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REGIONAL ANESTHESIA INTRODUCED INTO AN

EMERGENCY/TRAUMA SETTING

by

Jennifer Bryant Covalt

A Capstone Project Submitted to the Graduate School and the Department of Advanced Practice at The University of Southern Mississippi in Partial Fulfillment of the Requirements for the Degree of Doctor of Nursing Practice

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December 2016



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Published by the Graduate School





ABSTRACT

REGIONAL ANESTHESIA INTRODUCED INTO AN

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by Jennifer Bryant Covalt

December 2016

Emergency rooms across the United States have an incredibly large number of shoulder dislocations that need to be manipulated and reset on a daily basis. A costbenefit analysis in this Doctor of Nursing Practice Project will demonstrate a new form of care for shoulder dislocations in the emergency room with certified registered nurse anesthetists (CRNA) providing regional anesthesia with local lidocaine injections into the shoulder joint. A level II trauma center in Mississippi with many shoulder dislocations was the location that was used to evaluate conscious sedation, length of procedure, and pain scores. A retrospective chart review was performed at this hospital. The primary regional anesthetic evidence was provided using a focus review. The cost- benefit analysis suggested a decrease in cost with the direct variables of regional anesthesia and conscious sedation. The indirect variables were satisfaction through pain scores and length of procedure/stay. Descriptive statistics were used to evaluate the evidence. The findings suggested decreased cost with decreased pain scores and decreased length of procedures using regional anesthesia. The 54 patients in the retrospective review were calculated on the appropriate acuity level per procedure to determine cost. The calculated cost of conscious sedation patients per year was \$25,704; the calculated cost of regional anesthetic patients per year was \$15,660. The determined saving was \$10,044, and the difference in turnover was an additional 2.18 patients that can be seen per day in the



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emergency room if regional anesthetics were used to manipulate shoulder dislocations. Decreased cost for the patient, increased revenue and reimbursement for the hospital, and improved quality of care should lead healthcare provider and systems to consider this positive change. Regional anesthesia for shoulder manipulation has been used by other providers outside the nation and in military bases providing evidence of safe and effective practice.



ACKNOWLEDGMENTS

I would like to extend my sincere gratitude to my chair and committee members at the University of Southern Mississippi for their constant supervision and diligence in helping me complete this DNP project. This project would not have been developed without the cooperation, guidance, and patience of all the members involved. Dr. Nugent, thank you so much for the time and dedication to this project and the endless rewrites. Your perseverance and direction helped me pursue the finish line. Dr. Everson, your time and advice in prioritizing since the beginning of the project through the submission has been greatly appreciated. Dr. Anderson without your financial and analytical expertise and teaching, this project would not have been able to be completed. Apart from the stated assistance, my chair and committee put in countless hours for which I am sincerely thankful.



DEDICATION

I would like to extend my gratitude to my family and friends for the support and encouragement through many long hours developing this DNP project. The understanding of the long nights and early mornings is sincerely appreciated. The hospitality, knowledge, and wisdom from those who have gone before me, was encouraging and assisted me in persevering with this DNP project



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LIST OF ABBREVIATIONS

CINAHL	Cumulative Index of Nursing and Allied Health Literature
CRNA	Certified Registered Nurse Anesthetist
DNP	Doctor of Nursing Practice
ER	Emergency Room
FGH	Forrest General Hospital
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems
LOS	Length of Stay
NPO	Nothing per Oral



CHAPTER I – INTRODUCTION

Statement of the Problem

Emergency and/or Trauma medicine has a large population that needs regional anesthesia or conscious sedation. The American Academy of Orthopedic Surgeons published that there were 175,641 shoulder dislocations that presented to the emergency department in 2011 (Takemoto, Park, & Youm, 2014). Cost is a problem for the hospital, providers, and patients in the emergency setting. Reimbursement and revenue are the issues that affect cost for the hospital and providers, while procedure expense directly and pain indirectly are the patients' cost. Patients who have shoulder injury and who require regional anesthesia or conscious sedation, take up many of the beds in an emergency department and decreases revenue due to longer turnover times. Doing a costbenefit analysis with regional anesthesia and conscious sedation as the direct variables, has suggested that regional anesthesia provided an improved quality of care through satisfaction and improved cost for the providers and patients. The aim of this Doctor of Nursing Practice (DNP) Project was to provide information for cost and quality of care utilizing a certified registered nurse anesthetist (CRNA) providing regional anesthesia in the emergency department instead of the current practice of conscious sedation by emergency room nurses.

Background and Significance

A large population exists in the emergency setting throughout the nation with shoulder dislocations that are in need of adjusting by the emergency room physician. The dislocated shoulder is an orthopedic emergency and is the most common of all dislocations to be seen in the emergency room (Tamaoki et al., 2012). After working in



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the emergency room as a registered nurse for eight years, it is known through experience that the physician is unable to adjust the shoulder joint without some assistance with pain medicine or muscle relaxation due to the anxiety and guarding of the painful shoulder.

The use of conscious sedation for shoulder dislocations is the common practice in the emergency room. This practice of care requires the presence of a physician and one nurse who monitors the patient during a lengthy NPO (nothing per oral) time prior to procedure. The patient has decreased satisfaction due to a longer wait period and increased pain. The use of regional anesthesia would decrease the length of time a patient is NPO and decrease the amount of time physician and nursing assistance is needed. A CRNA providing regional anesthesia results in decreased pain scores and improved patient satisfaction. Regional anesthesia for shoulder manipulation has been used by other providers outside the nation and in military bases providing evidence of safe and effective practice.

Procedural guidelines for care with conscious sedation allow that NPO status should be achieved before any sedating medications or procedural intervention be implemented. The need for NPO is due to the potential risk for aspiration, unknown last time anything ingested orally, or a time of ingestion less than 6 hours before procedure start time. NPO time for the patient unaware of the last drink or meals starts at six hours. Procedural sedation staffing consist of the physician and the registered nurse at the bedside for monitoring and administering medications during the procedure. After the procedure, the registered must stay with the patient for monitoring of vital signs every 5 minutes for a minimum of 20 minutes or longer until the patient is stable and able to maintain their airway without assistance. The mean amount of time that was assessed in



the Mississippi hospital analysis was 382 minutes with the additional NPO time added to procedure length per guideline requirement. Pain scores for 77% of the patients at the level II trauma center were initially 9-10 out of a 0-10 scale. The mean decrease in the 52 patients assessed for pain post conscious sedation procedure was of 3.2, which is not a significant decrease from a 9 or 10 initial score. Conscious Sedation was recorded to lead to an increased time for the patient with shoulder dislocation and a minimal decrease in pain.

The guidelines for a regional anesthetic field block of the shoulder has much less staffing needed and no NPO time. Monitoring for hemodynamic stability of vital signs is mandatory for regional anesthesia prior to and during the procedure. Staffing for the procedure consists of a CRNA or trained anesthesia provider only. Median time for the average regional anesthetic treatment was seven – eleven minutes (Beaudoin, Nagdev, Merchant, & Becker, 2010). Pain scores according to the literature reviewed were decreased in 15 minutes by 44% and at 30 minutes by 67%; the decreased pain lasted for four hours after the procedure without the sedative effects of conscious sedation (Beaudin et al., 2010). Regional anesthesia is suggested to provide more efficient care through decreased pain and cost with less length of stay and monitoring needed for the patient.

The benefits of decreased pain, decreased NPO time, and decreased procedure time all led to the conclusion of regional anesthesia as the more satisfying choice for the patient. The length of the procedure and pain scores with conscious sedation would additionally cost the patient and the hospital more money due to the higher acuity mark of the patient per time needed and the decrease in revenue and reimbursement for the hospital due to decrease satisfaction and turnover time.



Concept Analysis

The term "cost" as a concept is frequently analyzed throughout the healthcare system and practices to determine the cost effective medical care for the patient and the system. The concept "cost" for the DNP project is associated with regional anesthesia introduced into the emergency room for dislocated shoulders versus the cost of conscious sedation. The joint reduction with regional anesthesia, will show a cost-benefit relationship where cost is reduced for the patient population. In addition to the cost, which improves for the patient directly, indirect cost is lowered for the hospital by having more staff available in the emergency room setting to turn over rooms. The indirect measures show how efficiency plays a role in developing the cost for the patient and the bill for the hospital. Faster turnover times for this dislocated shoulder patient frees the room for the next patient, which increases revenue for the hospital. Cost will be viewed directly and indirectly by assessing length of the procedures, pain, and satisfaction associated with the quality of care measure. The cost-benefit analysis is important in the DNP project to compare the difference in cost between regional anesthesia and conscious sedation for shoulder injuries due to the indirect measures of length of procedure and pain scores.

The Walker and Avant method of concept analysis serves as the framework for defining the concept "cost" and building a cost-benefit analysis. The steps in the Walker and Avant Method include: concept, aims of the analysis, uses of the concept, defining the attributes of the concept, model case, concept cases that define what the concept is not, antecedents and consequences, and empirical referents.



The aims of the cost-benefit analysis are towards more effective practice, care, and patient outcomes with a positive financial return in revenue for the healthcare systems. Walker and Avant have constructed an excellent framework to understand fully, the concept promoting the cost-benefit analysis. Defining the steps to portray structure and function in the DNP project with the Walker and Avant Method included: concept, aims of the analysis, uses of the concept, defining the attributes of the concept, model case, concept cases that define what the concept is not, antecedents and consequences, and empirical referents. A cost analysis is defined as, "the comparison of costs (as of standard with actual or for a given period with another) for the purpose of disclosing and reporting on conditions subject to improvement" ("Cost", 2015). There will be a direct and indirect measure of the cost in the analysis. Procedural sedation versus regional anesthetic techniques will be compared for direct cost. The indirect measures of providers, time, procedures, medications, room cost, and quality of care will be documented and analyzed to demonstrate improved revenue for the hospital and a higher quality of care, satisfaction, and quicker room turnover times.

The concept of "cost" will be utilized when trying to piece together elements to build a solid cost-benefit analysis theory. A cost-benefit theory utilizes analytical tools to evaluate the planned actions based on the pros and cons that formulate a net value (Butts & Rich, 2015). The concept identifies the pieces of the framework to move forward with the literature and research. The structure and function of the cost concept must build a solid framework for a clear understanding of the theory components and direction.

The direct cost would be the defining characteristics or attributes for the analysis, but furthermore the indirect costs play a significant part in the cost concept



measurements. The attributes of cost in any society, organization, and healthcare system are always changing with the stimulation of the economy. The regional economics will have to be considered if comparing the cost in other areas of the healthcare system, state, nation, or world due to the constant changing and flux.

A thirty-year-old man arrives at the emergency room with a dislocated left shoulder. The patient is in a great amount of pain 7/10, but blood flow is intact, and no major vascular injuries have ensued. The patient is a candidate for regional anesthetic techniques to assist relocating the joint or also a candidate for conscious sedation with medications to assist in relocating the joint. Per conscious sedation guidelines, if the patient has ingested food in the last six hours, a hold must be placed to avoid aspiration during the conscious sedation procedure. This NPO wait time is not mandated for the patient receiving regional anesthesia. The medications that are needed for regional anesthesia versus conscious sedation are different. The medication for regional anesthesia will be lidocaine and rarely minimal versed or opioids for comfort. The medications for conscious sedation are opioids, versed, or ketamine and at higher doses to decrease consciousness. One-on-one nursing care must be provided for the consciously sedated patient until the awakening of the patient with a minimum amount of monitoring for twenty minutes; then a driver must be with the patient at discharge. The regional anesthetized patient must have the anesthesia provider to manipulate the lidocaine injection into the joint, but one-on-one nursing is not needed. If the patient did not have additional medications pre-procedure for anxiety, then the patient may drive home and does not have to wait post procedure for an allotted amount of time. Follow-up with the patient will also be essential to measure satisfaction. Satisfaction equals



reimbursement due to the quality of care statutes with Medicare and Medicaid governmental payment assistance. The acuity rating scale used by the hospital takes into account the acuity of the patient's illness or injury, the amount of time or care that will be needed, and the type of procedure to be done by the provider in the emergency. This acuity scale summarizes all of the variables to provide the cost.

A contrary case example would pose all the contraindications to the suggested prior implications with regional anesthesia or conscious sedation. Patients at risk for deterioration, neurological compromise, compartment syndrome, or other symptoms that would put the patient at risk with regional anesthesia were not included. The analysis of cost could not be achieved due to the critical priorities of the unstable trauma patient.

An eighty-one-year-old female has arrived in the emergency room by ambulance as a trauma patient. The patient has a dislocated left shoulder when assessed, but no pulse is palpated below the area of the axillary region. The left arm is swollen and extremely taught when assessed. The patient's vital signs are unstable, and a large amount of blood loss has been noted. The patient's level of consciousness is not within normal limits and is very lethargic with respiratory distress. This patient is not a candidate for regional anesthesia or conscious sedation, and the concept of cost would not be a priority in this situation. Preserving life by assisting with stabilizing vital signs, assisting with respirations, scanning, x-rays, and possible surgery would be the priorities.

According to Walker and Avant (2010), antecedents are the events leading up to or building to promote the concept. For "cost" to be assessed as a concept, first, the appropriate dislocations of the joint must occur and a patient must go to the emergency room. Then, the emergency room physician must order or request conscious sedation



with the nursing staff or regional anesthesia with a qualified anesthesia provider. The patient must be assessed to be a candidate, and the consent for either procedure must be explained to and obtained from the patient. An anesthesia provider must also have expert training in the field of regional anesthetic techniques to sufficiently and safely provide the block of nerves to the joint causing pain during the relocation. The cost of the tools used, medications, providers, time, and satisfaction must be evaluated and analyzed to determine a cost-benefit relationship.

The consequences of this "cost" concept are a new form of practice with regional anesthesia techniques. Regional anesthesia for shoulder dislocations is suggested to improve care from the prior standardized conscious sedation in the emergency room setting with the decreased cost for the patients and the increased revenue for the healthcare systems. Decreased turnover time and increased patient satisfaction of care with decreased pain with the new techniques will be keys to a positive influence financially.

Empirical referents is defined as, "classes or categories of actual phenomena that by their existence or presence demonstrate the occurrence of the concept itself" (Walker & Avant, 2010, p. 168). The empirical referents in the emergency room utilization of regional anesthesia are defined by the attributes that conclusively form the patient and hospital bills and reimbursement for the healthcare system. When analyzing the final cost and bills of each of the variable attributes, one can produce a cost-benefit analysis.

In conclusion, the concept is an extremely important aspect in defining the direction towards theory and completing the DNP project. The concept of "cost" is a



broad framework branching into the direct and indirect cost for the variables leading to the theorized suggestion in the DNP project.

Application of the Walker and Avant framework promotes the concept "cost" with the aim of defining the variables that are being analyzed. The uses of the concept that are portrayed will be in the emergency room with a population of patients that are assessed to be stable and have dislocated joints needing to be reset. This population will have high satisfaction scores or will be satisfied from the decreased pain, length of stay, and cost. Defining the attributes is a comparison of two different forms of care. The form of care that has been utilized in the past is conscious sedation, which causes the patient to be more medicated and have a longer length of stay. The present/future form of care being presented as a business suggestion is the use of regional anesthesia in the emergency room setting, which will promote patient satisfaction with less medication usage, and a decreased length of stay. The model cases suggest the population and types of cases, which would be most appropriate for the literature contained only articles that were recent comparison. The antecedents and consequences were the promotion of a new form of policy and healthcare suggestion. This suggestion decreases cost for the patient and increased revenue for the hospitals based on patient satisfaction and the expense of time in the constantly revolving emergency room.



CHAPTER II – REVIEW OF LITERATURE

This body of literature is a review of several articles that supports the problem of emergency/trauma patients having an increasing need for regional anesthesia. The quantitative articles provide evidence of how the increased pain, cost, and length of stay is associated with sedation and narcotic use.

A conclusive search scheme was used to obtain relevant articles related to regional anesthesia in the trauma setting. Several medical databases were used to obtain published and unpublished studies and guidelines in nursing, health services, anesthesia, trauma medicine, emergency medicine, and regional anesthesia for the years 2009-2015. Databases included CINAHL, PUBMED, MEDLINE, and GOOGLE Scholar. Keywords used included *regional anesthesia* + *emergency room*, *emergency department*, trauma, *and fractures* single and in combination. Any recent articles that used regional anesthesia as an alternative to emergency treatments such as pain medications, conscious sedation, surgery, and ventilators with any age group was included. Articles that were guidelines, peer reviewed, or appeared in scholarly journals were included eighty-nine (89) articles, of which, ten articles were applicable to the search. The inclusion criteria for the following review was in the past five years, used regional anesthesia, setting was in the emergency room, and/or had a traumatic injury or fracture in the preoperative setting that could benefit from regional anesthesia.

Regional anesthesia has been introduced as an alternative to the sedation and systemic pain medications that healthcare providers taking care of trauma patients give during shoulder reductions. Pain is a variable of cost due to the ability to measure financial gain through satisfaction and HCAHPS (Hospital Consumer Assessment of



Healthcare Providers and Systems). Pain, secondary to dislocations in the emergency room, was assessed with a visual analog scale of zero to ten. Zero is measured to be the least amount of pain, and ten is measured the worst amount of pain. The pain was assessed prior to the reduction, setting, and/or casting of the injury. Pain was reassessed after the procedures in several different time intervals. Using a numerical rating scale, pain scores were also reviewed in many of the articles to decrease the pain faster and keep the pain scores down for a longer length of time. Beaudin et al. (2010), with regional anesthesia, for instance, documents that pain scores were decreased in fifteen minutes and lasted for four hours after the procedure without the sedative effects of conscious sedation. With a review of decreased pain, satisfaction was portrayed to be increased which increases HCAHPS scores. Improved HCAHPS scores lead to increased Medicare/Medicaid reimbursement.

According to Beaudoin et al. (2010), femoral blocks on 13 elderly patients, ranging 67-94, helped to decrease pain scores by 44% at 15 minutes and 67% at 30 minutes post procedure. The results were statistically significant at 15 and 30 minutes (both p< .05). Pain scores from 30 minutes to four hours after the procedure did not change. Pain was measured by the visual analog scale and by the need for additional systemic morphine after the nerve block. Per the criteria established: femoral nerve as seen per ultrasound, sensory hypoesthesia of the thigh, and decreased pain post procedure, the study was 100% successful. The importance of this nerve block technique "would permit the practitioner to control pain in elderly patients with hip fractures while avoiding the deleterious consequences of parenteral narcotics in this population (Beaudoin et al., 2010, p. 77)."



Blaivas, Adhikari, and Lander's (2011) prospective comparison between procedural sedation and a regional nerve block for shoulder reduction showed no statistically significant difference in pain level. The procedural sedation pain score ranged from zero to four, and the regional block pain scores ranged from zero to three. Neither pain ranges were statistically significant; p ranges were >.05.

Haines et al. (2012) conducted a study among twenty patients with hip fractures in an academic urban emergency room. Each patient while awaiting the regional block placement was medicated with 0.1 mg/kg of systemic morphine. An inclusive criterion to be part of this sample was that the pain had to be minimal five prior to starting any treatment. Then, the post-procedure pain was measured per patient scale and per rescue doses of morphine for an eight-hour period. No additional pain meds were required by 80% of the sample group after the fascia iliaca compartment block was completed. At the 120-minute interval, the pain was recorded as one out of ten scale.

The confusion assessment method test results showed light sedation, with propofol and spinal anesthesia, decreased the prevalence of postoperative delirium by 50%. The mean number of days difference was $.5\pm1.5$ Tamaoki et al. (2012) introduced an intra-articular lidocaine injection with shoulder reduction to minimize the pain in a randomized clinical trial. The research design had a control group of 20 and regional block group of 22. The regional block group had significantly lower pain statistically with a p less than 0.001 in the first and fifth minutes.

Bhoi et al. (2012) performed a prospective observational study with ultrasoundguided nerve block in the emergency room for limb injuries. Participants in this study were 5 years or older. Several different blocks were utilized such as sciatic, femoral,



brachial, median, and radial nerves. The pain decreases were significant across the nerve blocks with no rescue pain medications needed. The pain assessment intervals for the different nerve blocks were: the baseline, 15 minutes after the procedure, and 60 minutes after the procedure.

Increased sedation and narcotics, such as opioids, place the elderly at a heightened risk of deleterious side effects such as hypotension, respiratory depression and confusion (Beaudoin et al., 2010). Sieber et al. (2010) conducted a study specifically comparing the incidence of delirium after deep sedation versus light sedation in a hip fracture repair with the utilization of spinal anesthesia. The Bispectral index monitor was used to measure the amount of sedation with deep equaling approximately 50 and light being greater than 80. The delirium post surgery was assessed by using the day for light sedation compared to 1.4 ± 4 days for the deeply sedated patients. Deep sedation has a significant increase in hospital length of stay with p=.01 (Sieber et al., 2010). The extra amount of time the nurses have to contribute to the elderly, dementia or delirium patients, occasionally places the nurses on a one to one ratio with the patient. One on one care is very time-consuming and costly for healthcare providers due to the additional staffing that must be provided for other patients in need of a nurse in the emergency room.

A secondary outcome, measure of time, was found in the emergency room. Fifteen minutes was the minimal assessment time needed for pain control in most of the studies. This showed the rapid onset with regional anesthesia. The pain assessments on lengthened interval checks ranged to eight hours showing the length of time the patients remained pain-free without being sedated. Blaivas et al. (2011) found equal pain



presentation for regional anesthetics and procedural sedation; however, this study provided significant analysis of shorter emergency room length of stay by decreased procedure time and provider time. The mean length of stay in the emergency room was significantly higher with p< 0.0001 for the procedural sedation patients. The mean length of stay for procedural sedation was 177.3 ± 37.9 minutes and the mean length of stay for the ultrasound-guided interscalene block group was 100.3 ± 28.2 minutes. One on one provider time was analyzed to be significant with p<0.0001. Provider time in the procedural sedation group was 47.1 ± 9.8 minutes. Provider time in the ultrasound-guided interscalene block group was 5 ± 0.7 minutes. Provider time and length of stay are significant costs that could be decreased for the patient and the hospital.

Procedural sedation complications are airway and circulatory compromise. Procedural guidelines for conscious sedation allow that nothing by mouth (NPO) status should be achieved before any sedating intervention that has a risk of aspiration. NPO time for the patient unaware of the last drink or meals starts at six hours. If procedural sedation is used instead of regional anesthesia then the possibility for increased length of stay (LOS) time with procedural sedation will be greater. Median time for the average regional anesthetic treatment is seven – eleven minutes (Beaudoin et al., 2010). "Such patients require close monitoring during and after the procedure for several hours before emergency department disposal. Ultrasound-guided peripheral nerve block is a safe alternative that utilized minimal amounts of local anesthetic, and minimum monitoring is essential for any procedure requiring regional block" (Bhoi et al., 2012, p. 29).

The articles suggest that pain, cost, and length of stay can all be decreased with the addition of regional anesthesia for procedural pain purposes and post procedural pain



management. The emergency room is an optimal location with a wide range of patients and injuries that are capable of being a candidate for a regional anesthetic technique to better improve their experience.



CHAPTER III – METHODOLOGY

"A Cost-Benefit Analysis is the principal method used to evaluate decisions involving public expenditures" (Butts & Rich, 2015, p. 336). It is the methodology that formulates and organizes the collection of results to measure cost directly with the form of treatment and indirectly with pain, length of stay, and satisfaction in the emergency room. The design, data collection, and data analysis portrayed significant findings that pain and length of stay were decreased with regional anesthesia rather than procedural sedation for dislocations and other injuries in the emergency room. The cost-benefit analysis also portrayed the satisfaction with the cost of regional versus procedural sedation in a critical area such as the emergency department allowing for a higher level of quality of care.

Design and Target Population

The target population was patients in the emergency room setting with dislocated shoulders after an injury with a particular ICD-10 code. The design was a retrospective chart review of patients in the emergency room at a level II trauma center in Mississippi that needed conscious sedation to re-set their dislocated shoulders. Data was collected based on direct and indirect cost. The retrospective chart review for the conscious sedation procedures was compared with systematic reviews of regional anesthetic procedures since data was not available with regional anesthetic procedures and cost variables in the emergency room. The focus reviews were based on the military healthcare systems and other countries that are performing regional anesthesia for dislocations and fractures in the emergency rooms. Ethical considerations were not an issue with this project due to the use of data/results previously collected and some already



presented to the general public. The patient anonymity was maintained due to no identifiable data was removed from the chart. No new data was collected associated with the researcher participating in physical patient care. The variables collected were in an excel spreadsheet within a password locked computer.

The conclusive design will be a retrospective chart review with the use of the focus review results for a cost comparison. The independent variables were be regional anesthesia blocks and procedural/conscious sedation or no regional anesthesia. The independent variable, procedural/conscious sedation were established by retrospective chart review with ICD-10 code S43 to specific emergency room shoulder dislocations from September 1, 2015- September 1, 2016. The patients that meet the ICD- 10 code S43 inclusion criteria were part of the review if they had conscious sedation. The dependent variables were obtained on a data sheet to compare indirect variables of cost.

Detailed Procedures

A systematic review was completed for evidence-based practice of the regional anesthesia being done on patients in the military settings and other countries. A data sheet was constructed that is composed of information input on the dependent variable such as pain, procedure time/length of stay, and satisfaction.

The tools utilized for data collection for the cost-benefit analysis are the visual analog scale ranging from zero to ten for pain measurement and time in the frame of minutes and hours for the emergency department procedures being evaluated. The procedure for the data collection with pain is measured in time intervals with preprocedure visual analog scale first, and then other measurements with the same scale were measured post procedure. The length of time was measured as provider time with



the patients in different groups. Time to perform block and mean length of stay for the patients in the different groups was measured as well to have a conclusive explanation of the distribution of time. Sampling was over wide population ranging from pediatrics to elderly all patients of the emergency department in need of reduction and/or pain control. Patients at risk for deterioration, neurological compromise, compartment syndrome, or other symptoms that would put the patient at risk with regional anesthesia were not included. The data was portrayed in numerical comparisons within categories of having regional anesthesia or not; time was an influence on the recordings. The cost was analyzed using a data sheet to collect specific evidence.

Data Analysis and Evaluation

Descriptive statistics was the statistical method of data analysis comparing the two different groups: conscious sedation or regional anesthesia. Each variable, pain intervals, procedure time/length of stay, and satisfaction, was collected on a data sheet and entered into a spreadsheet for comparison in the cost-benefit analysis.

Limitations and Assumptions

There were many assumptions and limitations that come with doing a cost benefit analysis with a health care organization. The pain scores and length of procedures were fairly easy to obtain with permission from the hospital IRB. With the indirect measures, an assumption was made that decreased pain, wait time, and length of procedures would equal higher satisfaction. The start of the procedure time was a limitation and had to be reassessed since all charts did not document their timeout. The start of the procedure was then change to the pre aldrete score. In determining the length of procedures, it is assumed that the NPO time of 6 hours is included with the assessment and radiology wait



time, which is slightly less than 242 for the average emergency room patient. The actual billing however was not provided, which accounted for a limitation. Therefore, the acuity levels were used as an assumption in determining the cost. The limitation in determining these levels left out the prior comorbidities of the patient, which may suggest a higher scale.

Conclusion

The retrospective chart reviews and focused reviews of cost was a strong evidence-based study with a cost-benefit analysis being the final determinant of influence into practice. Not only is the literature suggesting improved care and benefit from pain reduction, but also the cost analysis of the results with the influence of time suggest an improved process of care that will be a decreased cost to the patient, provider, hospital, and insurance companies paying for the care and the time expense of healthcare utilization.



CHAPTER IV – RESULTS/FINDINGS

The data collection at the level II trauma center was completed. The total of patients that resulted from the criteria search of ICD 10 code S43 was 135 patients. The number of patients who had conscious sedation provided by a nurse and physician for the procedure to alleviate the dislocation was 52. The patients that did not have conscious sedation for the dislocated shoulder totaled 83. These patients did not have conscious sedation due to being admitted, going to surgery, or due to being hemodynamically unstable. The data collection at the level II trauma center was completed. The total of patients that resulted from the criteria search of ICD 10 code S43 was 135 patients. The number of patients who had conscious sedation provided by a nurse and physician for the procedure to alleviate the dislocation was 52. The patients that did not have conscious sedation for the dislocated shoulder totaled 83. These patients did not have conscious sedation for the dislocated shoulder totaled 83. These patients that did not have conscious sedation for the dislocated shoulder totaled 83. These patients that did not have conscious sedation for the dislocated shoulder totaled 83. These patients did not have conscious sedation for the dislocated shoulder totaled 83. These patients did not have conscious sedation for the dislocated shoulder totaled 83. These patients did not have conscious sedation due to being admitted, going to surgery, or due to being hemodynamically unstable.

Pain was measured prior to conscious sedation and after conscious sedation in the 54 patients. There was a minimal average decrease of 3.2 in the pain scale. In the evidence from international and military base anesthetic management of pain with regional anesthesia, the scores were proven with a statistical significance. The p scores prove to have decreased pain to a greater extent with regional anesthesia than conscious sedation. Pain scores indirectly play a major role in cost by increasing or decreasing satisfaction and possibly lengthening the hospital stay as well. Satisfaction scores manipulated the amount paid to the healthcare systems. Therefore, the indirect measures



of length of procedure and pain levels correspond to a decrease in cost and an increase in satisfaction with regional anesthesia rather than conscious sedation.

The conscious sedation start time was given by the hospital epic team with search criteria, but the start times were also verified by the time of the timeout and initial aldrete scores. An aldrete score is measured by the level of consciousness, blood pressure, color, respiration, and activity to determine baseline prior to sedation and post sedation in the recovery phase of care. The post sedation aldrete determines when a patient can be discharged from intense one-on-one nursing care. The conscious sedation stop time was collected by assessing the post sedation aldrete score.

The length of the regional anesthetic procedure time was based off the time of a similar regional anesthetic. A regional anesthetic that is comparable to the lidocaine field block being suggested, the interscalene block, was documented as a 5-7 minute procedure time by Blaivas et al. (2011). This procedure time of 5-7 minutes is much lower than the latter of 382 minutes for conscious sedation, placing the patient on a lower criteria level of acuity. Time is one of the factors considered in the acuity levels. A decreased acuity level indicates a decreased cost to the patient (University Hospitals, 2016).

The emergency room indirect cost had no bearing on time specifically, but the cost was from the acuity grading of the patient on a scale of 1-5. "The levels, with level 1 representing basic emergency care, reflect the type of accommodations needed, the personnel resources, the intensity of care and the amount of time needed to provide treatment (University Hospitals, 2016, p. 1)." The University Hospital's cost per acuity scale is labeled as Table 1. Therefore the length of stay variable can be used only abstractly as a measure of cost with the consideration of additional procedures, revenue,



and the average turnover of patients. According to the literature reviewed the mean amount of time for any patient in the emergency room is 242 minutes (Rathlev et al., 2012). The analysis was based on using 242 minutes for the regional anesthetic procedure. When patients continually exceed the national mean length of stay of 242 minutes, it only ensues more overcrowding and decreased revenue from turnover. The conscious sedation time of 382 minutes was calculated using the 6 hours NPO time which is 360 minutes plus the 22 minutes conscious sedation procedure time already stated.

The 382-minute procedure time for the conscious sedation at the level II trauma center, placed these patients as outliers compared to the 242-minute national average for entire emergency room visit.

Table 1

Cost per Acuity

Level 1	290.00
Level 2	476.00
Level 3	912.00
Level 4	1,246.00
Level 5	2,306.00
Critical care	3,439.00
Pediatric Trauma Team full activation	8,050.00
Pediatric Trauma Team partial activation	5,750.00

The level of care on the acuity scale for the shoulder dislocation using regional anesthesia was measured as level 1. The level of care being provided for conscious sedation during the shoulder reduction was measured using a level 2. Conscious sedation was measured on a higher scale due to the intensive care needed on a one-to -one nursing scale to assess the altered hemodynamics due to sedation. Level 1 was calculated as



\$290.00 per general room and board; Level 2 was measured as \$476.00 for general room and board. The acuity level cost did not take into account additional cost such as radiology expenses, medications, and labs.

The number of patients (54) that had conscious sedation were multiplied by the appropriate level 2 expense (\$476.00). The cost of shoulder reductions in the one year span measured was \$25,704 for conscious sedation. In contrast, if the (54) patients had regional anesthesia instead of conscious sedation, then 54 would be multiplied by the appropriate level 1 cost (\$290.00) to generate the cost of patients in one year times span to equal \$15,660. The difference in the cost of the procedures per year was \$10,044. The hospital could potentially save \$10,044 alone just be changing the procedure to regional anesthesia from conscious sedation to assist with shoulder dislocation. The largest cost saving comes from the increased availability of improved emergency room turnover.

The turnover time in the emergency room refers to the patient being treated and the bed being vacated and ready for the next patient to be assessed. Turnover time in the emergency room was calculated per patient, per procedure, per minute, per twenty our hour time frame to determine the amount of patients that potentially could be turned over in a single emergency room. There are 60 minutes in an hour; there are 24 hours in a day. Multiplying the amount of minutes in hour (60) by the amount of hours in a day (24) concluded that there is 1440 minutes in a day. When the amount of minutes per day (1440) was divided by the amount of minutes a patient needed for a conscious sedation procedure (382), the calculation equaled 3.77. The maximum amount of patients that could be seen in the emergency room in one day for conscious sedation is 3.77. When the amount of minutes per day (1440) was divided by the amount of time needed for a



regional anesthetic procedure patient (242), the calculation showed that 5.95 was the maximum amount of regional anesthetic procedure patients that could be seen. The difference in turnover between procedures was 2.18 more patients that could be seen in a 24 hour time period. This analysis of the improved turnover times in the cost-benefit analysis suggested improved patient satisfaction, decreased wait time in the emergency room, and increased revenue for the hospital.

Discussion

The purpose of this project was to decrease the cost directly by providing regional anesthesia for shoulder dislocations to reset the joint. Cost indirectly will be decreased by decreasing the length of stay, and indirectly reimbursement and revenue were increased for the healthcare systems through satisfaction from improved pain scores. The findings demonstrated of an increased procedure time when implementing conscious sedation for shoulder dislocation, which in turn led to the calculated conclusion that longer procedure times are directly related to increased length of stay for the emergency department. The longer length of stay/procedure decreased the amount of patients that could be turned over a 24 hour time period for the emergency room.

Implications for the Nursing Practice

The implications for the nursing practice are an increase in expertise for CRNAs that facilitate better outcomes and quality of care. This will be accomplished by using new regional anesthetic expertise into the emergency room. An additional implication will be the increase in the number of jobs available to the CRNA profession. As stated earlier in the project, CRNAs are already providing exceptional regional anesthetic care to military hospitals and internationally for such cases as shoulder dislocations. This



DNP project supported the introduction of regional anesthesia with CRNAs into the emergency rooms within our healthcare systems in the United States. The CRNAs will provide regional anesthesia, which promotes decreasing pain scores and faster turnover times to assist with the cost of healthcare and increase quality of care. Policy change will be of importance due to the change in procedure and care for the patient. Addition education will be needed from the staff to understand the regional anesthesia being performed. Other qualified anesthesia providers, such as Anesthesiologist, could be included in this introduction of regional anesthesia in the emergency room as well.

In future DNP projects, it is suggested to follow up with the actual HCAHPS scores and the correlations with satisfaction and reimbursement after this regional anesthesia is introduced. Anesthesia revenue is also a topic one might want to pursue further knowledge on in a DNP project. If the hospital hires the anesthesia staff, then the revenue would probably still be greater than the cost of anesthesia. However, if the anesthesia staffing is owned by an anesthesia company, then the cost might be greater to staff another area of the hospital. This project focused mainly on the patient and hospital cost, but there are more areas that can be look in to develop this analysis further.

Conclusion

Medicine as a whole is changing with new advances in medications, procedures, and guidelines to improve patient care and safety. Evidence must be documented for learning and positive change in healthcare systems. With this particular doctoral project, the evidence that was collected, suggested and promoted a positive change in the healthcare systems of the United States with decrease cost for the patient and healthcare system and increased reimbursements through satisfaction. This cost benefit analysis



exemplified through the collected evidence of regional anesthesia and conscious sedation with shoulder dislocations in the emergency room/trauma patient that regional anesthesia leads to a faster procedure, decreased level of pain, and a faster turnover time for the hospital. The satisfaction improved for the patient due to decreased cost, pain, and quicker procedure. The benefit for the hospital was faster turnover and higher level of satisfaction, which equals greater revenue and a higher level of reimbursement. This DNP project introduced the practice of administering regional anesthesia for manipulation of shoulder dislocations. Therefore, the findings of the cost-benefit analysis contributed to hospitals by promoting a higher level of care to patients in the most cost efficient way.



	Ooctor of Nursing Essentials	How the Essential is Achieved	
I.	Scientific Underpinnings for Practice	The cost- benefit analysis promotes anesthesia practices through regional anesthesia as compared to conscious sedation in the Emergency room setting. The anesthesia practice of regional blocks helps to improve cost directly and indirectly for all stakeholders.	
II.	Organizational and Systems Leadership for Quality Improvement and Systems Thinking	This doctoral project is to suggest a policy and practice change within an emergency/trauma setting. Quality improvement is suggested and defined in the project as an indirect cost benefit.	
III.	Clinical Scholarship and Analytical Methods for Evidence-Based Practice	Evidence based practice is displayed throughout the literature review with other countries already changing practice with regional anesthesia in the emergency room and the significance of positive change and efficiency. The doctoral programs in the United states are also already making regional anesthesia in clinical practice mandatory in school.	
IV.	Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care	Informational systems are suggested to be improved with efficiency, quality of care, and cost. This doctoral project will transform health care by promoting a new policy and improving quality.	
V.	Health Care Policy for Advocacy in Health Care	This doctoral project is suggested to create a new health care policy at Forrest General Hospital for the implantation of regional anesthesia in the emergency room to assist with cost and efficiency of care	
VI.	Interprofessional Collaboration for Improving patient and Population Health Outcomes	The doctoral project's implementation would rely upon the collaboration between emergency room nurses, anesthesia providers, and emergency room physicians in order to be successful.	
VII.	Clinical Prevention and Population Health for Improving the Nation's Health	Decreased pain, length of stay, and cost promote efficiency. In return this promotes satisfaction and quality of care. Quicker turnovers and better satisfactions rates decrease medical cost for the patient and increase revenue for	

APPENDIX A – Doctor of Nursing Practice Essentials



		the hospitals which provide the public healthcare.
VIII.	Advanced Nursing Practice	The descriptive analysis of retrospective evidence, the synthesis of data and evidence from literature, and the suggestion of regional anesthesia are all within the scope of an APN.



APPENDIX B – Data Collection Sheet





APPENDIX C - Data

PATIENTS- CONSCIOUS	PAIN SCORES	PROCEDURE
SEDATION	PRE/POST	TIMES
1	7/10- 6/10	2200-2237
2	10/10-4/10	2243-2316
3	7/10-6/10	2139-2150
4	10/10-8/10	2000-2117
5	10/10-10/10	1636-1706
6	10/10-8/10	1647-1658
7	8/10-0/10	1915-1944
8	10/10-10/10	0009-0028
9	10/10-10/10	1742-1802
10	10/10-10/10	0748-0757
11	10/10-8/10	2216-2257
12	10/10-10/10	1940-2022
13	6/10-4/10	2303-2316
14	10/10-10/10	0523-0544
15	10/10-5/10	1130-1148
16	8/10-2/10	1419-1456
17	10/10-0/10	0745-0758
18	10/10-10/10	1535-1548
19	10/10-6/10	2001-2026
20	4/10-0/10	1013-1028
21	8/10-8/10	1643-1653
22	10/10-6/10	1845-1854
23	8/10-0/10	2232-2307
24	9/10-2/10	0023-0053
25	9/10-0/10	0743-0801
26	0/10-8/10	2328-2349
27	10/10-8/10	0331-0346
28	10/10-2/10	1129-1202
29	10/10-8/10	1105-1130
30	10/10-9/10	2111-2119
31	10/10-0/10	0011-0041
32	10/10-0/10	2014-2030
33	10/10-10/10	1535-1550
34	10/10-10/10	1541-1615
35	8/10-10/10	1944-1952



26	0/10 7/10	1015 2005
36	9/10-7/10	1915-2005
37	10/10-10/10	2009-2036
38	10/10-0/10	1545-1558
39	9/10-3/10	0312-0332
40	10/10-0/10	2227-2242
41	10/10-4/10	1818-1835
42	9/10-9/10	2102-2116
43	10/10-0/10	1921-1933
44	9/10-9/10	1446-1505
45	10/10-4/10	1743-1756
46	8/10-4/10	1936-1953
47	9/10-10/10	1614-1624
48	7/10-3/10	2212-2225
49	10/10-10/10	1756-1824
50	10/10-10/10	1429-1455
51	8/10-8/10	1114-1122
52	9/10-3/10	1758-1832
		PROCEDURE
PATIENTS- CONSCIOUS	PAIN SCORES:	TIMES:
SEDATION	DIFFERENCE	DIFFERENCE
-		
1	1	17
2	6	33
2 3	6 1	33 11
2 3 4	6 1 2	33 11 77
2 3 4 5	6 1 2 0	33 11 77 30
2 3 4 5 6	6 1 2 0 2	33 11 77 30 11
2 3 4 5 6 7	6 1 2 0 2 8	33 11 77 30 11 29
2 3 4 5 6 7 8	6 1 2 0 2 8 0	33 11 77 30 11 29 19
2 3 4 5 6 7 8 9	6 1 2 0 2 8 0 0 0	33 11 77 30 11 29 19 20
2 3 4 5 6 7 8 9 10	6 1 2 0 2 8 0 0 0 0	33 11 77 30 11 29 19 20 9
2 3 4 5 6 7 8 9 10 11	6 1 2 0 2 8 0 0 0 0 2	33 11 77 30 11 29 19 20 9 41
2 3 4 5 6 7 8 9 10 11 12	6 1 2 0 2 8 0 0 0 0 0 2 0	33 11 77 30 11 29 19 20 9 41 42
2 3 4 5 6 7 8 9 10 11 12 13	6 1 2 0 2 8 0 0 0 0 0 2 0 2	 33 11 77 30 11 29 19 20 9 41 42 13
2 3 4 5 6 7 8 9 10 11 12 13 14	6 1 2 0 2 8 0 0 0 0 2 0 2 0 2 0	33 11 77 30 11 29 19 20 9 41 42 13 21
2 3 4 5 6 7 8 9 10 11 12 13 14 15	6 1 2 0 2 8 0 0 0 0 2 0 2 0 2 0 5	 33 11 77 30 11 29 19 20 9 41 42 13 21 18
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	$ \begin{array}{c} 6\\ 1\\ 2\\ 0\\ 2\\ 8\\ 0\\ 0\\ 0\\ 2\\ 0\\ 2\\ 0\\ 5\\ 6\\ \end{array} $	 33 11 77 30 11 29 19 20 9 41 42 13 21 18 37
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	$ \begin{array}{c} 6\\ 1\\ 2\\ 0\\ 2\\ 8\\ 0\\ 0\\ 0\\ 2\\ 0\\ 2\\ 0\\ 5\\ 6\\ 10\\ \end{array} $	 33 11 77 30 11 29 19 20 9 41 42 13 21 18 37 13
$ \begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ \end{array} $	$ \begin{array}{c} 6\\1\\2\\0\\2\\8\\0\\0\\0\\2\\0\\2\\0\\2\\0\\5\\6\\10\\0\end{array} \end{array} $	 33 11 77 30 11 29 19 20 9 41 42 13 21 18 37 13 13
$ \begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ \end{array} $	$ \begin{array}{c} 6\\ 1\\ 2\\ 0\\ 2\\ 8\\ 0\\ 0\\ 0\\ 2\\ 0\\ 2\\ 0\\ 5\\ 6\\ 10\\ 0\\ 4\\ \end{array} $	$\begin{array}{c} 33\\11\\77\\30\\11\\29\\19\\20\\9\\41\\42\\13\\21\\18\\37\\13\\13\\13\\25\end{array}$
$ \begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ \end{array} $	$ \begin{array}{c} 6\\1\\2\\0\\2\\8\\0\\0\\0\\2\\0\\2\\0\\2\\0\\5\\6\\10\\0\end{array} \end{array} $	 33 11 77 30 11 29 19 20 9 41 42 13 21 18 37 13 13



22	4	9
23	8	26
24	7	30
25	9	18
26	-8	21
27	2	15
28	2 8	33
29	2	25
30	1	8
31	10	30
32	10	16
33	0	15
34	0	34
35	-2	8
36	2	50
37	0	27
38	10	13
39	6	20
40	10	15
41	6	17
42	0	14
43	10	12
44	0	19
45	6	13
46	4	17
47	-1	10
48	4	13
49	0	28
50	0	26
51	0	7
52	6	34



APPENDIX D – USM IRB



INSTITUTIONAL REVIEW BOARD 118 College Drive #5147 | Hattiesburg, MS 39406-0001 Phone: 601.266.5997 | Fax: 601.266.4377 | www.usm.edu/research/institutional.review.board

NOTICE OF COMMITTEE ACTION

The project has been reviewed by The University of Southern Mississippi Institutional Review Board in accordance with Federal Drug Administration regulations (21 CFR 26, 111), Department of Health and Human Services (45 CFR Part 46), and university guidelines to ensure adherence to the following criteria:

- The risks to subjects are minimized.
- The risks to subjects are reasonable in relation to the anticipated benefits.
- The selection of subjects is equitable.
- Informed consent is adequate and appropriately documented.
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of all data.
- Appropriate additional safeguards have been included to protect vulnerable subjects.
- Any unanticipated, serious, or continuing problems encountered regarding risks to subjects must be reported immediately, but not later than 10 days following the event. This should be reported to the IRB Office via the "Adverse Effect Report Form".
- If approved, the maximum period of approval is limited to twelve months.
 Projects that exceed this period must submit an application for renewal or continuation.

PROTOCOL NUMBER: 16081502 PROJECT TITLE: Regional Anesthesia Introduced into an Emergency/Trauma Setting PROJECT TYPE: New Project RESEARCHER(S): Jennifer Covalt COLLEGE/DIVISION: College of Nursing DEPARTMENT: Nursing FUNDING AGENCY/SPONSOR: N/A IRB COMMITTEE ACTION: Exempt Review Approval PERIOD OF APPROVAL: 08/22/2016 to 0/21/2017 Lawrence A. Hosman, Ph.D. Institutional Review Board



APPENDIX E – Hospital IRB

Exempt Status



DATE:

August 3, 2016

TO: FROM:	Jennifer Covalt, DNP t General Hospital Institutional Review Board
STUDY TITLE:	[929557-1] Regional Anesthesia Introduced into an Emergency/Trauma Setting
SUBMISSION TYPE:	New Project
ACTION: DECISION DATE:	DETERMINATION OF EXEMPT STATUS July 20, 2016
REVIEW CATEGORY:	Exemption category # B4

Thank you for your submission of New Project materials for this research study. General Hospital Institutional Review Board H IRB) has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations.

Even though your project is exempt from IRB review, the research must be conducted according to the proposal submitted to the HIRB. If changes to the approved protocol occur, a revised protocol must be reviewed and approved by the IRB before implementation. Please be aware that changes to the research protocol may prevent the research from qualifying for exempt review and require submission of a new IRB application or other materials to the HIRB.

If an unexpected situation or adverse event happens during your investigation, please notify the FGH IRB as soon as possible. If notified, we will ask for a complete explanation of the event and your response. Other actions also may be required depending on the nature of the event.

If you have any questions, please contact Michele Stanley at 601-2 100-4 or mstanley@meral.com. Please include your study title and reference number in all correspondence with this office.

Sincerely,

Lewis E. Lewis M.D. Chairman, Institutional Review Board



IRB Approval



DATE: August 3, 2016 TO: Jennifer Covalt, DNP FROM: Hospital Institutional Review Board STUDY TITLE: [928557-1] Regional Anesthesia Introduced into an Emergency/Trauma Setting SUBMISSION TYPE: HIPAA IRB Waiver of Authorization ACTION: APPROVED APPROVAL DATE: July 20, 2016 July 19, 2017 EXPIRATION DATE: REVIEW TYPE: Full Committee Review

The energy energy energy is a service of Authorization for use of protected health information (PHI) for this research study as outlined in the approved research protocol.

In approving this Waiver of Authorization, the HIRB has determined the following criteria has been met

The use or disclosure of the requested information involves no more than a minimal risk to the privacy of individuals based on, at least, the presence of the following elements:

- · An adequate plan to protect the identifiers from improper use and disclosure
- An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
- Adequate written assurances that the requested information will not be reused or disclosed to any
 other person or entity, except as required by law, for authorized oversight f the research study, or for
 other research for which the use or disclosure of the requested information would be permitted by
 the Privacy Rule.
- · The research could not practicably be conducted without the waiver or alteration
- The research could not practicably be conducted without access to and use of the requested information

In making this determination the HIRB has followed the requirements of the Common Rule using Full Board Review procedures.

If you have any ouestions, please contact Michele Stanley at 001mstanley@monopeneral.com. Please include your study title and renormes number in all correspondence with this office.

Generated on IRENet



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