

The Effects of Preoperative Education on Parental Anxiety and Knowledge
with Children Undergoing a Posterior Spinal Fusion

by

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Abstract

Anxiety is high in parents with children undergoing a posterior spinal fusion. The research found demonstrates that it is important to have the proper educational materials, and to address the emotional and psychological aspect of a parent whose child is having surgery. It is important for the parents to increase their knowledge of their child's upcoming surgery, which will result in decreased anxiety. The purpose of this proposed project is to investigate the effects of preoperative education on parents' anxiety and knowledge with children undergoing a posterior spinal fusion. The outcomes for this research will demonstrate how preoperative education effects parents' anxiety and knowledge about spinal fusions. There is limited research on pediatric posterior spinal fusions and preoperative education for parents. Most research found discussed education for adult patients undergoing fusions and other invasive medical procedures. The results of this proposed project will be utilized to modify and improve current preoperative education for this group of patients and their families going through elective spinal surgery; with the goal of alleviating parental anxiety and increasing their knowledge. The ability to examine the education provided by nurses and healthcare professionals is invaluable so that quality, safe patient care is not compromised. Preoperative education is the knowledge that reduces anxiety experienced by our patients and their families, and success of that education is found in the researching, testing, and refining of that education for overall better outcomes.

Key Words: Anxiety, Preoperative, Education, Parents

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Chapter One

According to the National Scoliosis Foundation (2011), 38,000 adults, adolescents, and children combined required a posterior spinal fusion for correction of a spinal deformity last year alone. Scoliosis is the most common spinal deformity and is defined as an abnormal curvature of the spine as stated by the Scoliosis Research Society (2011). The body's spine has a natural curvature in the thoracic and lumbar regions of the back, and it is only when the spine begins to bend toward the right or the left that it is considered abnormal. There are three types of scoliosis: congenital, neuromuscular, and idiopathic (SRS, 2011). Approximately eighty to eighty-five percent of all scoliosis diagnoses are idiopathic, meaning there is no known cause or underlying abnormality (SRS, 2011). Idiopathic scoliosis is the leading cause of spinal deformity in children (SRS, 2011), and many children with this diagnosis might need surgical intervention to correct it. Surgical treatment is necessary when the curvature of the spine measures greater than forty-five degrees while still growing or greater than fifty degree once the child has stopped growing (SRS, 2011).

Posterior spinal fusion is considered to be a major, invasive surgical procedure performed by an Orthopedic Surgeon. A fusion of the spinal column involves insertion of metal implants into the spine (SRS, 2011). The spinal column is then manipulated to connect the implants to metal rods that hold the spine straight and correct the abnormal curve (SRS, 2011). The surgery portion, though long and intensive for the physician, is relatively the easy for the patient as they are under anesthesia. It is the preoperative and postoperative portions that require a great amount of learning and participation on the part of the patient and their family. According to Justus, Wyles, Wilson, Rode, Walther, &

Lim-Sulit (2006) the experience of surgery can be quite stressful for patients and their families because they are in unfamiliar surroundings and thrown into an environment different from their home and familiar routines.

Surgery is a high stress and anxiety producing intervention that requires intensive preparation by the health care professional for the parent and child involved. It is a decision that cannot be taken lightly by parents and mandates high quality preoperative education for them. Physicians and nurses play a key role as medical professionals in delivering that education in order for the parent and child to be properly informed of the risks and benefits of undergoing this major surgery. Preoperative education is important increasing knowledge about the prospective surgery, explain what will be experienced postoperatively, and helping decrease level of anxiety. According to Murphy-Taylor (1999), the rationale for preparing children for hospital admission is that they may cope better with their fear of the unknown and the anxiety that is produced due to their hospitalization. The author also explains that pre-admission preparation combats their anxiety and reduces psychological trauma (Murphy-Taylor, 1999).

Significance of the Problem

According to Scrimin, Haynes, Altoe, Bornstein, & Axia, (2009), children depend on parents for support and guidance in coping with stressful situations, which is why parents play a critical role when they undergo surgery. When parents are stressed and exhibiting high levels of anxiety the effectiveness of supporting their child may decline because they have become emotionally involved in the event (Scrimin et al., 2009). Parents that are anxious begin to lose their ability to process information, and the ability to care for their child. This has a huge impact on the parents' capacity to care for the child postoperatively.

It is important that preoperative education be clear and concise in order to inform the parent and reduce this fear and anxiety of the unknown. With this preoperative information, parent(s) may then be able to better support their child.

Lastly, according to Johansson, Nuutila, Virtanen, Katajisto, & Salanterä (2005) there is an abundance of information on patient education, but none specifically focused on the effectiveness of preoperative education in regards to children undergoing orthopedic surgeries. The lack of research on this topic demonstrates the need for further studies on preoperative education for not only children undergoing a spinal fusion, but preoperative education for parents as well.

Problem Statement

Surgery is a necessary treatment for correction of spinal deformities in the pediatric population and preoperative education is essential for not only the child, but the parents as well. When parents exhibit higher levels of stress due to their child's approaching surgery, it is more challenging for them to care for the child throughout their hospital stay.

Education provides knowledge, which assists in reducing anxiety levels, resulting in a better postoperative experience for both child and parent. The goal of physicians and nurses in providing healthcare for the patients is to consider the ways in which care and education are given.

There are numerous studies on patient education and preoperative anxiety. However, there is limited research on preoperative education specific to parental anxiety and knowledge with children undergoing a posterior spinal fusion.

This research will examine how preoperative education effects parental anxiety and knowledge. Parents with children undergoing a posterior spinal fusion will show a

reduction in anxiety and an increase in knowledge when provided with preoperative education.

Purpose Statement

The purpose of this project is to investigate the effects of preoperative education on parents' anxiety and knowledge with children undergoing a posterior spinal fusion. The outcomes for this research will demonstrate how preoperative education effects parents' anxiety and knowledge about spinal fusions.

Chapter Two

Literature Review

The purpose of this project is to investigate the effects of preoperative education on parental anxiety and knowledge with children undergoing a posterior spinal fusion. A comprehensive review of the literature from 1994-2012 was done. The key words utilized in researching this topic were anxiety, preoperative, education, orthopedic, spinal fusion, scoliosis, adults, Adult Learning Theory, and education materials. CINAHL, PUBMED, ProQuest, and Medline databases were searched. The articles reviewed were limited to publications in the English language only. The literature revealed numerous articles on patient education, and preoperative anxiety in adults, but very few in the areas of orthopedics, and parents of children undergoing orthopedic surgeries, such as a posterior spinal fusion.

The literature found will be presented for the following areas: 1) posterior spinal fusion 2) preoperative anxiety and fear of unknown, 3) effects of patient education, 4) summary statement, and 5) conceptual framework.

Posterior Spinal Fusion

A posterior spinal fusion is a surgical procedure utilized when there are structural abnormalities of the spine caused by scoliosis (Koya-Rawlinson, 2009). Structural deformities in the spine can be characterized into three types: congenital, neuromuscular, and idiopathic (Koya-Rawlinson, 2009). Many times a bracing or physical therapy is inadequate for correcting the deformity due to idiopathic scoliosis, and surgery is required (Koya-Rawlinson, 2009). A fusion of the spine involves making an incision, posteriorly, or

into the back and taking bone from the iliac crest to form a graft in order to correct the abnormal curvature (Koya-Rawlinson, 2009).

A study by Walters & Coad (2006) discusses the importance of preparing children and their families for posterior spinal fusions. This particular surgery can be very stressful on all parties involved and though health care professionals have excellent skills in educating and preparing children and their families for surgery, there are not many studies that explore this topic and the detailed preparation needed for this surgery (Walters & Coad, 2006).

Walters and Coad (2006), state it is nursing's fundamental goal is to reduce stress and anxiety for children when in the hospital and requiring surgery. In order to reduce this distress it is imperative that children and their families are provided information and understand their plan of care while in the hospital (Walters & Coad, 2006). The study goes on to show that unclear information, inappropriate delivery of health information, poor timing, and infrequent updates and teachings as to the child's plan of care foster stress and anxiety (Walters & Coad, 2006). Therefore, communication skills of nurses and the health care team are essential (Walter & Coad, 2006).

This exploratory study by Walters & Coad, (2006), demonstrates the need for proper and informative preoperative education for children and their families. Their findings suggest that techniques for preparing the patients may not be fully utilized and too general, which create more anxiety in the child and thus, their families (Walters & Coad, 2006). Lastly, Walters & Coad's (2006) study relay vital recommendations for future research and practice on this topic. More research is required on the patient and family's

perspective undergoing a spinal fusion, and on improving and developing education for the nurses and health care professionals delivering care.

Preoperative Anxiety and Fear of Unknown

Children depend on parents for support and guidance in coping with new or stressful situations, therefore, they play a critical role in pediatric surgery. However, the effectiveness of some parents in supporting their child may be compromised because they themselves become emotionally involved in the event, according to Scrimin et al., (2009). Anxiety is an important factor when providing education of any type to a patient or parent. In reviewing the literature, anxiety is defined as the fear of the unknown (Walker, 2002). Parents can be especially overwhelmed when surgery of their child is looming, and special consideration is required to address their emotional state. When anxiety is high, the tendency is to have a decreased working capacity to hold information, access it, and utilize it at a later time. Walker (2002) voices that it is imperative for nurses to understand the patient's fears in order to implement proper interventions regarding their care. In many cases, when dealing with the pediatric population, the parent-child unit should be considered 'the patient'.

The importance of reducing anxiety in parents via education is demonstrated in a randomized control trial, two group pre-test and repeated post-test performed by Li, Lopen, & Lee (2007). In this study, Li et al. (2007), utilized the State-anxiety assessment from Spielberger's State-Trait Anxiety Assessment Tool (1983) to measure the anxiety of parents with children undergoing surgery. Their objective was to emphasize the importance of parental involvement in the psycho-educational preparation of children and showing how therapeutic play can demonstrate a role in decreasing parental anxiety and

increasing satisfaction (Li et al., 2007). The authors of this study used simple complete randomization methods where 97 children with their parents were assigned to the experimental group and 106 children with their parents were designated as the control group (Li et al., 2007). The experimental group received the therapeutic play intervention, while the control group did not (Li et al., 2007).

The results showed statistically significant lower anxiety scores in both the child and their parent of the experimental group in the post-operative period ($p < .0001$). The Pearson correlation coefficient showed a positive correlation between the state anxiety of children and their parents preoperatively ($r = .67, n = 23, p = .01$) and in the post-operative period ($r = .45, n = 202, p = .01$), according to Li et al. (2007). The study illustrated that parents' state anxiety was high due to their child's high state anxiety and that this stress was conveyed to their child indirectly, hindering coping and healing in the postoperative recovery period (Li et al., 2007). When therapeutic play was introduced as means to deliver preoperative education, greater learning took place, resulting in less anxiety (Li et al., 2007).

Overall, there are few studies that focus on parental anxiety. However, if the anxiety of the parent can be decreased, often times the child's anxiety will be lowered (Zuwala & Barber, 2001). The studies in this literature review surveyed anxiety and knowledge of patients and their medical treatments, not of family members. The majority also examined the adult population with minimal studies dedicated to pediatrics.

Effects of Preoperative Education

Patient education is defined as any written and/or verbal instruction to patients regarding information on the status of their health in order to increase their

knowledge (Jones, 2007). Jones (2007) defines communication as an exchange of information. Communication must exist if patients are to receive safe and effective healthcare (Jones, 2007). The ability to communicate is a basic but essential skill any healthcare professional must possess when providing care. Education provides the bridge of communication between health care professionals, patient's, and their families. Winslow (2001) explains that if patients are to understand and benefit from the materials health care professionals provide, they must review and update the information so it is at an appropriate level of understanding for them (Winslow, 2001). If the patient or parent cannot read or speaks a different language, the nurse providing the education needs to make adjustments so that learning can take place. The best education is provided in different and multiple forms to reinforce the information given. According to Badarudeen, (2010), it is written information that reinforces the verbal education and teaching of patients (Badarudeen & Sabharwal, 2010). Once the appropriate education material is in place it is then important to consider the parent's emotional state.

The idea of surgery has been noted to increase patient anxiety and, therefore, reduce the individuals' ability to process information, to think, and comprehend. Fear of unknown creates the highest level of anxiety in patients before surgery (Walker, 2002). If patients are experiencing this anxiety, parents of these children must be operating at an even greater state of anxiety. Their functional capacity should be able to create an atmosphere of healing for their child during the recovery period. Information must be clearly stated, which provides the parents with instruction, direction, and inclusion into their child's plan of care without diminishing their emotional response.

Nurses must provide information to reduce fear, create an environment where parents can express their anxiety, and increase trust to develop their learning and knowledge base during this time of uncertainty. If the identified fears and anxieties are to be adequately addressed, and if the patient is to go to surgery in a positive and confident state of mind, the plan of care needs to be examined and discussed with the patient (Walker, 2002). The goal of preoperative education is to provide the plan of care and include the patient and family in the health care team, which enhances confidence in the health care providers and the parent's outlook on surgery. Again, the author for this study discusses the need for the plan of care to be discussed with the patient (Walker, 2002), but it is important to remember that when a child is involved, the plan of care should be include the parents.

Nurses have an ideal profession of caring for patients and promoting knowledge. The nurse must take every opportunity to educate. There are many different methods of education, but information needs to be presented in multiple forms so that parents of various intellectual, social, and cultural backgrounds can understand it (Murphy-Taylor, 1999). A primary example of this is seen in the effect of preoperative nutritional face-to-face counseling about children fasting for a tonsillectomy. Klemetti, Kinnunen, Suominen, Antila, Vahlberg, Grenman, & Leino-Kilpi (2010), demonstrates how face-to-face counseling combined with written information improves the knowledge of the parents regarding their child's fasting and preoperative nutrition, and alleviates confusion from unanswered questions and the anxiety its produces. The parent's knowledge of the child's fast increased ($p < 0.0003$) and anxiety decreased significantly ($p < 0.0001$) (Klemetti et al., 2010).

Another mode of education can be in the form of preparation programs. According to Justus et al. (2006), pre-surgical preparation programs allow children and parents to gain knowledge and reduce their anxiety by experiencing the hospital in a non-threatening way. The aim of this study was to create a program for children and their families that reduced the stress of having surgery and being hospitalized. This study evaluated children of different ages, their parents, how they perceived the surgery they were undergoing, and their hospital experience with the pre-surgical preparation from the Mount Sinai program. Preparation for surgical interventions are difficult because physicians, nurses and other health care team members fail to recognize the importance of providing education appropriate for the family's cognitive and emotional level (Justus et al., 2006). For parents this experience of having their child undergo surgery can be traumatic because they are dealing with their child's fear and anxiety along with their own fear and anxiety. Allowing parents to be part of the process of their child's surgical preparation enables them to take control of this new experience and cope better with the stress (Justus et al., 2006).

There is limited research on pediatric posterior spinal fusions and preoperative education for parents. Most research found discussed education for adult patients undergoing fusions and other invasive medical procedures. The Mount Sinai study by Justus et al. (2006) was the only study providing a perspective on a fully implemented program that incorporated parents into the educational process alongside their children (Justus et al., 2006).

Overall, the review of the literature highlights the lack of preoperative education for patients in the pediatric orthopedic population. Empowerment is the bridge between

education and the ability for the patient and parents to participate in their care (Johansson, et al., 2005).

Summary Statement

In summary, the research is limited in regards to preoperative education for parents of children undergoing surgery and specifically, posterior spinal fusions. The research found demonstrates that it is important to have the proper educational materials, and to address the emotional and psychological aspect of a parent whose child is having surgery. It is important for the parents to increase their knowledge of their child's upcoming surgery, which will result in decreased anxiety.

Conceptual Framework

The conceptual framework for this project takes shape from Knowles' Adult Learning Theory (1973). Malcolm Knowles was a professor of education in adult education at Boston University School of Education. Research on how adults learn has been derived from theories about how children learn, which were based on testing done to observe how animals learn (Knowles, 1973). Through various models of learning it has been shown that adults learn differently than children (Knowles, 1973). Knowles' adult learning theory is an excellent theory to help in the development of educational programs for adults (Knowles, 1973), much like providing appropriate preoperative education programs for parents with children undergoing a posterior spinal fusion.

Knowles pushed the standard pedagogy of how children learn aside and developed a new andragogical theory based on how adults learn by incorporating their life experiences (Knowles, 1973). He proposed four assumptions; adult learners have a different self concept from children in which they operate from, their experience plays a role in how they

learn, readiness to learn is a factor, and lastly, their orientation to learning (Knowles, 1973). It is because adults learn differently than children that preoperative education must be appropriate for the adult learner in order to reduce anxiety and increase knowledge. Knowles (1973) acknowledged that educational methods for adult learning must deviate from the traditional methods of teaching and educating children and youth.

Chapter Three

Proposed Method Section

The Design

A pre- and post- anxiety and knowledge assessment design will be used to assess the anxiety and knowledge level of parents, legal guardian, or caregivers with children undergoing a posterior spinal fusion. This is a quasi-experimental design. The instruments that will be used in this study are the State-Trait Anxiety Inventory Tool developed by Charles D. Spielberger (1983) (Appendix A), and a knowledge assessment (Appendix B). The knowledge assessment was developed by the Principal Investigator (PI) to survey the parents', legal guardians, or caregivers' knowledge of their child's spinal fusion surgery, the preoperative plan, and their postoperative period. The knowledge assessment was reviewed by the orthopedic nurse educator, and spinal fusion nurse to establish inter-rater reliability. A demographic data form (Appendix C) will be used to collect demographics. IRB approval will be obtained from the Children's Hospital's Research Committee.

Measurement

The State-Trait Anxiety Inventory Tool (STAI) is used to measure a person's anxiety state and anxiety trait (Spielberger, 1983). Extensive research has been conducted using the STAI in the areas of medicine, dentistry, education, psychology, and other social sciences (Spielberger, 1983, p 8,48). The State or S-Anxiety Scale evaluates how participants feel at that very moment by having them rate twenty different 'I feel' statements (Spielberger, 1983). The S-Anxiety scale examines feelings of apprehension, tension, nervousness and worry, and can also be used to examine a recent past experience and how they felt at that particular moment (Spielberger, 1983). It is recommended that the S-Anxiety be administered before the T-Anxiety assessment to prevent their trait scores from influencing their state scores, according to Spielberger (1983). This scale can also assess the level of anxiety in individuals induced by unavoidable life stressors, dental treatments, job interviews, school exams, and surgery (Spielberger, 1983).

The Trait or T-Anxiety Scale evaluates how the participant feels by assessing twenty different 'I feel' statements (Spielberger, 1983). It is often used as a screening tool in high

school and college students, military recruits, and in assessing various types of medical, surgical, and psychiatric patients for clinical anxiety (Spielberger, 1983). The stronger the anxiety trait in an individual means the more likely that person will experience an increase in the state anxiety in an intense, stressful situation (Spielberger, 1983).

The STAI should be referred to as the Self-Evaluation Questionnaire rather than a tool that measures anxiety, and it can be administered either in a group setting or individually (Spielberger, 1983). The participants will self-report how they feel by answering one of the items on the scales provided for State and Trait Anxiety.

The STAI is shown to be a reliable and valid tool for anxiety. Internal consistency and reliability for the STAI was measured by the alpha coefficient (Spielberger, 1983). The median co-efficient for both the state and trait inventory tools were 0.93 (Spielberger, 1983). The validity criteria for the STAI meet each stage of the test development process performed by Spielberger and Gorsuch (1966). Permission has been granted to use the STAI for this research study (see Appendix D for permission letter).

Study Procedures. This study will utilize a purposive convenience sample of parents at one institution whose child is scheduled to undergo a spinal fusion procedure. Preoperatively, a list will be provided to the Principal Investigator (PI) of scheduled spinal fusion surgeries from nurses employed by the orthopedic surgeon with the demographic information including: patient's name, date of birth, date of surgery, procedure, and physician who performed the surgery. From this list of scheduled surgeries, the parent(s), legal guardian, or caregivers that meet the inclusion criteria, will be provided the Introductory letter to elicit voluntary participation for the study including the anxiety and knowledge assessments, and the demographic data form from the orthopedic nurses, the PI, or the co-investigator.

Each parent will write the last 4 digits of their cell phone on top of each of the forms in the study packet. The parent will be instructed to put the post-assessment forms back in the envelope, seal it, and place their name on the outside of the envelope. A designated co-investigator will collect the packets and place them in a designated, secure area. The PI will pick up the packets and pre-assessments once a week and then place them in a secure, locked area on the surgical unit. A designated co-investigator will then administer the anxiety and knowledge assessments and the demographic data form. Once the parent has

completed the assessments and demographic form the designated co-investigator or PI will collect and place into a locked file cabinet located in a locked office.

The PI or designated co-investigator will make a phone call to the unit and obtain patient information including patient name, surgery, doctor, date of birth, and if parent present. If the parent, legal guardian, or caregiver did not consent prior to surgery or was not present at preoperative education session they will still be given the opportunity to participate in the study. The PI or designated co-investigator will approach the parent, legal guardian, or caregiver and provide the Consent Letter and elicit voluntary participation in the study. The Introductory letter will be attached to the post-assessment. The post-assessments will then be distributed to the participant and a designated co-investigator will collect the packets and place in a secure, designated area. The PI will pick up the packets, including the pre-assessments and post-assessment once a week, and then place in a locked office on the surgical unit. The PI will also be responsible for tracking the number of administrations of the STAI Inventory Tool completed by the participants.

Data Management

All data sources will be de-identified. No personal identifiable information will be utilized in this data collection. The parents, legal guardians, caregivers information will be coded by the last 4 digits of their cell phone number, thus, maintaining anonymity. No Protected Health Information (PHI) will be collected from the patients, except during the recruitment and screening process. All data will be coded and kept in a locked file cabinet in a locked office and only available to the Principal Investigator and Co-Investigators. The pre- and post- anxiety and knowledge assessments will be returned in a sealed envelope to a designated area in the Orthopedic Clinic and on 3 East Surgical, and only the Principal Investigator and Co-investigators will have access to this area to collect data once a week. Computer data will be password protected and study findings will only be reported in aggregate. The Principal Investigator and co-investigators will have access to the patient's PHI in order to identify the appropriate subject for the study, the parent, legal guardian, or caregiver. This information will not be used in the study.

Data Analysis

Descriptive statistics will be utilized to calculate the frequencies, percentages, means, medians, and standard deviations. Cohen's Kappa statistics and percentage observer agreement will be calculated to assess inter-rater reliability of the items on the knowledge test. Independent t-test will be performed to compare the knowledge mean scores between the pre- and post-test data. Analyses will be conducted using SPSS version 18.0. For the purpose of this study, the significance level will be set at 0.05.

Subjects and Recruitment

A purposive sample of parents with children diagnosed with idiopathic scoliosis and who are scheduled to have a posterior spinal fusion during the time of this study will be selected. The study will be conducted between March 2014 through September 2014. The parent, legal guardian, or caregiver who meet the study's inclusion criteria will be approached by the Principal Investigator or by the research assistant(s) to discuss the study and elicit voluntary participation. The Principal or co-investigators will provide them with the Introductory/Consent Letter (Appendix E). They will be assured that they can withdrawal from the study at any time and it will not affect the care they or their child receives during their hospitalization.

The inclusion and exclusion criteria are as follows. Inclusion criteria: include parents, legal guardians, or caregivers of children diagnosed with idiopathic scoliosis and scheduled for a posterior spinal fusion at Rady Children's Hospital. The exclusion criteria includes (a) any non-English speaking/reading parents, legal guardians, or caregivers since the anxiety tools and knowledge test will be in English only and because a clear understanding of the preoperative education given will be required in order to take both the anxiety and knowledge assessments, and (b) all other parents, legal guardians, or caregivers of children that do not have a diagnosis of idiopathic scoliosis and did not have a scheduled posterior spinal fusion, including patients diagnosed with scoliosis that have undergone recent trauma and resulting in the need for emergent spinal surgery.

In order to obtain permission from parents, legal guardians, or caregivers a waiver of documented informed consent is being sought from the participants, as it is important to

protect anonymity. This would ensure the responses to the research material are valid and truthful.

The Consent Letter, including the informed consent statement, will be given to each participant at the preoperative education session and prior to the start of the education. The anonymity of the parents, legal guardians, or caregivers will be protected by using the last 4 digits of their cell phone in order to link the pre- and post-anxiety and knowledge assessment data. Each participant will be asked to: (a) read the terms of the consent for participation in the Consent Letter, (b) note that completion of the research forms implies that consent has been given, (c) complete the demographic data form, the State-Trait Anxiety Inventory, and the Knowledge Assessment, and (d) place the forms back in the envelope and return the envelope to the designated area. Anticipated data completion time will be approximately 10-15 minutes. By placing the last 4 digits of their cell phone number on the envelope, participants will be assured that their individual responses will be kept confidential and that no personal, identifying information has been collected or reported.

An alternative to the study participation is any participant may opt out of the study at any time. If a participant chooses not to participate in the study, they and their child will still be provided with the same quality care as provided to all other families and patients undergoing spinal fusion surgery.

“Risks of harm anticipated in the proposed research are not greater than those ordinary encountered in daily life or during the performance of routine physical or psychological examination” (45 CFR 46.102). There are no risks to the 3 East Surgical Staff or Orthopedic Clinic staff. For participants, there are minimal physical and psychological risks to participating in the study. Filling out the anxiety and knowledge pre- and post-assessments may cause emotional discomfort by answering questions on anxiety while their child is recovering from surgery, but they will be ensured that they may withdrawal from the study at any time. The parents, legal guardians, or caregivers who elect not to participate and their children will be treated no differently than those that do participate in the study.

The procedures for risk management and confidentiality are as follows. All data will be kept confidential and stored in a secure file, with only the Principal Investigator and Co-

Investigators having access to these documents. No participant identifiers will be used, and there is no risk of PHI being reported. All data will be collected and stored in an anonymous format in order to protect participant's identity and prevent any risks to participating in this study. All documents and data obtained will be in a locked file cabinet in a secure office on 3 East Surgical or in the Orthopedic Clinic. The last four digits of the participants' cell phone will be used to keep the data anonymous and allow for the pre-and post-assessment data to be linked. These measures are not considered sensitive and pose no risk to confidentiality. No patient identifiers will be used, and any public dissemination of the project results will maintain anonymity and describe only the hospital data site as Children's Hospital in Southern California.

The potential benefits for the participants are that it could reduce their anxiety, increase their knowledge, and improve patient education for other parents, legal guardians, or caregivers of children undergoing posterior spinal fusions. For patients, the benefit might be parents are more educated and less anxiety about the surgical process and therefore better able to care for the patient. The risk/benefit ratio is that the benefits of the study outweigh any risks. Improvements in preoperative education for parents are significant potential benefits by analyzing their anxiety and knowledge level both pre- and postoperatively. All the data will remain anonymous and there will be no use for patient identifiers. Participants will be reminded that participation in the study remains entirely voluntary. There will be no expense to the subjects and no compensation will be offered.

Chapter 4

Proposed Evaluation of Data

The proposed evaluation of data for this project includes analyzing the information obtained from both the pre- and post- STAI Assessments, the pre- and post-knowledge assessment, and the demographic data. Data will be entered using SPSS version 18, utilizing Cohen's Kappa and t-test statistical analysis with a significance level set at 0.05. The demographic data will be analyzed using descriptive statistics. Additionally, validity and reliability of the STAI will be analyzed for this sample. Following the data analysis, all documents will be destroyed.

Measures of internal consistency using the alpha coefficient for the State and Trait anxiety scales will be computed by Formula KR-20, as modified by Cronbach (1951). Participants with a high Trait anxiety score generally have a higher State anxiety score, even in non-stressful, everyday situations, according to Spielberger (1983). Scoring of the State anxiety assessment is as follows: each item is given a weighted score of 1 to 4 with 1=not at all, 2=somewhat, 3=moderately so, 4=very much so. Scoring of the Trait anxiety assessment is as follows: 1=almost never, 2=sometimes, 3=often, 4=almost always. A rating of 4 indicates a high level of anxiety (Spielberger, 1983). The weighted scores for both the scales are added together, measuring anywhere between a minimum of 20 and a maximum of 80, according to Spielberger (1983).

The purpose of this project is to investigate the effects of preoperative education on parents' anxiety and knowledge with children undergoing a posterior spinal fusion. The results of this study will be utilized to modify and improve current preoperative education

for this group of patients and their families going through elective spinal surgery; with the goal of alleviating parental anxiety and increasing their knowledge.

Chapter 5

Discussion and Conclusions

As previously defined, anxiety is fear of the unknown (Walker, 2002). Recognizing, understanding, and putting interventions into place to combat or at least minimize anxiety can have a profound effect on parents and their children. Knowledge is an essential tool to reduce that fear of the unknown, which can then reduce anxiety and produce better parent and patient outcomes.

The lack of formal research on this topic illustrates the crucial need for further study on parental anxiety when their children are faced with surgery, particularly a posterior spinal fusion. The literature found did promote the value of implementing preoperative education, educational materials, and/or programs for both parents and children undergoing invasive surgical procedures. When preoperative education was initiated prior to surgery, patients and their parents had better outcomes, including decreased use of pain medication, decreased length of stay, and overall, decreased anxiety. Closing the gap in the literature on this topic is necessary to ensure quality care and promote better outcomes for hospitals, parents, and the patients they care for.

Knowles' adult learning theory is an excellent theory to help in the development of educational programs for adults (Knowles, 1973) because it examines how adults learn versus children, and factors how various life experiences of the adult assist in their learning process. Knowles (1973) acknowledges that adults must be treated differently when it comes to learning than from the traditional methods of teaching and educating children and youth. It is because adults learn differently than children that preoperative education must be appropriate for the adult learner in order to reduce anxiety and increase

knowledge. Therefore, by incorporating adult learning theory principles as part of the educational process, learning by the parent will be enhanced.

Limitations

There are several limitations in conducting this research study. Actual and potential limitations of this project are the inability to carry out the experiment, small sample size, and skewing of data.

The main limitation in this proposed project is the inability to carry out the study. Required participation and time constraints of the orthopedic surgeon performing the spinal fusion surgeries and the staff who provided the preoperative education for this surgery prevented the approval and commencement of this study. After several attempts to make revisions and suggested changes in the proposed methods, the author was still unable to gain the needed support of the staff and the study became a proposed project.

If the study had been conducted, a potential limitation would be obtaining an adequate sample size. Although spinal fusion surgeries are performed throughout the year, there is a season in which healthcare staff see larger numbers of this patient population; March through September tend to be the busiest times these scheduled surgeries occur due to children being out of school for spring and summer vacations. The goal would be to conduct this study during this stated time of year as to obtain as many participants as possible, however, there is the possibility that even during this time, a limited number of participants meeting eligibility criteria are available. And, if participants decline participation in the study that limits the sample size even more.

Lastly, scores from the post-anxiety assessment taken by the parents may be skewed based on what post-op day their child was when they took the assessment. For

example, a parent taking the assessment immediately or one day after the child's surgery may possess a higher level of anxiety than a parent answering the questions the day before the child is discharged. It would be important to maintain consistency by having the parents take the anxiety assessments on days 2-4 as to avoid skewed data.

Areas for Further Research

The gap in research regarding this topic is large. It is imperative more research be conducted on the effects of preoperative education on parental anxiety and knowledge with children undergoing a posterior spinal fusion. This research lends itself to multiple topics in which more research and studies must be done. They include preoperative education for parents, anxiety and knowledge in both children and parents, and the effects on parents who have children undergoing a posterior spinal fusion. There is also need to develop a standardized knowledge assessment tool for both the pediatric and adult populations to assess and provide appropriate education for that individual.

The ability to conduct this research may also benefit other children's hospitals by examining their preparation methods, and refining them in order to produce better patient outcomes.

Lastly, other modalities of reducing stress should be researched and incorporated in addition to preoperative education and materials provided to parents and their children. Many hospitals and healthcare team members utilize methods of relaxation including deep breathing and guided imagery, healing touch, pet therapy, and art therapy are also helpful. These are all valuable resources that can enhance the education and the hospital experience of both the patient and parent.

Education should also be developed to focus on the parent specific learning style. After proper assessment of learning style, designing educational materials and informational meetings to illustrate visual, hearing, or kinesthetic styles can enhance overall learning of the information presented. The way information is processed by an individual can play a huge part in their understanding and retaining of that information at a later time.

Conclusions

Nurses have a variety of duties and responsibilities they perform daily, and one of their main roles is as an educator. The American Nurses Association (ANA) recognizes that nurses, as educators, hold the key to the healthcare of this nation (nursingworld.org, 2013), and healthcare begins with knowledge. This project has profound significance. Providing knowledge as the key to reduce anxiety and produce better outcomes for patients and their families should be part of any plan of care. The ability to examine the education provided by nurses and healthcare professionals is invaluable so that quality, safe patient care is not compromised. Preoperative education is the knowledge that reduces anxiety experienced by our patients and their families. Success of that education is found in the researching, testing, and refining of that education for overall better outcomes.

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Appendix A

State-Trait Anxiety Inventory Tool

Below are 5 sample questions from the State and Trait Anxiety Self-Evaluation Questionnaire participants in the study would be filling out.

STAI form Y-2

Directions: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number on the right to indicate how you *generally* feel.

1. I feel pleasant..... 1 (almost never) 2 (sometimes) 3 (often) 4 (almost always)
2. I feel nervous and restless.... 1 (almost never) 2 (sometimes) 3 (often) 4 (almost always)
3. I am a steady person..... 1 (almost never) 2 (sometimes) 3 (often) 4 (almost always)

STAI form Y-1

Directions: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number on the right of to indicate how you feel *right now*, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

1. I feel calm..... 1 (not at all) 2 (somewhat) 3 (moderately so) 4 (very much so)
2. I am tense..... 1 (not at all) 2 (somewhat) 3 (moderately so) 4 (very much so)

Appendix B
Knowledge Assessment

Last 4 digits of cell:

The Effects of Preoperative Education on Parental Anxiety and Knowledge with Children
Undergoing a Posterior Spinal Fusion

Directions: Please answer the following questions by circling one answer. You may only select one answer for each question.

1. Your child has scoliosis and has to have a posterior spinal fusion. A posterior spinal fusion is:

- a. Repair of a broken leg
- b. Removal of bone from the spine
- c. Insertion of metal rods to keep the spine straight**

2. In the post-operative period (after surgery), your child's pain will be controlled by

- a. Medications taken by mouth (pills)
- b. Intravenous (IV) medications
- c. Both a & b**

3. After surgery, your child will be positioned either on their right side, left side, or their back every 2 hours. The nurse will turn your child side to side to:

- a. Promote comfort**
- b. Prevent healing
- c. Both a & b

4. Your child will come back from surgery with a nasogastric (NG) tube. This tube is inserted through their nose and goes down the back of their throat, into their stomach to:

- a. Prevent nausea and vomiting**
- b. Stop back and muscle pain
- c. None of the above

5. Increasing your child's activity after surgery is very important. The nurse will have your child start to increase their activity level by sitting at the bedside and walking a few steps on what day after surgery?

- a. Immediately after surgery
- b. Day 2 or 3 after surgery**
- c. Right before they are discharged home

6. Before your child can be discharged from the hospital and go home, they must be able to

- a. Drink, eats, walks, and takes pain medication by mouth to control their pain**
- b. Drink, sits up in bed, use a wheelchair, and need IV pain medication
- c. Drink, eats, has no pain, and has a bowel movement (stool)

Last 4 digits of cell: _____

Appendix C

Demographic Form

Directions: These questions concern the backgrounds of those who are participating in the Anxiety and Knowledge pre- and post-assessment for the effects of preoperative education on Parental Anxiety and Knowledge with Children Undergoing a Posterior Spinal Fusion. Your responses will be kept confidential. Please circle the appropriate letter or fill in the blank. **Do not put your name on this form.**

1. What is your gender?

- a. Male
- b. Female

2. What is your age? _____

3. What best describes your ethnic group?

- a. Hispanic
- b. Black (non-Hispanic)
- c. White (non-Hispanic)
- d. Asian/Pacific Islander
- e. Other

4. What is your highest degree earned?

- a. High School Diploma or equivalent
- b. Some College
- c. Bachelor's Degree
- d. Graduate Degree or Higher

5. Did you attend the preoperative education session with the spinal fusion nurse prior to your child's surgery?

- a. Yes
- b. No

6. What is your relationship to the patient?

- a. Mother
- b. Father
- c. Legal guardian
- d. Caregiver

Appendix D
Permission Letter for Use of STAI Inventory Tool

License for Heather Garcia to reproduce/administer
Up to a quantity of 50 within one year of February 11, 2013.



www.mindgarden.com

To whom it may concern,

This letter is to grant permission for the above named person to use the following copyright material for his/her thesis or dissertation research.

Instrument: ***State-Trait Anxiety Inventory for Adults***

Authors: ***Charles D. Spielberger, in collaboration with R.L. Gorsuch, G.A. Jacobs, R. Lushene, and P.R. Vagg***

Copyright: ***1968, 1977 by Charles D. Spielberger***

Five sample items from this instrument may be reproduced for inclusion in a proposal, thesis, or dissertation.

The entire instrument may not be included or reproduced at any time in any other published material.

Sincerely,

Robert Most
Mind Garden, Inc.
www.mindgarden.com

Appendix E

Introductory Letter to Potential Research Participants

Dear Research Participants,
Heather Garcia, RN (Principal Investigator), Jennifer Turney MSN, CNS, Barbara Taylor, PhD, RN, and Chris Sloan CNS, PhD(c), RN are conducting a research study to examine the effects of preoperative education on parental anxiety and knowledge with children undergoing a posterior spinal fusion on the 3 East Surgical Unit at Rady Children's Hospital. You have been asked to participate in this project because you are currently a parent, legal guardian, or caregiver with a child that will have a posterior spinal fusion.

Completing these assessments will take approximately 10-15 minutes. A study packet will be distributed to you at the end of your preoperative education session with the spinal fusion nurse and again at some point during your child's postoperative period in the hospital (anytime on postop days 2-6).

Your participation in this study is entirely voluntary, and if you do not wish to participate, you do not need to do anything further. If you choose to take part, your completion of the assessments in the packet will indicate that you have read this consent letter, have had a chance to ask any questions about the study, and that you consent to participate. You can change your mind and stop your participation at any time. Your choice to participate or not to participate will not affect the care you or your child receives here at Rady Children's Hospital or your relationship with us.

Your individual responses to the research assessments will be held in strict confidence. Your responses will not be shared with anyone at Rady Children's Hospital and will be accessible only to the researchers. There will be no individual patient identifiers attached to the survey. Your individual responses will be combined with all other participants in the study and reported only in the combined form.

There are minimal risks associated with your participation in this study. There may be emotional discomfort caused by answering questions about anxiety and the knowledge of your child's surgical procedure. You can choose to withdraw from the study at any time. To maintain confidentiality, your survey responses will be kept in a secure and locked file cabinet. There may be no direct benefit to you from your participation in this study, however it is hoped that the information collected during this study may be used to further improve the preoperative education at this facility and help parents reduce their anxiety and increase the knowledge of their child's surgical procedure.

If you have any questions at any time, please contact Heather Garcia at (858) 966-8074. If you have any questions about your rights as a participant you may contact the office for Human Subjects Protection Program at Rady Children's Hospital at (858) 966-4008.

Thank you for your time and consideration of this study,
Heather Garcia, RN

Appendix F
Point Loma IRB Proposal

Point Loma Nazarene University
Institutional Review Board (IRB)
Section B:
Expedited Review, Category 7

Project Title:

The Effects of Preoperative Education on Parental Anxiety and Knowledge with Children Undergoing a Posterior Spinal Fusion.

Principal Investigator:

Heather Garcia, RN, 3 East Surgical Unit

Facilities:

3 East Surgical Unit at Rady Children's Hospital
RCHSD Orthopedic Clinic

Estimated Duration of Study:

March 2014 – September 2014

A. Background and Significance:

Surgery is a necessary treatment for correction of spinal deformities in pediatric populations and preoperative education is essential for not only the child, but the parents as well. When parents exhibits higher levels of stress due to the child's approaching surgery, it is more challenging for them to deliver care throughout their hospital stay. Education provides knowledge, which helps to reduce anxiety levels, resulting in a better postoperative experience for both parent and child. The goal of physicians and nurses in providing healthcare for the patients is to consider the ways in which care and education are given. There are many ways to deliver them, but what will be the most effective at increasing knowledge and decreasing anxiety. Preoperative education is one way to accomplish this.

According to Scrimin et al. (2009), children depend on parents for support and guidance in coping with stressful situations and that is why parents play a critical role when they undergo surgery. When parents are stressed and exhibiting high levels of anxiety the effectiveness of supporting their child may decline because they have become emotionally involved in the event (Scrimin, Haynes, Altoe, Bornstein, & Axia, 2009). Parents that are anxious begin to lose their ability to process information, and the ability to care for their child. This has a huge impact on the parents' capacity to care for the child postoperatively. It is important that preoperative education be clear and concise in order to inform the parent and reduce this fear and anxiety of the unknown. The parents can then better support their child.

According to Justus et al. (2006), pre-surgical preparation programs allow children and parents to gain knowledge and reduce their anxiety by experiencing the hospital in a non-threatening way. The aim of this study was to create a program for children and their families that reduced the stress of having surgery and being hospitalized. For parents this experience of having their child undergo surgery can be traumatic because they are dealing with their child's fear and anxiety along with their own fear of the unknown. Allowing parents to be part of the process of their child's surgical preparation enables them to take control of this new experience and cope better with their stress (Justus et al., 2006).

Zuwala & Barber (2001), also bring to light that there are few studies focusing on decreasing parental anxiety in order to reduce the anxiety of the child and that it is important to recognize that the parent's anxiety affects the child's level of anxiety. The purpose of this study is to examine the effect of preoperative education on parents' anxiety and knowledge level with children undergoing a posterior spinal fusion both preoperatively and postoperatively. The hypothesis is that the preoperative education received will decrease the parents' anxiety and increase their knowledge level, which will improve patient outcomes.

For the design, a pre- and post- anxiety and knowledge assessment design will be used to assess the anxiety and knowledge level of parents, legal guardian, and caregivers with children undergoing a posterior spinal fusion.

This is a Quasi-experimental.

The methods used will involve: Preoperatively, a list will be provided to the Principal Investigator (PI) of scheduled spinal fusion surgeries from the doctor's nurses, Jennifer or Amy, that includes patient name, date of birth, date of surgery, procedure, and physician.

From this list of scheduled surgeries, the parents, legal guardian, or caregivers that meet the inclusion criteria, Jennifer, Amy, the Principal Investigator, or co-investigator will provide the Introductory letter to elicit their voluntary participation for the study including the anxiety and knowledge assessments and the demographic data form.

Each parent will write the last 4 digits of their cell phone on top of each of the forms in the study packet. The parent will be instructed to put the post-assessment forms back in the envelop, seal it, and place their name on the outside of the envelope. A designated co-investigator will collect the packets and place in a secure, designated area. The PI will pick up the packets, pre-assessments, once a week and then place in a locked secure area on the surgical unit.

Designated co-investigators will administer the anxiety and knowledge assessments and demographic data form. Once the parent has completed the assessments and demographic form the designated co-investigator or PI will collect and place into a file located in a secure, locked area.

The PI or designated co-investigator will make a phone call to the unit and obtain patient information including patient name, surgery, doctor, date of birth, and if parent present. If the parent, legal guardian, or caregiver did not consent prior to surgery or was not present at preoperative education session they will still be given the opportunity to participate in the study. The PI or designated co-investigator will approach the parent, legal guardian, or caregiver and provide the Consent Letter and elicit voluntary participation in the study.

The Introductory letter will be attached to the post-assessment. The post-assessments will then be distributed to the participant and a designated co-investigator will collect the packets and place in a secure, designated area. The PI will pick up the packets, pre-assessments, once a week and then place in a locked secure area on the surgical unit.

Data Management –

All data sources will be anonymous. No personal identifiable information will be utilized in this data collection. The parents will be coded by the last 4 digits of their cell phone number, thus, maintaining anonymity. No Protected Health Information (PHI) will be collected from the patients. All data will be coded and kept in a locked file cabinet in a locked office and only available to the Principal Investigator and Co-Investigators. The pre- and post- anxiety and knowledge assessments will be returned in a sealed envelope to a designated area on the Orthopedic Clinic and on 3 East Surgical, and only the Principal Investigator and Co-investigators will have access to this area to collect data once a week. Computer data will be password protected and any individual data will be described as an aggregate in reporting the study findings.

The Principal and Co-Investigators will access to the patient's PHI in order to identify the appropriate subject for the study, the parent, legal guardian, or caregiver. The information will not be used in the study.

Data Analysis –

Descriptive statistics will be utilized to calculate the frequencies, percentages, means, medians, and standard deviations. Cohen's Kappa statistics and percentage observer agreement will be calculated to assess inter-rater reliability of the items on the knowledge test. Independent t-test will be performed to compare the knowledge mean scores between the pre- and post-test data. Analyses will be conducted using SPSS version 18.0. For the purpose of this study, the significance level will be set at 0.05.

B. Subjects/Recruitment:

A purposive sample of parents with children diagnosed with idiopathic scoliosis and who are schedule to have a posterior spinal fusion during the time of this study will be selected. The number of subjects will be collected from March 2014 through September 2014. The parent, legal guardian, or caregiver who meet the study's inclusion criteria will be approached by the Principal Investigator or by the research assistant(s) to discuss the study and elicit voluntary participation. The Principal or Co-investigators will provide them with the Consent Letter (Appendix D). They will be assured that they can withdrawal from the study at any time and it will not affect the care they are their child receives during their hospitalization.

Inclusion Criteria – The eligibility criteria include parents/legal guardians/caregivers of children diagnosed with idiopathic scoliosis and undergoing a posterior spinal fusion at Rady Children’s Hospital.

Exclusion Criteria – (a) any non-English speaking parents/legal guardians/caregivers since the anxiety tools and knowledge test will be in English only and because a clear understanding of the preoperative education given will be required in order to take both the anxiety and knowledge assessments, (b) all other parents/legal guardians/caregivers of children that do not have a diagnosis of idiopathic scoliosis and did not undergo a posterior spinal fusion.

C/D. Permission from Parents and Consent or Assent from Subjects:

A waiver of documented informed consent is being sought for parents, legal guardians, or caregiver participants, as it is important to protect anonymity, as this would ensure the responses to the research material are valid and truthful.

The Consent Letter (Appendix D), including the informed consent statement, will be given to each participant at the preoperative education session and prior to the start of the education. The anonymity of the parents, legal guardians, and caregivers will be protected by using the last 4 digits of their cell phone in order to link the pre- and post-anxiety and knowledge assessment data. Each participant will be asked to: (a) read the terms of the consent for participation in the Consent Letter, (b) note that completion of the research forms implies that consent has been given, (c) complete the demographic data form, the State-Trait Anxiety Inventory, and the Knowledge Test, and (d) place the forms back in the envelope and return the envelope to the designated area. Anticipated data completion time will be approximately 10-15 minutes. Parents, legal guardians, and caregivers will be assured that their individual responses will be kept confidential and that no personal, identifying information will be obtained or reported.

E. Equipment used:

The equipment used will include paper and pen/pencil surveys.

F. Instruments used:

State-Trait Anxiety Inventory Tool. (Appendix A).

Knowledge Test: developed by the Principal Investigator to survey the parents', legal guardians, or caregivers' knowledge of their child's spinal fusion surgery, the preoperative plan, and their postoperative period. The test was reviewed by two orthopedic nurse educators, and the spinal fusion nurse expert to establish inter-rater reliability (Appendix B).

Demographic data form (Appendix C).

G. Duration of subject participation:

It will take approximately 10-15 minutes for parents to complete anxiety and knowledge assessments.

H. Expense to subjects:

None and no compensation is offered.

I. Potential Risks:

"Risks of harm anticipated in the proposed research are not greater than those ordinary encountered in daily life or during the performance of routine physical or psychological examination" (45 CFR 46.102).

There are no risks to the 3 East Surgical Staff or Orthopedic Clinic staff. For the parents, legal guardians, or caregivers, there are minimal physical and psychological risks to participating in the study. Filling out the anxiety and knowledge pre- and post-test that may cause emotional discomfort by answering questions on anxiety while their child is recovering from surgery, but they will be ensured that they may withdrawal from the study at any time. The parents, legal guardians, or caregivers who elect not to participate and their children will be treated no differently than those that do participate in the study. All data will be kept confidential and stored in a secure file, with only the Principal Investigator and Co-Investigators having access to these documents. No patient or parent,

legal guardian, or caregiver identifiers will be used, and there is no risk of PHI being obtained.

Risk Management and Confidentiality Procedures:

All data will be in an anonymous format in order to protect participant's identity and prevent any risks to participating in this study. All documents and data obtained will be in a locked file cabinet in a secure office.

The participant's date of birth will be used to keep the data anonymous and allow for the pre-and post-test data to be linked. These measures are not considered sensitive and pose no risk to confidentiality. No patient identifiers will be used.

Any public dissemination of the project results will maintain anonymity and describe the hospital data site as Children's Hospital in Southern California.

Potential Benefits:

The benefit for the participants is that it could reduce their anxiety, increase their knowledge, and improve patient education for other parents, legal guardians, or caregivers of children undergoing posterior spinal fusions. For patients, the benefit could improve patient outcomes.

Risk/Benefit Ratio:

From a societal continuum, the benefits of the study outweigh any risks. Improvements in preoperative education for parents are significant potential benefits by analyzing their anxiety and knowledge level both pre- and postoperatively. All the data will remain anonymous and there will be no use for patient identifiers and participation in the study remains entirely voluntary.

HIPAA:

Protected health information of the patient or the parents, legal guardians, or caregivers of the patient will not be obtained or used in this study. The parents' demographic data form will be collected, including gender, age, and ethnicity. No patient identifiers will be used in

data collection or analysis. HIPAA consent will be obtained by all parent participants (Appendix E).

I. Informed Consent

See Consent Letter, Appendix D.

K. Debriefing:

At the completion of data collection the subjects will be thanked for their participation, and encouraged to ask questions or bring up any concerns about the study. They will be listened to, offered reassurance, and referred to someone with professional training if they need assistance. The Principal Investigator's contact information will be given when informed consent is obtained, along with my advisor, and IRB contact at the pre- and post-test administration.

L. Copyrighted inventories and approval letter:

Appendix A, State-Trait Anxiety Inventory Form.

Appendix B, Knowledge Assessment.

Appendix C, Demographic Data Form.

Appendix D, Permission Letter for Use of STAI Inventory Tool.

Appendix E, Introductory Letter to Potential Research Participants.

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Murphy-Taylor, C. (1999). The benefits of preparing children and parents for day surgery. [Review]. *British Journal of Nursing*, 8(12), 801-804.

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Zuwala, R., & Barber, K. R. (2001). Reducing anxiety in parents before and during pediatric anesthesia induction. [Clinical Trial Randomized Controlled Trial]. *AANA journal*, 69(1), 21-25.

Impact on Staff:

This study will not have any impact on the staff other than the above specified co-investigators that currently work on the 3 East Surgical Unit and in the Orthopedic Clinic. The co-investigators will receive a 10-minute in-service on the project, how to obtain informed consent, distribute the assessments, and how to properly collect the data. The study plan has been discussed with the leadership team on the 3 East Surgical unit and the Orthopedic Clinic including the director, manager, supervisor on 3 East, and both Orthopedic surgeons performing the posterior spinal fusions, their nurses, and has been approved.

Appendix G

Rady Children's Hospital IRB Proposal

Project Title:

The Effects of Preoperative Education on Parental Anxiety and Knowledge with Children Undergoing a Posterior Spinal Fusion.

Principal Investigator:

Heather Garcia, RN, 3 East Surgical Unit

Facilities:

3 East Surgical Unit at Rady Children's Hospital
RCHSD Orthopedic Clinic

Estimated Duration of Study:

March 2014 – September 2014

Specific Aims of Study:

The purpose of this study is to examine the effect of preoperative education on parents' anxiety and knowledge level with children undergoing a posterior spinal fusion both preoperatively and postoperatively. The hypothesis is that the preoperative education received will decrease the parents' anxiety and increase their knowledge level, which will improve patient outcomes.

Background and Significance:

Surgery is a necessary treatment for correction of spinal deformities in pediatric populations and preoperative education is essential for not only the child, but the parents as well. When parents exhibits higher levels of stress due to the child's approaching surgery, it is more challenging for them to deliver care throughout their hospital stay. Education provides knowledge, which helps to reduce anxiety levels, resulting in a better postoperative experience for both parent and child. The goal of physicians and nurses in

providing healthcare for the patients is to consider the ways in which care and education are given. There are many ways to deliver them, but what will be the most effective at increasing knowledge and decreasing anxiety. Preoperative education is one way to accomplish this.

According to Scrimin et al. (2009), children depend on parents for support and guidance in coping with stressful situations and that is why parents play a critical role when they undergo surgery. When parents are stressed and exhibiting high levels of anxiety the effectiveness of supporting their child may decline because they have become emotionally involved in the event (Scrimin, Haynes, Altoe, Bornstein, & Axia, 2009). Parents that are anxious begin to lose their ability to process information, and the ability to care for their child. This has a huge impact on the parents' capacity to care for the child postoperatively. It is important that preoperative education be clear and concise in order to inform the parent and reduce this fear and anxiety of the unknown. The parents can then better support their child.

According to Justus et al. (2006), pre-surgical preparation programs allow children and parents to gain knowledge and reduce their anxiety by experiencing the hospital in a non-threatening way. The aim of this study was to create a program for children and their families that reduced the stress of having surgery and being hospitalized. For parents this experience of having their child undergo surgery can be traumatic because they are dealing with their child's fear and anxiety along with their own fear of the unknown. Allowing parents to be part of the process of their child's surgical preparation enables them to take control of this new experience and cope better with their stress (Justus et al., 2006).

Zuwala & Barber (2001), also bring to light that there are few studies focusing on decreasing parental anxiety in order to reduce the anxiety of the child and that it is important to recognize that the parent's anxiety affects the child's level of anxiety.

The purpose of this project is to examine the effects of preoperative education on parental anxiety and knowledge with children undergoing a posterior spinal fusion. The findings for this study will demonstrate how preoperative education reduces parents' anxiety and increases their knowledge (or increased their knowledge and reduces their anxiety).

Progress Report/Preliminary Studies:

N/A

Research Methods and Design:

Design –

A pre- and post- anxiety and knowledge assessment design will be used to assess the anxiety and knowledge level of parents, legal guardian, and caregivers with children undergoing a posterior spinal fusion.

This is a quasi-experimental.

Instruments -

State-Trait Anxiety Inventory Tool. See Appendix A.

Knowledge Test: This test was developed by the Principal Investigator to survey the parents', legal guardians, or caregivers' knowledge of their child's spinal fusion surgery, the preoperative plan, and their postoperative period. The test was reviewed by an orthopedic nurse educator, and the spinal fusion nurse expert to establish inter-rater reliability (Appendix B).

Demographic data form (Appendix C).

Methods –

Preoperatively, a list will be provided to the Principal Investigator (PI) of scheduled spinal fusion surgeries from the doctor's nurses, Jennifer or Amy, that includes patient name, date of birth, date of surgery, procedure, and physician.

From this list of scheduled surgeries, the parents, legal guardian, or caregivers that meet the inclusion criteria, Jennifer, Amy, the Principal Investigator, or co-investigator will provide the Introductory letter to elicit voluntary participation for the study including the anxiety and knowledge assessments, and the demographic data form.

Each parent will write the last 4 digits of their cell phone on top of each of the forms in the study packet. The parent will be instructed to put the post-assessment forms back in the envelop, seal it, and place their name on the outside of the envelope. A designated co-investigator will collect the packets and place in a secure, designated area. The PI will pick

up the packets, pre-assessments, once a week and then place in a locked, secure area on the surgical unit.

Designated co-investigators will administer the anxiety and knowledge assessments and demographic data form. Once the parent has completed the assessments and demographic form the designated co-investigator or PI will collect and place into a file located in a secure, locked area.

The PI or designated co-investigator will make a phone call to the unit and obtain patient information including patient name, surgery, doctor, date of birth, and if parent present. If the parent, legal guardian, or caregiver did not consent prior to surgery or was not present at preoperative education session they will still be given the opportunity to participate in the study. The PI or designated co-investigator will approach the parent, legal guardian, or caregiver and provide the Consent Letter and elicit voluntary participation in the study. The Introductory letter will be attached to the post-assessment. The post-assessments will then be distributed to the participant and a designated co-investigator will collect the packets and place in a secure, designated area. The PI will pick up the packets, pre-assessments, once a week and then place in a locked secure area on the surgical unit.

Data Management –

All data sources will be anonymous. No personal identifiable information will be utilized in this data collection. The parents will be coded by the last 4 digits of their cell phone number, thus, maintaining anonymity. No Protected Health Information (PHI) will be collected from the patients. All data will be coded and kept in a locked file cabinet in a locked office and only available to the Principal Investigator and Co-Investigators. The pre- and post- anxiety and knowledge assessments will be returned in a sealed envelope to a designated area on the Orthopedic Clinic and on 3 East Surgical, and only the Principal Investigator and Co-investigators will have access to this area to collect data once a week. Computer data will be password protected and any individual data will be described as an aggregate in reporting the study findings.

The Principal and Co-Investigators will have access to the patient's PHI in order to identify the appropriate subject for the study, the parent, legal guardian, or caregiver. This information will not be used in the study.

Data Analysis –

Descriptive statistics will be utilized to calculate the frequencies, percentages, means, medians, and standard deviations. Cohen's Kappa statistics and percentage observer agreement will be calculated to assess inter-rater reliability of the items on the knowledge test. Independent t-test will be performed to compare the knowledge mean scores between the pre- and post-test data. Analyses will be conducted using SPSS version 18.0. For the purpose of this study, the significance level will be set at 0.05.

Subjects/Recruitment:

A purposive sample of parents with children diagnosed with idiopathic scoliosis and who are schedule to have a posterior spinal fusion during the time of this study will be selected. The number of subjects will be collected from March 2014 through September 2014. The parent, legal guardian, or caregiver who meet the study's inclusion criteria will be approached by the Principal Investigator or by the research assistant(s) to discuss the study and elicit voluntary participation. The Principal or Co-investigators will provide them with the Consent Letter (Appendix D). They will be assured that they can withdrawal from the study at any time and it will not affect the care they are their child receives during their hospitalization.

Inclusion Criteria – The eligibility criteria include parents/legal guardians/caregivers of children diagnosed with idiopathic scoliosis and undergoing a posterior spinal fusion at Rady Children's Hospital.

Exclusion Criteria – (a) any non-English speaking parents/legal guardians/caregivers since the anxiety tools and knowledge test will be in English only and because a clear understanding of the preoperative education given will be required in order to take both the anxiety and knowledge assessments, (b) all other parents/legal guardians/caregivers of children that do not have a diagnosis of idiopathic scoliosis and did not undergo a posterior spinal fusion.

Permission from Parents and Consent or Assent from Subjects:

A waiver of documented informed consent is being sought for parents, legal guardians, or caregiver participants, as it is important to protect anonymity, as this would ensure the responses to the research material are valid and truthful.

The Consent Letter (Attachment D), including the informed consent statement, will be given to each participant at the preoperative education session and prior to the start of the education. The anonymity of the parents, legal guardians, and caregivers will be protected by using the last 4 digits of their cell phone in order to link the pre- and post-anxiety and knowledge assessment data. Each participant will be asked to: (a) read the terms of the consent for participation in the Consent Letter, (b) note that completion of the research forms implies that consent has been given, (c) complete the demographic data form, the State-Trait Anxiety Inventory, and the Knowledge Test, and (d) place the forms back in the envelope and return the envelope to the designated area. Anticipated data completion time will be approximately 10-15 minutes. Parents, legal guardians, and caregivers will be assured that their individual responses will be kept confidential and that no personal, identifying information will be obtained or reported.

Alternative to Study Participation:

Any parent, legal guardian, or caregiver may opt out of the study at any time. If a parent, legal guardian, or caregiver chooses not to participate in the study, they and child will still be provided with the same quality care expected in our 3 East Standards of Care and same quality customer service expected of all Rady Children's Hospital Employees.

Potential Risks:

"Risks of harm anticipated in the proposed research are not greater than those ordinary encountered in daily life or during the performance of routine physical or psychological examination" (45 CFR 46.102).

There are no risks to the 3 East Surgical Staff or Orthopedic Clinic staff. For the parents, legal guardians, or caregivers, there are minimal physical and psychological risks to participating in the study. Filling out the anxiety and knowledge pre- and post-test that

may cause emotional discomfort by answering questions on anxiety while their child is recovering from surgery, but they will be ensured that they may withdrawal from the study at any time. The parents, legal guardians, or caregivers who elect not to participate and their children will be treated no differently than those that do participate in the study. All data will be kept confidential and stored in a secure file, with only the Principal Investigator and Co-Investigators having access to these documents. No patient or parent, legal guardian, or caregiver identifiers will be used, and there is no risk of PHI being obtained.

Risk Management and Confidentiality Procedures:

All data will be in an anonymous format in order to protect participant's identity and prevent any risks to participating in this study. All documents and data obtained will be in a locked file cabinet in a secure office.

The participant's date of birth will be used to keep the data anonymous and allow for the pre-and post-test data to be linked. These measures are not considered sensitive and pose no risk to confidentiality. No patient identifiers will be used.

Any public dissemination of the project results will maintain anonymity and describe the hospital data site as Children's Hospital in Southern California.

Potential Benefits:

The benefit for the participants is that it could reduce their anxiety, increase their knowledge, and improve patient education for other parents, legal guardians, or caregivers of children undergoing posterior spinal fusions. For patients, the benefit could improve patient outcomes.

Risk/Benefit Ratio:

The benefits of the study outweigh any risks. Improvements in preoperative education for parents are significant potential benefits by analyzing their anxiety and knowledge level both pre- and postoperatively. All the data will remain anonymous and there will be no use for patient identifiers and participation in the study remains entirely voluntary.

Expense to subjects:

None.

Compensation for Participation:

No compensation is offered.

Privileges/Certifications/Licenses and roles of research team:

Heather Garcia, RN will oversee the entire study as the Principal Investigator and help to obtain informed consent, distribute anxiety and knowledge surveys, and securely maintain all data records.

Co-Investigators –

Jennifer Turney, RN, MSN, CNS will serve as a co-investigator to the Principal investigator. She will assist with obtaining informed consent, distributing anxiety and knowledge surveys, and assist with IRB proposal.

Barbara Taylor, PhD, RN is a doctorally prepared nurse and will serve as thesis advisor of the Principal Investigator and is the Dean of Students at the Point Loma Nazarene University, School of Nursing.

Chris Sloa, PhD(c), RN is a doctorally prepared nurse and will serve as a chairperson of the Principal Investigator. She will assist with the study design, methodology, submission of IRB proposal and data analysis. She is a professor at Point Loma Nazarene University, School of Nursing.

Amy Kager RN, is the spinal fusion nurse for Dr. Newton at CHSD Orthopedic Clinic. She performs the preoperative education sessions for the parents, legal guardians, or caregivers. She will assist with obtaining informed consent and distributing the pre-anxiety and knowledge assessments.

Jennifer Widmer, RN is the spinal fusion nurse for Dr. Yaszay at CHSD Orthopedic Clinic. She performs the preoperative education sessions for the parents, legal guardians, or caregivers. She will assist with obtaining informed consent and distributing the pre-anxiety and knowledge assessments.

Jessica Morgan, RN, BSN is a nurse on the 3 East Surgical Unit at Rady Children's Hospital. She will assist with obtaining informed consent and distributing post- anxiety and knowledge assessments.

Beth O'Connell, RN, BSN is a nurse on the 3 East Surgical Unit at Rady Children's Hospital. She will assist with obtaining informed consent and distributing post- anxiety and knowledge assessments.

Carrie Svendsen, RN, BSN is a nurse on the 3 East Surgical Unit at Rady Children's Hospital. She will assist with obtaining informed consent and distributing pre- and post-anxiety and knowledge assessments.

Bibliography:

Justus, R., Wyles, D., Wilson, J., Rode, D., Walther, V., & Lim-Sulit, N. (2006). Preparing children and families for surgery: Mount Sinai's multidisciplinary perspective. [Case Reports Review]. *Pediatric nursing*, 32(1), 35-43.

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Industry-Sponsored or Collaborating Studies:

N/A

Other Funding Support For This Study:

N/A

Investigational Drug Fact Sheet:

N/A

Impact on Staff:

This study will not have any impact on the staff other than the above specified co-investigators that currently work on the 3 East Surgical Unit and in the Orthopedic Clinic. The co-investigators will receive a 10-minute in-service on the project, how to obtain informed consent, distribute the assessments, and how to properly collect the data. The study plan has been discussed with the leadership team on the 3 East Surgical unit and the

Orthopedic Clinic including the director, manager, supervisor on 3 East, and both Orthopedic surgeons performing the posterior spinal fusions, their nurses, and has been approved.

Conflict of Interest:

N/A

Procedures for Surrogate Consent and/or Decisional Capacity Assessment:

N/A

HIPAA:

Protected health information of the patient or the parents, legal guardians, or caregivers of the patient will not be obtained or used in this study. The parents' demographic data form will be collected, including gender, age, and ethnicity. No patient identifiers will be used in data collection or analysis. HIPAA consent will be obtained by all parent participants (Appendix E).

Debriefing:

At the completion of data collection the subjects will be thanked for their participation, and encouraged to ask questions or bring up any concerns about the study. They will be listened to, offered reassurance, and referred to someone with professional training if they need assistance. The Principal Investigator's contact information will be given when informed consent is obtained, along with my advisor, and IRB contact at the pre- and post-test administration.

Copyrighted inventories and approval letter:

Appendix A, State-Trait Anxiety Inventory Form.

Appendix B, Knowledge Assessment.

Appendix C, Demographic Data Form.

Appendix D, Permission Letter for Use of STAI Inventory Tool.

Appendix E, Introductory Letter to Potential Research Participants.

