# The Development of a Post Anesthesia Care Unit Patient Quantitative Assessment/Predictive Tool to Manage Post-Operative Health Alterations

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August 19, 2017

Presented to the Faculty at the University of Michigan-Flint
In partial fulfillment of the requirements for the
Doctor of Anesthesia Practice Program
(Spring 2017)

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#### Acknowledgements

I would like to express my sincerest appreciation to my mentor, Srikiran Ramarapu, MD. His guidance through the VA clinical research process was invaluable. He was instrumental in helping me with the research credentialing process, obtaining IRB approval, and the implementation of this study. Dr. Ramarapu's vast knowledge of anesthesia and the research process made him an ideal mentor. I am honored to have collaborated with him on this project. I would also like to give thanks to my program advisor, Jane Motz CRNA, DrAP. She invaluably provided me with constructive criticism, and sound advice through the entire scholarly project sequence. Dr. Motz also served as a project reader, alongside Lawrence Stump, CRNA. Both have provided countless hours of reading and editing for me, and have vastly improved the authorship of this project.

I want to acknowledge that this rigorous journey would not have been possible without the loving support of my friends and family. My fiancée, Megan Ginter, CRNA, provided me with needed encouragement, and was my biggest cheerleader. She helped me channel my abilities, and strength to persevere to completion. I want to thank my parents, Joe and Shu Mei Adams, for instilling a strong work ethic in me, and for raising me to be the man I am today. To my sister Kathy Gradnigo, for always believing in me and giving me confidence. Lastly, I want to thank my children for giving me purpose to work hard every day: Ella, Nicolas, Harper, Payton, and Claire. Although they did not directly contribute to my education, they made me want to be a better me.

# **Table of Contents**

Abstract	4
Introduction	5
Review of Literature	8
Historical Perspective	8
Call for Change	9
PACU Education and Standards	11
Proper Handoff of Care Post-operatively	13
Recovery Phases	16
Recovery Monitoring	19
PACU Complications	25
Quantitative Scoring.	27
Gaps in Literature	29
Summary and Research Question	30
Theoretical Model	32
Methods and Material	34
Project Design	40
Population	42
Implementation	43
Results	44
Primary Outcome Result	45
Secondary Outcome Results	47
Discussion	48
Major Findings and Implications of Study	48
Study Limitations	50
Recommendations for Future Research	50
Dissemination	51
Conclusion	52
Appendices	54
References	60

#### **Abstract**

Purpose: Post anesthesia care units (PACUs) play an important role in the provision of safe patient care. Patients that possess comorbidities may have exacerbated medical conditions when exposed to surgical intervention and anesthesia. Physiologic changes related to surgery alter a patient's baseline physical state. Medical and nursing interventions are often needed to return patients to their pre-procedure health. American Society of Anesthesiologists (ASA) physical status classification may be a poor predictor of post-surgical complication. Nearly 20% of all PACU admissions require anesthesia intervention. Determining patient's acuity and staffing PACU appropriately maybe challenging. Recovery room workload responsibilities are different from other hospital units. Patient census can vary widely based on time of day, types of surgeries and whether scheduled/emergent. Nurses may care for more than one patient at varying degrees of recovery. The aim of the study was to develop a simple and reliable scoring tool [Rapid System Review (RSR) score] for recovery room nurses, that can predict the number of nursing interventions a patient may require during their stay in PACU.

**Methods:** This prospective, non-randomized, observational pilot study was conducted in the Post Anesthesia Care Unit (PACU) at the Veterans Affairs Medical Center, Oklahoma City. The pilot clinical evaluation tool was evaluated during a 4-month pilot period. A total of 100 patients were enrolled in the data collection. All data were entered on a form, and completed forms were collected for data entry and analysis, using Microsoft Excel. Pearson Correlation Coefficient was completed to evaluate trend, and the two-tailed unpaired t test with p values to evaluate significance. Graph Pad Prism (Version 7) and Pearson Correlation was used to calculate statistics. Significance was defined as (p < 0.05).

**Results:** The primary outcome was to predict the amount of interventions needed, to achieve a baseline health score for a patient admitted to the PACU, at the time of discharge. The secondary outcome was to evaluate if these patients achieved their baseline ideal score, or better at discharge. The Pearson Correlation Coefficient between the RSR high score, and actual interventions were 0.908 and p value was 0.000. The Pearson Correlation Coefficient between the ASA class and actual interventions was 0.273 and p value was 0.006. The mean patient ideal score was  $9.57 \pm 0.99752218$ , and the mean discharge score was  $9.96 \pm 0.695149$ . The two-tailed unpaired t test p-value was 0.0016 with a 95% confidence interval of difference. The RSR highest score (mean= $5.3636 \pm 3.14471576$ ) and the RSR discharge score (mean= $3.82716 \pm 2.58742$ ) were compared. The two-tailed unpaired t test p-value was 0.0002 with a 95% confidence interval of difference.

**Conclusion:** The pilot RSR tool had a strong positive relationship between the RSR scores, and the number of medical/nursing interventions. The RSR scoring system is more specific, and accurate, compared to the ASA physical status when determining PACU patient's needs. Patients discharged from the PACU achieved their preoperative ideal score or better.

**Keywords:** Rapid System Review, RSR score, Post anesthesia care units, PACU, predictive tool, anesthesia

### Introduction

Post anesthesia care units (PACUs) play an important role in the provision of safe patient care, as this dedicated observation area serves to minimize post procedure disasters. Patients that possess comorbidities may have exacerbated medical conditions when exposed to surgical intervention and anesthesia. Physiologic changes related to surgery alter a patient's baseline physical state. Medical and nursing interventions are often needed to return patients to their preprocedure health. Nursing interventions are often the first line actions needed to prevent post-surgical crisis, and without watchful nursing care in the PACU, medical interventions may be implemented too late. The amount of inadvertent negative outcomes post-operatively are as high as 40% of all hospital complications.<sup>1</sup>

Data shows there may be a link between surgical interventions, PACU events, and hospital complications.<sup>2</sup> American Society of Anesthesiologists (ASA) physical status classifications may be a poor predictor of post-surgical complications. Contributing factors that are predictive for adverse events in recovery are: complexity of surgery, heart arrhythmias, heart failure, and history of anesthetic complications.<sup>2</sup> A recent study<sup>2</sup> showed the contributing factors for critical events are apnea, hypotension, and desaturation. Nearly 20% of all PACU admissions require some form of anesthesia intervention.<sup>2</sup>

Fatalities caused by mismanaged post anesthesia care prompted the proliferation of dedicated recovery units.<sup>3</sup> In 1947 the Journal of the American Medical Association (JAMA) published a report by the Philadelphia Anesthesia Study Commission that demonstrated, 47% of post anesthesia care deaths were preventable.<sup>3</sup> The study occurred over an 11-year period, and the causes of the complications revealed in the 1947 publication, are still the reasons for complications that can lead to death in modern era recovery such as; laryngospasm, hypoventilation, and

respiratory obstruction.<sup>3</sup> The Anesthesia Study Commission vastly changed the process of recovering surgical patients and prompted standard requirements for a recovery room that are still utilized today.<sup>3</sup>

Post anesthesia care evolved from an afterthought at the discovery of anesthesia. Today, it is an important aspect of the hospital course, and continues to evolve. Recovery rooms were almost nonexistent in the past; however dedicated recovery rooms grew exponentially after World War II. PACU nurses evolved to serve in a progressive role as coordinator of care for patient advocacy. This advocacy includes being prepared for challenging patients and monitoring/managing dynamically fluctuating health states post-operatively.<sup>3</sup>

Determining a patient's acuity and appropriately adjusting PACU staffing may be challenging. Recovery room workload responsibilities are different from other hospital units. Patient census can vary widely based on time of day, types of surgeries scheduled/emergent, and the expectation of no delay in the transfer of a patient to recovery. Nurses may care for more than one patient at varying degrees of recovery.

Classifying patients and assigning an acuity rating can help in staffing justification and preparedness. A recent study conducted using nursing interventions to monitor acuity scoring is helpful in explaining productivity and justifying perceived overstaffing.<sup>5</sup> This study used similar measures as the Rothman Index, which is often used in intensive care to determine predictors for patient condition change.<sup>5</sup> Quantitative tools are being utilized throughout the hospital setting, and can have an impact on patient care and cost savings, or provide justification for utilization of hospital resources.

Gaps in literature exist, there are numerous quantitative tools used in healthcare to gage preoperative risks. There are few tools used universally in the PACU that quantify acuity and

predict interventions necessary to return patients to baseline health states. The PACU is a dynamic and evolving entity that greatly benefits from research directed interventions to guide the next level of care for healthcare innovations.

This project focuses on developing a PACU Rapid System Review (RSR) tool for recovery room nurses that addresses the respiratory system, cardiovascular system, neurological system, pain management, post-operative nausea/vomiting, blood glucose, and body temperature. The goal is to minimize post-operative complications leading to re-intubations, acute cardiac and neurological PACU events. Quantitative assessment tools (ex. Apgar, Aldrete, LEMON, STOP BANG, Goldman cardiac risk, etc.), are widely used in predicting health situations that may help guide medical and nursing interventions.<sup>42</sup> A carefully developed tool for the PACU may assist in predicting acuity and interventions for the post-surgical patient.

Information obtained in the investigation for this project was used in the development of the RSR for the Veteran's Affairs (VA) in Oklahoma City. The RSR was assessed every 15 minutes, and compared the predicted needed interventions with the actual interventions to analyze reliability. This study established a quantitative basis for acuity, and assisted in management of recovery room resources to accommodate staffing/preparation needs. Fluctuating patient clinical conditions were immediately addressed medically to avoid unnecessary stays in the PACU, and delays in discharge to home.

The questions leading this inquiry are: 1) How effective is implementing a rapid system review (RSR) tool immediately upon arrival to the PACU, to quantify acuity of post-operative patients at the VA in Oklahoma City? 2) Is there a correlation between the quantitative score and the number of interventions needed to bring the patient back to baseline health?

#### **Review of Literature**

#### <u>Historical Perspective</u>

The concept of a recovery room was first documented in 1751 in England.<sup>6</sup> Little is known about early history of recovery rooms, and why the concept didn't catch on. The birth of inhalation anesthesia followed in 1842 when sulfuric ether was delivered by Dr. Crawford Long in Georgia.<sup>7,8</sup> Ether was used recreationally during this time for intoxication purposes. Dr. Long was a user himself, noted the anesthetic/amnestic properties, and convinced a patient to use ether during surgery. Anesthetic induction was performed by having the surgical candidate inhale ether from an infused towel. Dr. Long dissected a small tumor off the back of the first patient's neck. He replicated the anesthetic/surgical intervention on a separate occasion with the same patient yielding similar results. Success was attested when the patient reported little of no pain during the two separate procedures.<sup>7</sup>

The anesthetic delivery by Long was a triumph but his experiment went unpublished until later. The ether inhalation technique was not main stream until 1846.<sup>7</sup> Dr. William Morton demonstrated the use of ether in the famed "Ether Dome" in Boston Massachusetts General Hospital. He performed his surgical/anesthetic procedure in the presence of an audience and this event became a pivotal point in anesthesia history. The world quickly accepted ether, thereby a new age of surgery and anesthesia emerged.<sup>8</sup> Ensuing advances in surgical techniques were largely due to the advances in anesthesia. Surgical patients were able to tolerate procedures that were once unbearable, and surgeons were able to perfect their techniques.<sup>8</sup>

The art of surgery and anesthesia advanced in technology in their respective fields.

Monitoring and post anesthetic management struggled to keep pace with post immediate care.

Recovery rooms were not a widespread idea, and few understood the importance of

observation/interventions. Florence Nightingale was a pioneer in the recovery care concept. In the 1860's, she was one of the first health providers to separate patients that received anesthesia, and assign them to a special room.<sup>3,6</sup> She recognized the importance and advantages of caring for someone that was rendered unconscious. The benefits of special care after anesthesia did not have the notoriety as the anesthetic itself. Ether anesthesia was a marvel, but presented new challenges.

The discovery of anesthesia is a recognized benefit to all of humanity because it allows for excruciating interventions to be tolerated. The innovation of inhaled anesthetic agents carries unique consequences to surgical outcomes. The patient must overcome aspects of anesthetics such as muscle relaxation, altered conscience state, and pain medications. These once nonexistence concepts in early surgeries, now pose additional risks. Patients may survive a life-saving surgery only to succumb to anesthetic complications. The safety aspect of anesthesia did not come to realization until later.<sup>6</sup>

The notion that a surgical patient must first overcome anesthesia before recovering from surgery, wasn't a cognitive belief until the 1940s.<sup>6</sup> Almost 100 years had passed before people placed importance on a dedicated area for post anesthesia care.<sup>6</sup> It was realized that the recovery area needs to be in the vicinity of the operative suite, and the anesthesia department must take part in the management of the patient's care.<sup>6</sup> This enlightenment was due to research and improvement process inquiry.

### Call for Change

The Anesthesia Study Commission of Philadelphia County Medical Society exposed the dangers of post-operative events in 1947. This group of Anesthesiologists met for 11 years, and chronicled the death rates following surgeries from multiple hospitals.<sup>3,9</sup> Discussions about cases

involving mortality were highly scrutinized for the purpose of learning, and improving outcomes.<sup>9</sup>

Data showed that of 307 cases reviewed; nearly half of the post-surgical deaths were preventable. <sup>9</sup> The numbers demonstrated that approximately 12 preventable deaths per year occurred at any given hospital. The statistics were alarming, and the Anesthesia Study Commission suggested that anesthesia was not keeping up with the pace of surgical advancements. It was concluded that anesthesia services must evolve with the times to advocate for patient safety. Confounding factors were identified, and sound implementation recommendations were made based on the findings of this study. <sup>9</sup>

Consistent factors in the study findings included; post-operative care mismanagement, poor oxygenation, and frequent anesthetic overdose. Additionally, 63% of the reported deaths were due to lack of nursing interventions, when patients obstructed their airway. Respiratory obstruction is a critical event that occurs frequently post-operative, and interventions must be swift. The conclusion of the Anesthesia Study Commission was, anesthesia providers must be involved in the care of patients following surgical procedures. This care should take place in a dedicated recovery room, with trained staff to identify potential complications.

The Anesthesia Study Commission's findings were a revelation in healthcare. The evidence of bad outcomes gave way to a necessary system overhaul. A need to efficiently use nurses during the shortage in World War II, along with the Commission's findings, prompted the growth of recovery rooms across the country.<sup>3</sup> This new-found recommendation for standardized care required guidance. In 1950, Dr. Philip Lowenthal and Dr. Arch Russell, presented guidelines for the recovery area that are still relevant today.<sup>3,10</sup> "Recovery Room: Life Saving and Economical", was a paper presented to the Southern Society of Anesthesiologists, that listed

the basic characteristics of a successful recovery area, and described dedicated recovery area benefits.<sup>10</sup>

Conceptually, the recovery room should be in the vicinity of the operating room (OR); there should be two recovery beds available for every OR room. Emergency equipment should be accessible to include; oxygen, intravenous fluids, suction, airways, and emergency medications. Ideally the recovery room should be open 24 hours a day, and staffed by nurses that have been specially trained to take care of post-operative patients. The surgeon should be readily on hand, and an anesthesiologist should be trained to care for these patients. <sup>3,10</sup> Creating a dedicated area for recovery has several advantages; patients are less likely to suffer adverse events, cost containment of resources, centralization of resources, increased safety, and may offer liability protection. <sup>3,10</sup>

## PACU Education and Standards

Training and education of nurses working in the recovery room has evolved from the early days of recovery. In the 1920's a hand book called "Pocket Cyclopedia", provided references on how to take care of patients. Directions such as keeping the patients mouth "mopped out" to prevent pulmonary aspiration, was a recommendation. Training recovery room staff was primarily on the job training, through the 1960's. Today, advanced technology and a growing knowledge base regarding disease, created an enhanced need for standards and education.

The American Society of Peri Anesthesia Nursing (ASPAN) is the specialty organization that sets forth guidelines, conducts research, and provides educational offerings for the post anesthesia care unit setting.<sup>11</sup> This organization formed soon after the American Society of Anesthesiologist (ASA) sponsored a regional nursing meeting in 1979. The objective was to

discuss the formation of a national organization that advocates for post anesthesia recovery. In 1980, the first meeting took place, and The American Society of Peri Anesthesia Nursing (ASPAN), became the founding organization for recovery room nurses.<sup>6</sup>

The first order of business for ASPAN, was to establish national standards for the care of post-operative patients. The first draft of the developed standards was published in 1983, and has been revised over the years. The goal of the ASPAN standards was to apply safety practices to patients of all ages, clinical settings, and medical conditions. The standards were endorsed by the ASA until 1990. After that time, ASPAN became and independent association.<sup>12</sup>

In the 1990's, standards soon reflected the template of the American Nurses Association in that it was structured, included outcome framework, and process. Key inclusion to the standards at that time, was adopting oxygen saturation as a requirement, and adjusting nurse/patient ratio. Guidelines were set to 1:2 nurse-patient ratios in an uncomplicated Phase I recovery. A ratio was established for PACU nurses to assume care at 1:3 ratios in an uncomplicated Phase II recovery. Phase II recovery. In the process of the American Nurses Association in that it was structured, included outcome framework, and process. Key inclusion to the standards at that time, was adopting oxygen saturation as a requirement, and adjusting nurse/patient ratio.

Competency based guidelines were formulated in 1995. The expanded standards included all areas of the peri anesthesia realm. Guidance was now offered in the non-traditional recovery areas such as endoscopy, heart catheter lab, labor/delivery, radiology and pre-operative holding. A position statement was formulated to address the competencies needed for nurses to take care of intensive care overflow patients, and minimal standards were set. Advanced cardiac life support became a requirement for those nurses that cared for phase 1 patients, which includes the intensive care overflow population.<sup>12</sup>

Competencies extended to all phases of the peri-anesthesia practice. Standards were eventually written to add clarity, reasoning, show outcomes, and provided a road map to achieve

accepted goals. ASPAN continues to strive to advocate for peri anesthesia practice by setting guidelines for staff proficiency, promote research, provide education, use evidenced based practice, write policy, and set standards in care and monitoring.<sup>12</sup>

## Proper Handoff of Care Post-operatively

Policy changes often occur after perceived preventable poor outcomes. The case of Eyoma verses Falco in 1991 is a basis for proper handoff of care. <sup>13</sup> This lawsuit involved a nurse in the PACU. Nurse Falco was taking care of a healthy man post non-complex gall bladder removal that lasted less than an hour. The patient was stable upon arrival to the recovery room, moved purposefully to commands, and pulled out his own oral airway. <sup>13</sup>

At some point, nurse Falco left the patient's bed side to care for another patient. She handed off care to another nurse in the PACU, but did not receive verbal confirmation from the nurse that was supposed to assume care. When Nurse Falco returned to the PACU, she discovered the patient was unattended. The anesthesiologist checked on the patient, and discovered the patient was in respiratory distress, that progressed to cardiac arrest.<sup>13</sup>

A code blue ensued, and it took 20 minutes to restore cardio-pulmonary circulation. The patient died from this proximate cause a year later after being in a persistent coma. Nurse Falco later admitted that the anesthesiologist told her to watch the respirations, but did not know the patient received narcotics. She admitted she did not get verbal acknowledgement that another nurse would assume care.<sup>13</sup>

The court's opinion was that Nurse Falco breached basic standards that directed PACU practice. She did not properly inquire what medications the patient was given, left the patient without proper handoff, and did not detect that the patient quit breathing. <sup>13</sup> Rapid assessment and interventions were absent due to lack of information, communication, and observations.

A joint effort by the American Society of Anesthesiologists (ASA), and the American Society of Peri Anesthesia Nursing (ASPAN,) created a standard for proper handoff, so cases such as Nurse Falco's can be prevented. Standards are created to protect patients from harm. The combined collaboration from the ASA and ASPAN produced standard 3 for post anesthesia care. Notable standards include; 1) the patient's condition needs to be re-evaluated by the anesthesia provider at the time of handoff, a verbal report should be given to the PACU nurse receiving care, and the patient's condition should be documented, 2) data about pre-operative condition and anesthesia/surgical course should be communicated to the nurse, and 3) the anesthesia provider must remain with the patient until the PACU nurse accepts care of the patient.<sup>14</sup>

Communication lapse can be a major factor in the continuum of care. Important facts must be revealed to tend to a crisis, and can possibly be managed instead of merely treating the symptoms. For example, if a patient is having respiratory difficulties, the fact that a paralytic was administered intra-operative is useful information. A reversal agent could be given to restore respiratory effort instead of reintubation. This communication, and endless others could help guide management, or prevent complications.

The Joint Commission identified a breakdown of communications as the factor in 80% in medical mistakes<sup>15,16</sup> The World Health Organization (WHO) ranks communication breakdown as an important safety issue. The WHO ranked communication during care handoff in their top 5 priority actions.<sup>17,18</sup> The Joint Commission required accredited health institutions to put into practice uniform handoff protocols in 2006. The communication in handoff must stress mutual understanding between the person giving report, and the person accepting the patient care report.<sup>19,22</sup>

Proper handoff is vital for transfer of care in surgery patients, but crucial when patients undergo, in high acuity procedures. A study done by Hudson et al (2015), found that patients who undergo cardiac surgery have a likelihood of a 27% increase of morbidity, and 43% increase of inpatient mortality. Risk stratification to decrease risks may come from enhanced handoffs. Anesthesia is frequently compared to the aviation industry. A safe "landing" for airlines is comparable to a safe hand off in anesthesia. A poor handoff in the airline or energy industries can lead to devastation and loss of life, as with anesthesia. 18,20

A study published in the New England Journal of Medicine concluded that a formal well-designed handoff program decreases medical errors, and increases communications. Medical errors decreased by 23%, and avoidable adverse events declined by 30% in their study. <sup>21</sup> The decrease due to the newly implemented handoff did not have negative workflow associated with it. The handoff consisted of a written and a verbal report. The study's written portion contained; assessment of illness severity, summary of the patient, allergies, list to do, contingency plan, medication lists, code status, laboratory values with dates, and vital signs with time/dates. The verbal report included; patient summary, illness assessment severity, to do list, contingency plan, and the person accepting report should read back the information for clarity of facts. <sup>21</sup>

A large study involving several pediatric centers tracked handoff over a year's time. The goal of this collaborative research was to evaluate the validity of handoff safety at multilocations. Twenty-three medical centers participated, and 7,864 handoffs of care were evaluated. The results showed hand-off associated care failures declined by 17.9% overall, when a standardized handoff process was implemented. Critical points of the handoff process were emphasized in this report.<sup>22</sup> Single studies and large studies of the handoff process have consistently shown positive benefits within the anesthesia aspect of care.

The main theme of handoffs is their importance in the safety of patient care. Anesthesia handoffs increase a patient's risk of major mortality and morbidity by 8% hospital wide. <sup>23</sup> The incidences of deleterious effects of handoff outcomes are similar amongst providers.

Anesthesiologists, Certified Registered Nurse Anesthetists (CRNAs), and anesthesia residents adverse encounters are identical. There are no universally accepted handoffs or guides for use intraoperatively. The success of a newly developed PACU Rapid Assessment Tool will be contingent on an accurate handoff. Care must be taken to ensure information is transmitted to the receiving care units, allowing them to anticipate care within the phases of post anesthesia recovery. <sup>23</sup>

### **Recovery Phases**

A pivotal point in the history of PACU nurse to patient staffing ratio occurred in 1969. Laidlaw verses Lions Gate hospital lawsuit sparked change to the standard of care in acuity monitoring. This legal case involved a recovery room nurse that was left alone in the PACU with newly admitted post-surgical patients. The second nurse was on break. Several back to back admissions occurred in a short time span. The nurse that was by herself had a total of six patients at one point. One of the six patients went into respiratory arrest, and suffered brain damage. <sup>24,25</sup>

The courts found both nurses negligent because they placed themselves at unreasonable risks to patient safety. The patients were not observed constantly which led to a bad outcome. Predicted needs of the patient with appropriate interventions would have most likely occurred if two nurses were present. The initial phase of recovery is deemed the most vital in the hospital, and priority vigilance should occur. This initial phase is known as Phase I level of care.<sup>24,25</sup>

The purpose of the Phase I level of care standard is to provide safety measures by which, the primary nurse should never be left alone. A back up nurse must be within an ear shot of the

primary nurse, and be able to provide immediate assistance. The initial admission is considered a critical point until specific guidelines are met; the anesthetist gives report to the nurse and questions are addressed, the patient's airway is secure, head to toe assessment complete, stable hemodynamics, and the patient is not thrashing in bed uncomfortably.<sup>25</sup>

Acuity should guide the staffing pattern. Patient conditions are often dynamic, and can revert to Phase I from Phase II. Phase I and Phase II are not physical locations, but a level of care. A patient may be completely alert and return to an unconscious state in a short amount of time. The rapid change in physical status may be attributed to; the length/type of surgery, method of anesthesia, pre-operative comorbidities, and patient's tolerance to medication/anesthesia. The patient may once again require a higher level of observation if a change in condition occurs. The PACU staffing profile should be dynamic to adjust to the constant changing needs of the patients. <sup>26</sup> For instance, an alert obese patient with sleep apnea who received fentanyl for pain control post herniorrhaphy, may revert to an asleep state causing his airway to obstruct. This situation necessitates a higher level of care/observation.

The highest level of care in Phase I, is the two nurses to one patient ratio (2:1). This means that patient acuity requires two nurses to adequately care for a single patient safely. This occurs when the patient is critically ill or unstable. The second highest level of care within Phase I is the one nurse to one patient ratio (1:1). The 1:1 ratio should be observed at the time of admission until the critical elements are met. If the patient is hemodynamically or airway unstable, they are in a 1:1 status. Patients requiring interventions such as jaw thrust or oral airway to assist, would be considered unstable. Signs of respiratory obstruction including chocking, crowing, wheezing, or respiratory distress would require close observation.

Unconscious pediatric patients eight years and younger must be at the 1:1 ratio until the child is awake.<sup>25</sup>

The second tier of observation in Phase I care is the 1:2 patient ratio. This pairing can be; two patients that are awake, but not meeting all discharge criteria, although stable and free from complications, two stable awake patients age eight and under with competent support at the bedsides such as family members, one asleep patient over age eight, but hemodynamically/respiratory stable, paired with one awake stable patient.<sup>25</sup>

Patients transition to Phase II care when the patient requires fewer nursing interventions. The objective of this level of care is to prepare the patient for care at home or an extended care facility. Staffing can still range from 1:1 ratio if the patient is critical, and requires a transfer to higher level of care, such as an intensive care unit. Otherwise staffing in Phase II is a ratio of 1:2 or 1:3, depending on the acuity.<sup>25</sup>

The least acute phase of post-operative recovery is the extended care level. This is the phase when patients no longer meet the criteria for constant monitoring and interventions. Typically, extended care patients are awaiting transportation, are patients with no available caregivers, those awaiting hospital admission, or patients that have undergone procedures, which may require extended observation. The nurse to patient ratio is typically 1:3 to 1:5, in this phase of observation.<sup>25</sup>

The ASPAN's standards are guides for observation; it is up to PACU managers to meet the needs of personnel. Managers must staff the recovery room appropriately to provide for safe observations and interventions. To match staffing needs with peak times, considerations should include: 1) assess when patients will arrive based on operation schedule, 2) recognize time of day, hours, and number of recovery beds needed, 3) allocate support employees to help with

lunches and patient transfers, 4) operate with 1:2 ratio, and have contingency plans to account for any 1:1 ratio acuity.<sup>27</sup>

The staff should be familiarized with ASPAN's standards for phases of observation. Evidence shows that employees who are knowledgeable regarding the Phase I and Phase II guidelines, can contribute to a decrease in a patient's length of stay. A decrease in the length of admissions translates to increased efficiency, decreased hold times, cost effectiveness, and fosters nurse satisfaction. As a standard of the st

#### **Recovery Monitoring**

Standards of care and monitoring have evolved to meet the challenges of the dynamic PACU environment. Quantitative patient monitoring devices have been utilized in the PACU, to assist nurses to detect changes in a patient's condition these include; carbon dioxide monitoring, invasive/non-invasive blood pressure devices, oxygen saturation monitoring, telemetry, thermometers, and point of care testing techniques. This technology can quantify patient condition changes, and give meaning via a scaled score/number, to alert the practitioner that a situation is outside of a referenced norm. Coupled with qualitative measures such as assessment of skin color, patient intensity, and pain; nurses can quickly, critically identify changes in the patient's condition.

There is no doubt that early post-anesthesia recovery nurses had to rely on qualitative measurements alone, to gauge recovery or deterioration in a patient's status. This author has identified the PACU nurse as vital in appraising information to critically evaluate a patient's condition. These nurses must be able to detect a change in clinical status, and be ready to intervene. The ASPAN monitoring standards guide minimal required assessment for post-operative patients to include; airway monitoring/interventions to prevent respiratory issues,

assessment of carbon dioxide status when needed, documentation of cardiac rhythm per hospital policy, and monitoring for critical changes in vital signs.<sup>25</sup> It is the PACU nurse's responsibility to utilize monitoring techniques, and interpret results, to make appropriate decisions regarding patient's condition.

Clinical judgement is a requisite to determine vital sign frequency and interpret values.

Currently there is no clinical evidence that guides how often vital signs must be assessed for best outcomes. The American Society of Peri Anesthesia Nursing (ASPAN) Evidence Based Practice Strategic Work Team met in October 2009, to discuss vital signs best practice. <sup>29</sup> The question of, "What frequency should vital signs be assessed?", was examined. The team reviewed 523 relevant clinical articles, and it was concluded that there was zero evidence of how often vital signs should be taken for best outcomes. <sup>29,30</sup>

Since the literature did not support monitoring guidelines, it is suggested to follow institutional policy. Generally, the experts recommend taking complete vital signs every five minutes for the first 15-30 minutes, and every 15 minutes for the duration of Phase I recovery. In Phase II, vital signs should be analyzed every 30-60 minutes. Monitoring frequency can be increased based on the patient's clinical condition. To decrease the frequency of vital signs, the patient should have a secure airway, and be hemodynamically stable.<sup>29</sup>

Hemodynamic evaluation of blood pressure in the recovery room consists of invasive and non-invasive monitoring. Non-invasive blood pressure assessment was a qualitative measure in early history used by the Chinese, Greeks, and Egyptians.<sup>31</sup> Modern day, quantitative non-invasive forms of blood pressure monitoring consist of oscillometry, tonometric and volume clamp devices. The oscillometry method (via blood pressure cuff), was invented in 1860 and is

the most widely used method of monitoring anesthesia blood pressures. It is estimated that over 80% of all patients undergoing surgery will have an oscillometry method of measurement.<sup>31</sup>

The oscillometric blood pressure method is easy to use, but has disadvantages. Measurements can be inaccurate in patients that are excessively obese, or if the patient has inelastic arteries. <sup>31</sup> Oscillometry is an estimate of blood pressure, and has a 12.5+ or – mmHg standard deviation difference, compared to an arterial monitor (when the mean arterial pressure is 75 mmHg). The accuracy of the blood pressure cuff (oscillometry) is nonexistent in severe hypotension or hypertension states. <sup>31,32</sup> Other disadvantages include, oscillometry is non-continuous and does not display an arterial waveform.

The tonometric and volume clamp methods both offer a displayed arterial waveform. The tonometric method measures blood pressure waveform by assessing tone by placing a sensor over the radial artery. Tonomentry has a 6.3 mmHg standard deviation difference from invasive arterial measurement, but is primarily used in research settings.<sup>31</sup> Volume clamp method is a way to measure continuous pressure by counter pressure in the finger. This method requires good peripheral circulation. Vasoconstrictive states and extreme temperatures can affect measurements. Overall, the volume clamp method has a standard deviation mean arterial pressure difference of 9.4 mm Hg compared to invasive arterial monitoring. The benchmark method for blood pressure monitoring is the direct arterial route.<sup>31</sup>

Intra-arterial blood pressure monitoring is considered the most accurate way to assess blood pressure.<sup>31,33</sup> The first arterial access was described in 1733 by Stephen Hales. He performed the arterial access on a horse using a brass tube, and noted the blood pressure oscillation matched the heart rate.<sup>31</sup> The first use of continuous monitoring in an operation was described in 1949 by Peterson.<sup>33</sup> Today, arterial cannulation is performed on an estimated 16%

of patients undergoing anesthesia.<sup>31</sup> Patients having surgical procedures that require continuous pressure readings or frequent blood draws, may benefit from an arterial line.<sup>33</sup>

The radial route is the most common way to cannulate the artery because of ease, low infection, and vascular complication rates. The femoral route is often used in the event of an emergency because it is easy to access, and allows for other invasive devices such as intra-aortic balloon pump or extracorporal membrane oxygenator (ECMO) to be introduced.<sup>34</sup> Complications do occur with invasive monitoring such as nerve damage, pseudo aneurysm, hematoma, occlusion of artery, and infection. Risk and benefits should be weighed prior to selecting a route of monitoring, and invasive routes should be discontinued as early as possible when there is no need for continuous assessment.<sup>31</sup>

There are no recommended post- operative blood pressure ranges that are shown to improve patient outcomes. Keeping a blood pressure range at a set range depends on the patient's co-morbidities and surgical situation. It has been suggested in the literature that higher mean arterial pressures (MAP) would lead to better outcomes. <sup>31</sup> The blood pressure goal directed therapy of keeping the MAP 65-70 mmHg compared to MAP 80-85 mmHg in septic patients found no difference in outcomes in studies. It is suggested that MAP should always be greater than 55 mmHg though. A large study of 33,330 non-cardiac surgeries revealed a risk of heart and kidney injury if the MAP remains less than 55 mmHg for as little as 1-5 minutes. <sup>31,35</sup>

Hemodynamic risk assessment telemetry is another measurement tool used in the recovery room. It is estimated that 70% of all patients that undergo general anesthesia will experience dysrhythmia of some sort peri-operatively.<sup>36</sup> Rhythm disturbances can be benign in the form of tachycardia, bradycardia, or other non-lethal rhythms. The cause for variations may be from a primary disease process, or reversal changes due to medication administration. It has

been well established that anesthetic drugs and medications used during surgical cases can alter the way the heart responds. <sup>36</sup> A small percentage (1.6%) of heart dysrhythmia peri-operative requires intervention. Heart telemetry is a quick way to assess electro-physiologic disturbances of the heart, and ASPAN recommends documenting heart rhythm strips in the PACU per institution policy. <sup>25</sup>

Pulmonary status is an equally important assessment in hemodynamic surveillance. Pulse oximetry is a widely-accepted monitor to detect hypoxemia in acute care areas in health institutions. This oxygen saturation tool allows practitioners to spot trends in hypoxemia. This is a helpful and a dependable way of guiding the administration of oxygen to avoid complications. The accuracy of an oximeter's measure of arterial saturation (SpO2) is within 2%, in patients with a SpO2 reading of over 90%. Readings of less than 90% are less precise. <sup>37</sup> Near patient testing arterial blood gas monitors available in some PACUs can assist in the assessment of oxygenation, if the SpO2 reading is in question.

In a study of more than 20,000 patients, the pulse oximetry detected desaturation (SpO2 less than 90%) in 7.9% in patients who were monitored with a pulse oximetry, and only 0.4% were identified as hypoxic without a monitor. Despite this fact, the largest randomized study of 20,802 patients failed to demonstrate the utility of decreased complication and death with SpO2 use. <sup>37</sup> In a survey by Moller et al., 94% of all anesthesiologists believe the SpO2 monitor is useful in guiding treatment, and spotting declining oxygenation status to avoiding ischemic injury, and therefore should be a standard of care, despite a lack of evidence. <sup>37,38</sup>

Another useful tool in alerting care takers to respiratory status changes is monitoring the presence of end tidal carbon dioxide (ETCO2). Capnography is a device which monitors ETCO2, and provides an extra dimension for respiratory status monitoring, by assisting in the

early detection of respiratory difficulties. Respiratory ventilation and high carbon dioxide levels can be detected with capnography, and coupled with pulse oximetry, can be a valuable assessment device. <sup>39</sup> The utility of this device is recognized for detecting decreased ventilation due to central respiratory depression and airway obstruction, by changes in the CO2 waveform. A recent systemic review showed that monitoring capnography reduced the incidence of hypoxemia. <sup>40</sup>

Capnography has been a standard monitoring device for anesthesia providers in the operating room for many years. The ASA and ASPAN both recognize the usefulness of ETCO2 monitoring in the PACU, but stop short from recommending it as a standard monitoring device at this time. Both organizations recognize capnography is one of best ways to continuously monitor ventilation. The ASA suggests ventilation needs to be monitored, but does not specifically state capnography is needed. ASPAN recommends the use of capnography if available and indicated. ASPAN believes continuous ETCO2 monitoring is especially useful for those with sleep apnea, during opioid administration, and for obtunded patients. Both organization believe that ETCO2 monitoring will be a standard someday. <sup>29</sup>

Other common monitors in the PACU include the glucometer, and the thermometer. ASPAN's guideline for a temperature goal is 36-38 degrees Celsius, to prevent post-operative complications. Cited evidence based risks from hypothermia includes; infection, adverse myocardial outcomes, increased duration of hospitalization/delayed PACU discharge, increased blood loss, increased risk of requiring a blood transfusion, prolonged anesthetic effects, pressure ulcers, and patient dissatisfaction. ASPAN offers a protocol for rewarming the patient, to maintain a normal temperature.<sup>41</sup>

Glucometers are available in many PACUs. Diabetes is a common disease that impacts the perioperative course. Diabetics post operation are at an increased risk of cardiac events, volatile blood pressures, and may be hemodynamically unstable. The stress of surgery increases blood sugars and circulating catecholamines. It is suggested to keep the patient's glucose levels peri-operatively less than 200mg/dl, but greater than 72 mg/dl. A Hemoglobin A1C above 7% suggests a patient has poor glycemic control. This substandard level of control can lead to a difficult to manage post-operative blood sugar levels. Hyperglycemia has known effects of poor wound healing and incidences of infection, so it is important to keep the patient's glucose normal peri-operatively. 42

## **PACU Complications**

Data suggests there may be a link between surgical interventions, PACU events, and hospital complications.<sup>2</sup> Physiologic changes related to surgery alter a patient's baseline physical state, prompting medical interventions to return the patient to pre-procedure health. Incidences of inadvertent negative outcomes have been reported. A large study<sup>1</sup> of 18,473 patients at a university hospital, determined post-operative complications occurrence to be 23.7%. It is estimated that post-operatively, complications can be as high as 40% of all hospital complications.<sup>1</sup>

Post-operative nausea and vomiting are identified as the most common problems experienced by patients in the PACU. The calculated percentage of nausea and vomiting (PONV) after anesthesia is between 10-30% of all patients. <sup>43</sup> This complication is the most feared by patients, more so than pain. Patients really hate to vomit, and this experience is reflected on patient satisfaction surveys. Extended stays can occur in the PACU, or patients may require an unscheduled admission resulting from PONV. Populations at the highest risk for

developing PONV are; patients with a history of PONV, non-smokers, females, patients with motion sickness, younger populations, and type of surgical procedure. It is suggested that preemptive nausea/vomiting treatment should be instituted to prevent PONV. <sup>43</sup>

The second leading complications identified in the immediate post-operative period are upper airway issues. These occur in 6.9% of all patients. Factors contributing to airway problems include patient history, surgical procedure, and anesthetic factors. <sup>43</sup> Patients with obstructive sleep apnea (OSA), are at a higher risk for experiencing post-operative respiratory complications, cardiac complications, and requiring intensive care admissions. This condition can be difficult to prepare for anesthetically, because a large percentage of patients experiencing OSA are undiagnosed. This population has 14 times the risk of requiring mechanical ventilation, and 46 times the risk of needing non-invasive positive pressure support. <sup>43</sup>

Contributing factors leading to respiratory insufficiency in the PACU may be caused by lower airway problems, upper airway obstruction, or pulmonary complications. These factors include; asthma, chronic obstructive pulmonary disease (COPD), obstructive sleep apnea (OSA), obesity, pulmonary hypertension, heart failure, upper respiratory tract infection, tobacco use, metabolic factors, (blood urea nitrogen >30 mg/dL, albumin <3 g/dL), and a higher ASA classification.<sup>43</sup>

Surgical considerations for complications are numerous. Interventions that occur near the diaphragm impede breathing. Ear, nose, and throat procedures can cause obstruction/laryngospasms. Neuro surgery can cause a decreased level of conciseness, that leads to hypoventilation or aspiration. Miscellaneous factors that attribute to increased risk are severe surgical site pain that results in voluntary restriction of breathing, large volume fluid resuscitation, and procedures that last longer than 3 hours.<sup>43</sup>

Patients receiving general anesthetics (GA) have a greater incidence of respiratory complications compared to those where regional anesthesia techniques are used. Anesthetic gases and opioid administration und in general anesthetics, cause respiratory depression.

Neuromuscular blockade used to provide adequate surgical access during GA, can be inadequately reversed. Residual neuromuscular blockade occurs in 31% of PACU patients, which suggests it is a common finding. Enduring muscular blockade has been associated with post-operative respiratory critical events. 46

Events that contribute to PACU complications which occur to a lesser extent include; hypotension (2.7 %), dysrhythmias (1.4 %), elevated blood pressure (1.1 %), mental status alteration (0.6 %), and suspected or serious cardiac events (0.6 %). The rare complications of awareness during anesthesia, and visual loss may first present in the PACU. <sup>43</sup>

# **Quantitative Scoring**

Methods to quantify health status have been instituted in most areas of medicine.

Assigning numbers to variables can give additional meaning when describing health conditions.

With this concept, a numerical value is assigned to an idea, and it instantly conveys a universal understanding. The profession of anesthesia uses this concept to classify the health status of patients presenting for anesthesia services. This system is known as the American Association of Anesthesiologist' physical status classification or ASA classification. Anesthesia providers recognize a patient with a ASA I as a patient that is healthy, non-smoking, and has a normal body mass index (BMI).

The purpose of the ASA classification system is to stratify perioperative risks, and is a measure of health status.<sup>48</sup> A large study determined that the ASA classification system has good inter-rater reliability, and is a valid predictor of patients' pre-operative health conditions. The

ASA physical status system classifies a progression of health severity through level numbers I through VI.<sup>48</sup> A low number classification signifies wellbeing, and higher numbers designate various stages of illness. Patients classified with an ASA I have no co-morbidities, whereas patients with a classification of ASA VI have experienced brain death, and they present for organ harvest. This easy to understand ordinal level of assignment allows the anesthesia practitioner to consider the best means to manage the patient's care.<sup>47</sup>

Patient care management may depend on what a numerical scoring value means. A value may mean a patient can be discharged, whereas another value may mean the patient is comatose. Statistically speaking, medical scoring tools are descriptive variables associated to medical finding and the outcome is the feedback variable that guides the treatment success of the medical findings.<sup>47</sup> Another example of a medical scoring tool that are describes medical findings is the PACU is the Aldrete score.

The Aldrete scoring system has been in use internationally since 1970. This quantitative scoring tool is used to assess the recovery from anesthesia. The ease of application made this a widely-accepted tool around the world.<sup>49</sup> Dr. J Antonio Aldrete developed his medical scoring system to reflect common physical signs that were observed in the PACU. He wanted the tool to be easy and applicable to all aspects of anesthesia whether it is sedation, general, or regional anesthesia. Dr. Aldrete mirrored his evaluation tool after Dr. Virginia Apgar's scoring tool of newborn assessment.<sup>50</sup>

Dr. Aldrete gave credit in his opening paper to Dr. Apgar's work. She developed her scoring system 18 years earlier. The Apgar scoring system was developed to objectively assess physical conditions of babies at birth. He used similar assessments to numerically calculate variables; activity, respiration, circulation, level of consciousness, and color are scored. A score

is assigned 0-2, depending on the presence or absence of an observed condition. The sum of all numbers indicates the physical condition. A score of 10 is the highest achievable score. His research indicated a score greater than 7, was needed to meet discharge criteria.<sup>50</sup>

Dr. Aldrete modified his scoring system in 1995. The scores were changed to meet the needs of technology (pulse oximetry), and the trend of outpatient surgery. This updated scoring system includes 10 variables consisting of; activity, respiration, circulation, consciousness, oxygenation, dressing, pain, ambulation, feeding, and urine output. The maximum score for the Modified Aldrete is 20, compared to 10 with the old rating system.<sup>51</sup>

ASPAN does not specifically endorse a clinical scoring system for discharge. ASPAN recognizes Aldrete, White, and Post Anesthetic Discharge Scoring System (PADSS) commonly to gauge discharge internationally. The White system is also a numerical measure that is useful for fast tracking recovery, and PADSS is useful in Phase 2 recovery. If a scoring system is used, it must be done on admission, and at time of discharge at a minimum. The official recommendation from ASPAN is that written discharge criteria should be developed in agreeance with the Department of Anesthesia, to meet the needs of the patient population served. Clinical assessment and nursing critical thinking must be taken into consideration with a scoring system.

### Gaps in Literature

Gaps in literature exist, there are numerous quantitative tools used in healthcare to gage medical variables, or treatment success in a numeric value.<sup>47</sup> The ASA physical status helps stratify risks for surgery, and the Aldrete assesses discharge readiness.<sup>48</sup> There are no tools used universally in the PACU that quantify acuity, and predict interventions necessary to return a

patient to their baseline health. An added tool would help gauge patient care labor intensiveness, and help prepare the PACU accordingly.

The PACU is a dynamic, and evolving entity that greatly benefits from research directed interventions. To add to the body of knowledge, this study's quantitative/intervention scoring tool enhances both descriptive and feedback variables that describes medical findings, and treatment success. This added knowledge can help determine expected care needed, to gauge interventions needed to reach discharge.

Discharge assessments are often delegated to PACU nurses. Critical thinking must be used to evaluate if a patient meets discharge criteria. <sup>29</sup> There is limited consensus on PACU discharge assessment criteria. A systemic review shows evidence that pain, conscious state, nausea, and vomiting should be key assessments for discharge from the PACU. Vital signs are listed as important factors to observe, but there is no consensus on inclusion. <sup>49</sup> A developed PACU tool will include the research based variables, to prepare for clinical care. The quantitative/predictive study factors in workload needs, by establishing acuity in numerical form, and the number of interventions needed to reach discharge.

### Summary and Research Question

Inhalation anesthetics emerged in 1842 when Dr. Crawford Long experimented with the use of sulfuric ether during surgery. Emerging success in surgical techniques was due in part to anesthesia advances. The use of a dedicated recovery area post anesthesia care was not a widely-accepted concept for nearly 100 years. Continuous monitoring and post anesthetic care management, struggled to keep pace with post immediate care.

The landmark study by the Philadelphia County Medical Society, exposed the dangers of post-operative events in 1947. Research and discussions about post-operative complications

produced evidence of the need for close watchful care and interventions. Post anesthesia care units proliferated, and were widely accepted at that time.<sup>3.9</sup>

Challenges of patients undergoing surgical interventions, and anesthesia are complicated by added patient co-morbidities. Physiologic changes related to surgery alter a patient's baseline physical state, prompting medical interventions to return to pre-procedure health. Incidences of inadvertent negative outcomes post-operatively, are as high as 24% in recovery rooms.<sup>1</sup>

The PACU is unique for the fact that patient acuity status is frequently changing and rapid. No other health specialties endure the volatility of a patient condition from being unarousable, and unstable to awake and completely stable. Within this fluctuating state, there are critical moments in which the nurse must be prepared to recognize potential complications, and intervene appropriately.<sup>52</sup>

Preventing post procedure complications have improved over the years. Credit goes to technology, education, and protocols to minimize risks. Research is the key to improving process that enhance good patient outcome. Assessment and implementation (decision making) in post anesthesia care is under researched.<sup>52</sup>

Recovery room care generally falls under the auspices of anesthesia service. Quality improvement projects are needed to elevate excellence in care delivery. The aim of the study is to develop a simple and reliable scoring tool [Rapid System Review (RSR) score] for recovery room nurses, that can predict the number of nursing interventions a patient may require during their stay in PACU (Appendix A). This may help in preparedness and staffing justification. At the time of discharge from PACU, each patient would be evaluated to see if they achieve their baseline ideal score.

Quantitative tools compliment qualitative observations to holistically formulate a better clinical picture. Prompt medical interventions occur if the nurse's critical appraisals suggest an impending complication. For example, a carbon dioxide (CO2) reading may display zero (quantitative measure) which may alert the nurse of cessation of respirations. Further investigations by the nurse would include a qualitative assessment. If the patient is talking and responsive, the nurse could critically think and dismiss the zero CO2 as an artifact. The flip side, if the patient is unresponsive with a zero CO2 reading, then nurse could intervene and insure the patient is breathing. This is an example of how a quantitative tool numerically gives meaning. A number or lack of causes closer observations and interventions. The study's goal was to produce a score that is meaningful the PACU nurse in terms of acuity and interventions.

The developed study's scoring system was formatted to assess the patient's changing physiology during the perioperative period, and alert the PACU staff for possible interventions to optimize patient's health back to baseline health status. The immediate time following the surgical procedure has been identified by the anesthesia department as an area of concern.

The questions leading this inquiry are: 1) How effective is implementing a rapid system review (RSR) tool immediately upon arrival to the PACU, to quantify acuity of post-operative patients at the VA in Oklahoma City? 2) Is there a correlation between the quantitative score and the number of interventions needed to bring the patient back to baseline health?

#### **Theoretical Model**

The Post Anesthesia Care Unit (PACU) is an area where nurses are vital in responding to patient's health alterations, secondary to surgery and anesthesia. Typically, interventions are purposeful and goal directed. Some actions are automatic secondary to muscle memory, and reactions occur without cognitive thoughts. Responsiveness of actions should yield an expected

or predictable result.<sup>53</sup> An example may be when a recovery nurse assesses a patient that may have a respiratory obstruction, and immediately provides jaw thrust to open the airway. This action should have an expected result of keeping the patient breathing.

Ernestine Wiedenbach's Prescriptive Theory brings a relationship of an abstract phenomenon into a clinical meaning. Her theoretical basis of care is that a prescribed course of action, should yield beneficial/predictable result. The process of doing is predictive in nature, because if a specified action is carried out, a specific outcome should be expected. The situation should guide how one would act, to achieve their goals. Three factors that direct actions include; central purpose, prescription, and the realities.<sup>53</sup>

The central purpose is a nursing philosophy that composes a professional commitment of care. Concepts important to this philosophy are; the caretaker's appreciation for life, respect for patient's individual worth, dignity, autonomy, and acting swiftly in connection to one's beliefs.<sup>53</sup> These concepts are individual to a nurse's beliefs and can influence how they react. If there is meaning and importance, a person's moral guide will tell them how to respond.<sup>53</sup>

The prescription is the actions taken to fulfill the obligation of care. The central purpose drives the thought process for interventions. The nurse thinks through of what the end results should be, and how to intervene to accomplish the result. Three purposeful actions may be; nurse driven, patient driven, or mutually agreed upon between the nurse and patient. The purposeful action depends on the situation. The end result of actions or lack of actions places the nurse accountable for outcomes.<sup>53</sup>

The final factor that has an influence on decision making is the realities of the holistic environment. Clinical situations consist of physiological, physical, emotional, spiritual, and psychological factors. These realities are represented in five parts, and are always present in each

nursing decision making situations.<sup>53</sup> These realities are: agent; the nurse who acts to combine central purpose with realities; identifies objectives that can be obtained; practice nursing according to objectives; engage in activities that lead to improvements in practice, 2) recipient; this is the patient that is the receiver of interventions chosen by the nurse, 3) framework; any outside circumstances that could prevent or make harder for the nurse to complete tasks, 4) goal; the desired end result from actions taken by the nurse. Steps to getting to the goal includes: goal-in-intent, goal-in-application, and goal-in-execution, 5) means; the method of achieving the goal whether it is nursing skill, medications, equipment or any physical or cognitive factors to achieve a desired end result.<sup>53</sup>

Wiedenbach's theory underlies, and guides practice that is relevant to the PACU and this project. The project goal is to quantitatively determine acuity, and predict how much intervention is needed to return a patient to health. Interventions, whether it is therapeutic or diagnostic, will mostly be carried out by recovery room nurses. Responsiveness of these actions should be purposeful and predictive. How a nurse carries out these needed interventions relies on the central purpose, prescription, and the realities of Wiedenbach's thery.<sup>53</sup>

#### **Methods and Materials**

An extensive literature review was performed for this project. Data shows there may be a link between surgical interventions, PACU events, and hospital complications.<sup>2</sup> American Society of Anesthesiologists (ASA) physical status classifications may be a poor predictor of post-surgical complications. Contributing factors that are predictive for adverse events in recovery are; complexity of surgery, heart arrhythmias, heart failure, and history of anesthetic complications.<sup>2</sup>

Prior to the implementation of this project, the Oklahoma City VA recovery room nurses were instructed about the study. Since this was an observational study, and nurses did not collect data, they were not given formal training on the tool use. An informal in-service was administered individually.

The aim of this study was to quantify baseline health status by utilizing a PACU tool that takes a numerically assigned optimal health score, and adjust for comorbidities to net an adjusted ideal score for the patient (Appendix A). An adjusted recovery score was calculated by adding a surgical intervention score and recovery assessment score. The adjusted recovery score was subtracted from the patient's numerically assigned baseline health score (adjusted ideal score) to compute a Rapid Systems Review (RSR) score. This RSR score was ultimately used as a predictor to compare the number of nursing/medical interventions needed to return the patient to their preoperative baseline state (adjusted ideal score) or better.

Patients arriving for surgery, typically undergo a pre-anesthesia history and physical examination. For this project, baseline physiological status was evaluated according to the Rapid System Review (RSR) scoring method. Study participants were assessed on eleven criteria. Presence of unfavorable co-morbidities, involving ten physiological areas, was also reviewed. One point was added for each favorable criteria. One point was subtracted for each unfavorable criteria. Two points each were subtracted for unresponsiveness, requiring endotracheal tube, and hemodialysis dependence. The maximum possible score is 11. An "ideal score" for each patient would be 11 if no unfavorable criteria are present. An "adjusted ideal score" is established by subtracting points for unfavorable criteria and presence of co-morbidities. Calculations and descriptions are shown in Table 1.

# Adjusted Ideal Score = Ideal Score - Co-morbidity Score

Intra-operative "Surgery" score is calculated by adding points involving six criteria. Point allocations vary from one to four depending upon the degree of complexity.

**"Recovery"** score is calculated by reviewing the same ten physiological areas used for baseline health assessment. However, the point allocations are from zero to four depending upon the patient health. The recovery score is assessed every 15 minutes upon arrival to PACU until 120 minutes, and then at the time of discharge.

Adjusted Recovery Score = Recovery score + Surgery score

RSR score (Rapid System Review) = Adjusted Recovery score – Adjusted Ideal score

**Table 1.** Calculations and Descriptions

If the RSR score was <1, no interventions were expected for the patient while in PACU, however as the RSR score increased, the number of possible interventions was also expected to increase. For each patient admitted to the PACU, the number of expected interventions, and the actual number the interventions patients received was collected every 15 minutes. At the time of discharge from PACU, each patient was evaluated to see if they achieved the baseline adjusted ideal score. The following steps offer an example of how scores were calculated.

Step 1: Calculate the ideal score for the patient by adding up the favorable criteria in Table 2. A maximum ideal score is 11; a patient gets a point for each favorable condition. For example: if they are awake (add 1), breathing on their own (add 1) at 12 breaths per min (add 1), heart rate of 60 (add 1), systolic blood pressure of 140 (add 1), oxygen saturation of 98% (add 1), no pain (add 1), no nausea (add 1), no neuro disease (add 1), and the temperature is 36.6 degrees Celsius (add 1). The patient does have diabetes so a point would not be given in that instance. Adding the positive attributes would equal 10 in this example. This score is assessed pre-operatively. The ideal score for this patient is 10.

IDE A	L SCORE										
Score	General	Airway	Breathing	Circulation	Sp02	Pain	N/V	Neuro	Diabetes	Temp	Total
1	Awake	Patent	10-20/min	HR 50-100/min	97%-100%	No pain	None	No disease	No	36-37C	
1				SBP 100-160							
1											

Table 2. Favorable Criteria

Step 2: Add up the selected co-morbidities by assigning a 1 or 2 if present (Table 3). For example; this patient has a body mass index (BMI) of 32 (add 1 point), smoker (add 1 point), and has heart valve disease (add 1 point). This score is assessed pre-operatively. The co-morbidity score for this patient is 3.

C O - N	M O R B I D I T Y	SCOR	E								
1	Confused	Obesity	Smokin	CHF	Oxygen	Alcoholism,	Cirrhosis	Seizure	CKD	Sepsis	Total
	Sleepy	OSA	Copd	AF		Substance	abuse	CVA			
	Agitated	CPAP	Asthma	PPM/ICD		Motion Sickness					
				Valvular disease		PONV, GER	RD				
2	Unresponsive	ETT							Hemodialysis		

**Table 3.** Selected Co-morbidities

Step 3: Add the surgery score (Table 4). For this example; the patient is having an open gall bladder removal (add 3 points), lasting 2.5 hours (add 3 points), under general anesthesia (add 3 points). This score is assessed immediately post-op. The total surgery score is 9 for this patient.

5 U R (	GERY					
	Surgery	Duration	Anesthesia	Vasoactive Rx	Invasive Monitor	Total
1	Surface	<1 hr	MAC	Med#1	CVP	
1					Arterial	
2	Videoscope	1-2 hrs	Epi/spinal/Reg	Med#2		
3	Open	2-4 hrs	GA	Med#3		
4		>4 hrs		Med#4		

Table 4. Surgical Procedure

Step 4: Add the recovery score immediately upon admission to the recovery room (Table 5). For example; the patient has pain (add 1 point) and the systolic blood pressure is 172 (add 1 point). The recovery score for this patient is 2.

PACU	SCORE		
System	Grade	Score	PACU ad mission
Gen	Awake	0	
	Sleepy	1	
	Agitated	2	
	Unresponsive	3	
Airway	Patent	О	
	Oral	1	
	Nasal	1	
	LMA	2	
	ETT	3	
Breathing	10-20/min	0	
	<10 or >20	1	
	Difficulty breathing	1	
	Bronchospasm	1	
Circulation	HR 50-100/min	O	
	SBP 90-160	0	
	HR <50 or >100/min	1	
	SBP <90 or >160	1	
Sp02	97%-100%	0	
	<97	1	
Pain	No pain	0	
	Pain [+]	1	
N/V	None	O	
	N/V [+]	1	
Neuro	No disease	O	
	Seizure	1	
	New deficit	1	
	CVA	1	
Diabetes	None or BG 70-200	0	
	<70 or >200	1	
Temp	36-37C	O	
	<36 or >37	1	
	Total		

**Table 5.** Condition Immediately Upon Arrival to PACU

Step 5: Calculate th	e scores for the a	lata ( <u>Table 6).</u>
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Baseline Ideal Score	10
Co-morbidity score	3
Surgery Score	9
Recovery Score	2
Adjusted Recovery Score	
(Co-morbidity Score + Surgery Score +	3 + 9 + 2 = 14
Recovery Score)	
Rapid System Review Score	
(Adjusted Recovery Score – Baseline Ideal	14 - 10 = 4
Score)	

**Table 6.** Calculations for Example Parameters

The Rapid System Review Score is 4 in this example; therefore, it is expected that up to 6 interventions are needed to bring the patient back to baseline health (Table 7).

	RAPIDSY	STEN	1 R E V I	EW (	RSR)	SCC	) R E
RSR Score	<0	0-3	4-6	7-9	10-12	13-15	16-20
Interventions	None	1-3	1-6	1-9	1-12	1-15	1-20

**Table 7.** RSR Score Correlation with Number of Interventions

The Rapid System Review Score is assessed every 15 minutes, and is on the record shown in Figure 1.

Time		Admit	0-15 min	16-30min	31-45 min	46-60 min	61-75 min	76-90 min	91-105 min	106-120min	Discharge
RSR Score											
Expected intervention	S										
Actual interventions											

Figure 1. Documentation for RSR Scores

# Project Design

This is a prospective, non-randomized, observational study that was conducted in the Post Anesthesia Care Unit (PACU) at the Veterans Affairs Medical Center, Oklahoma City between January 2017 and May 2017. The study scoring system was formatted to assess the patient's changing physiology during the perioperative period and alert the PACU staff for possible interventions to optimize patient's health back to baseline health status (Figure 2).

The design and statistics of this study were similar to that of Reed's et al<sup>54</sup> research study. Their research consisted of predicting the difficulty of endotracheal intubation by quantifying the LEMON (look externally, evaluate 3-3-2 rule, Mallampati, obstruction, and neck mobility) method. A scoring system of 0-10 was used to numerically stratify the risk of difficult intubations. Unfavorable intubation criteria were assigned a point for each step of the evaluation. A score of zero indicates a patient is most likely to have a good laryngoscopic view. A high score would indicate a poor laryngoscopic view (p <0.05).<sup>54</sup>

The statistics for the PACU tool developed for this research, are similar to those used by the Reed's et al study. All data were entered on a form, and completed forms were collected for data entry and analysis, using Microsoft Excel. Categorical variables comparison was accomplished using Fisher's extract test and Student's *t* test for parametric data. Categorical variables were evaluated by Spearman's rank sum test which is used to assess correlation.

Statistical significance was defined as p<0.05.<sup>54</sup>

The intent of the statistical measurements was to predict the number of interventions needed to bring a patient back to pre-operative condition. Srikiran Ramarapu, MD is the inventor of the RSR tool. Permission was granted by Dr. Ramarapu to use the tool for this project. The measuring tool/product measures actual interventions, and compares them to predicted

interventions. The actual intervention serves as a control. The results numerically provide meaning to acuity, and may possibly direct allocation of hospital resources and patient care preparation.

It took 4 months to complete this study, and evaluate the data. The cost of this inquiry consists of lost wages to observe (at the cost to the researchers), and printing fees for the PACU tools, which were minimal. Should the results of this study prove to be valuable, policy changes could occur. Long term cost of the product is minimal because paper copies would be part of the patient handoff. A computer adaptive PACU tool can be formulated at a later date.

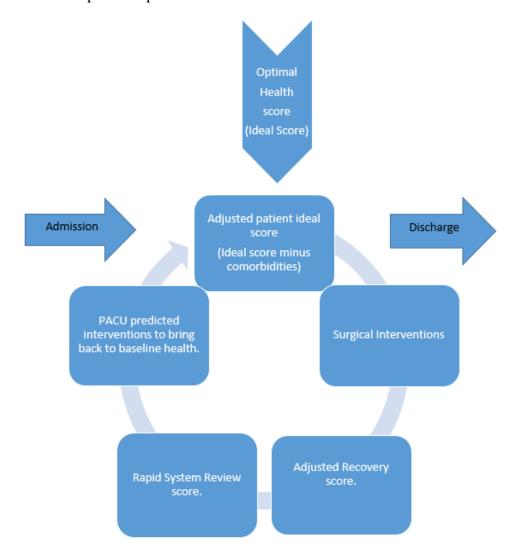
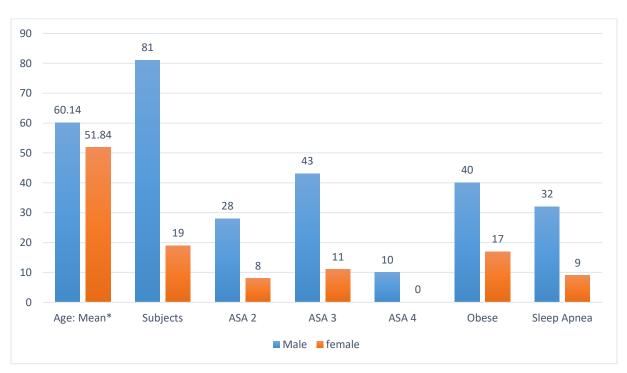


Figure 2. Process to return a patient to a preoperative condition

# **Population**

The study population included; any patients that required post-operative recovery at the Department of Veteran's Affairs (VA) in Oklahoma City, Oklahoma (Figure 3). This research project was intended to be used universally, no matter the procedure or disease process. The patients in this study had their identity protected. Names were not used; only the patient's age, sex, disease process, ASA classification, and surgical procedure were identifiers.

Data was collected by Srikiran Ramarapu, MD and Robin Cook, CRNA. Patients were followed from the pre-operative area until discharge from the PACU. Observational data were extracted and evaluated. No interventions were provided by the researchers. No human subjects were harmed during the course of this study, and Institutional Review Board (IRB) permissions were obtained. The sample size for this study was 100 patients.



**Figure 3.** Study Population Abbreviations: ASA, American Society of Anesthesiologists Physical Status

# Implementation

The University of Michigan-Flint (Appendix B), The University of Oklahoma, and The Oklahoma City Veteran's Affairs institutional review boards (IRB) approved this study (Appendix C). Patients aged 21-90 years scheduled for elective/emergency surgeries were eligible for participation in this study. A total of 100 patients were enrolled in the data collection from January 2017 to April 2017. Inclusion criteria were any patients admitted to PACU at the Department of Veteran's Affairs (VA) in Oklahoma City, Oklahoma. Exclusion criteria were patients expected to go to the intensive care unit (ICU) postoperatively.

The respective IRBs determined that due to the observational nature of the study, no additional consent or Health Insurance Portability and Accountability Act (HIPAA) information above what was given upon admission to the facility was required. As such, a waiver of consent and HIPAA waiver were granted by the IRBs. Study data was collected by the Investigators at the time of patient discharge from the PACU. A review of patient anesthesia records, PACU nurse flow sheets, continuous clinical monitor recordings of the patient vital signs/triggered alarms/events, and the patient's Computerized Patient Record System (CPRS) was completed.

Interventions were recorded on the Rapid System Review Tool form (RSR). Standard patient care was not recorded as an intervention; such as placing patients on PACU monitors or administering oxygen for the first 15 minutes of admission. Any actions that all patients receive regardless of conditions were not considered interventions. Examples of these include: initial assessment, giving ice chips, continuing sequential stockings, discontinuing monitors on discharge, etc.

Interventions patients may receive while in PACU as part of their clinical care,

were assessed on eleven criteria involving; the respiratory system, cardiovascular system, neurological system, pain management, post-operative nausea/vomiting, blood glucose, and body temperature. Interventions could be verbal instructions, physical interventions, medications administration, investigations to evaluate and treat vital parameters triggered by clinical examination, and alarms set for patient monitoring.

All research data was de-identified. None of the 18 HIPAA identifiers were collected. No risks were encountered during the study. All identifiable patient data was de-coded, and entered onto a designated database on the computer belonging to the Veterans Affairs (VA) hospital, which is encrypted and protected with passwords. All standards were maintained per VA hospital research and development department guidelines, to protect the patient data. Research data were recorded in an excel document and maintained on the VA network. All research records are subject to the VA's Records Control Schedule (RCS) and disposition requirements. Research records were labeled with a subject number of 1-100. All data was entered on a form, and completed forms were collected for data entry and analysis using Microsoft Excel.

## **Results**

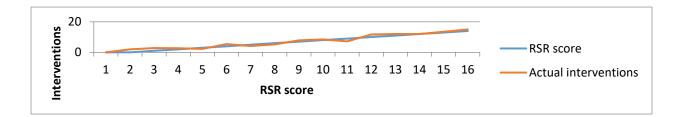
This was an observational prospective controlled study. The primary outcome was to predict the amount of interventions needed, to achieve a baseline health score for a patient admitted to the PACU, at the time of discharge. The secondary outcome was to evaluate if these patients achieved their baseline ideal score, or better at discharge. Categorical data (male/female) was expressed as a percentage. Continuous data was presented as a mean +/- standard deviation. Pearson Correlation Coefficient was completed to evaluate trend (does scoring system predict interventions needed?), and the two-tailed unpaired t test with p values to evaluate significance. Graph Pad Prism (Version 7) and Pearson Correlation was used to calculate statistics.

Significance was defined as (p < 0.05).

# **Primary Outcome Result**

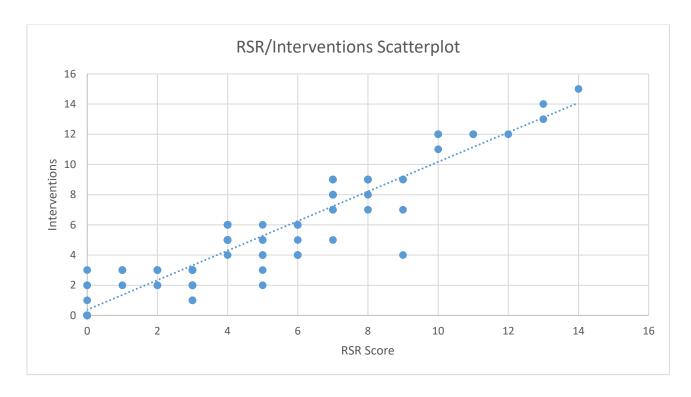
There is a strong positive relationship between the RSR scores, and the number of interventions. The p value was 0.000, which is statistically significant. The Pearson Correlation Coefficient between the RSR high score, and actual interventions were 0.908. This suggests the relationship was statistically significant. For every RSR score change, the number of interventions increased by 0.908 (Figure 4).

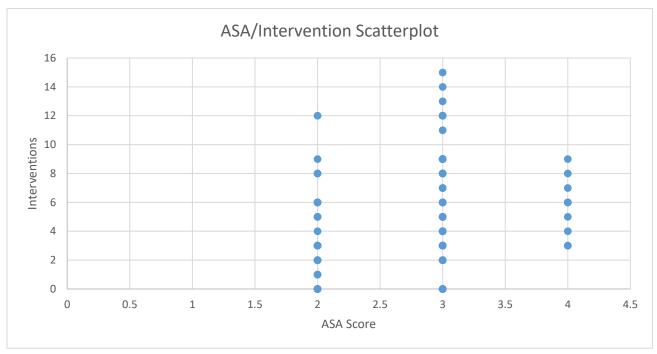
	RSR Scores Compared to Interventions								
RSR score	<0	0 - 3	4 - 6	7 - 9	10 - 12	13 - 15			
Actual									
interventions	0	2.39	5.03	7.9	11.83	14			
Mean[Average]									



**Figure 4.** Primary Study Outcome. Abbreviation: RSR, Rapid System Review. Interventions expressed as mean.

The RSR scoring system was found to be more specific, and accurate, compared to the ASA physical status when determining PACU patient's needs. It is assumed that as the ASA score goes up, the amount of interventions will go up too. This relationship is weaker compared to the RSR scoring system. The *p* value was 0.006, which shows the relationship. The Pearson Correlation Coefficient between the ASA class and actual interventions was 0.273. This indicates the relationship was positive. For each ASA class increase, the number of interventions increased by 0.273 (Figure 5).





**Figure 5.** Correlation Between RSR/Interventions and ASA/Interventions Abbreviations: RSR, Rapid System Review; ASA, American Society of Anesthesiologists.

# Secondary Outcome Results

Patients discharged from the PACU achieved a preoperative ideal score or better. The mean patient ideal score was  $9.57 \pm 0.99752218$ , and the mean discharge score was  $9.96 \pm 0.695149$ . The two-tailed unpaired t test p-value was 0.0016 with a 95% confidence interval of difference. By traditional standards, this difference is considered statistically significant. Intermediate values used in the calculations were; t =3.2090, degree of freedom (df)=198, and the standard error of difference was 0.122 (Figure 6).

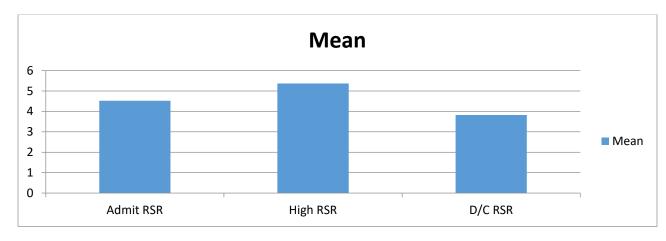
	Ideal score	D/C score	RSR admit	RSR highest	RSR D/C	Comorb S	urgery score	PACU score
Mean	9.57	9.96	4.523255814	5.363636364	3.827160494	3.28	8.11	1.68
Median	10	10	4	5	4	3	8	2
Mode	10	10	3	3	2	2	9	2
Std.Dev	0.997522183	0.695149137	2.953469522	3.144715758	2.587422093	1.886046584	2.352282365	1.246246891
t test	p=0.0016		0.0778	0.0002				

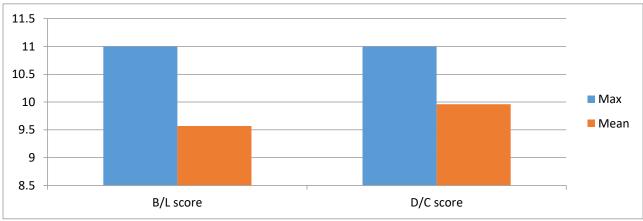
**Figure 6.** PACU Patients Achieved a Preoperative Ideal Score or Better was Statistically Significant. Abbreviations: RSR, Rapid System Review; D/C, discharge; Comorb, comorbidity; PACU, post anesthesia care unit; B/L, baseline

There was no statistical significance with the RSR admission score (mean=  $4.52325 \pm 2.9534695$ ), and the RSR discharge score (mean=  $3.82716 \pm 2.587422$ ). The two-tailed unpaired t test *p*-value was 0.0778 with a 95% confidence interval. Intermediate values used in the calculations were; t =1.7728, (df)=198, and the standard error of difference = 0.393.

Surgical interventions attributed to the RSR highest score. Factors such as pain and nausea will raise the RSR score, and thereby increase the amount of interventions needed by discharge (Figure 7). There was significance between the RSR highest score (mean= $5.3636 \pm 3.14471576$ ) and the RSR discharge score (mean= $3.82716 \pm 2.58742$ ). The two-tailed unpaired t test *p*-value was 0.0002 with a 95% confidence interval of difference. Intermediate values used

in the calculations were; t = 3.7729, (df)=198, and the standard error of difference = 0.407.





**Figure 7.** Patients Discharged From the PACU, Achieved Their Preoperative Ideal Score or Better. Abbreviations: RSR, Rapid System Review; D/C, discharge; Comorb, comorbidity; PACU, post anesthesia care unit; B/L, baseline.

## **Discussion**

# Major Findings and Implications of Study

The results of this study may be the impetus for a revolutionary patient care tool for the PACU. Hospital leadership may better prepare for resource needs of the recovery room.

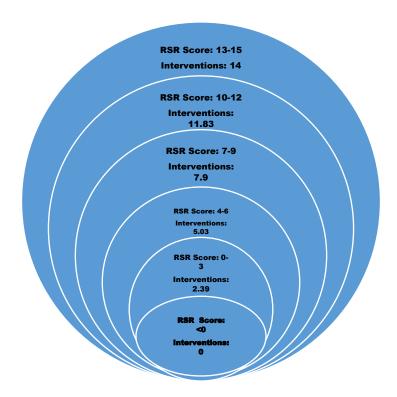
Workflow in the PACU can be translated in a quantitative fashion and have meaning. There is a correlation between the RSR score, and the number of interventions needed for a patient to establish their baseline state. Study findings indicated, if the RSR increases, the number of

interventions increases. This translates to a measurable patient care acuity, expressed in a numerical fashion (Figure 7).

Acuity is defined by researchers as the physical work required by a nurse. This physical work could be verbal or interventional when caring for patients in the PACU. Surgical intervention alters a RSR score post-operatively. There was no clinical significance when comparing the RSR admission score, and the RSR discharge score. This is due to the fact that the patient's baseline health was not altered by surgery yet. Since the RSR score is <1, no intervention is needed. Interventions or lack of interventions can be measured.

Average monthly RSR scores over time, can establish an acuity pattern and trend. The cost savings may prove to be substantial in terms of human resource, and supply management in the PACU. Managers may be able to determine trends, hire staff accordingly, and limit stock of costly supplies that may expire before use.

The Aldrete White, and Post Anesthetic Discharge Scoring System (PADSS), are commonly used tools to gauge PACU discharge internationally.<sup>29</sup> The RSR scoring system can enhance these discharge scoring tools by predicting what it takes to get to discharge. The literature investigated for this project, demonstrated that there are no studies that predict the amount of interventions needed to bring a patient to their pre-operative baseline health. This new body of knowledge can lead to further studies to improve PACU workflow, and define acuity in terms of staff interventions necessary to bring a patient to their pre-operative health.



**Figure 8.** RSR Relationship to Interventions. Abbreviation: RSR, Rapid System Review. Interventions are expressed as mean.

# **Study Limitations**

This pilot study had limitations. It was performed at a single VA Medical Center, and the results may not be generalizable. Patient populations such as pediatrics, obstetrics, and patients classified as ASA1 were not represented. Male (81%) ASA 2 and 3 (71%) veterans were predominant in the sample size. Female subjects only consisted of 19 % of the study subjects.

The complex RSR tool can lead to Interobserver variability. Facility protocols, local standards, and policy may affect the number of interventions nurses provide. Formal training must be instituted to ensure the correct use of the RSR tool for researchers.

# Recommendations for Future Research

Recommendations for future research include; a larger multicenter study within the VA system. Patient study population should include a representative sample of ASA 1-4, and an

equal gender study pool. Patients admitted to the intensive care unit should still be excluded. These patients are often unstable or critically ill, and may require high-acuity nursing interventions. All patients that are transferred to the PACU from the operating room should be included in the study. If the multi-VA center study yields similar results, the RSR study should be conducted at a civilian tertiary hospital to establish generalizability. The Oklahoma City VA is a university-affiliated teaching institution, and may not be representative of the general surgical population.

The current paper and pen version of the RSR tool may be viewed as cumbersome and complex. A computer adapted electronic medical record (EMR) version, could capture real-time RSR scores and extract patient health data. This could make the tool user friendly for PACU staff, and provide meaningful data to management. The EMR could send alerts of trending patient status to the nurse, so they may prepare to intervene. A small-scale computer adaptive study using the RSR tool would need to be completed. Feasibility of the computer adaptive program would have to be assessed for software compatibility and reliability.

# **Dissemination**

After the 4-month pilot period, the RSR data was evaluated statistically. The results of the study were checked for errors, and interpretations were made. Once the analysis was completed, the information was shared with the Oklahoma City VA research department.

Discussion regarding future plans for a larger multi-VA study ensued. There is no set timeline yet for the larger research study. Results were shared with the anesthesia/PACU staff during the surgical department weekly meeting, and questions were answered.

There are no immediate plans to implement the RSR tool for use at the Oklahoma City VA, until the tool can be effectively tied to an electronic platform. Based on feedback, nurses do

not want to track an extra form in the patient care area. The VA system is currently changing their computer software to Cerner. Once the new software is in place, and employees are trained, the RSR tool may be implemented within the system.

An electronic manuscript was also formulated for publication to *Anesthesia and Analgesia*. Sirkiran Ramarapu, MD served as the sponsoring physician for submission to this anesthesia peer reviewed journal. Guidelines for observational studies in the "information for authors" section was reviewed. The completed manuscript was submitted via the Editorial Manager online submission system.

# **Conclusion**

The RSR patient health scoring tool is a recently developed, reliable scoring method for recovery room nurses at the VA Medical Center in Oklahoma City. This PACU tool was designed to meet the dynamic changes of post-surgical patients. A patient's physical condition may be labile after surgery. Data indicates there may be a link between surgical interventions, PACU events, and hospital complications.<sup>2</sup> Contributing factors for critical events are apnea, hypotension, and desaturation.<sup>2</sup> The RSR tool adapted for this project, was designed to help PACU nurses anticipate medical/nursing actions needed to care for their patients, and return them to their baseline health.

The focus of care with the use of the RSR, was on the respiratory system, cardiovascular system, neurological system, pain management, post-operative nausea/vomiting, blood glucose, and body temperature. This study established a quantitative basis for acuity, and assisted in management of recovery room resources to accommodate staffing/preparation needs. Fluctuating patient clinical conditions were immediately addressed medically, to avoid unnecessary stays in the PACU.

Long term, this project could be sustainable in the PACU, and provide valuable information to hospital administrators to break down labor intensive patients verses work flow patterns. Additional dimensions of care are added, by giving relative meaning to acuity by establishing the number of interventions needed to recover a patient. The ability to more accurately predict acuity, and adjust staffing accordingly, may increase patient safety as they recover from surgery.

The RSR in this study was assessed every 15 minutes, and compared the predicted needed interventions with the actual interventions. The study results were encouraging, and can potentially add a new dimension of care. The PACU nurses may now predict the number of nursing/medical interventions a patient may require during their stay in the PACU. In conclusion, the RSR assessment tool can quantify the work needed to bring a PACU patient back to their baseline health.

The questions of this study inquiry were answered: 1) How effective is implementing a rapid system review (RSR) tool immediately upon arrival to the PACU, to quantify acuity of post-operative patients at the VA in Oklahoma City? This was achieved by implementing the RSR tool (Appendix A) and compared the RSR score to interventions, and ASA score to interventions. The RSR scoring system was found to be more specific, and accurate, compared to the ASA physical status when determining PACU patient's needs. 2) Is there a correlation between the quantitative score and the number of interventions needed to bring the patient back to baseline health? This study demonstrated statistical significance between the quantitative score, and the number of interventions needed to bring the patient back to baseline health.

Secondary outcomes demonstrated that patients who were discharged from the PACU, achieved their preoperative ideal score or better.

# Appendix A

Score	General		Breathing				Pain	N/V	Neuro	Diabetes	Temp	Total
	Awake		10-20/min	HR 50-1	.00/min		No pain	None	No disease	No	36-37C	
1				SBP 10	0-160							
			-	ļ								
0 1	1 O R B I D I T Y	SCOB	-	-								
	Confused	Obesity	Smokin	CHE	_	Ovygen	Alcoholism,	Cirrhosis	Seizure	CKD	Sepsis	Total
	Sleepy	OSA	Copd	AF		Oxygen	Substance		CVA	CKD	БСРЗІЗ	l ota.
	Agitated	CPAP	Asthma		CD		Motion Si					
				Valvular o			PONV, GER		l			
2	Unresponsive	ETT					,			Hemodialysis		
URC	ERY SCORE			ĺ								
	Surgery		Duration	1	Anesth	esia	Vasoactive			sive monito	ring	Total
1	Surface		<1 hr		MAC		Medicatio		Arterial			
					Regio	nal	Medicatio	n #2	CVP			
	Videoscope		1-2 hrs		Epi/sp	inal	Medicatio					
3	Open		2-4 hrs		GA		Medicatio	n #4				
4 2 A C L	SCORE		>4 hrs	1		1			ļ			
	Grade	Score	PACU admission	1-15min	16-30min	31-45	46-60min	61-75min	76-90min	91-105min	106-120	BACH die 1
ie n	Awake	0	PACU admission	1-13IIIII	10-30min	31-43	-0-00IIIII	01-73HHH	, 0-30IIIII	21-10311111	100-1201	FACU disch
	Sleepy	1			1		-		l			
	Agitated	2										
	Unresponsive	3										
Airway		0										
	Oral Nasal	1								) ·		
	LMA	2	<b>-</b>							1		
	ETT	3				-			5 5			<b>-</b>
reathing	10-20/min	0										
	<10 or >20	1										
	Difficulty breathing	1							)			
	Bronchospasm	1										
irculation	HR 50-100/min	0										
	SBP 90-160	0										
	HR <50 or >100/min	1									ļ	
Sp02	SBP <90 or >160 97%-100%	0	-		-			-				-
3p02	<97	1		-							<u> </u>	
Pain	No pain	0										
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N/V	None	0							,			
	N/V [+]	1										
Neuro	No disease	0					,					
	Seizure	1										
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iabetes	None or BG 70-200	0			-		-	<b>—</b>	l	<del>                                     </del>	<del>                                     </del>	<del>                                     </del>
Labetes	<70 or >200	1				-						<b>†</b>
Гетр	36-37C	0							i i			
	<36 or >37	1										
	Total											
	ne Ideal Score						-			-		
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	ore (Postopera				leal Sco	re) =						
						-						
	RAPIDSY											
SR Score	<0	0-3	4-6	7-9	10-12							
erventions	None	1-3	1-6	1-9	1-12	1-15	1-20	J				
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# Appendix B



Flint Institutional Review Board • 530 French Hall, 303 E. Kearsley St, Flint, MI 48502 • phone (810) 762-3383 • fax (313) 593-0526 • research@umflint.edu

To: Mr. Robin Cook

From:

Marianne McGrath

Cc:

Jane Motz Robin Cook

**Subject**: Initial Study Approval for [ HUM00126066 ]

## SUBMISSION INFORMATION:

Study Title: Rapid System Review (RSR) score

Full Study Title (if applicable): Rapid System Review (RSR) score - Tool to measure predictive interventions to patients admitted to the Post Anesthesia Care Unit (PACU).

Study eResearch ID: HUM00126066

Date of this Notification from IRB:2/1/2017

Review: Expedited

Initial IRB Approval Date: 2/1/2017

**Current IRB Approval Period:2/1/2017 - 1/31/2018** 

Expiration Date: Approval for this expires at 11:59 p.m. on 1/31/2018

UM Federalwide Assurance (FWA): FWA00004969 (For the current FWA expiration

date, please visit the **UM HRPP Webpage**)

OHRP IRB Registration Number(s): IRB00000248

# **Approved Risk Level(s):**

Name Risk Level

HUM00126066 No more than minimal risk

## **NOTICE OF IRB APPROVAL AND CONDITIONS:**

The IRB Flint has reviewed and approved the study referenced above. The IRB determined that the proposed research conforms with applicable guidelines, State and federal regulations, and the University of Michigan's Federalwide Assurance (FWA) with the Department of Health and Human Services (HHS). You must conduct this study in accordance with the description and information provided in the approved application and associated documents.

#### APPROVAL PERIOD AND EXPIRATION:

The approval period for this study is listed above. Please note the expiration date. If the approval lapses, you may not conduct work on this study until appropriate approval has been re-established, except as necessary to eliminate apparent immediate hazards to research subjects. Should the latter occur, you must notify the IRB Office as soon as possible.

#### IMPORTANT REMINDERS AND ADDITIONAL INFORMATION FOR INVESTIGATORS

#### **APPROVED STUDY DOCUMENTS:**

You must use any date-stamped versions of recruitment materials and informed consent documents available in the eResearch workspace (referenced above). Date-stamped materials are available in the "Currently Approved Documents" section on the "Documents" tab.

## **RENEWAL/TERMINATION:**

At least two months prior to the expiration date, you should submit a continuing review application either to renew or terminate the study. Failure to allow sufficient time for IRB review may result in a lapse of approval that may also affect any funding associated with the study.

## **AMENDMENTS:**

All proposed changes to the study (e.g., personnel, procedures, or documents), must be approved in advance by the IRB through the amendment process, except as necessary to eliminate apparent immediate hazards to research subjects. Should the latter occur, you must notify the IRB Office as soon as possible.

## **AEs/ORIOs:**

You must inform the IRB of all unanticipated events, adverse events (AEs), and other reportable information and occurrences (ORIOs). These include but are not limited to events and/or information that may have physical, psychological, social, legal, or economic impact on the research subjects or other.

Investigators and research staff are responsible for reporting information concerning the approved research to the IRB in a timely fashion, understanding and adhering to the reporting guidance (

http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/guidance/adverse-events-aes-other-reportable-information-and-occurrences-orios-and-other-required-reporting), and not implementing any changes to the research without IRB approval of the change via an amendment submission. When changes are necessary to eliminate apparent immediate hazards to the subject, implement the change and report via an ORIO and/or amendment submission within 7 days after the action is taken. This includes all

information with the potential to impact the risk or benefit assessments of the research.

# **SUBMITTING VIA eRESEARCH:**

You can access the online forms for continuing review, amendments, and AEs/ORIOs in the eResearch workspace for this approved study (referenced above).

# **MORE INFORMATION:**

You can find additional information about UM's Human Research Protection Program (HRPP) in the Operations Manual and other documents available at: <a href="http://research-compliance.umich.edu/human-subjects">http://research-compliance.umich.edu/human-subjects</a>.

Marianne McGrath Chair, IRB Flint

# Appendix C



## Institutional Review Board for the Protection of Human Subjects

#### Initial Submission - Expedited Approval

Dafe: January 18, 2017 IRB#: 7556

To: Snkian Ramarapu, MD Approval Date: 01/18/2017 Reference Number: 659987 Expiration Date: 12/31/2017

Study Title: Rapid System Review (RSR) Score - Tool to Measure Predictive Interventions to Patients Admitted to the Post Anesthesia Care Unit (PACU)

Collection/Use of PHI: Yes

Expedited Criteria: Expedited Category 5

On behalf of the Institutional Review Board (IRB), I have reviewed and granted expedited approval of the abovereferenced research study. Study documents associated with this submission are listed on page 2 of this letter. To review and/or access the submission forms as well as the study documents approved for this submission, click I/dy Studies, click to open this study, under Protocol Nems, click to view/access the current approved Application, Informed Consent, or Other Study Documents.

If this study required routing through the Office of Research Administration (ORA), you may <u>noz begin your</u> szudy yez, as per OUHSC institutional policy, until the contract through ORA is finalized and signed.

As principal investigator of this research study, you are responsible to:

- Conduct the research study in a manner consistent with the requirements of the IRB and federal regulations 45 CFR 46 and/or 21 CFR 50 and 56.
- Request approval from the IRB prior to implementing any/all modifications.
- Promptly report to the IRB any harm experienced by a participant that is both unanticipated and related per IRB policy.
- Maintain accurate and complete study records for evaluation by the HRPP Quality Improvement Program and, if applicable, inspection by regulatory agencies and/or the study sponsor.
- Promptly submit continuing review documents to the IRB upon notification approximately 60 days prior to the expiration date indicated above.

This study meets the criteria for Waiver of Informed Consent and is approved to be conducted without obtaining consent.

If you have questions about this notification or using IRIS, contact the IRB at 405-271-2045 or irb@ouhsc.edu.

Karen Beckman, MD Chairperson, Institutional Review Board

Sincerely

1105 N. Stonewall Avenue, Oklahuma City, OK 73117 (FWAB007961)

Initial Submission - Expedited Approval [confid.]

Page 2

Study documents associated with this submission:

Study Documents									
Title Version Number Version Date Outco									
Research Privacy Form 5	Version 1.0	12/20/2016	Approved						
Protocol	Version 1.0	12/19/2016	Approved						

\*\*Information for Industry Sponsors: the columns titled Version Number and Version Date are specific to the electronic submission system (iRIS) and should not to be confused with information included in the Document and/or Consent title(s).\*\*

1101 N. Stenemall Avenue, Oklahuma City, DK 72117 (FWA0007961)

#### References

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