tables 15 and 16):

Table 15

STOP-Bang Prediction of Desaturation Duration (minutes) at SpO_2 <90%

	Estimate	Standard Error	t Value	p-value
Intercept	36.39	32.14	1.72	0.09
Duration.STOP.Bang	15.88	5.37	2.96	0.005***

Note. *** denotes significance at p <0.05

Table 16

STOP-Bang Prediction of Desaturation Duration (minutes) at SpO_2 <88%

	Estimate	Standard Error	t Value	p-value
Intercept	44.23	39.71	1.11	0.27
Duration.STOP.Bang	6.17	10.08	0.61	0.54

The output in Table 15 demonstrates that, for every STOP-Bang score greater than 0, an individual would be expected to spend 15.88 minutes with a SpO_2 <90%. A STOP-Bang score of 0 did not show a statistically significant duration of desaturation at the SpO_2 <90% threshold. Neither of the STOP-Bang score groups of 0 or >0 showed a statistically significant increase in the duration of desaturation at the <88% threshold. Additionally, STOP-Bang score at any score did not predict the average length of a desaturation event in a statistically significant manner (measured in seconds at SpO_2 <90%; Table 17):

Table 17

STOP-Bang Prediction of Average Event Duration (seconds) at SpO_2 <90%

	Estimate	Standard Error	t Value	p-value
Intercept	46.86	3.10	15.11	0.00***
AvgEvent.STOP.Bang	-0.92	0.79	-1.17	0.25

Note. *** denotes significance at p <0.05

Specific components of the STOP-Bang questionnaire appear to better predict desaturation events than others. Table 18 and Table 19 present outputs from negative binomial regression for each of the STOP-Bang questionnaire components: snoring; tiredness; apnea; hypertension; BMI >35 kg/m^2; age >50 years; neck circumference >16 inches; and male gender. Table 18 is the threshold of minor desaturation events (SpO_2 <90%), and Table 19 is the threshold of critical desaturation events (SpO_2 <88%). P-values of <0.05 were considered significant:

Table 18

STOP-Bang Component Prediction of Desaturation at SpO_2 <90%

	Estimate	Standard Error	z Value	p-value
Intercept	2.31	0.78	2.95	0.003***
Snoring	0.12	0.32	0.37	0.71
Tiredness	0.18	0.28	0.62	0.54
Apnea	-0.41	0.50	-0.82	0.41
Hypertension	0.43	0.30	1.42	0.16
BMI >35	1.54	0.61	2.53	0.01***
Age >50	0.03	0.01	2.23	0.03***
Neck Size	-0.82	0.62	-1.33	0.18
Male Gender	0.64	0.34	1.88	0.06

Note. *** denotes significance at p <0.05

Table 19

STOP-Bang Component Prediction of Desaturation at SpO2 <88%

	Estimate	Standard Error	z Value	p-value
Intercept	-2.01	1.16	-1.74	0.08
Snoring	-0.06	0.46	-0.13	0.89
Tiredness	-0.24	0.42	-0.58	0.56
Apnea	0.18	0.72	0.24	0.81
Hypertension	0.31	0.44	0.71	0.48
BMI >35	2.69	0.88	3.05	0.002***
Age >50	0.08	0.02	4.096	$4.2x10^{-5}$***
Neck Size	-0.90	0.89	-1.01	0.31
Male Gender	0.56	0.49	1.13	0.26

Note. *** denotes significance at p <0.05

The full STOP-Bang model demonstrated significance for predicting desaturation events at the SpO_2 <90% threshold but failed to show significance at the <88% threshold. As independent predictors of desaturation at the SpO_2 <90% and <88% thresholds, BMI >35 and Age >50 each showed significant capacity for predicting desaturation events. Remaining questionnaire components did not independently predict events of <90%, though male gender demonstrated marginal significance at the <90% threshold. For the age component, every year over 50 increases the frequency of desaturation events by 3% (SpO_2 <90%) and 8% (SpO_2 <88%). BMI demonstrated the greatest magnitude in this model: an individual would experience 269% more desaturation events at the SpO_2 <90% threshold, and 1468% more events at the <88% threshold.

Hypothesis 2 (H_2) tested quality of life and physical/perioperative data parameters as predictors of postoperative arterial hemoglobin oxygen desaturation:

> H_2: There are quality of life and physical/perioperative data predictive of postoperative arterial oxygen hemoglobin desaturation events at mild (SpO_2 <90%) and critical (SpO_2 <88%) thresholds.

To examine this hypothesis, negative binomial regression, $\log_{10}$ transformation, and least-squares regression were used to identify statistical significance according to each variable. Physical and perioperative data was coded for analysis. ASA Class was coded ordinally from 1 through 4 physical status classifications. STOP-Bang was also coded ordinally from 0 through 8 possible 'yes' responses to the questionnaire. Anesthetic modality was coded either 0 for general anesthetics or 1 for regional/monitored anesthesia care. Limb laterality and whether it was an upper or lower extremity were each coded individually, and subsequently combined for total effect. CPAP use was coded 'yes' or 'no' if the patient used a device in their home. Table 20 summarizes the regression output for physical/perioperative data at both the SpO_2 <90% and SpO_2 <88% desaturation thresholds:

Table 20

Physical/Perioperative Predictors of Desaturation Events at SpO_2 <90% and SpO_2 <88%

	SpO_2 <90%		SpO_2 <88%	
	Estimate	Standard Error	Estimate	Standard Error
Intercept	3.88***	0.56	3.38***	0.81
ASA Class	0.12	0.19	0.44	0.33
STOP-Bang	0.29***	0.08	0.33***	0.14
Anesthetic	0.06	0.21	-0.19	0.37

	SpO_2 <90%		SpO_2 <88%	
	Estimate	Standard Error	Estimate	Standard Error
Left/Right Limb	0.03	0.37	-0.12	0.64
Upper/Lower Limb	-0.63	0.33	-0.59	0.56
Combined Limb	-0.32	0.49	0.60	0.79
CPAP Use	-1.90**	0.69	-3.65**	1.18

Note. Significance denoted ** as p<0.01 and *** as p<0.001

Of the physical and perioperative data collected, STOP-Bang score and home CPAP use significantly predicted desaturation events at both mild and critical thresholds. As STOP-Bang scores increased, predicted desaturation events at both thresholds increased in a statistically significant manner. CPAP use was protective: as participants used home CPAP devices, predicted desaturation events decreased exponentially. Other metrics, as demonstrated, were not statistically significant.

The capacity for quality of life metrics in predicting postoperative arterial hemoglobin oxygen desaturation is shown in Table 21. Both desaturation events at the SpO_2 <90% and <88% are noted. Pain was measured according to the average of reported pain entries from the journal as measured by the visual analog scale (VAS). Opiate medication treatment was calculated as the average number of times a participant reported taking an opiate paid medication (as was over-the-counter, OTC, medication treatment; other pain treatment modalities were omitted from analysis due to underreporting). Sleep was calculated as total minutes slept across the 48 hours data collection. Too few participants responded to the sleepiness VAS for an appropriately powered, generalizable analysis. Cigarettes, or use of another smoking product, was a total count sum smoked. Lastly, happy mood was the average number of times a

participant noted feeling happy (note: sad, angry, frustrated, and other mood categories were omitted from the regression analysis due to underreporting).

Table 21

Quality of Life Predictors of Desaturation Events at SpO_2 <90% and SpO_2 <88%

	SpO_2 <90%		SpO_2 <88%	
	Estimate	Standard Error	Estimate	Standard Error
Intercept	3.88***	0.56	3.38***	0.81
Pain VAS Rating	0.05	0.06	-0.13	0.11
Opiate Medication	-1.00**	0.37	-1.91**	0.63
OTC Medication	-0.13	0.09	---	---
Sleep	0.03	0.02	0.03	0.03
Cigarettes	0.01	0.02	---	---
Happy Mood	-0.20*	0.06	-0.34*	0.10

Note. Significance denoted * as p<0.05 ** as p<0.01 and *** as p<0.001

In this regression analysis, the primary negative predictors of postoperative desaturation events were both opiate pain medication ($p < 0.01$) and participants reporting a happy mood ($p < 0.05$). Predicted desaturation events decreased as participants reported taking opiate pain medication and reported a happy mood. The participant's pain rating, use of OTC medications, duration of sleep, and cigarette smoking did not predict postoperative desaturation events at either threshold.

The regression of the SpO_2 <90% threshold produced a theta value of 1.98 (SE 0.39), Akaike's Information Criterion (AIC) value of 581.57, and -2 log-likelihood (-2LL) of 551.57. This compares to a theta value of 0.64 (SE 0.13), AIC value of 456.66, and -2LL of 432.66 for

the SpO_2 <88% model. These values suggest the regression for the SpO_2 <88% offers a better fit for predicting desaturation events than the <90% regression.

Hypothesis 3 (H_3) assessed the degree to which basal (baseline) arterial oxygen saturation inversely predicted critical postoperative desaturation events at SpO_2 <88% (i.e., as the participant's basal saturation increased, critical desaturation events decreased):

> H_3: Basal arterial hemoglobin oxygen saturation will negatively predict postoperative desaturation events at the SpO_2 <88% threshold.

Critical events used as dependent variables in this analysis included: Time88 (total time in minutes where SpO_2 <88%); Events88 (total number of events where SpO_2 <88%); and MaxTime88 (total time in seconds of the single longest event where SpO_2 <88%). As discussed earlier in Chapter 4, time related variables had high standard deviations relative to their means, which is an indicator of the spread of data points from highly variable, continuous time reporting.

Figure 6 shows a scatterplot matrix for Model 1 of y = Time88, Events88, MaxTime88, and x = BasalSpO2. None of the independent variables appeared to have strong marginal relationship with the dependent variable:

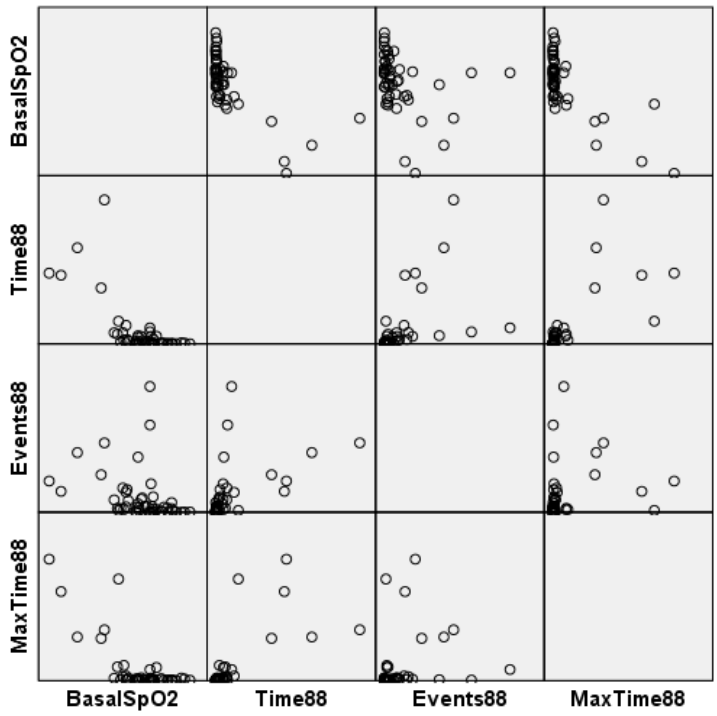


Figure 6. Scatterplot matrix of model 1: y = Time88, Events88, MaxTime88; x = BasalSpO2.

Pearson correlation coefficients were calculated based on Model 1 (Table 22). There were statistically significant, moderate negative correlations between BasalSpO2 and Time88 (r = -0.691, $p < 0.001$), and BasalSpO2 and MaxTime88 ($r = -0.733$, $p < 0.001$). BasalSpO2 and Events88 had a small, though statistically significant, negative correlation ($r = -0.318$, $p = 0.012$).

Table 22

Pearson Correlation of Model 1: y = Time88, Events88, MaxTime88; x = BasalSpO2

		BasalSpO2	Time88	Events88	MaxTime88
Pearson	BasalSpO2	1.000	-0.691	-0.318	-0.733
Correlation	Time88	-0.691	1.000	0.520	0.698
Coefficient	Events88	-0.318	0.520	1.000	0.233
	MaxTime88	-0.733	0.698	0.233	1.000
Sig. (1-tailed)	BasalSpO2	.	<0.001	0.012	<0.001

		BasalSpO2	Time88	Events88	MaxTime88
	Time88	<0.001	.	<0.001	<0.001
	Events88	0.012	<0.001	.	0.052
	MaxTime88	<0.001	<0.001	0.052	.

Multiple regression analysis showed BasalSpO2 having a statistically significant negative impact on Time88, that is, a lower participant's baseline oxygen saturation predicted a longer average duration of a desaturation event of SpO_2 <88%. The standardized coefficient (beta) for this comparison (Model 2) was -0.691, which was significant at $p < 0.001$. However, Model 2's adjusted R^2 was 0.467 (SE = 106.378); 46.7% of the variation in Time88 is explained by Basal SpO_2. Table 23 provides the regression outputs for this model:

Table 23

Regression Coefficients of Model 2: Dependent Variable Time88

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
(Constant)	3608.608	535.245		6.742	<0.001
BasalSpO2	-38.238	5.773	-0.691	-6.623	<0.001

To assess model assumptions, a P-P plot of standardized residuals was examined (Figure 7). When comparing the theoretical model with observed model, negative skew is apparent. According to this model, the data are not normally distributed and the inferred duration of desaturation events at the SpO_2 <88% threshold are not definitive.

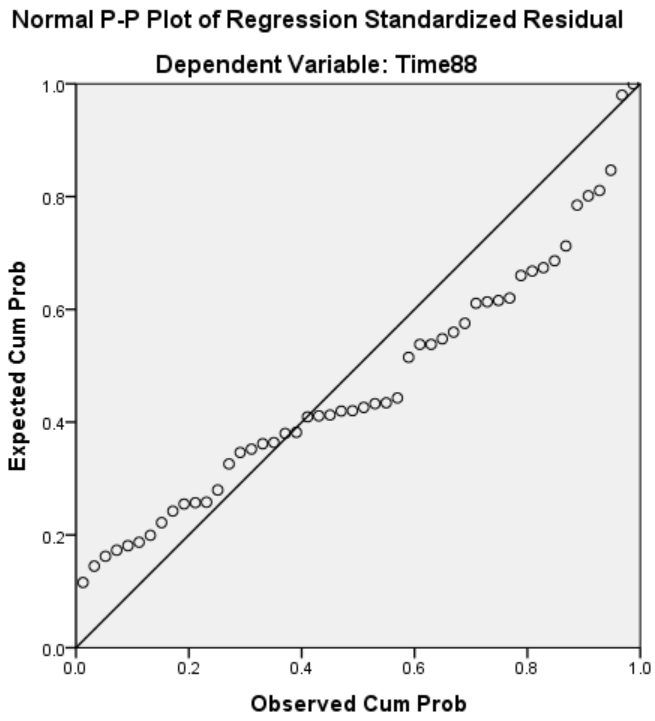


Figure 7. P-P plot of model 2: Dependent variable time88.

The multiple regression analysis results for the number of critical desaturation events at the SpO_2 <88% (Events88, Model 3) yielded a standardized coefficient of -0.318 at a significance of 0.024, which was within the significance threshold for this study. The adjusted R^2 for this model was 0.082 (*SE* = 78.798); only 8.2% of the variance of the predicted number of critical events could be explained by the baseline oxygen saturation level, which is suggestive of a weak regression model (Table 24). A P-P plot of this model demonstrated the data was not normally distributed, and severely negatively skewed.

Table 24

Regression Coefficients of Model 3: Dependent Variable Events88

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
(Constant)	970.054	396.472		2.447	0.018
BasalSpO2	-9.941	4.276	-0.318	-2.325	0.024

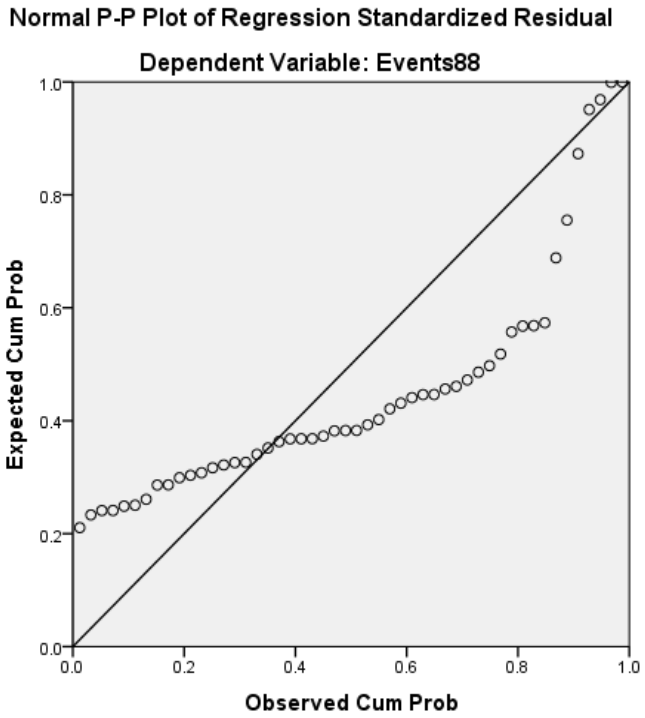


Figure 8. P-P plot of model 3: Dependent variable time88.

Model 4 of multiple regression analyzed if the basal arterial hemoglobin oxygen saturation significantly predicted the maximum duration (in seconds) a participant's oxygen saturation was <88% (MaxTime88). The standardized coefficient of this model was -0.733 ($p <$ 0.001). The adjusted R^2 for MaxTime88 was 0.528 (SE = 1195.164); 52.8% of the variance in the duration of critical desaturation events could be explained by the basal oxygen saturation.

Table 25 presents these results. The P-P Plot for Model 4 is presented in Figure 9. For MaxTime88 and BasalSpO2, there is a slight negative skew from normal distribution, though normality is grossly improved from prior models.

Table 25

Regression Coefficients of Model 4: Dependent Variable MaxTime88

Model	Unstandardized Coefficients		Standardized Coefficients	T	Sig.
	B	Std. Error	Beta		
(Constant)	45591.213	6013.492		7.581	<0.001
BasalSpO2	-482.121	64.863	-0.733	-7.464	<0.001

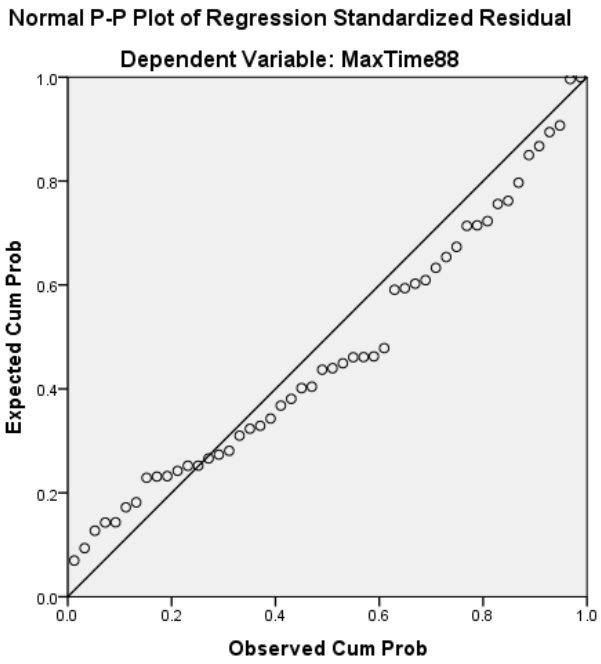


Figure 9. p-p plot of model 3: Dependent variable maxtime88.

Summary

This chapter presented statistical analyses assessing the capacity of the STOP-Bang score for predicting desaturation events, quality of life and physical/perioperative predictors of desaturation events, and the relationship of basal oxygen saturation and metrics of critical desaturation events.

Negative binomial regression and least-squares regression revealed the STOP-Bang score significantly predicted both mild and critical desaturation events, as well as the average duration of mild desaturation events. Components of the STOP-Bang questionnaire that significantly predicted both mild and critical events included age and BMI. Of the quality of life metrics studied, opiate pain medication treatment and participants describing a happy mood appeared to have protective influences on both desaturation thresholds. Multiple regression analysis examining basal oxygen saturation as a prediction of critical desaturation events yielded

significant results with small effect sizes and skewed distributions. Basal oxygen saturation as a predictor of the maximum duration of a critical desaturation event appeared to be the strongest model with the least skew.

Chapter Five summarizes the study, purpose, and hypothesis. There is a review of the methodology and major findings. The study's findings are linked with the purpose of this research, theoretical framework, and literature. Implications, both theoretical and practical, are presented. There is a discussion of the limitations, recommendations, and lastly, conclusion.

Chapter 5 – Discussion

Introduction

Chapter 5 summarizes the study, its methodology, and significant results. There is a review of the theoretical framework used in this research, and this study's theoretical and practical implications. Study limitations and threats to validity are reviewed. The chapter concludes with recommendations for future research and conclusion.

Review of the Problem

Pulse oximetry is the gold standard of assessing respiratory function along the anesthesia continuum. The arterial hemoglobin oxygen saturation is a derived metric used in patient care along the anesthesia continuum. Following discharge to home, patient desaturation events immediately following surgery are poorly understood. This is especially true in at-risk populations, such as patients with confirmed or suspected obstructive sleep apnea (OSA). Further, delineation of the characteristics of desaturation events such as frequency, duration, and if baseline levels hold predictive power is necessary to fully understand the breadth of the problem. Though the STOP-Bang questionnaire has been established as a reliable preoperative predictor of OSA, how well it predicts postoperative at-home desaturation events is not reported in the literature.

Additional factors may contribute to postoperative desaturation events. Subjective patient quality of life experiences and objective physical and perioperative factors could predict desaturation events. Understanding a patient's at-home experiences and their relationship to desaturation events is critical to effecting evidence-based change in perioperative and anesthesia care. As patient safety has become integral to quality outcomes research, integrating clinical data such as pulse oximetry and physical findings with qualitative, experiential metrics could decrease adverse postoperative desaturation events, improve outcomes, and contribute to overall quality of care.

Research Purpose and Hypotheses

The purpose of this research is to explore the relationship between ambulatory orthopedic patient-reported activities (quality of life metrics) and diagnostic factors (physical and perioperative care data) in the immediate post-operative period that are predictive of arterial oxygen desaturation. The hypotheses of this dissertation were:

H_1: Postoperative arterial hemoglobin oxygen desaturation events occur in ambulatory orthopedic surgery patients in positive correlation to STOP-Bang scores.

H_2: There are quality of life and physical/perioperative data predictive of postoperative arterial oxygen hemoglobin desaturation events at mild (SpO_2 <90%) and critical (SpO_2 <88%) thresholds.

H_3: Basal arterial hemoglobin oxygen saturation will negatively predict postoperative desaturation events at the SpO_2 <88% threshold.

Methodology

This was a prospective, exploratory, quasi-experimental study of qualitative and quantitative metrics evaluating predictive capacity for postoperative at-home desaturation. Fifty participants were recruited based on convenience sampling. They included ambulatory orthopedic surgical patients. Participants wore a portable pulse oximeter during periods of rest or sleep and completed a standardized quality of journal over the immediate first 48 hours following surgery. Descriptive statistical analysis demonstrated characteristics of desaturation events in the postoperative period. Negative binomial and least-squares regression evaluated the significance of STOP-Bang score and component questions for predicting postoperative desaturation at mild (SpO_2 <90%) and critical (SpO_2 <88%) thresholds. Negative binomial and least-squares regression also reported the significance of quality of life data from the journal and physical/perioperative data for oxygen desaturation. Log_{10} transformation was necessary to account for the wide variance of data points from the mean. Lastly, multiple regression examined if a participant's basal SpO_2 significantly predicted critical desaturation events.

Results

The results of the various statistical tests were reported in Chapter Four. Interpretation of the results as they apply to the study hypotheses follow.

H_1 hypothesized that the STOP-Bang questionnaire for OSA risk positively predicts desaturation events in the postoperative, at-home environment. The findings of this study suggest there is a statistically significant relationship of a patient's STOP-Bang score predicting both mild (SpO_2 <90%) and critical (SpO_2 <88%) desaturation events. Incidentally, isolating a patient's age and body mass index (BMI) yielded significant predictive capacity for both mild and critical event counts.

H_2 assessed the relationship of quality of life and physical/perioperative measures on desaturation event outcomes. Of the quality of life metrics included in the participant journal, opiate pain medication and a self-described happy mood significantly predicted a decrease in mild or critical desaturation events, that is, they had protective influences. Of physical and perioperative assessment data, again, STOP-Bang significantly predicted both mild and critical desaturation events. Additionally, home CPAP use was a negative predictor of desaturation events; the protective effect of home CPAP use suggested a decrease in both mild and critical desaturation events.

H_3 examined the relationship of a patient's at-home baseline oxygen saturation level and critical (SpO_2 <88%) postoperative desaturation events. Due to high variance, results of this hypothesis are not definitive and have modest effect sizes, though they were statistically significant. Basal oxygen saturation negatively predicted the number of critical desaturation events with mild, statistically significant reliability. Basal oxygen saturation also negatively

predicted the average and maximum duration of critical events with statistical significance, and with higher reliability than the number of critical events.

Theoretical Framework

Avedis Donabedian's theory of healthcare quality provided the foundation for this research. He described three constructs necessary to ensure quality outcomes: structure; process; and outcome. Structure is the first and most basic construct to achieve quality; Donabedian (1988) describes it as "the blunt instrument in quality care." Structure is inclusive of the places, people, and policies of a care system, which is directly tied to the second construct of process (Donabedian, 1988). Processes are what was done to effect some change in something and can be descriptive (care as it happened), prescriptive (care that should have happened), and proscriptive (something that should be avoided) (Donabedian, 2003). Lastly, the outcome as a criterion of quality is the measurable result of the combined influences of the structure and process (Donabedian, 2005). He asserted that how these combined constructs defined quality was highly subjective and conceptual, but that quality could be defined generally as "a reflection of values and goals current in the medical care system and in the larger society of which it is a part" (Donabedian, 2005).

Theoretical Implications

This study incorporated each of Donabedian's constructs of quality and adapted them according to the hypotheses and purpose of research. Rather than defining structure as a component of where care occurred (e.g., hospital, operating room, etc.), this dissertation

synthesized structure as a continuum from the hospital structure into the home environment where patients are discharged. Indeed, the effects (positive and negative) of care processes that occurred in a traditional health care institution continue into the home environment following discharge.

Processes can be descriptive, prescriptive, and proscriptive based on quality outcomes. For this study, the process construct was quality of life and physical/perioperative data. Analysis suggested that opiate pain medication treatment (process) that occurred in the home (structure) had a protective relationship to mild and critical desaturation events. The use of CPAP in the home demonstrated a similar protective relationship, and also fits the structure-process constructs.

The pulse oximetry data (postoperative desaturation events) represented the outcome construct in this research, since an outcome is the measurable result of a structure-process interaction and the determinant of quality. Outcome measures are not necessarily positive outcomes or indicators of good quality care. For this study, statistically significant quality of life and physical/perioperative processes yielded binary outcomes—they either positively or negatively predicted postoperative desaturation events. Though processes in this study were of a descriptive nature, upon evaluation of the outcome, processes could be assigned as prescriptive or proscriptive for future research. For example, the analysis suggested home CPAP use protected individuals from postoperative desaturation events at both mild and critical thresholds. Home CPAP use would be classified as a prescriptive process, or what should be done. Contrastingly, a low baseline oxygen saturation in the postoperative period suggests and increase

in the average duration of critical desaturation events. Intuitively, this could be applied as a proscriptive process: if a patient demonstrates a low basal oxygen saturation, enhanced postoperative monitoring and risk mitigation are recommended.

Extending the Donabedian framework beyond discharge, especially to the immediate at-home postoperative period, is a novel application of quality theory. With reimbursement and accreditation standards often tied to adverse patient outcomes, use of structure-process-outcomes throughout the anesthesia continuum is appropriate even beyond discharge (Nicolescu, 2017). An example of this is a proscriptive process leading to readmission following postoperative discharge, resulting in a negative patient outcome. This paper could provide a foundation for further research into the construct validity of adapting Donabedian's framework of quality beyond the hospital and into the home, remodeling the framework to more patient-centric focuses.

Practical Implications

This study provides several practical implications for anesthesia providers. First, this study supports prior research that the STOP-Bang questionnaire significantly predicts desaturation events (Chung et al., 2008; Silva et al., 2011). Compared to polysomnography, which is costly and time-intensive, the STOP-Bang questionnaire is a rapid, noninvasive, reliable instrument useful for predicting a patient's postoperative respiratory risk. At present, including a patient's STOP-Bang score in their preanesthetic assessment is not the standard of care. As a result, it is likely that it is not routinely assessed across anesthesia providers. The results of this

study overwhelmingly support previous findings and intuitively recommend incorporating the STOP-Bang questionnaire into routine assessments.

In addition to the overall STOP-Bang score, age and BMI independently yielded significant predictive relationships for postoperative desaturation events. Anesthesia providers could use this information for rapidly flagging patients in their practices for follow-up care or advanced postoperative monitoring.

The results of this study suggest home CPAP use is protective for both mild and critical postoperative desaturation events. This finding supports aggressive patient teaching of the need for CPAP compliance, especially in the postoperative period. Furthermore, preoperatively identifying patients at risk for obstructive sleep apnea and referring them for appropriate testing could increase CPAP prescription and utilization of previously undiagnosed OSA individuals.

Little is reported on the reliability and validity of baseline oxygen saturation for the assessment of the temporal risk of postoperative desaturation events. The results of this study suggest statistically significant mild to moderate relationships between the basal oxygen saturation of a patient and subsequent critical desaturation events in the immediate postoperative period. These results are foundational, though future research may warrant changes in the standard of care following postoperative discharge.

Anecdotally, there was high compliance with the use of an in-home portable pulse oximeter in this study. Of 52 participants originally recruited, 51 were consistently compliant

with wearing the device during the prescribed periods of sleep during the 48-hour study period. Incorporating portable pulse oximetry into postoperative quality and patient safety assurance is possible. Pulse oximeter devices exist that transmit data wirelessly from the device to a centralized monitor. Technology such as this could be useful for extended in-home postoperative monitoring in patients who are considered a risk for desaturation events.

Limitations

This dissertation described a non-randomized, exploratory study. Such research is limited by the inability to determine causal inferences (Polit & Beck, 2012). Research involving human behavior is difficult to model into an experimental design, especially those incorporating self-reported experiences, as was the case in this study.

Though 51 of 52 recruited participants completed some portion of the quality of life journal, there were swaths of independent variables with limited or no response, which prevented them from consideration in the statistical analysis. The VAS sleepiness assessment had poor response. Nausea presence and treatment modalities also had poor response, however this could be a function of improvements in antiemetics and nausea prophylaxis. The alcohol use and non-cigarette category of nicotine products were also grossly underreported. Incorporating electronic cigarettes into this category could have yielded an increase in response. The appetite variable set was the least reported, which is perhaps a function of postsurgical decreases in appetite and consumption. Aggressive recategorization and operationalization of the aforementioned variables is necessary should this study be replicated.

Generalizability is limited for this study due to being underpowered. Power analysis calculated a necessary sample size of 61 participants. Due to factors beyond the author's control, recruitment garnered 50 participants included for analysis. In addition, the sample size was calculated with a large anticipated effect. Based on the statistical analysis, especially of the basal oxygen saturation model, a more modest effect size would have been appropriate.

Threats to Internal Validity

This study collected self-reported data over 48 hours from within a participant's home. Researchers could not control for personal events that may have occurred during data collection in the participant's life. This threat refers to history: outside events occurring simultaneously with the independent variables that could affect the dependent variables (Polit & Beck, 2012). A key factor in this study was the in-home component of data collection, preventing the author from controlling environmental, person influences on the participant.

Though participants were included based on preset inclusion and exclusion criteria, selection bias could have an effect on the interpretability and generalizability of this study's findings. Data collection occurred at a major metropolitan hospital and a rural hospital. There could be unknown characteristics germane to each location that omitted a particular individual from inclusion. The author did not account for participant race in the analysis, and there could be a theoretical difference among races not accounted for. Selection bias could have been minimized by accounting for such differences prior to the study's implementation (Polit & Beck, 2012).

Several of the variables in the quality of life journal contained multiple entries of the same data points. Though this was not a pretest/posttest design, testing effect or repeated testing could impact the interpretability of the results and impact internal validity. As participants completed the journal entries, some could have arbitrarily marked entries. This would especially become a concern on the second day of data collection when the participant is exposed to a duplicate set of data to complete.

Threats to Construct Validity

There are two threats to this study's construct validity. First, there is a risk the Hawthorne effect affected participant response. Participants knew they were enrolled and participating in a study because the research design could not realistically be blinded to the participant. Some participants may have assumed that their performance improved with total completion of every entry (regardless of experience or not), or that specific desirable responses were preferred by the author. The study attempted to minimize the Hawthorne effect through participant education and reassurance of there not being a "right answer."

The novelty effect could have also affected this paper's results. The novelty effect is the altered behavior of a participant because of a new treatment or instrument (Polit & Beck, 2012). Participants may have altered their normal sleep-wake cycle given the novelty of the portable pulse oximeter, which would contaminate and cloud the results.

Threats to External Validity

The author attempted to address external validity (replicability) by collecting data across two disparate locations: an urban, academic medical center in Richmond, Virginia and a smaller community hospital in West Burlington, Iowa. The rationale for choosing two separate sites was to improve generalizability. Each institution, however, sees patients very specific to the area, and the surrounding areas are also microcosms of their own. Improving external validity would involve expanding research to multiple sites, thus addressing the reproducibility of future studies "across time, space, people, and settings" (Polit & Beck, 2012).

Conclusion and Recommendations for Future Research

The purpose of this research was to explore the relationship between ambulatory orthopedic patient-reported activities (quality of life metrics) and diagnostic factors (physical and perioperative care data) in the immediate post-operative period that are predictive of arterial oxygen desaturation. The study explored associations between the STOP-Bang score, quality of life experiences, and physical and perioperative metrics in predicting postoperative desaturation events. Results of the study suggest that the STOP-Bang score reliably predicts postoperative desaturation. Age and BMI, as individual components of the score, appeared to predict desaturation events. For this study, CPAP use significantly decreased postoperative desaturation, though future studies will require a larger sample for generalizability. In contrast with the literature, opiate pain medication appeared to have a protective relationship with postoperative desaturation. Participants reporting a happy mood also demonstrated fewer desaturation events.

A participant's baseline oxygen saturation appeared to have an inverse relationship with desaturation events, though further research is necessary to strengthen the hypothesis.

This was a broad study exploring many quality of life, physical, and perioperative variables. Exploring real-world, quality of life metrics not previously discussed in the literature offers many interesting research opportunities. Exploring individual quality of life experiences could strengthen the findings offered in this dissertation.

In this study, the STOP-Bang score significantly predicted postoperative desaturation events, potentially expanding its utility beyond assessment of obstructive sleep apnea risk. Results suggesting a protective effect of opiate pain medication warrants further research, as it is incongruent with current literature. Anecdotally, there is a precedent for outcomes research exploring novel in-home monitoring following hospital discharge (or post-anesthesia). With advances in medical technology, new devices are entering the market regularly, many of which could significantly improve patient safety and outcomes. Expanding anesthesia research into the home environment, beyond discharge, offers a new frontier of scholarly endeavor.

Appendix A

Patient Journal

Pulse Oximeter Serial Number (*Last 4 digits*): _____ _____ _____ _____

Date of Surgery (*MMDD format*): _____ _____ _____ _____

Patient Journal

For research purposes only. All information is confidential.

Instructions

After you leave the hospital, you will fill out this "patient journal" for the first two days after surgery. This journal will ask about your sleep, pain, nausea, and appetite, as well as about smoking or alcohol use if you smoke or drink alcohol. The journal is six (6) pages long, or three (3) pages for each day. You will write on it with pen or pencil.

You will also wear an oxygen monitor on your wrist whenever you rest or sleep. The monitor is connected to a Velcro strap that you can adjust for your comfort. There is also an attached soft plastic finger probe that you will place over any one of your fingers that is more comfortable. The monitor will collect your heartbeat and oxygen levels when you wear it. The monitor does not need to be turned on or off- it turns on and off when you put it on or take it off. Take the monitor off when you are not sleeping or resting.

After the second day, you will return the journal and oxygen monitor to the research team in the postage-paid envelope provided.

Postoperative Day 1

Serial Number ____________________
(Research staff use only)

Sleep (record daytime napping and nighttime sleep)

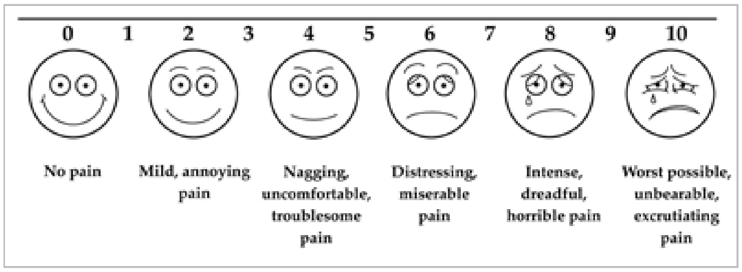
				
1	**2**	**3**	**4**	**5**

Time to bed	*Time Awake*	*Duration and number of times awakened*	*Total Sleep Time*	*How would you rate your feeling of restfulness after waking (use smiley faces above)*	*Describe your mood in the morning. Circle the best one that describes your mood.*
________ AM/PM	________ AM/PM	________ minutes ________ times	________ minutes		Happy / Sad / Angry / Frustrated / Other
________ AM/PM	________ AM/PM	________ minutes ________ times	________ minutes		Happy / Sad / Angry / Frustrated / Other
________ AM/PM	________ AM/PM	________ minutes ________ times	________ minutes		Happy / Sad / Angry / Frustrated / Other
________ AM/PM	________ AM/PM	________ minutes ________ times	________ minutes		Happy / Sad / Angry / Frustrated / Other
________ AM/PM	________ AM/PM	________ minutes ________ times	________ minutes		Happy / Sad / Angry / Frustrated / Other
________ AM/PM	________ AM/PM	________ minutes ________ times	________ minutes		Happy / Sad / Angry / Frustrated / Other

Postoperative Day 1

Serial Number ________________
(Research staff use only)

Pain (every 4 hours)



Time	***Pain Rating*** ***(use smiley faces above)***	***What did you do (circle one or more)?***
________ AM/PM		Over the Counter (OTC) Pain Pill / Prescription Pain Pill / Ice / Heat / Rest / None
________ AM/PM		Over the Counter (OTC) Pain Pill / Prescription Pain Pill / Ice / Heat / Rest / None
________ AM/PM		Over the Counter (OTC) Pain Pill / Prescription Pain Pill / Ice / Heat / Rest / None
________ AM/PM		Over the Counter (OTC) Pain Pill / Prescription Pain Pill / Ice / Heat / Rest / None
________ AM/PM		Over the Counter (OTC) Pain Pill / Prescription Pain Pill / Ice / Heat / Rest / None
________ AM/PM		Over the Counter (OTC) Pain Pill / Prescription Pain Pill / Ice / Heat / Rest / None

Nerve Block

_____ Yes, I received a nerve block.

_____ Yes, I received a nerve block and have a catheter (tube) giving me pain medicine.

_____ No, I did not receive a nerve block.

Postoperative Day 1

Serial Number _____
(Research staff use only)

Nausea (every 4 hours)

Time	*Nausea*	*What did you do (medication, other)?*
_____ AM/PM	Yes / No	Medicine / Drank something / Ate something / Rest / None
_____ AM/PM	Yes / No	Medicine / Drank something / Ate something / Rest / None
_____ AM/PM	Yes / No	Medicine / Drank something / Ate something / Rest / None
_____ AM/PM	Yes / No	Medicine / Drank something / Ate something / Rest / None
_____ AM/PM	Yes / No	Medicine / Drank something / Ate something / Rest / None
_____ AM/PM	Yes / No	Medicine / Drank something / Ate something / Rest / None

Alcohol Intake

Did you drink alcohol? If so, please indicate the number of ounces:

_____ No, I did not drink alcohol.

_____ Yes, I drank alcohol and drank _____ ounces of beer / liquor / wine (circle one).

Tobacco Use

_____ No, I did not smoke cigarettes, cigars, pipe, etc.

_____ Yes, I smoke and smoked _____ cigarettes / cigars / pipes (circle one).

_____ Yes, I used chewing tobacco, snuff, or smokeless tobacco _____ times.

Food (breakfast, lunch, dinner)

Meal	*I had an appetite (circle one)…*	*I ate a (circle one)…*
Breakfast	Yes / No	Full meal / Partial meal / Nothing
Lunch	Yes / No	Full meal / Partial meal / Nothing
Dinner	Yes / No	Full meal / Partial meal / Nothing

Postoperative Day 2

Serial Number ___________________
(Research staff use only)

Sleep (record daytime napping and nighttime sleep)

				
1	**2**	**3**	**4**	**5**

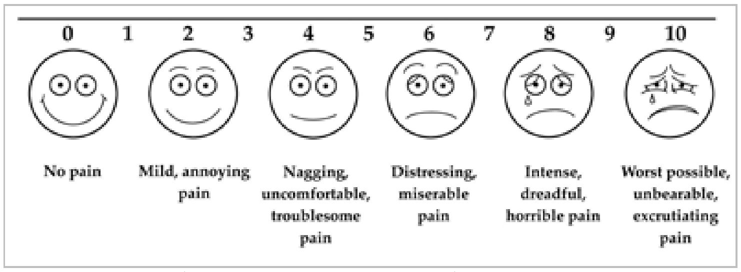
Time to bed	***Time Awake***	***Duration and number of times awakened***	***Total Sleep Time***	***How would you rate your feeling of restfulness after waking (use smiley faces above)***	***Describe your mood in the morning. Circle the best one that describes your mood.***
_______ AM/PM	_______ AM/PM	_______ minutes _______ times	_______ minutes		Happy / Sad / Angry / Frustrated / Other
_______ AM/PM	_______ AM/PM	_______ minutes _______ times	_______ minutes		Happy / Sad / Angry / Frustrated / Other
_______ AM/PM	_______ AM/PM	_______ minutes _______ times	_______ minutes		Happy / Sad / Angry / Frustrated / Other
_______ AM/PM	_______ AM/PM	_______ minutes _______ times	_______ minutes		Happy / Sad / Angry / Frustrated / Other
_______ AM/PM	_______ AM/PM	_______ minutes _______ times	_______ minutes		Happy / Sad / Angry / Frustrated / Other
_______ AM/PM	_______ AM/PM	_______ minutes _______ times	_______ minutes		Happy / Sad / Angry / Frustrated / Other

4

Postoperative Day 2

Serial Number ____________________
(Research staff use only)

Pain (every 4 hours)



Time	*Pain Rating (use smiley faces above)*	*What did you do (circle one or more)?*
________ AM/PM		Over the Counter (OTC) Pain Pill / Prescription Pain Pill / Ice / Heat / Rest / None
________ AM/PM		Over the Counter (OTC) Pain Pill / Prescription Pain Pill / Ice / Heat / Rest / None
________ AM/PM		Over the Counter (OTC) Pain Pill / Prescription Pain Pill / Ice / Heat / Rest / None
________ AM/PM		Over the Counter (OTC) Pain Pill / Prescription Pain Pill / Ice / Heat / Rest / None
________ AM/PM		Over the Counter (OTC) Pain Pill / Prescription Pain Pill / Ice / Heat / Rest / None
________ AM/PM		Over the Counter (OTC) Pain Pill / Prescription Pain Pill / Ice / Heat / Rest / None

Nerve Block

_____ Yes, I received a nerve block.

_____ Yes, I received a nerve block and have a catheter (tube) giving me pain medicine.

_____ No, I did not receive a nerve block.

Postoperative Day 2

Serial Number _____
(Research staff use only)

Nausea (every 4 hours)

Time	*Nausea*	*What did you do (medication, other)?*
_____ AM/PM	Yes / No	Medicine / Drank something / Ate something / Rest / None
_____ AM/PM	Yes / No	Medicine / Drank something / Ate something / Rest / None
_____ AM/PM	Yes / No	Medicine / Drank something / Ate something / Rest / None
_____ AM/PM	Yes / No	Medicine / Drank something / Ate something / Rest / None
_____ AM/PM	Yes / No	Medicine / Drank something / Ate something / Rest / None
_____ AM/PM	Yes / No	Medicine / Drank something / Ate something / Rest / None

Alcohol Intake

Did you drink alcohol? If so, please indicate the number of ounces:

_____ No, I did not drink alcohol.

_____ Yes, I drank alcohol and drank _____ ounces of beer / liquor / wine (circle one).

Tobacco Use

_____ No, I did not smoke cigarettes, cigars, pipe, etc.

_____ Yes, I smoke and smoked _____ cigarettes / cigars / pipes (circle one).

_____ Yes, I used chewing tobacco, snuff, or smokeless tobacco _____ times.

Food (breakfast, lunch, dinner)

Meal	*I had an appetite (circle one)…*	*I ate a (circle one)…*
Breakfast	Yes / No	Full meal / Partial meal / Nothing
Lunch	Yes / No	Full meal / Partial meal / Nothing
Dinner	Yes / No	Full meal / Partial meal / Nothing

Appendix B

NONIN WristOX2™ Model 3150

Appendix C

Physical/Perioperative Data Form

HM20002533 Participant Information Sheet C. Biddle

Contact Information (For Stipend Use Only)

Legal Name: _____

Mailing Address:

Street _____

_____

City _____ State _____ Zip _____

Telephone: (_____) _____ - _____

Case Number

Pulse Oximeter Serial Number (*Last 4 digits*): _____ _____ _____ _____

Date of Surgery (*MMDD format*): _____ _____ _____ _____

History and Physical

Age: _____ years Gender: Male Female ASA Class: _____

Planned Anesthesia Modality (*Circle all that apply*): General Regional Neuraxial MAC

Surgical Extremity: LUE RUE LLE RLE

STOP-Bang Score

1. Do you ***snore*** loudly (loud enough to be heard through closed doors)? Yes No
2. Do you often feel ***tired***, fatigued, or sleepy during daytime? Yes No
3. Has anyone ***observed*** you stop breathing during your sleep? Yes No
4. Do you have or are you being treated for high blood ***pressure***? Yes No
5. ***BMI*** more than 35 kg/m^2? Yes No
6. ***Age*** over 50 years old? Yes No
7. ***Neck*** circumference greater than 40 cm? Yes No
8. ***Gender*** male? Yes No

Total 'Yes' answers: _____

Home CPAP Use?
Yes No

For research purposes only. All information is confidential.

Appendix D

Sample Pulse Oximeter Data

Report Title

Patient Data
Age: 0
Physician:
Note 1:

Name: No Patient
DOB:

Height: 0 in
Weight: 0 lb
Note 2:

Gender: Unspecified
BMI: 0.0
ID: 50168556792

Recording Date: 24 March 2010 **Time:** 05:25:56 **Duration:** 30:03:20 **Analyzed:** 12:04:24
Comments:
Data storage rate of 4 seconds every sample.

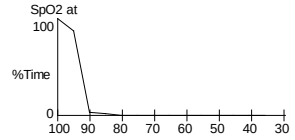
Event Data	SpO2	Pulse
Total Events	28	305
Time In Events (min)	18.1	95.2
Avg. Event Dur. (sec)	38.7	18.7
Index (1/hr)	0.9	10.1
% Artifact	61.6	61.7
Adjusted Index (1/hr)	2.4	26.5
%SpO2 Data		
Basal SpO2(%)	93.1	
Time (min) < 88%	19.5	
Events < 88%	3	
Max Single Time < 88%	768 sec at 08:18:40	
Minimum SpO2 (%)	80	
Avg. Low SpO2 (%)	89.9	
Avg. Low SpO2 < 88%	86.3	
Pulse Data		
Avg. Pulse Rate(bpm)	58.7	
Low Pulse Rate (bpm)	47	

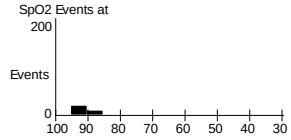
%SpO2 Level	Events	Below(%)	Time(%)
99 - 95	0	100	100.0
94 - 90	19	95	87.3
89 - 85	9	90	3.2
84 - 80	0	85	2.0
79 - 75	0	80	0.0
74 - 70	0	75	0.0
69 - 65	0	70	0.0
64 - 60	0	65	0.0
59 - 55	0	60	0.0
54 - 50	0	55	0.0
49 - 45	0	50	0.0
44 - 40	0	45	0.0
39 - 35	0	40	0.0
34 - 30	0	35	0.0

Analysis Parameters
Desaturation Event: drop in SpO2 by at least 4% for a minimum duration of 10 seconds.
Pulse Event: Change in rate by at least 6 bpm for a minimum duration of 8 seconds.

Graphic Summary
SpO2 (10 % per division)

Pulse (10 BPM per division)





Name: No Patient ID: 50168556792

Appendix E

Informed Consent Form

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Predicting Ambulatory Orthopedic Surgery Post-Operative Decline Via Patient Journal and Pulse Oximetry Data

VCU IRB NO.: HM20002533

SPONSOR: *AANA Foundation*

If any information contained in this consent form is not clear, please ask the study staff to explain any information that you do not fully understand. You may discuss this with your family or friends today, but we need your signed consent today to enroll.

PURPOSE OF THE STUDY
The purpose of this study is to explore your experiences after surgery and compare them to your blood oxygen levels.

DESCRIPTION OF THE STUDY AND YOUR INVOLVEMENT
If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered and understand what will happen to you.

For this study, you will undergo a pre-surgery physical and questionnaire that all patients have before surgery. We will ask about your medical and surgical history, medicines, allergies, and review your full medical record.

If you consent to this study, we will ask you to fill out a "patient journal" for the first two days after surgery. The journal will ask about your sleep, pain, nausea, and appetite, as well as about smoking or alcohol use if you smoke or drink alcohol. The journal is six (6) pages long, or three (3) pages for each day. You will write on it with pen or pencil.

You will also wear an oxygen monitor on your wrist whenever you rest or sleep. The monitor is connected to a Velcro strap that you can adjust for your comfort. There is also an attached soft plastic finger probe that you will place over any one of your fingers that is more comfortable. The monitor will collect your heartbeat and oxygen levels when you wear it. The monitor does not need to be turned on or off- it turns on and off when you put it on or take it off. Take the monitor off when you are not sleeping or resting.

After the second day, you will return the journal and oxygen monitor to the research team in the postage-paid envelope provided. You will be in a group of about 150 other surgery patients and your information will remain confidential.

RISKS AND DISCOMFORTS

There is a risk of minor discomfort when wearing the oxygen monitor. To ensure comfort, adjust the Velcro strap so that it is not too tight. You may wear it on either wrist. Also, wear the soft plastic finger probe on whichever finger you feel is more comfortable.

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Authority to Request Protected Health Information

The following people and/or groups may request my Protected Health Information:

- Principal Investigator and Research Staff
- Research Collaborators
- Data Safety Monitoring Boards
- Others as Required by Law
- Study Sponsor
- Institutional Review Boards
- Government/Health Agencies

Authority to Release Protected Health Information

The VCU Health System (VCUHS) may release the information identified in this authorization from my medical records and provide this information to:

- Health Care Providers at the VCUHS
- Study Sponsor
- Data Coordinators
- Data Safety Monitoring Boards
- Others as Required by Law
- Principal Investigator and Research Staff
- Research Collaborators
- Institutional Review Boards
- Government/Health Agencies

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

Type of Information that may be Released

The following types of information may be used for the conduct of this research:

☒ Complete health record	☐ Diagnosis & treatment codes	☐ Discharge summary
☒ History and physical exam	☒ Consultation reports	☐ Progress notes
☒ Laboratory test results	☒ X-ray reports	☐ X-ray films / images
☐ Photographs, videotapes	☐ Complete billing record	☐ Itemized bill
☒ Information about drug or alcohol abuse	☐ Information about Hepatitis B or C tests	
☐ Information about psychiatric care	☐ Information about sexually transmitted diseases	

☐ Other (specify):

Right to Revoke Authorization and Re-disclosure

You may change your mind and revoke (take back) the right to use your protected health information at any time. Even if you revoke this Authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization you may no longer be allowed to participate

in the research study. To revoke this Authorization, you must write to the Principal Investigator.

BENEFITS TO YOU AND OTHERS
You may not receive any direct benefit in this study. Your participation might help your health care team identify future patients at risk for low oxygen levels after surgery.

COSTS
There are no costs for your participation in this study except for your time to complete the journal and wear the oxygen monitor for two days after surgery.

PAYMENT FOR PARTICIPATION
You will receive a $50 Visa gift card. In order to receive this gift card, you need to complete the journal and wear the oxygen monitor when you rest or sleep for two days after surgery, and you must mail the journal and oxygen monitor to the research team in the provided envelope. After the research team receives your oxygen monitor and completed journal, we will mail the gift card to your address you provide to us.

ALTERNATIVES
You have the option to not participate in this study.

CONFIDENTIALITY
Potentially identifiable information about you will consist of your medical history, physical, and oxygen monitor measurements. Data is being collected only for research purposes.

Your data will be identified by a number code, not names, and stored in a password protected computer program. All personal identifying information will be kept in password-protected files and these files will be deleted at the end of the study. Access to all data will be limited to study personnel. A data and safety monitoring plan is established.

If, as part of this research, we learn about real or suspected child or elder abuse, the law says that we have to let people in authority know so they can protect the person(s) at risk. If something we learn through this research indicates that you may intend to harm yourself or others, we are obligated to report that to the appropriate authorities.

What we find from this study may be presented at meetings or published in papers, but your name will not ever be used in these presentations or papers.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

You do not have to participate in this study. If you choose to participate, you may stop at any time without any penalty. You may also choose not to answer particular questions that are asked in the study.

Your participation in this study may be stopped at any time by the study staff or the sponsor without your consent. The reasons might include:

- the study staff thinks it necessary for your health or safety;
- you have not followed study instructions;
- the sponsor has stopped the study; or
- administrative reasons require your withdrawal.

If you leave the study before the final regularly scheduled visit, return the journal and oxygen monitor in the provided envelope. You will not receive payment for participation if you do not fully complete the journal and oxygen monitoring for the full two days after surgery.

QUESTIONS

If you have any questions, complaints, or concerns about your participation in this research, contact:

Chuck Biddle, PhD, CRNA: Principle Investigator
VCU Department of Nurse Anesthesia
1200 East Broad Street
P.O. Box 980226
Richmond, VA 23298
(804) 828-9808

The researcher named above is the best person to call for questions about your participation in this study.

If you have any general questions about your rights as a participant in this or any other research, you may contact:

Office of Research
Virginia Commonwealth University
800 East Leigh Street, Suite 3000
P.O. Box 980568
Richmond, VA 23298
Telephone: (804) 827-2157

Contact this number for general questions, concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk with someone else. General information about participation in research studies can also be found at http://www.research.vcu.edu/irb/volunteers.htm.

CONSENT

I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing to participate in this study. I will receive a copy of the consent form once I have agreed to participate.

Participant name printed	Participant signature	Date

Name of Person Conducting Informed Consent Discussion / Witness [3]
(Printed)

Signature of Person Conducting Informed Consent Discussion / Witness	Date

Principal Investigator Signature (if different from above)	Date

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