THE EFFECTS OF A PATIENT- AND FAMILY-CENTERED NON-SEDATION/GENERAL ANESTHESIA PREPARATION INTERVENTION FOR PEDIATRIC MAGNETIC RESONANCE IMAGING ON MAGNETIC RESONANCE IMAGE QUALITY, HEALTHCARE COSTS, AND OPERATIONAL EFFICIENCY

by

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The aim of this quasi-experimental study was to address a gap in the empirical literature by testing theoretically supported relationships between a Patient-and-Family-Centered Non-Sedation/General Anesthesia Preparation (PFC-NP) intervention for non-sedation pediatric MRI and (1) the magnetic resonance image quality, (2) hospital costs, and (3) operational efficiency.

Data from all children ages 3 through 17 who underwent MRI from January 2015 through September 2016 in an urban academic medical center in the United States were evaluated. This was a four-group designed study in which there was a PFC-NP Intervention Group and three comparison groups: (a) Standard Care Sedation/GA (i.e., general anesthesia), (b) CCLS (i.e., certified child life specialist) Preparation for Sedation/GA, and (c) No Preparation and No Sedation/GA. This study compared three outcomes between the subjects in the intervention group and comparison groups: (1) quality of magnetic resonance image, (2) healthcare cost, and (3) operational efficiency in which seven hypotheses were investigated using multiple linear regression.

After analysis of unadjusted and adjusted multiple linear regression models, the PFC-NP Intervention group as compared to Standard Care Sedation/GA group was found to have statistically significantly lower quality of magnetic resonance images (0.418-per-unit
increase in quality rating), lower healthcare costs ($1,848.90 per encounter), and shorter procedural times (31.83 minutes).

The Intervention group compared to the CCLS Preparation for Sedation/GA group had lower quality of magnetic resonance images (0.492/unit increase), lower healthcare cost ($1,663.03 per encounter), and shorter procedural times (24.74 minutes).

The adjusted model comparison of the effect of the PFC-NP Intervention group as compared to the No Preparation and No Sedation/GA group on healthcare costs and procedural time revealed no statistical difference. The quality of magnetic resonance image quality was statistically significantly better in the unadjusted group.

The PFC-NP intervention has shown that children have the ability to successfully complete a MRI without sedation/GA. The results of this research reveal that taking a patient- and family-centered approach to care improves the safety of care for this population. Findings from this study provided evidence to support a safer, more cost effective, and more efficient alternative to sedation/GA use in children needing a diagnostic MRI.

The form and content of this abstract are approved. I recommend its publication.

Approved: Linda Flynn
I dedicate this work to all the children and their families who are entrusted to our care. May we, as healthcare providers, always strive to improve the care we provide to the most precious and vulnerable amongst us, our children.
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CHAPTER I
INTRODUCTION, SIGNIFICANCE, AND PURPOSE

Background

With the changes in healthcare in the United States (U.S.) and the economic challenges brought about by these changes, a new and invigorated focus on patient safety, satisfaction, and care quality has taken center stage. U.S. healthcare reform and the new national health plan enacted under the Patient Protection and Affordable Care Act have compelled healthcare systems to use innovative approaches to (a) improve the quality of patient care, patient safety, and patient satisfaction and (b) reduce healthcare waste (Patient Protection and Affordable Care Act, 2013). The Institute of Medicine (2011), the Institute for Healthcare Improvement (2011), and the Picker Institute (2011) all brought forth the challenge for healthcare organizations to improve patient outcomes related to patient safety and quality using a patient-centered approach.

Responding to this challenge, the pediatric literature indicates that patient-and-family-centered care (PFCC) is the transformational and innovative approach to improving safety, quality, and satisfaction outcomes, as compared to traditional care (Kuo, Houtrow, Arango, 2012; Ladak et al., 2012; Rappaport, Ketterer, Nilforoshan, & Sharif, 2011; Rosen, Stenger, Bochkoris, Hannon, & Kent, 2009; Tidwell et al., 2011; Voos et al., 2011). Yet despite an emphasis on implementing PFCC across all areas of pediatric care, no study in the U.S. had explored a comprehensive multimodal PFCC approach to reducing sedation/general anesthesia (GA) use during pediatric magnetic resonance imaging procedures (MRI).

The primary rationale for the use of sedation/GA during MRI is to ensure that the child lies still during the procedure in order to achieve a high quality magnetic resonance
image (Miller, 2015). However, there are risks and side effects associated with sedation/GA use in children. While strategies to reduce or minimize these side effects are being explored, the effectiveness of strategies in reducing the need for sedation/GA in children requiring MRI and associated outcomes have been limited.

Although there is emerging international evidence to support different modalities in reducing sedation and GA in children requiring MRI, these studies, conducted outside of the U.S., have produced mixed results (Bates, Comeau, Robertson, Zurakowski, & Netzke-Doyle, 2010; Carter, Greer, Reay, & Ware, 2010; de Bie et al., 2010; Ericson, Scott-Van Zeeland, Hamilton, Lincoln, & Golomb, 2012; Harned & Strain, 2001; Hartman, Bena, McIntyre, & Albert, 2009; Kahn, Donnelly, Koch et al., 2007; Lemaire, Moran, & Swan, 2009; Munn & Jordan, 2013; Netzke-Doyle, 2010; Nordahl et al., 2008; Rupprecht et al., 2000; Silva, Mackenzie, Hallowell, Stewart, & Ditchfield, 2006; Smart, 1997; Tye, Leigh, Mulhern, Srivastava, & Bruce, 1997; Rosenberg et al., 1997).

There has been a clear gap in the empirical literature related to the effects of a patient- and family-centered non-sedation/GA preparation (PFC-NP) interventional approach on reducing the need for sedation/GA during pediatric MRI, reducing the safety risks associated with sedation/GA, reducing hospital cost, and improving operational efficiency. Therefore, the purpose of this quasi-experimental study was to address this important gap in the empirical literature by testing, in a U.S. hospital, the theoretically supported relationships between a PFC-NP intervention for non-sedation pediatric MRI and its effects on (1) the magnetic resonance image quality, (2) hospital costs, and (3) operational efficiency such as procedural time. By doing so, findings from this study provided evidence to support a safer,
more cost effective and efficient alternative to sedation/GA use in children needing a diagnostic MRI.

**Problem Statement**

What are the effects of a PFC-NP intervention for pediatric MRI on the magnetic resonance image quality, healthcare costs, and operational efficiencies including procedural time (Figure 1)?

**Sub-Problems/Research Questions**

1. Will there be a difference in quality of magnetic resonance images between children who received the PFC-NP intervention compared to those who received standard care sedation/GA?

2. Will there be a difference in quality of magnetic resonance images between children who received the PFC-NP intervention compared to those who received certified child life specialist (CCLS) preparation for sedation/GA?

3. Will there be a difference in quality of magnetic resonance images between children who receive the PFC-NP intervention compared to those who received no preparation and no sedation/GA?

4. Will the PFC-NP intervention for MRI reduce hospital costs among intervention children compared to those who received (a) standard care sedation/GA and those who received (b) CCLS preparation for sedation/GA or (c) no preparation and no sedation/GA?

5. Will the PFC-NP intervention reduce procedural turnaround time as compared to patients who received standard care sedation/GA?
6. Will the PFC-NP intervention reduce procedural turnaround time as compared to patients who received CCLS preparation for sedation/GA?

7. Will the PFC-NP intervention reduce procedural turnaround time as compared to patients who received no preparation and no sedation/GA?

Operational Definition of Terms

Patient- & Family Centered Non-Sedation/General Anesthesia Preparation (PFC-NP) Intervention

The PFC-NP intervention was operationally defined and characterized by three main activities of care: (1) caregiver consultation conducted by a certified child life specialist (CCLS) with the parent (or parent and child) prior to or on the day of a visit to determine their interest in pursuing a non-sedation/GA alternative, (2) a pre-MRI preparation session
for the PFC-NP intervention child, and (3) personalized interventions and support during the MRI procedure.

CCLSs create therapeutic relationships and use knowledge of the child/family to implement care strategies specific to the individual, ultimately maximizing the true potential of the child (Squires & Allen, 2009; Thompson, 2009). The practice of child life at its core builds upon the relationship created with the child and child’s family to understand individual strengths, weaknesses, and vulnerabilities (Thompson, 2009). In the PFC-NP intervention, the CCLS initially consults with the parent prior to the MRI, asking questions outlined below. During this consultation, the parent partners with the CCLS, sharing knowledge of the child’s behaviors, fears, difficulties, concerns, and developmental nuances. In the event of cognitive or behavioral disabilities, the CCLS addresses the individual needs of the child and tailors delivery of the intervention in ways that are most appropriate given the respective disability. Based on parental input about her/his child, the CCLS develops a personalized plan of care to meet the specific needs of the child. If the child is old enough to participate in the consultation, the questions below are asked also of the child and used in the development of the patient-specific intervention.

1. Questions asked during caregiver consultation prior to MRI visit are as follows:
   a. Has your child had an MRI before?
      i. Did your child have sedation for the MRI?
      ii. What was that experience like for your child?
   b. Is your child fearful of tight spaces?
   c. What normally soothes your child when anxious?
   d. Does your child have difficulty with loud noises or other sensations?
e. What is your child’s primary language?

f. Have you spoken to your child about coming to MRI?

Next, during the pre-MRI session, the CCLS prepares the child, using developmentally appropriate, patient-centered methods. Those methods include a preparation book downloaded onto an iPad, developmentally appropriate medical play session and demonstrations, and practice of developmentally appropriate coping strategies.

2. The pre-MRI preparation session includes the following elements:

a. A preparation book on iPad (with sounds, pictures, and text) introduces (1) the front desk administrative staff; (2) the registration room and application of identification wrist band; (3) the waiting room; (4) the exam room and nursing staff, how vital signs are obtained, and hospital pajamas; (5) the wait-and-play area with child life and play normalization; (6) the preparation room; (7) the MRI room with sounds of the MRI and photos of child receiving an MRI; (8) the technician room with pictures of technicians; and (9) the process of leaving the MRI;

b. A medical play session led by the child, allowing the child to express fears, concerns, or comfort level;

c. A preparation session with mock toy MRI scanner with figures and dolls
d. Practice of coping techniques such as keeping still, guided imagery, audio music, and movie with MRI goggles.

Finally, the CCLS and/or parent provides intervention and support during the actual MRI, operationalized as coaching by the CCLS, parental presence, and/or MRI movie goggles or music.
Standard Care

Standard care was operationally defined in this study as instances wherein (1) families chose not to have their child receive sedation/GA, and the CCLS was not available to deliver the PFC-NP intervention and (2) families chose for their child to have sedation/GA for the MRI, and the CCLS was not available for preparation for sedation/GA. Standard care for non-sedation/GA and sedation/GA does not include any aspect of the intervention as described.

CCLS Preparation for Sedation/GA

CCLS preparation for sedation/GA was operationally defined in this study as those instances wherein families chose sedation/GA for their children, and a CCLS prepared them for sedation/GA to reduce the risk of anxiety and distress prior to sedation/GA. When the CCLS prepared a child, he/she initially assessed their level of knowledge about sedation/GA and MRI as well as their levels of anxiety and distress. The CCLS then prepared the child by sharing with them a facemask similar to those used for oxygen delivery or for delivery of inhaled anesthesia. The CCLS showed the child a picture of all the people the child would meet prior to receiving sedation/GA so as to familiarize the child with the anesthesiologist, nurse, and MRI technician.

Magnetic Resonance Image Quality

Image quality was operationally defined as a score on a 5-point Likert-type rating scale measuring the quality of the magnetic resonance image and the level of motion artifact of the image. For all patients receiving an MRI during the study period, the actual magnetic resonance image was reviewed from the Picture Archiving Computer System (PACS) and graded on the 5-point Likert-type rating scale by a qualified radiologist. Numeric scores on
the rating scale corresponded with the following values: 1—excellent quality and no motion artifact; 2—good quality and little motion artifact; 3—acceptable quality and moderate motion artifact; 4—poor quality and excessive motion artifact; 5—child was unable to complete the magnetic resonance image.

**Hospital Costs**

For the purpose of this study, hospital costs was operationally defined as hospital charges. For all patients receiving an MRI during the study period, data were extracted from the hospital cost accounting system, “Eagle.” Total charge was displayed as a continuous variable in dollars and consisted of two sub-charges: medication charge and facility charge. Total charge was defined as the cumulative charge released either to the insurance company or to the patient directly should they not have insurance coverage.

**Procedural Time**

For all patients receiving an MRI during the study period, procedural time was operationally defined as “In-MRI Time.” In-MRI Time included the total procedural time from when the patient entered the MRI room to when the patient exited the MRI room. Since anesthesia begins and ends while the child is in the MRI room, In-MRI Time included the initiation of pharmacologic medications, when used. The In-MRI Time variable was displayed in minutes and was extracted from two existing health information systems: Image Cast and CompuRecord. Both date and time variables were extracted.

**Use of Sedation/GA**

Sedation/GA was operationally defined as receipt of a pharmacological agent for the purpose of sedating or anesthetizing the child during MRI. Alternatively, non-sedation/GA use was operationally defined as non-receipt of any pharmacological agent for the purpose of
sedating or anesthetizing the child during MRI. These data were obtained from AllScripts, the hospital health information record. These data were displayed as dichotomous variables indicating use or non-use of sedation/GA.

**Delimitations**

The participants in this study were delimited to children from three through 17 years old who spoke English and required outpatient magnetic resonance imaging at an urban academic medical center in the US from January 2015 through September 2016. Since the age span encompassed varied developmental stages, the age of the child was controlled for in the analytical model. In addition, there were children who had prior experience in MRI, and as such, this variable was also controlled for in the model. See Chapter IV for all covariates adjusted for in the analysis. There were no other limitations to participation in this study.

**Significance**

In 2015, national statistics indicated that there were 73.6 million children in the US; a total of 9.6 million of those children between the ages of 5-17 years were reported to have activity limitations related to one or more health conditions (Child Stats, 2015). Furthermore, the population of children in the U.S. is projected to increase by an additional 1.4 million by 2025 (Child Stats, 2015). With 13% of children in the U.S. having activity limitations related to one or more health conditions, the likelihood of these children requiring health services is projected to increase to over 10.8 million children per year by 2025. This increase has the potential to place tremendous financial burden on and create access challenges for an already struggling healthcare system.

With technology advancement and projected increases in healthcare utilization among U.S. children, the probability of children needing diagnostic imaging is, likewise, expected to
increase. Additionally, as diagnostic imaging technology has advanced over the past 15 years, there is appreciable growth in the use of MRI as a diagnostic modality for children (Agarwal et al., 2010; Rankey, Leach, & Leach, 2008; Wachtel, Dexter, & Dow, 2009). There are benefits for the use of MRI as an alternative diagnostic tool, with the most significant benefit noted as reduction in exposure to radiation. However, the length of time needed to complete a MRI study requires the child to remain still for a prolonged period of time; therefore, sedation/GA is typically used.

Rates of sedation/GA use for children requiring MRI in the U.S. are rising at an estimated 7-8% per year, exposing an increasing number of children to sedation/GA-associated risks and side effects (Wachtel et al., 2009). These risks and side effects are specifically associated with the pharmacological agents used to sedate or anesthetize the child. These side effects vary greatly, and they include emergence delirium, respiratory depression, oxygenation, nausea, vomiting, agitation, and cardiovascular bradycardia. A recent and most concerning side effect explored in the empirical literature is the effect of sedation/GA on the developing brain. Emerging evidence indicates a significant negative impact on neurocognitive functioning later in life specifically related to the exposure, duration of exposure, and type of drug used during this critical time period. While the literature about strategies to reduce or minimize sedation/GA-associated side effects in MRI is robust, research evaluating the effectiveness of strategies in reducing the need for sedation/GA in children requiring MRI and associated outcomes is limited.

There is considerable national interest in the implementation of patient-and-family-centered care (PFCC) interventions and the quantification of their effectiveness. Although the theoretical literature defines the components of PFCC, there has been limited empirical
literature measuring the effects of PFCC interventions on patient outcomes, healthcare system costs, and operational efficiencies. There are a small number of quasi-experimental studies indicating that PFCC improves patient outcomes. There is emerging evidence supporting a relationship between PFCC and patient satisfaction as well as staff satisfaction. What had not been tested prior to the current study is the theoretical relationship between PFCC interventions and indicators of other outcomes such as safety, quality, healthcare system costs, and operational efficiencies.

PFCC research is critically important to U.S. healthcare as it has the potential to inform healthcare reform strategies that will drive patient quality, safety, satisfaction, and healthcare-related economic outcomes. The existing gap in this research provided the opportunity to investigate the effects of a patient- and family-centered non-sedation preparation (PFC-NP) intervention on healthcare cost and hospital efficiency for children undergoing magnetic resonance imaging.

**Implications for Nursing and Policy**

The PFC-NP intervention is a new and innovative approach to care delivery and responds to the national call to action to embrace a patient-centered approach to care. PFCC has long been recognized as a concept that is vital to and inherent within nursing practice (Hughes, 2011). Furthermore, the American Nurses Association has strongly asserted that nurses are strategically positioned to advocate for PFCC within their practice organizations and should take the lead on the design and implementation of PFCC practices (Connecticut Nursing News, 2012). Heeding this call, the PFC-NP intervention tested in this study was designed by a nurse administrator who was also the principal investigator for this research. To support this research, the nurse administrator obtained a $72,000 grant from the Hugs for
Brady foundation to fund the equipment and supplies needed for this intervention. An additional $16,000 was obtained through an in-kind philanthropic donation to support PFCC research; these funds were used specifically for the radiologist’s time in reading and coding the 4,610 magnetic resonance images that were among the outcome variables of this study. Thus, this study exemplified nursing’s important role in design, implementation, and evaluation of PFCC practices. Furthermore, this study serves as a model for nurse leaders in other organizations. The findings of this study inform the activities of pediatric nurse administrators in their efforts to enhance child safety and operational efficiencies during MRI procedures.

**Summary**

In summary, this quasi-experimental study quantified the effects of a PFC-NP intervention to prepare children for MRI on healthcare costs and operational outcomes. Measured outcomes included (1) the quality of MRI scans, (2) hospital costs, and (3) operational efficiencies such as MRI time, sedation/GA time, and total procedural time when compared to children receiving current standard care. Importantly, this research tested the relational propositions between patient/parent partnership and healthcare costs and operational efficiencies. Findings from this study advance the limited body of knowledge regarding PFCC outcomes and spur the continued emergence of innovative PFCC interventions occurring within our healthcare systems. Notably, findings have the potential to inform policy and guidelines regarding best and safest practices for the preparation and conduct of pediatric MRIs.
CHAPTER II
LITERATURE REVIEW AND CONCEPTUAL FRAMEWORK

Literature Review

This research investigated the effectiveness of a patient- and family-centered non-sedation preparation (PFC-NP) intervention for children undergoing MRI, compared to standard care, in reducing hospital costs and improving operational efficiency. This chapter provides a review of the pediatric theoretical and empirical literatures related to sedation and general anesthesia (sedation/GA) use for MRI, pediatric non-sedation and general anesthesia (non-sedation/GA) use for MRI, and the emerging literature related to the effects of patient- and family-centered care on patient outcomes. This chapter also provides a description of the theoretical framework used to guide this study.

Specifically, this literature review (a) summarizes the physiological and biological principles of sedation/GA for children receiving an MRI; (b) describes what is known about non-sedation/GA practices for children receiving an MRI; (c) describes the state of the evidence regarding the implementation of patient- and family-centered care (PFCC) and its associated key outcomes; (d) defines the concept of PFCC for children; and (e) presents the framework that guides this study. Derived from the theoretical framework, the chapter concludes with the theory-based hypotheses that were tested in this study.

A search of the scientific literature was conducted using research databases such as CINAHL, Academic Search Premier, PubMed, PsychINFO, AMED, The Cochrane Library, Ovid, and MEDLINE to ensure that all literature pertaining to the fields of pediatric sedation/physiologic implications and child life were included in the review. All reviews included peer-reviewed literature from January 2005 through June 2015, and abstracts were
reviewed to determine eligibility for inclusion. Additional citations from visual magnetic resonance images of relevant studies were included if inclusion criteria were met. Studies were eligible if they were (a) published in English and (b) explored sedation/GA practices in pediatric MRI, non-sedation/GA practices in pediatric MRI, and PFCC in the pediatric setting. Studies were excluded if they were not published in English or were not theoretically or empirically based.

All reviews utilized the following search terms “infant,” “child,” “pediatric,” “adolescent,” “juvenile,” “teenager,” and “youth” to ensure literature pertaining only to pediatrics was included in the review. Sedation/GA in pediatric MRI search terms also included “anesthesia,” “analgesia,” “sedation,” “brain,” “pediatric brain,” “brain/growth and development,” “developing brain,” “magnetic resonance imaging,” and “MRI” and resulted in 20 studies. Non-sedation/GA in pediatric MRI search terms also included “non-anesthesia,” “non-analgesia,” “non-sedation,” “magnetic resonance imaging,” and “MRI” and resulted in 16 studies. For the PFCC literature search, the additional search terms employed were “patient- and family-centered care,” “family-centered care,” “patient-centered care,” “partnership with patients,” and “patient partnership” as the terminologies are used interchangeably within the literature. This resulted in a total of 19 studies included for review in this section.

**Data Extraction and Analysis**

Quantitative data were extracted and categorized by the following: author(s), title, journal, year, study purpose, independent variable, dependent variable, number of subjects, subject characteristics, sample design, source or instrument, year data collected, theoretical framework, and study results. Qualitative data themes and key concepts were categorized by
the following: author(s), year, qualitative design, research question, sample, data collection methods, and themes/categories. The data were then evaluated for commonality in themes and definitions, outcomes measured, and strength of relationships. Findings were then summarized.

**Potential Bias and Limitations of Review**

To control for biases, the initial search was broad to include all published studies and then narrowed to the focus of this review. Intrinsic in this review are biases based on the choice to include only English language studies and studies occurring only within pediatrics. Only electronic databases were used for this search; therefore, the exclusion of research outside the boundaries of the electronic search method might present some bias. Citations of included studies were examined for appropriateness of inclusion.

**Sedation/GA use in MRI: Physiological and Biological Principles and Side Effects**

A synthesis of the literature related to MRI sedation indicates that there are several reasons why children are sedated for MRI. The primary rationale for sedation in MRI is to ensure that the child remains still for a prolonged period of time while the MRI is being conducted (Arlachov & Ganatra, 2012; Edwards & Arthurs, 2011; Vanderby, Babyn, Carter, Jewell, & McKeever, 2010; Miller, 2015). However, for the pediatric patient, there are many additional factors that can negatively affect the quality of the magnetic resonance image and that are believed to be mitigated through the use of sedation/GA. These include the cognitive and developmental abilities of the child to remain still for prolonged periods of time and to follow directions (e.g., to hold one’s breath) required for certain MRIs. Additionally, feelings of distress or anxiety related to the procedure, fear of the unknown, or fears related to past experiences also limit the child’s ability successfully to complete an MRI without sedation,
so sedation/GA may be used (Edwards & Arthurs, 2011). Because of these common biological and physiological challenges faced by children, sedation/GA is used when MRI is required. However, there are real and potential physiological and biological risks/side effects of the sedation and anesthetic agents used in sedation/GA for children. The next section will explore the current empirical literatures associated with specific risks and side effects of sedation/GA in children requiring MRI as follows: (1) common drugs used with risks and side effects including emergence delirium and recovery times and (2) the effects of anesthesia on the developing brain.

**Risks and Side Effects of Anesthetic Agents Used for Children in MRI**

The literature explored the efficacy, risks, and side effects associated with the pharmacological agents used to sedate or anesthetize children needing an MRI. Common drugs used for MRI sedation include chloral hydrate, dexmedetomidine, midazolam-pentobarbital-fentanyl combination, isoflurane, sevoflurane, nitrous oxide, and propofol (Bong et al., 2015; Gyanesh, Srivastava, & Singh, 2014; Heard et al., 2015; Ogurulu et al., 2012; Serafini & Zada, 2008; Slovis, 2011). Incident of side effects from the drugs used for sedation/GA in children for MRI range in occurrence. Potential side effects include emergence delirium, respiratory depression, oxygenation, nausea, vomiting, agitation, and cardiovascular bradycardia (Bong et al., 2015; Millar, 2015; Serifini et al., 2005; Slovin, 2011). Many studies explore the effects of drugs used in sedation/GA to understand the best combinations of drugs to minimize side effects and the best type of drug to use based on the patient’s physiologic challenges. For the purposes of this review, a synthesis of the literature was delineated into two categories: emergence delirium and recovery time.
Emergence delirium (ED) is a troubling side effect of sedation/GA in children. It is described as “a mental disturbance during the recovery from general anesthesia consisting of hallucinations, delusions and confusion manifested by moaning, restlessness, involuntary physical activity and thrashing about in bed” (Wilson & Graves, 1990, p. 16). The incidence of ED in children ranges from 18% to 80%, and the reason for this phenomenon is still being explored. However, it is thought to be a direct result of the time it takes the child to awaken from anesthesia (Bong et al., 2015; Voepel-Lewis, Malviya, & Tait, 2003). In 2004 Sikich and Lerman developed the Pediatric Anesthesia Emergence Scale to measure the ED phenomenon in children. The Pediatric Anesthesia Emergence Scale was tested for its psychometric properties and was found to be both reliable and valid in measuring ED in children post-anesthesia (Sikich & Lerman, 2004). In a randomized control trial evaluating ED in 120 pediatric patients undergoing sedation/GA for MRI and using the Pediatric Anesthesia Emergence Scale, Bong et al. (2015) explored the incidence of ED between single-dose dexmedetomidine and propofol. They found that in the dexmedetomidine group the incidence of ED was 42.5%, and in the propofol group, the incidence of ED was 33.3%. However, the differences in these incident rates were not found to be statistically significant (Bong et al., 2015). While there was no statistical difference in rates, the high rates of ED with both of these drugs are of particular concern. Although neither dexmedetomidine nor propofol was found to be a predictor of ED, the time it took for the child to awaken from sedation/GA was a significant predictor of ED (Bong et al., 2015). The longer it took for the child to wake up from anesthesia, the lower the odds of ED (Bong et al., 2015).

Multiple studies explored different drugs such as sevoflurane, isoflurane, nitrous oxide, propofol, and dexmedetomidine and the effects of awakening or recovery time. In this
review, five studies have specifically explored drug dosage, route of drug delivery, and anxiety-reducing strategies to improve awakening time and reduce recovery times. Three studies explored the use of propofol as compared to other anesthetic agents or methodologies of infusion. Heard et al. (2015) explored the use of propofol versus isoflurane with nitrous oxide and found that propofol had more rapid awakening time than isoflurane-nitrous oxide with fewer adverse events during emergence and recovery. However, the recovery times for the two drugs were similar. Similarly, Hassan et al. (2011) explored the effects of propofol infused intermittently versus continuously for children undergoing an MRI in an effort to understand the effects this drug delivery methodology had on total dose needed to keep the patient still and the child’s recovery time. Less drug was used with the continuous infusion of propofol versus intermittent use. However, neither type of drug delivery method affected recovery time or MRI image quality (Hassan et al., 2011). For these two studies, neither drug type, drug dose, nor drug delivery methodology resulted in shorter recovery times. Cho et al. (2010) explored the use of a single dose propofol protocol to a continuous infusion protocol to determine which methodology was more efficacious in shortening recovery times. In contrast to Heard et al. (2015) and Hassan et al. (2011), the single dose propofol protocol had statistically significantly shorter recovery times than the continuous infusion protocol ($p < 0.001$). However, this type of drug delivery method was found to be effective only for short-sequenced MRIs such as those lasting less than 30 minutes (Cho et al., 2010).

Gyanesh et al. (2014) compared awakening time and time to discharge between intranasal dexmedetomidine, ketamine, and a placebo given pre-procedurally in children undergoing MRI. They found that both the ketamine and dexmedetomidine had earlier awakening and recovery than did the children who received the placebo. The uses of these
pre-procedural drugs are thought to reduce (a) anxiety and fears prior to the procedure and (b) the amount of sedation/GA used during the actual MRI, thus improving awakening time and shortening recovery time.

Ogurlu et al. (2012) explored the use of headphones to reduce audible MRI noise in children undergoing MRI with anesthesia. The aim of this study was to reduce experienced MRI noise so as to reduce the amount sevoflurane required to keep the child asleep during the MRI and, as a result, shorten the awakening time and discharge time from the post-anesthesia care unit (PACU). They found statistically significant shorter discharge times from PACU as well as faster awakening times with children who used the noise-reducing headphones \( (p < 0.001; \text{Ogurlu et al.}, 2012) \).

In summary, drug types, dosages, and routes of administration used inter-procedurally did not appear to have significant impact on awakening times or recovery times. Interventions used to reduce anxiety pre-procedurally, however, as well as inter-procedurally appear to have a positive effect on awakening and recovery time. While there are many strategies being explored to lessen the side effects of anesthetic drugs used for children undergoing MRI, the risks associated with sedation/GA remain.

**Effects of Sedation/GA on the Developing Brain**

Over the past 15 years, animal studies exploring the effects of anesthesia on the developing brain have shown dramatic negative effects on neurodevelopment early in life and subsequent learning performance issues (Aker, Blick, & Biddle, 2015; Sinner, Becke, & Engelhard, 2014). The generalization of the findings of these animal studies to humans, however, has been criticized due to the differences in physiology between animal and human species. Additionally, the environment in which animal lab research is performed is quite
different from the practices of monitoring and controlling for the side effects of anesthesia in humans. While findings from animal studies are difficult to translate directly to humans, they do provide the basis on which current physiologic research related to pediatric anesthesia use is being explored. It is known that the most crucial part of human brain development occurs in the third trimester of pregnancy up to the third year of life and continues through childhood.

Human research has employed primarily a retrospective methodology to evaluate these effects, mainly due to the large ethical issues of randomizing children with anesthesia use. There have been a few studies using large data sets of children, which have retrospectively explored associations between exposure to anesthetics for surgical intervention, academic aptitude scores, and other biobehavioral challenges such as attention disorders (Sinner et al., 2014). Two studies in particular explored the effects of anesthesia exposure in children. One found a statistically significant association with lower test scores and the other with incidence of attention disorders (Block et al., 2012; Sprung et al., 2012). While these findings provide a rationale for concern, the retrospective methodology cannot be used to explain a causal relationship.

The physiologic effects of anesthesia on the developing brain have also been scientifically explored in primates. What has been hypothesized is that “by inducing apoptosis or interfering with the neurogenesis, anesthetic exposure during a critical period of neuronal development can have significant impact on neurocognitive function later in life” (Sinner et al., 2014, p. 1009). It is the exposure, duration of exposure, and type of drug used during this critical time period that is thought to lead to significant inhibition of neuronal development. Although the consequences of these effects on the human brain has yet to be
determined, in primates, the prolonged use of anesthetics early in life has shown to increase apoptosis, neuronal death, and necrosis (Sanders, Hassell, Davidson, Robertson, & Ma, 2013). In addition to the physiological effects, the cognitive effects in primates have also been explored. Paule et al. (2011) investigated the lasting effects of ketamine anesthesia in monkeys administered during the first week of life and found lower motivation and inferior performance in learning at age seven months that continued at three and a half years of age.

Summary

Animal research has sparked a concern with regards to the extent to which anesthesia affects the developing brain and the significance of that effect in humans. Regardless of the magnitude of the effect anesthesia has on the developing brain, any risk should be avoided when possible. There are times when the risk of not performing a procedure, surgery, or radiological test outweighs the risks of anesthesia for children. In those cases, strategies to reduce exposure to anesthesia must be implemented. New and emerging strategies are being explored to avoid anesthesia use during MRI specifically, where anesthesia is used primarily to ensure that the child remains still for the duration of the procedure. Descriptions of those strategies and their effectiveness in ensuring high quality magnetic resonance images are presented in the next section.

Non-Sedation/Anesthesia use in Pediatric MRI: The Emerging Evidence

There has been sporadic interest over the past 20 years to reduce the use of sedation/GA in children receiving MRI. As the use of MRI for diagnostic clinical decision-making is growing, there is emerging interest to explore and test effective strategies to support children in successful MRI without sedation/GA. The interest and the concerted exploration of these strategies stems from the growing concerns related to the side effects of
the drugs used for sedation/GA and the effects of sedation/GA on the developing brain.

Although the scant literature that does exist indicates that the risks for sedation or GA in pediatric MRI are minimal, any risk should be avoided when possible. This review presents the empirical literature from the past 18 years and explores the relationship of sedation/GA-reducing strategies in children for MRI and their effectiveness on the outcomes measured.

A total of 16 empirical studies were evaluated: three experimental, five quasi-experimental, four retrospective reviews of existing data, one descriptive study, one quality improvement project, one systematic review, and one integrated review (Bates et al., 2010; Carter et al., 2010; de Bie et al., 2010; Ericson et al., 2012; Harned & Strain, 2001; Hartman et al., 2009; Kahn et al., 2007; Lemaire et al., 2009; Munn & Jordan, 2013; Netzke-Doyle, 2010; Nordahl et al., 2008; Rupprecht et al., 2000; Silva et al., 2006; Smart, 1997; Tye et al., 1997; Rosenberg et al., 1997). Nine of these studies were conducted in the US and five outside the US. The two systematic/integrated literature reviews that were conducted in the US, however, included all relevant studies throughout the world. Excluding these reviews, 11 of the 14 studies measured the ability for children to obtain an MRI without sedation/GA. Seven of these studies showed a statistical significance in reducing sedation/GA use in children using modalities such as open versus closed MRI, mock MRI, audio/visual techniques, cognitive behavioral strategies, and parent partnership. Four were conducted in the US, two in Australia, and one in the Netherlands. The results of these studies will be described in the next section.

Strategies to Reduce Sedation and General Anesthesia Use

A systematic review completed and published in 2013 focused on understanding the strategies that are effective in reducing fear, anxiety, and claustrophobia in children who
require an MRI and determining if those strategies were effective in reducing the need for sedation/GA (Munn & Jordan, 2013). A total of eight studies met inclusion criteria for that review. These eight studies along with six additional studies will be presented in this section.

**Open MRI versus closed MRI.** There was only one study that evaluated the modality of an open MRI in reducing sedation/GA use in children. Rupprecht et al. (2000) evaluated the effectiveness of an open MRI in reducing sedation rates as compared to a closed MRI system. For children greater than 10 years of age, sedation rates were lower for open MRI than for closed MRI ($p < 0.0001$). As this is the only study found that explored this modality, further exploration is needed to determine its efficacy in reducing sedation/GA for children.

**Mock (practice) MRI.** There were a total of five studies in which a mock MRI methodology was utilized as an intervention to reduce the need for sedation/GA. Only one study explored the effects of a mock MRI protocol intervention of self-reported child distress. Rosenberg et al. (1997) used a mock MRI scanner to determine if preparation using a mock scanner decreased distress in children for MRI. All participants successfully completed the MRI without sedation. There were statistically significant reductions in heart rate and self-reported distress level during the simulator session and throughout the actual MRI ($p = 0.01$; Rosenberg et al., 1997). This provides early evidence that preparation with a mock MRI scanner prior to MRI may reduce self-reported distress in children. Four studies compared the age of the child with her/his ability to successfully complete an MRI without sedation/GA. Carter et al. (2010) conducted a retrospective review to evaluate the effectiveness of a new mock MRI program and used a standardized mock scanner with cognitive behavior strategies in children ages 3 to 14 years living in Australia. Results
showed a decreased need for general anesthesia (GA) for children ages 3 to 8 years and a rate of GA that was 16.8% lower than the non-mock MRI group ($p < 0.05$; Carter et al., 2010). While there were statistically significant decreases in GA use in the 3 to 8 year-old group, children ages 9 and older resulted in an increase in GA use. This finding is of particular interest and may be best explained by limitations inherent in a standardized preparation approach for preparing the child for MRI.

Bates et al. (2010) also used a standardized mock scanning approach along with other supportive preparation techniques specifically for children ages 4 to 7 years needing a brain MRI. While the children were successful in completing the MRI without sedation/GA, there was statistically significantly more motion artifact found for the non-sedated patients ($p = 0.02$). The findings of these two studies is of importance as the results indicate that the use of a mock scanning protocol in young children may be an effective strategy to reduce the use of sedation/GA in young children needing an MRI.

In the Netherlands, de Bie et al. (2010) used a mock scanner with standardized practice. They also found a positive relationship between the age of the patient and their ability to pass the mock scanner protocol. However, in contrast to Carter et al. (2010) and Bates et al. (2010), de Bie et al. (2010) found that older children had a statistically significantly higher mock scanning protocol passing rate than younger children ($p = 0.026$; deBie et al., 2010). While these results contrast with those of Carter et al. (2010) and Bates et al. (2010), all three studies provide initial evidentiary support that preparation using a mock MRI scanner prior to MRI can be useful in reducing the need for sedation/GA in children.

Silva et al. (2006) also explored the use of a mock MRI to reduce the need for sedation/GA in children who live in Australia. In addition to the mock MRI, other strategies
used were a phone interview with the parent to understand the patient’s specific needs, a storybook that showed pictures of the MRI and personnel, and procedural sensory information such as MRI sounds, an audio/visual (AV) system, and parental contact during MRI (Silva et al., 2006). The children were taught relaxation and coping strategies and had the ability to practice at home. With this preparation technique, 90% of the children passed the practice session, with 94% successfully completing their MRI without sedation/GA (Silva et al., 2006). This study, conducted outside of the US, provides the strongest evidence for a PFCC approach and the groundwork from which to further investigate this type of approach in the US.

**Audio/visual systems.** Three studies explored the use of an audio/visual (AV) system. A meta-analysis was performed for two studies for three different outcomes related to the use of an audio/visual system modality (Munn & Jordan, 2013). Harned & Strain (2001) examined the use of video goggles and earphones in reducing the need for sedation/GA and the impact on time, throughput, and cost. They found a statistical difference in sedation/GA use when comparing pre-post use of audio/visual MRI-compatible goggles. Additionally, the results noted that in the 3 to 10 year-old group, there was a decrease in sedation requirements \( p < 0.001; \) Harned & Strain, 2001). Likewise, there was a significant difference in the time they spent in the room, from a mean of 42 minutes for sedated patients to 35 minutes for non-sedated patients \( p < 0.0001; \) Harned & Strain, 2001). Nursing costs plus direct supply costs were noted. However, results of a statistical analysis were not presented. Lamaire et al. (2009) also explored the impact of video goggles and earphones on sedation rates in children for MRI. Results revealed an increase in pediatric patients scanned using an MRI \( p < 0.05 \) and a decrease in sedation use of 15.4%. This decrease, however,
was not statistically significant ($p = 0.32$; Lemaire et al., 2009). There was a decrease in wait times for MRI ($p < 0.05$; Lemaire et al., 2009).

The third study used multiple approaches, one of which was the use of earphones and a video system. Ericson et al. (2012) evaluated using a patient-centered approach in a sample of 12 autistic children requiring an MRI. Results indicated that 97% of the older children were successful in completing the MRI without sedation/GA as compared to 80% of the younger children. However, the success rate of completing MRI without sedation/GA was not found to be statistically significant. The very small sample of participants in this study may have contributed to the lack of statistical significance. Nonetheless, these results provide support for a patient- and family-centered approach that is individualized to the patient.

In summary, all three studies resulted in a decrease in the use of sedation/GA with the use of the audio/visual systems modality. Only one study, however, was able to show a statistically significant decrease. Additionally, Harned & Strain (2001) and Lemaire et al. (2009) were the only two studies found in this literature search that compared operational efficiencies (length of time in the MRI room and wait time for MRI) of sedated versus non-sedated children. A finding in both studies that is of particular importance is the statistically significantly better efficiency with non-sedated children than sedated children.

**Cognitive behavioral therapy.** The effectiveness of cognitive behavioral therapy was explored in three studies. Smart (1997) used a randomized control trial methodology in which the intervention group utilized an audiotape that consisted of guided imagery, relaxation guides, and music; the control group did not have any audio. Seven of the 10 children in the intervention group completed the MRI procedure without sedation compared
to eight of the 10 children in the control group, who needed sedation to complete the MRI procedure (Smart, 1997).

Tye et al. (1997) also used randomized control trial methodology. The intervention group received multiple cognitive intervention strategies while the control group received standard care. There were no statistically significant differences between the control and intervention groups in staff ratings or parents’ ratings of distress.

In addition to the use of a mock scanner, Carter et al. (2010) used a play-based therapy desensitization, which included exposure to stimulus using age-based coping strategies at a pace appropriate for the child. They also taught the children breathing techniques and used cognitive strategies such as visual imagery. As discussed earlier, results support the use of these techniques in the 3 to 8 year-old group.

The use of cognitive behavior strategies in all three studies produced varying results. However, two of the three studies indicate that in the younger age groups, cognitive behavioral therapy addresses children’s fears of the unknown and may play a role in successful pediatric MRI without sedation/GA.

**Photo diary.** A randomized control trial performed by Heartman et al. (2009) explored the effectiveness of a photo diary on child and parent pre-procedural stress and anxiety. No statistical difference was found in total anxiety between the control and intervention group ($p = 0.16$) or total stress score ($p = 0.88$; Heartman et al., 2009). Results indicate that the photo diary does not reduce stress and anxiety in this population, but it may be helpful if used in combination with other strategies.

**Patient- and family-centered approach.** There were three studies in the US that discussed the partnership with parents in developing an individualized approach to reduce
sedation/GA use for MRI. Two studies focused on autistic children, and one study was a data comparison of pre-/post-implementation of a sedation reduction program of children under 7 years of age who required an MRI. Nordahl et al. (2008) partnered with parents of autistic children to understand the child’s natural sleep patterns and attempted to mimic those normal patterns during MRI at night. Three out of 45 children were not able to complete the MRI procedure with either video or natural sleep, yet 34 were successful on the first attempt (Nordahl et al., 2008). While this approach was clinically successful, the statistical significance of these findings was not presented.

Ericson et al. (2012) also used a patient-centered approach to evaluate autistic children (N = 12) requiring a MRI and found that older children were better able than younger ones successfully to complete the MRI without sedation/GA. However, the results were not statistically significant. Nonetheless, these clinically significant results begin to provide support for the concept that engagement of the patient/parent as a partner in care may result in safer options for children needing an MRI.

Kahn et al. (2007) evaluated the incidence of requiring sedation/GA before and after the implementation of a program that utilized the expertise of a certified child life specialist, MRI video goggles, and a culture change that was described as emphasizing to all MRI staff avoidance of sedation/GA whenever possible. Study results revealed a decrease in overall frequency of sedation/GA and more specifically a statistically significant decrease in frequency of sedation in children ages 7 and younger (p < 0.001; Kahn et al., 2007). This was the only study found in the US supporting the concept that a patient- and family-centered approach decreases the need for sedation/GA use in children for MRI. While two of these
studies provide clinical support for the use of a PFCC approach in autistic children, all three studies support the need for further exploration.

Summary

While a few studies explored a methodology to reduce anxiety and distress for children requiring a MRI, no study in the US tested the use of a patient- and family-centered approach on quality, efficiency, and cost. Additionally, no study in the US explored the use of a comprehensive multimodal approach in diverse populations that varies based on the parent’s or patient’s participation, engagement, knowledge sharing of their child’s individualized needs, and shared decisions of what is best for the child. The emerging evidence is beginning to support different modalities in reducing sedation/GA in children requiring MRI. However, the gap in the literature related to the effects of a patient- and family-centered preparation intervention for children receiving a MRI in reducing the need for sedation/GA, hospital costs, and efficiency requires further exploration. Nonetheless, these results begin to provide limited support that engagement of the patient/parent as a partner in care may result in decreased use of sedation/GA with no difference in the quality of the magnetic resonance image for some aggregate within the pediatric population. There have been no studies conducted in the US that have tested the use of a patient- and family-centered intervention on indicators of quality, cost, and efficiency such as length of stay and procedural turnaround time variables. However, based on the emerging evidence, it is a logical assumption, when comparing the PFC-NP intervention group to patients who did not have the intervention and chose to not have sedation/GA, that the magnetic resonance image quality as well as the turnaround time for the MRI procedure will be better in the intervention group, particularly for younger aggregates of the pediatric population.
Concepts and Definitions of Patient Family-Centered Care: Theoretical Review

Mastro et al. (2014) synthesized the existing literature and developed a parsimonious theoretical model of PFCC (Figure 2). The model proposes sequenced phases of partnership development in PFCC, as well as propositional statements regarding the associations between PFCC and outcomes.

![Theoretical Model of Patient- and Family-Centered Care (Mastro et al., 2014)](image)

Figure 2. Theoretical Model of Patient- and Family-Centered Care (Mastro et al., 2014)

The PFCC Theoretical Model is well supported in the extant literature. The published review by Mastro et al. (2014) demonstrated that the defining attributes of PFCC include the development of a caring and trusting relationship, the leveling of power, information and knowledge sharing, participation and shared decision making, and dignity and respect (Coyne, 2006; Curtis-Tyler, 2010; D’Amour, Ferranda-Videla, Rodriguez, & Beaulieu, 2005; Eldh, Ehnfors, & Ekman, 2004; Hobbs, 2009; Hook, 2006; Kinnaman & Bleich, 2004; Klein, 2011; Sahlsten, Larsson, Sjostrom, & Kaety, 2008). Analysis of the literature indicates that the development of a caring and trusting relationship and the leveling of power are antecedent to PFCC and are critical for the patient to fully engage in her/his care. Once actualized, this leads to the empowerment of the patient to participate as a full partner in care and care decisions (Coyne, 2006; Curtis-Tyler et al., 2010; D’Amour et al., 2005; Eldh et al.,...
From a healthcare provider perspective, information and knowledge sharing is exemplified when the provider shares knowledge of health and illness and the patient/family shares personal experiences of the illness, social and family support, values, beliefs, and culture and results in a stronger partnership (Hook, 2006; Latta, Dick, Parry, & Tamura, 2008; Klein et al., 2011; Macdonald, Liben, Carnevale, & Cohen, 2012). Shared decision making is exemplified through empowered participation in which the provider and the patient/family share in the decisions of care through the development of mutually agreeable goals (Eldh et al., 2004; Hobbs, 2009; Hook, 2006). This relationship between the provider and the patient/family is critical to the success of a strong partnership. The leveling of power, in which the provider surrenders power and control to become an equal partner with the patient/family, is critical, as without it, partnership cannot be realized (Coyne, 2006; Curtis-Tyler et al., 2010; Eldh et al., 2004; Hobbs, 2009; Hook, 2006). The final attribute is that of respect and dignity. In partnership with patients/families, the provider must have respect for the patient and family and “openly listen to and honor the patient and family’s perspectives and choices” (Piper, 2011. P. 127). When the patient’s/family’s views are seen as the most valuable contributions to the planning of their care and together, a full partnership is realized (Johnston et al., 2006; Hook, 2006; Hutchenfield, 1999; Stahlsten et al., 2008).

**Patient-and Family-Centered Care Empirical Review**

Mastro et al. (2014) synthesized the existing empirical literature and developed propositional statements regarding the associations between patient/family partnerships and
outcomes. This search of quantitative research yielded nine studies. Five were quasi-experimental (Kuntaros et al., 2007; Ladak et al., 2012; Rosen et al., 2009; Tidwell et al., 2011; Voos et al., 2011), two cross-sectional (Mah, Tough, Fung, Douglas-England, & Verhoef, 2006; Neal et al., 2007), one prospective cohort (Kuo et al., 2012), one observational (Rappaport et al., 2011), and one survey design (Wanzer et al., 2004). Eight studies were conducted in the US (Kuo et al., 2012; Mah et al., 2006; Neal et al., 2007; Rappaport, 2011; Rosen et al., 2009; Tidwell, 2011; Voos et al., 2011; Wanzer et al., 2004) and one in Pakistan (Ladak et al., 2012). All studies defined the partnership with patients/families as the independent variable, which included family-centered rounds, bedside nursing-shift report, patient-centered communicative behaviors by staff, and the active participation of parent and adolescent in care. Depending on the design of the study, control groups were defined as “standard care.” Outcome variables included parent satisfaction, patient satisfaction, satisfaction with care, parent-perceived stress, family experience, healthcare economic outcomes, and healthcare professional satisfaction.

Multidisciplinary patient- and family-centered rounds (FCR), in which parents were present and active participants of the rounds, were the most common evidence of patient/parent partnership for hospitalized children. Five studies measured outcomes of FCR process (Kuntaros et al., 2007; Kuo et al., 2012; Rosen et al., 2009; Neal et al., 2007; Voos et al., 2011) and one study focused on nursing bedside shift report (Tidwell et al., 2011). These studies found statistically significant relationships with staff satisfaction, parental satisfaction, parental understanding of the plan of care, and teamwork.

The results of a study by Neal et al. (2007) indicated that staff satisfaction with FRC as compared to parent satisfaction was statistically significantly different and that parents
were more satisfied with FCR than staff ($\chi^2 = 418.9, p = 0.000005$). Rosen et al. (2009) noted that with FRC, the staff reported a “greater understanding of the patient’s plan of care, greater feeling of working as a team, and improved communication between family and staff” (Rosen et al., 2009, p. 606). They did not find a statistical difference in patient satisfaction between the families who reviewed FCR and those who did not (Rosen et al., 2009). However, Rappaport et al. (2011) did determine that families reported higher satisfaction and increased knowledge of staff’s role in care ($p = .04$). A finding in both studies that is particularly important to practice is the duration of FCR as compared to the conventional rounds. Rosen et al. (2011) noted no statistical difference in rounding time ($t = 1.83, p = 0.07$), and Rappaport et al. (2011) noted rounding time decreased with parental involvement ($p = 0.0001$), thereby challenging the notion that FCR takes longer than conventional rounds.

Ladak et al. (2004) noted that FCR were significantly associated with higher parental satisfaction. Parents who participated in FCR had feelings of inclusion ($p = 0.03$), involvement in decision-making ($p = 0.01$), teamwork caring ($p = 0.007$) and preference for FCR ($p = < 0.0001$; Ladak et al., 2012). In a study by Voos et al. (2011), FCR did not decrease parental stress; however, it was significantly associated with increased parent satisfaction and enhanced communication between staff and parents ($p < 0.01$). Kuo et al. (2012) explored the relationship between FRC and family experiences and health services use and found that parents who participated in FCR were able to report consistent medical information ($p < 0.001$), the option of discussing the plan of care ($p < 0.001$), and doctors showing respect ($p < 0.01$). There was no association between FCR and discharge time or hospital charges (Kuo et al., 2012). Wanzer et al. (2004) outlined patient-centered
communication (PCC) behaviors and studied the association between those behaviors in staff and parent satisfaction with communication. They determined that PCC behaviors were positively associated with satisfaction with care and communication ($p = 0.03$; Wanzer et al., 2004).

In three studies, the participating staff noted that the plan of care was significantly enhanced through parental participation in FCR (Kinnaman & Bleich; 2004; Tidwell et al., 2011; Voos, Ross, & Ward, 2011). Mah et al. (2006), evaluated adolescents’ perceived quality of care and identified key differences between their perception and the parents’ perception of service quality, thus emphasizing the importance of adolescent patients’ participation in care (Mah et al., 2006). Neal et al. (2007) identified significant differences between staff and family perception of the family’s participation in the child’s pain assessment. Families “reported that they were not given an opportunity to provide input into the staff’s assessment of their child’s pain and had concerns that their child’s pain was inadequately treated” (Neal et al., 2007, p. 483).

Summary

The review of the empirical literature indicates there is emerging empirical support for the theoretical proposition that partnering with patients and families results in improved quality, safety, satisfaction, and healthcare system costs and efficiencies (Mastro et al., 2014).

Patient- and Family-Centered Care Theoretical Framework

As described in the PFCC theoretical review of the literature, Mastro et al. (2014) published a theoretical framework that defines the phases of patient/family partnership and the relational proposition of patient/family partnerships on outcomes such as patient
satisfaction, staff satisfaction, quality, safety, self-care, healthcare costs, and healthcare efficiencies. The development of this PFCC theoretical framework was synthesized from an integrated review of the theoretical and empirical literatures published within the children’s literature worldwide (see Figure 1. Theoretical Model of Patient- and Family-Centered Care; Mastro et al., 2014).

Mastro et al. (2014) describes PFCC as a unique relationship developing from a foundation of care and trust with the leveling of power between the healthcare provider and the patient/family. Dignity and mutual respect, information and knowledge sharing, empowered patient/family participation with shared decision making, and collaboration and engagement are the sub-concepts. Patient/family as full partners in care is the core concept. The theory posits that when care, trust, and leveling of power are present, the patient/family is empowered to share information and knowledge specific to themselves and actively participate in decision-making as full partners in care. Once the full patient/family partnership is actualized, the model posits a positive relationship with patient satisfaction, staff satisfaction, quality and safety outcomes, self-care, healthcare efficiencies, and an inverse relationship with healthcare costs (Mastro et al., 2014).

As discussed in the review of the PFCC theoretical literature, PFCC as it relates to healthcare includes the development of the structural relationship between the patient/family and the healthcare provider and the process in which the patient/family and provider share their power, knowledge, and information (Gallant et al., 2002). The relationship between the patient and the provider is defined as a caring and trusting relationship in which care and trust along with the leveling of power form the foundation for the success of the partnership and lead to intended outcomes (Kettunen et al., 2003; D’Amour et al., 2005).
Summary

In summary, the PFCC theoretical framework (Mastro et al., 2014) proposes that the development of a caring and trusting relationship and leveling of power lead to the empowerment of the patient/family to participate as full partners in care and posits the following relational outcome propositions: (1) a positive relationship between patient and family partnership and patient satisfaction; (2) a positive relationship between patient and family partnership and staff satisfaction; (3) a positive relationship between patient and family partnership and quality; and (4) a positive relationship between patient and family partnership and the ability of the patient to care for her or himself (self-care). The final three propositions provide the theoretical rationale for this study: (5) an inverse relationship between patient and family partnership and healthcare costs; (6) a positive relationship between patient and family partnership and operational efficiency; and (7) a positive relationship between patient and family partnership and safety. In this study, safety was indicated by the use/non-use of sedation/GA; cost was indicated by hospital charges; and operational efficiency was indicated by in-MRI procedural times.

In this study, a PFCC approach to care was operationalized via the PFC-NP intervention as previously described. Thus, based on the theoretical propositions of PFCC theory (Mastro et al., 2014), the following hypotheses were tested among children receiving a diagnostic MRI:

1. **HA:** There is no difference in quality of magnetic resonance images between children who received the PFC-NP intervention and those who received standard care sedation/GA.
2. **HA:** There is no difference in quality of magnetic resonance images between children who received the PFC-NP intervention and those who received CCLS preparation for sedation/GA.

3. **HA:** Children who received the PFC-NP intervention have better quality of magnetic resonance images as compared to children who opted for no preparation and no sedation/GA and did not receive the intervention.

4. **HA:** The PFC-NP intervention reduces hospital costs associated with MRI as compared to (a) patients who received standard care sedation/GA, (b) patients who received CCLS preparation for sedation/GA, and (c) patients who received no preparation and no sedation/GA.

5. **HA:** Children who received the PFC-NP intervention have reduced procedural turnaround time as compared to patients who received standard care sedation/GA.

6. **HA:** Children who received the PFC-NP intervention have reduced procedural turnaround time as compared to patients who received CCLS preparation for sedation/GA.

7. **HA:** Children who received the PFC-NP intervention have reduced procedural turnaround time as compared to patients who opted for no preparation and no sedation/GA.
CHAPTER III

DESIGN AND METHODS

Chapter III describes the design and methods for this study. This chapter also presents the setting, sampling method, study population, procedure, operational definitions of the variables, procedure for data collection and analysis, and human subject protection. This study used a quasi-experimental design exploring retrospective patient-level data extracted from medical records in order to test the effectiveness of the patient- and family-centered non-sedation/GA preparation (PFC-NP) intervention in reducing healthcare costs and improving efficiency through improving procedural turnaround times and ensuring equivalent quality of magnetic resonance images among children receiving an MRI.

Setting, Sampling Method, and Study Population

Setting

The setting for this study was a major metropolitan pediatric hospital located within an academic medical center in the northeast region of the US. This medical center is a quaternary healthcare facility serving children locally, regionally, nationally, and internationally. The radiology department has one dedicated MRI device that serves the needs of the pediatric inpatient, outpatient, and emergency department populations. All sedation/GA needs of the population of children needing MRI are provided by a board-certified pediatric anesthesiologist during anesthesia scheduled(blocked) times. No research participants needed to be recruited as this study analyzed existing data extracted from the electronic health records of patients who received a PFC-NP intervention when a certified child life specialist (CCLS) was present or standardized care when the CCLS was not present.
Sampling Method

This quasi-experimental design study used data from all children ages 3 through 17 who underwent an MRI from January 2015 through September 2016 in an urban academic medical center in the United States. To assess the potential of selection bias, which would present a threat to the study’s internal validity, the demographic data including age, ethnicity, primary language, and gender of the intervention group and standard care group were analyzed to ensure that there was no statistical difference in participant characteristics. Although differences were found, those variables that were correlated with the dependent variable were included in the analytic model as control variables. There was a potential threat to internal validity of history and repeated testing as some children had prior experience with MRI, so this variable was controlled during the data analysis phase. External validity for this study was limited to facilities of similar size, population, and demographics.

A power analysis for multiple regression was used a priori to determine sample. A multiple regression analysis was estimated to evaluate the effect of the PFC-NP intervention, age, MRI type, and prior experience on quality of magnetic resonance image, hospital cost, and operational efficiencies. The original plan for power analysis was based on four predictor variables (PFC-NP intervention, age, MRI type, prior experience), an anticipated moderate effect size of $R^2 = 0.15$, desired statistical power of 0.8, and probability of $\alpha = 0.05$, which indicated a sample size of 84 children per group was needed (Statistical Calculators, 2016). Data analysis showed six covariates statistically significantly associated with the outcome variable, so a power analysis was rerun to ensure an appropriate sample size for a seven predictor model (see Chapter IV).
Study Population

All patients who received outpatient MRI at an acute care pediatric hospital between January 2015 and September 2016 were included in the study. Since this is the evaluation of an existing PFC-NP interventional program, existing data were extracted from the electronic health records. The extraction and analysis of electronic health record data does not require that patients be recruited to participate in the study, nor are additional consents required. The study protocol was reviewed and approved by the Colorado Multiple Institutional Review Board (COMIRB) and Columbia University Review Board prior to data extraction. All electronic health record data of patients who met inclusion criteria and received an MRI during the study period (January 2015 through September 2016) were included in the study.

Inclusion criteria consisted of English-speaking children chronologically ages 3 through 17 years and who had an outpatient MRI during the study period. Exclusion criteria were comprised of non-English speaking children, children under age 3 and older than age 17, and any hospitalized patient receiving a MRI.

Procedure

Operational Definition of Variables

The operational definitions of the variables are summarized in Tables 1 through 6. (i.e., Intervention variable, Sedation/GA variable, Magnetic Resonance Imaging variables, Hospital Cost variable, and Calculated MRI Turnaround Time-Procedural Time variable).
### Table 1 - Intervention Variable

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Variable Definition</th>
<th>Variable Type</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>Type of Intervention</td>
<td>Categorical</td>
<td>1 = PFC-NP Intervention&lt;br&gt;2 = CCLS Preparation for Sedation/GA&lt;br&gt;3 = No Preparation and No Sedation/GA&lt;br&gt;4 = Standard Care Sedation/GA</td>
</tr>
</tbody>
</table>

### Table 2 - Sedation/GA Variable

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Variable Definition</th>
<th>Variable Type</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>LevelAnes</td>
<td>Received Anesthesia or Sedation</td>
<td>Categorical; dichotomous dummy variable</td>
<td>0 = No Sedation/GA&lt;br&gt;1 = Sedation/GA</td>
</tr>
</tbody>
</table>

### Table 3 - MRI Variables

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Variable Definition</th>
<th>Variable Type</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>QualityMRI</td>
<td>MRI scan quality</td>
<td>Continuous</td>
<td>1 = Excellent quality, no motion artifact&lt;br&gt;2 = Good quality, little motion artifact&lt;br&gt;3 = Acceptable quality, moderate motion artifact&lt;br&gt;4 = Poor quality, excessive motion artifact&lt;br&gt;5 = Incomplete MRI scan</td>
</tr>
<tr>
<td>#Scans</td>
<td>Total number of MRI scans per patient per encounter</td>
<td>Continuous</td>
<td>Defined in whole numbers</td>
</tr>
<tr>
<td>PriorEx</td>
<td>Prior experience with a MRI dummy coded</td>
<td>Categorical; dichotomous dummy variable</td>
<td>0 = All others&lt;br&gt;1 = Any experience</td>
</tr>
<tr>
<td>AnyPriorExp</td>
<td>Any prior experience with MRI</td>
<td>Continuous</td>
<td>0 = No prior experience&lt;br&gt;1 = 1 Prior experience&lt;br&gt;2 = 2 Prior experiences&lt;br&gt;3 = 3 Prior experiences&lt;br&gt;4 = 4 Prior experiences&lt;br&gt;5 = 5 Prior experiences&lt;br&gt;6 = 6 Prior experiences&lt;br&gt;7 = 7 Prior experiences&lt;br&gt;8 = 8 Prior experiences</td>
</tr>
</tbody>
</table>

### Table 4 - Hospital Cost Variable

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Variable Definition</th>
<th>Variable Type</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>TotalChrg</td>
<td>Total hospital charge</td>
<td>Continuous</td>
<td>Defined in dollars&lt;br&gt;Includes medication charge and recovery room charge</td>
</tr>
</tbody>
</table>
Table 5 - Calculated MRI Turnaround Time Variable (Procedural Time)

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Variable Definition</th>
<th>Variable Type</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>InMRI2</td>
<td>Anesthesia induction time to MRI complete time (All inclusive time from when the child enters the MRI until the MRI is completed and anesthesia ends)</td>
<td>Continuous</td>
<td>Defined in minutes; calculated variable of the difference between the expected time of the MRI and actual time of the MRI</td>
</tr>
</tbody>
</table>

Table 6 - Demographic and Patient Characteristic Variables

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Variable Definition</th>
<th>Variable Type</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diag</td>
<td>Patient’s diagnosis</td>
<td>Categorical</td>
<td>0 = All others 1 = Epilepsy 2 = Sickle cell 3 = Autistic disorder and attention deficit disorder</td>
</tr>
<tr>
<td>BodyArea</td>
<td>Body area of MRI</td>
<td>Categorical;</td>
<td>1 = MRI head 2 = MRI thorax, pelvis, upper ext 3 = Lower extremity</td>
</tr>
<tr>
<td></td>
<td>dichotomous dummy variable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ChronAge</td>
<td>Chronological age</td>
<td>Continuous</td>
<td>Ages 3 through 17 years (displayed in years)</td>
</tr>
<tr>
<td>Ethnic</td>
<td>Ethnicity</td>
<td>Categorical;</td>
<td>0 = All others or missing 1 = Caucasian 2 = Hispanic 3 = Black</td>
</tr>
<tr>
<td></td>
<td>dichotomous dummy variable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PriLang</td>
<td>Primary language</td>
<td>Categorical;</td>
<td>0 = All others or missing 1 = English 2 = Spanish</td>
</tr>
<tr>
<td></td>
<td>dichotomous dummy variable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gen</td>
<td>Gender</td>
<td>Categorical;</td>
<td>0 = Male 1 = Female</td>
</tr>
<tr>
<td></td>
<td>dichotomous dummy variable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>InsType</td>
<td>Insurance type</td>
<td>Categorical;</td>
<td>0 = All other 1 = Commercial/contracted</td>
</tr>
<tr>
<td></td>
<td>dichotomous dummy variable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Procedure for Data Collection and Analysis

Data Entry and Setup

Retrospective patient-level data were extracted from the medical records of all children ages 3 through 17 years of age who had received an MRI during the study period. For all patients for whom MRI occurred during the study period, the data were extracted and entered into Statistical Package for Social Sciences (SPSS) as outlined in Tables 1 through 6.

Initial Data Analysis

There were four groups studied: one intervention group and three comparison groups. The comparison groups are as follows: (a) Standard Care Sedation/GA, which includes families who chose sedation/GA standard care and the CCLS was not available for preparation; (b) CCLS Preparation for Sedation/GA, which includes those families who chose Sedation/GA and the CCLS was available for preparation; and (c) No Preparation and No Sedation/GA, which includes those families who chose non-sedation/GA and the CCLS was not available to deliver the PFC-NP Intervention. This study compared three outcomes between the subjects in the intervention group and comparison groups: (1) quality of magnetic resonance image, (2) healthcare cost, and (3) operational efficiency of MRI turnaround time.

Missing Data, Data Errors, and Outliers

Missing data were evaluated based on the pattern of missing data, the percent of cases with missing data, and the percent of missing data per case. In this study, the largest risk for missing data was the patient characteristic variables where data were provided by the parent or guardian and entered into the information system. There is the possibility that the caregiver might purposefully have chosen not to answer questions specific to ethnicity or
preferred primary language. Univariate statistics were used to identify any data issues, and no issues were found.

There were no missing data identified with any of the outcome variables (i.e., quality of magnetic resonance imaging, healthcare cost, and procedural time). There was only one patient encounter in which the patient characteristic “Gender” was identified as “unknown.” That patient was not part of the intervention group and was recoded as “male” for the analysis. There were 32 (0.68%) patient encounters in which the patient/caregiver declined to define ethnicity. For the purposes of this analysis, the ethnicity variable was coded as Hispanic, Caucasian, Other/Missing. The patient encounters in which ethnicity was missing were included in the “Other/Missing” category. Finally, there were 29 (0.61%) patient encounters in which the patient/caregiver did not identify a primary language. For the purposes of this analysis, the primary language variable was coded as English, Spanish, Other/Missing. The patient encounters in which primary language was missing were included in the “Other/Missing” category.

Sample Characteristics

Descriptive statistics were used to analyze the data in order to describe characteristics of the sample. Measures of central tendency and dispersion for continuous variables (mean, median, mode, range, and standard deviation) were assessed to determine if the assumption of normality was met. The frequency (%) of the distributions for categorical variables was analyzed to provide a detailed description of the sample characteristics being studied. These data are displayed in a chart in Chapter IV for ease of comparison.

Next, descriptive variables in each group were analyzed to ensure that the intervention group and comparison groups were not statistically significantly different in
patient characteristics. Differences in groups for continuous variables such as age were analyzed using an ANOVA, and categorical variables such as magnetic resonance image type, diagnosis, primary language, insurance type, gender, and ethnicity were analyzed using chi-squared tests. Since differences were found, those variables were included in the analytic model as control variables. The level of significance at which the research hypotheses were tested was established at 0.05.

**Inferential Statistics and Analysis**

**Correlation**

Bivariate correlations were conducted to determine if sample characteristic variables were associated with the dependent variables of each model. The variables that were mildly to strongly correlated with the dependent variables were included in an analysis of covariance (ANCOVA) formula or a multiple regression formula as covariates.

**Analysis of Covariance**

ANCOVA was used to analyze differences in the quality of images defined in Research Questions 1-3:

1. Will there be a difference in quality of magnetic resonance images between children who received the PFC-NP intervention compared to those who received standard care sedation/GA?

2. Will there be a difference in quality of magnetic resonance images between children who received the PFC-NP intervention compared to those who received CCLS preparation for sedation/GA?
3. Will there be a difference in quality of magnetic resonance images between children who receive the PFC-NP intervention compared to those who received no preparation and no sedation/GA?

All assumptions of ANCOVA test were evaluated prior to performing the analyses. Since differences between groups were found, a post hoc analysis was conducted to determine which groups differ from each other.

**Multiple Regression**

Multiple regression was used to investigate the effect of the intervention on healthcare costs and procedural times as compared to the comparison groups for Research Questions 4-7 as follows.

4. Will the PFC-NP intervention for MRI reduce hospital costs among intervention children compared to those who received (a) standard care sedation/GA, (b) CCLS preparation for sedation/GA, or (c) no preparation and no sedation/GA?

5. Will the PFC-NP intervention reduce procedural turnaround time as compared to patients who received standard care sedation/GA?

6. Will the PFC-NP intervention reduce procedural turnaround time as compared to patients who received CCLS preparation for sedation/GA?

7. Will the PFC-NP intervention reduce procedural turnaround time as compared to patients who received no preparation and no sedation/GA?

In preparation for regression, the categorical variable of “group” with four levels was recoded into separate, dichotomous variables, a procedure known as dummy coding (Fields, 2013). In estimating the regression models, each model was estimated as an unadjusted model (not including the covariates) and then as an adjusted model including covariates. All
assumptions for a multiple regression test were analyzed and confirmed prior to performing the analyses. The Durbin-Watson test was used to test the assumption of Independence of Observations. A Durbin-Watson statistic of approximately 2.0 would indicate that there is independence of errors; a value of less than 1 or greater than 3 is potential cause for concern.

The assumption of a linear relationship between the independent variables and the dependent variable was analyzed. To ensure there was no multicollinearity among study variables, tolerance values were evaluated and determined to be greater than 0.1 with a variance inflation factor (VIF) of less than 10.

In the analysis of each research question, the model fit was evaluated. The Beta was evaluated to determine the strength of the relationship between the independent variables and dependent variable. The $R^2$ and adjusted $R^2$ values were evaluated to understand the extent to which the total variability of the dependent variable was explained by the independent variables and covariates. Finally, statistical significance of each model was evaluated to ensure that the regression model was a good fit for the data.

Table 7 - Research Questions and Analysis Plans

<table>
<thead>
<tr>
<th>Research Question</th>
<th>Dependent Variable, Analysis Plan, and Schematic</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Will there be a difference in quality of magnetic resonance images between children who received the PFC-NP intervention compared to those who received standard care sedation/GA?</td>
<td>Image quality</td>
</tr>
<tr>
<td>2. Will there be a difference in quality of magnetic resonance images between children who received the PFC-NP intervention compared to those who received CCLS preparation for sedation/GA?</td>
<td>Image quality</td>
</tr>
<tr>
<td>Research Question</td>
<td>Dependent Variable, Analysis Plan, and Schematic</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>3. Will there be a difference in quality of magnetic resonance images between</td>
<td>Image quality ANCOVA with post hoc analysis</td>
</tr>
<tr>
<td>children who receive the PFC-NP intervention compared to those who received no</td>
<td></td>
</tr>
<tr>
<td>preparation and no sedation/GA?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Will the PFC-NP intervention for MRI reduce hospital costs among intervention</td>
<td>Hospital cost (charges) Multiple regression with dummy coding</td>
</tr>
<tr>
<td>children compared to those who received (a) standard care sedation/GA and those</td>
<td></td>
</tr>
<tr>
<td>received (b) CCLS preparation for sedation/GA (c) no preparation and no sedation/</td>
<td></td>
</tr>
<tr>
<td>GA?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Will the PFC-NP intervention reduce procedural turnaround time as compared to</td>
<td>Procedural turnaround time (in-MRI time) Multiple regression with dummy coding</td>
</tr>
<tr>
<td>patients who received standard care sedation/GA?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Will the PFC-NP intervention reduce procedural turnaround time as compared to</td>
<td>Procedural turnaround time (in-MRI time) Multiple regression with dummy coding</td>
</tr>
<tr>
<td>patients who received CCLS preparation for sedation/GA?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Will the PFC-NP intervention reduce procedural turnaround time as compared to</td>
<td>Procedural turnaround time (in-MRI time) Multiple regression with dummy coding</td>
</tr>
<tr>
<td>patients who received no preparation and no sedation/GA?</td>
<td></td>
</tr>
</tbody>
</table>
Human Subjects Protection

Institutional Review Board

This study was reviewed and approved by the University of Colorado Multiple Institutional Review Board and the Columbia University Institutional Review Board prior to data extraction/collection and analysis.

Informed Consent Process

There was an approved request of a waiver of study consent. This was a review of existing data, and no patients were contacted to participate in the study.

Potential Risks and Benefits

The biggest risk to study participation is a loss of confidentiality. Therefore, all data were encrypted and stored on password-protected electronic devices. There was no risk to participating in this retrospective, quasi-experimental study as this was an existing program and the control group received standard care. There was no immediate benefit to participating in this study. The results of the study did, however, provide opportunities for improvement in the preparation of children prior to MRI so as to reduce the need for sedation/GA, reduce costs associated with MRI, and improve MRI efficiency. The direct benefit to society was based on the potential for improved patient safety through enhanced quality of care due to the reduced need for sedation in children ages 3-17 receiving an MRI. The findings of this study helped to inform the design of strategies aimed at improving PFCC practices to improve safety, reduce healthcare cost, and improve healthcare system efficiencies.

Privacy and Confidentiality of Study Data

Study privacy and confidentiality were assured. Privacy of subjects was protected and confidentiality maintained by locking any paper data-extraction tools in a cabinet in the PI’s office. Only the PI had access to the locked cabinet. No personal health information data
were collected, such as name, zip code, birth date, and address. Medical record numbers were included to provide the ability to link data from the multiple electronic information systems. This data element was the only information that could link the identity of the subject to the data. In the final database, however, medical record numbers were eliminated.

To ensure privacy and confidentiality and to protect the safety of electronic research data, extracted electronic data were stored in an electronic file for the purpose of data analysis. A coding system was used for data entry to computer. The electronic file was password-protected and stored on the hospital’s password-protected and networked computer. The file was only accessible to the PI. There was a need to transport the electronic data file to a different location for further statistical data analysis. Prior to transport, the data in the file were de-identified by eliminating the medical record number, thus anonymizing the dataset. The file was emailed as an encrypted and password-protected file and was also transported on an encrypted and password-protected portable memory stick.

In addition to the researcher, the statisticians and major advisor were able to review the dataset. Before sharing the dataset, the PI de-identified the data by eliminating the medical record number, thus anonymizing the dataset.

The findings of the study were reported in the aggregate and disseminated to the hospital’s radiology leadership and staff, the University of Colorado College of Nursing, and the Columbia University College of Nursing. Findings, presented in the aggregate, will also be published in journal articles.
CHAPTER IV

RESULTS

The purpose of this study was to examine the effects of a patient- and family-centered non-sedation/GA preparation (PFC-NP) intervention for pediatric MRI on the image quality, healthcare costs, and operational efficiencies including procedural time. This quasi-experimental designed study used data from all children chronologically 3 through 17 years of age who underwent an outpatient MRI from January 2015 through September 2016 in an urban pediatric academic medical center in the United States. Chapter IV provides the analysis and interpretation of the study data. Data were exported to Statistical Package for Social Sciences (SPSS) version 23 for analysis.

Sample Descriptives

Sample Size

The sample consisted of the total population of children chronologically 3 through 17 years of age who had an outpatient MRI at an acute care pediatric hospital from January 2015 through September 2016. Data were extracted from electronic health records. Cases were categorized into one of four study groups, depending upon the services received: (1) children who received the PFC-NP intervention for no sedation/GA; (2) children who received CCLS preparation for sedation/GA; (3) children who received no intervention and no sedation; and (4) children who received standard care consisting of sedation/GA with no preparation.

A priori sample size was determined based on four predictor variables (PFC-NP intervention, age, MRI type, prior experience). Bivariate correlations, however, identified six variables statistically significantly associated with the outcome variables, which were used in the model as covariates. Covariates included age, gender, diagnosis, prior experience, body
area of MRI, and number of magnetic resonance images per encounter. To ensure a moderate
effect size of $R^2 = 0.15$, desired statistical power level of 0.8, and probability level of $\alpha = 0.05$, the post hoc power analysis indicated that a minimum sample size of 103 for each group was needed for the analyses (Statistical Calculators, 2016).

The outcomes measured in this study focused on two units of analysis: (1) patient encounters, defined as each patient visit for MRI; and (2) the actual magnetic resonance image or images, defined as each individual MRI scan. For the outcome variables of (a) procedural time and (b) healthcare cost, patient encounters were the unit of analysis, and outcomes were analyzed using multiple regression. The outcome variable of quality of magnetic resonance image was analyzed at the MRI unit of analysis using ANCOVA, Kruskal-Wallis, and multiple regression.

A total sample size of 3,250 encounters was used to investigate the encounter outcome variables including (a) procedural time and (b) healthcare cost; a total sample size of 4,610 individual MRIs was used to investigate the quality of magnetic resonance image outcome. These samples consisted of the total population of patient encounters and MRI scans during the study period. Membership in the four study groups for the outcome variables of (a) procedural time and (b) healthcare costs is displayed in Table 8, and membership in the four groups for outcome variable (c), quality of magnetic resonance image, is displayed in Table 9.
Table 8 - Number of Encounters per Study Group

<table>
<thead>
<tr>
<th>Group</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFC-NP Intervention</td>
<td>132</td>
<td>4.1%</td>
</tr>
<tr>
<td>No Intervention &amp; No Sedation/GA</td>
<td>2111</td>
<td>65.0%</td>
</tr>
<tr>
<td>CCLS Prep for Sedation/GA</td>
<td>224</td>
<td>6.9%</td>
</tr>
<tr>
<td>No Intervention &amp; Sedation/GA</td>
<td>783</td>
<td>24.1%</td>
</tr>
<tr>
<td>Total</td>
<td>3250</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 9 - Number of Magnetic Resonance Images per Study Group

<table>
<thead>
<tr>
<th>Group</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFC-NP Intervention</td>
<td>202</td>
<td>4.4%</td>
</tr>
<tr>
<td>No Intervention &amp; No Sedation/GA</td>
<td>2936</td>
<td>63.7%</td>
</tr>
<tr>
<td>CCLS Prep for Sedation/GA</td>
<td>334</td>
<td>7.2%</td>
</tr>
<tr>
<td>No Intervention &amp; Sedation/GA</td>
<td>1138</td>
<td>24.7%</td>
</tr>
<tr>
<td>Total</td>
<td>4610</td>
<td>100%</td>
</tr>
</tbody>
</table>

Sample Characteristics

Overall Sample

The overall sample contained 3,250 patient encounters within the patient sample of 2,698 unduplicated patients. A majority of the patients (82.8%) had no prior MRI experience. Most children had only one MRI per encounter (74.7%), with half (50.2%) of the images consisting of MRIs of the head.

The patient sample was delimited to those patients chronologically 3 through 17 years of age who received an outpatient MRI during the study period. In review of the data, there were seven patient cases that were deleted from the data analysis as they did not meet the inclusion criteria. All of these patients were scheduled for outpatient MRI as part of their treatment plan and were anesthetized for a subsequent planned additional interventional procedure. See Table 10 for descriptives of each study group and overall sample characteristics.
Table 10 - Sample Unduplicated Patient Descriptives of Each Study Group

<table>
<thead>
<tr>
<th>Variable</th>
<th>Categories</th>
<th>PFC-NP Intervention</th>
<th>No Intervention &amp; No Sedation/GA</th>
<th>CCLS Prep for Sedation/GA</th>
<th>No Intervention &amp; Sedation/GA</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=132</td>
<td>N=2111</td>
<td>N=224</td>
<td>N=783</td>
<td>N=3250</td>
<td></td>
</tr>
<tr>
<td>Chronological Age in Years</td>
<td>Mean (SD)</td>
<td>9.76 (3.49)</td>
<td>12.33 (3.17)</td>
<td>6.82 (3.52)</td>
<td>7.06 (3.56)</td>
<td>10.67 (4.08)</td>
</tr>
<tr>
<td></td>
<td>Min-Max</td>
<td>3-17</td>
<td>3-17</td>
<td>3-17</td>
<td>3-17</td>
<td>3-17</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>Epilepsy</td>
<td>0.0%</td>
<td>1.4%</td>
<td>3.2%</td>
<td>8.0%</td>
<td>3.1%</td>
</tr>
<tr>
<td></td>
<td>Sickle Cell</td>
<td>1.1%</td>
<td>0.2%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.1%</td>
</tr>
<tr>
<td></td>
<td>Autism</td>
<td>0.0%</td>
<td>0.1%</td>
<td>0.8%</td>
<td>1.9%</td>
<td>0.6%</td>
</tr>
<tr>
<td></td>
<td>All Others</td>
<td>98.9%</td>
<td>98.3%</td>
<td>96.0%</td>
<td>90.0%</td>
<td>96.1%</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Caucasian</td>
<td>21.7%</td>
<td>15.4%</td>
<td>42.4%</td>
<td>12.0%</td>
<td>16.0%</td>
</tr>
<tr>
<td></td>
<td>Black</td>
<td>7.6%</td>
<td>2.7%</td>
<td>13.6%</td>
<td>1.9%</td>
<td>3.2%</td>
</tr>
<tr>
<td></td>
<td>Hispanic</td>
<td>8.7%</td>
<td>17.2%</td>
<td>7.2%</td>
<td>19.1%</td>
<td>16.9%</td>
</tr>
<tr>
<td></td>
<td>All Others</td>
<td>62.0%</td>
<td>64.7%</td>
<td>36.8%</td>
<td>67.0%</td>
<td>63.9%</td>
</tr>
<tr>
<td>Primary Language</td>
<td>English</td>
<td>70.7%</td>
<td>60.1%</td>
<td>72.0%</td>
<td>58.1%</td>
<td>60.5%</td>
</tr>
<tr>
<td></td>
<td>Spanish</td>
<td>21.7%</td>
<td>23.4%</td>
<td>20.8%</td>
<td>20.1%</td>
<td>22.4%</td>
</tr>
<tr>
<td></td>
<td>All Others</td>
<td>7.6%</td>
<td>16.5%</td>
<td>7.2%</td>
<td>21.8%</td>
<td>17.1%</td>
</tr>
<tr>
<td>Gender</td>
<td>Female</td>
<td>46.7%</td>
<td>52.7%</td>
<td>36.0%</td>
<td>42.2%</td>
<td>49.1%</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>53.3%</td>
<td>47.3%</td>
<td>64.0%</td>
<td>57.8%</td>
<td>50.9%</td>
</tr>
<tr>
<td>Insurance Type</td>
<td>Commercial</td>
<td>77.2%</td>
<td>67.4%</td>
<td>92.0%</td>
<td>62.0%</td>
<td>67.5%</td>
</tr>
<tr>
<td></td>
<td>All Other</td>
<td>22.8%</td>
<td>32.6%</td>
<td>8.0%</td>
<td>38.8%</td>
<td>32.5%</td>
</tr>
<tr>
<td>Body Area of MRI</td>
<td>Head</td>
<td>45.7%</td>
<td>41.9%</td>
<td>70.4%</td>
<td>69.5%</td>
<td>50.3%</td>
</tr>
<tr>
<td></td>
<td>Thorax, Pelvis, &amp; Upper Ext</td>
<td>50.0%</td>
<td>47.9%</td>
<td>26.4%</td>
<td>28.1%</td>
<td>42.0%</td>
</tr>
<tr>
<td></td>
<td>Lower Ext</td>
<td>4.3%</td>
<td>10.2%</td>
<td>3.2%</td>
<td>2.4%</td>
<td>7.7%</td>
</tr>
<tr>
<td>Number of MRIs per Encounter</td>
<td>1 Scan</td>
<td>69.6%</td>
<td>75.4%</td>
<td>76.0%</td>
<td>73.3%</td>
<td>74.7%</td>
</tr>
<tr>
<td></td>
<td>2 Scans</td>
<td>22.8%</td>
<td>13.3%</td>
<td>17.6%</td>
<td>16.0%</td>
<td>14.5%</td>
</tr>
<tr>
<td></td>
<td>3 Scans</td>
<td>5.4%</td>
<td>9.5%</td>
<td>2.4%</td>
<td>7.4%</td>
<td>8.5%</td>
</tr>
<tr>
<td></td>
<td>4 Scans</td>
<td>2.2%</td>
<td>1.5%</td>
<td>2.4%</td>
<td>2.7%</td>
<td>1.9%</td>
</tr>
<tr>
<td></td>
<td>5+ Scans</td>
<td>0.0%</td>
<td>&lt;0.2%</td>
<td>&lt;1.7%</td>
<td>&lt;1.0%</td>
<td>&lt;1.0%</td>
</tr>
<tr>
<td>Prior Experience</td>
<td>0 Prior Exp</td>
<td>68.9%</td>
<td>85.5%</td>
<td>53.1%</td>
<td>86.3%</td>
<td>82.8%</td>
</tr>
<tr>
<td></td>
<td>1 Prior Exp</td>
<td>18.2%</td>
<td>8.7%</td>
<td>18.8%</td>
<td>10.1%</td>
<td>10.1%</td>
</tr>
<tr>
<td></td>
<td>2 Prior Exp</td>
<td>6.8%</td>
<td>3.2%</td>
<td>12.1%</td>
<td>2.0%</td>
<td>3.7%</td>
</tr>
<tr>
<td></td>
<td>3 Prior Exp</td>
<td>3.8%</td>
<td>1.3%</td>
<td>9.8%</td>
<td>0.8%</td>
<td>1.9%</td>
</tr>
<tr>
<td></td>
<td>4+ Prior Exp</td>
<td>&lt;1.0%</td>
<td>&lt;1.0%</td>
<td>&lt;5.0%</td>
<td>&lt;0.5%</td>
<td>&lt;0.4%</td>
</tr>
</tbody>
</table>

Analysis

Correlations

Bivariate correlations were computed to determine which demographic characteristics, if any, were significantly associated with the dependent variables. No statistically significant correlation was found between the three main study outcome variables and ethnicity, primary language, or type of insurance. The variables of age, gender,
diagnosis, body area of MRI, and number of magnetic resonance images per encounter were found to have statistically significantly low-to-moderate correlation with the main outcome variable (i.e., procedural time) and were included as covariates in the final analysis. The variables age, gender, diagnosis, prior experience, body area of MRI, and number of magnetic resonance images per encounter were found to have statistically significantly low-to-moderate correlation with the outcome variables healthcare cost and quality of magnetic resonance image, and therefore, were used as covariates in the final analysis. Pearson correlation statistics for procedural time are displayed in Table 11, for healthcare costs in Table 12, and for quality of magnetic resonance image in Table 13. In preparation for multiple and logistic regression analyses, categorical covariates were dummy coded in accordance with the procedure outlined by Fields (2013).

Table 11 - Pearson Correlations for Main Study Variables and Procedural Time

<table>
<thead>
<tr>
<th>Variables</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Procedural Time</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Age</td>
<td>.144** 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Gender</td>
<td>.035* .078** 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Diagnosis</td>
<td>-.102** -.074** -.039* 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Prior Experience</td>
<td>-.013 -.035* -.033 -.044* 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Body Area of MRI</td>
<td>.130** .167** .024 -.133** -.083** 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Number of MRIs per Encounter</td>
<td>.249** .002 .024 -.029 .109** .205** 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Table 12 - Pearson Correlations for Main Study Variables and Healthcare Cost

<table>
<thead>
<tr>
<th>Variables</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Healthcare Cost</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Age</td>
<td>-.436** 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Gender</td>
<td>-.085** .078** 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Diagnosis</td>
<td>.070* -.074** -.039* 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Prior Experience</td>
<td>.084** -.035* -.033 -.044* 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Body Area of MRI</td>
<td>-.111** .167** .024 -.133** -.083** 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Number of MRIs per Encounter</td>
<td>.352** .002 .024 -.029 .109** .205** 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

** Correlation is significant at the 0.01 level (2-tailed)
* Correlation is significant at the 0.05 level (2-tailed)
Table 13 - Pearson Correlations for Main Study Variables and Quality of Magnetic Resonance Image

<table>
<thead>
<tr>
<th>Variables</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Quality of MRI</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Age</td>
<td>-.067**</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Gender</td>
<td>-.051**</td>
<td>.068**</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Diagnosis</td>
<td>-.042**</td>
<td>-.069**</td>
<td>-.026</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Prior Experience</td>
<td>.035*</td>
<td>-.026</td>
<td>-.036*</td>
<td>-.043**</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Body Area of MRI</td>
<td>.140**</td>
<td>.159**</td>
<td>.021</td>
<td>-.129**</td>
<td>-.081**</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>7. Number of MRIs per Encounter</td>
<td>.099**</td>
<td>.008</td>
<td>.034*</td>
<td>-.034*</td>
<td>.165**</td>
<td>.219**</td>
<td>1</td>
</tr>
</tbody>
</table>

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

**Hypothesis #1**

There will be no difference in quality of magnetic resonance images between children who received the PFC-NP intervention compared to those who received standard care sedation/GA.

Analysis of Covariance (ANCOVA)

An ANCOVA was conducted to determine the difference in scores between the PFC-NP Intervention and the Standard Care Sedation/GA groups for quality of magnetic resonance image. Assumptions of ANCOVA were analyzed. Standardized residuals were normally distributed as assessed by the Normal P-P Plot of Regression of Standardized Residuals. There was a linear relationship between covariates and quality of magnetic resonance image as assessed by visual inspection of a scatterplot. The assumption of homogeneity of regression slopes was violated as evidenced by a significant Levene’s Test of Equality of Error Variances, $F(3,4606) = 13.876, p < 0.0005$. Additionally, the assumption of Independence of Covariates and Treatment effects was violated as the covariates differed across the four groups ($p < 0.0005$). Although according to statistical references, a significant Levene’s Test of Quality of Error Variances is a common finding in large sample sizes and
not a cause of concern, ANCOVA results are reported below. However, additional analyses were conducted using the nonparametric test, Kruskal-Wallis, and followed by multiple linear regression unadjusted model and adjusted model controlling for covariates, including dummy coded factors (Nordstokke & Zumbo, 2007).

The unadjusted ANCOVA statistic (or ANOVA) revealed that there is a statistically significant difference in the mean scores for the quality of magnetic resonance images between the groups $F(3, 4606) = 31.593$, $p < 0.0005$, partial $\eta^2 = 0.020$. Post hoc analysis was performed with a Bonferroni adjustment. The quality of magnetic resonance images is significantly lower in the PFC-NP Intervention group ($M = 2.297$, $SE = 0.050$) compared to the Standard Care Sedation/GA group ($M = 1.930$, $SE = 0.021$), with a statistically significant mean difference of $M_{\text{diff}} = 0.37$, 95% CI [0.22, 0.51], $p < 0.0005$.

After adjustment for all correlated covariates and fixed factors, an ANCOVA statistic revealed that there is a statistically significant difference in the mean scores for the quality of magnetic resonance images between the groups $F(3, 4597) = 66.676$, $p < 0.0005$, partial $\eta^2 = 0.042$. Post hoc analysis was performed with a Bonferroni adjustment.

Hypothesis #1 was not supported in that differences between the PFC-NP Intervention group and the Standard Care Sedation/GA group were found. The quality of magnetic resonance image was rated significantly lower within the PFC-NP Intervention group ($M = 2.233$, $SE = 0.046$) compared to the Standard Care Sedation/GA group ($M = 1.816$, $SE = 0.022$). The statistically significant mean difference is reported as $M_{\text{diff}} = 0.418$, 95% CI [0.283, 0.552], $p < 0.0005$ (see Table 14).
Table 14 - Adjusted and Unadjusted Means for Quality of Magnetic Resonance Image Study Group 1 & 4 with Age, Gender, Diagnosis, Prior Experience, Body Area of Exam, Number of Magnetic Resonance Images per Encounter as Covariates

<table>
<thead>
<tr>
<th>Group</th>
<th>$N$</th>
<th>$M$</th>
<th>$SD$</th>
<th>$M$</th>
<th>$SE$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Group 1 (Intervention)</td>
<td>202</td>
<td>2.30</td>
<td>.799</td>
<td>2.233</td>
<td>.046</td>
</tr>
<tr>
<td>Study Group 4 (Standard Care Sedation/GA)</td>
<td>1138</td>
<td>1.93</td>
<td>.635</td>
<td>1.815</td>
<td>.022</td>
</tr>
</tbody>
</table>

Note: $N$ = Number of MRIs, $M$ = Mean, $SD$ = Standard Deviation, $SE$ = Standard Error

Kruskal-Wallis

Since the Levene’s Test for Homogeneity was found to be statistically significant, the nonparametric test Kruskal-Wallis was conducted using an unadjusted model to investigate Hypothesis #1. The Kruskal-Wallis test confirmed a statistically significantly difference in quality of magnetic resonance images between study groups $\chi^2(3) = 88.152, p < 0.0005$ with the PFC-NP Intervention group having the highest mean rank (higher score equates to a lower quality of magnetic resonance image) (see Table 15).

Table 15 - Unadjusted Quality of Magnetic Resonance Image Study Group Mean Ranks

<table>
<thead>
<tr>
<th>Group</th>
<th>$N$</th>
<th>Unadjusted Mean Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Group 1 (Intervention)</td>
<td>202</td>
<td>2702.79</td>
</tr>
<tr>
<td>Study Group 4 (Standard Care Sedation/GA)</td>
<td>1138</td>
<td>2115.04</td>
</tr>
</tbody>
</table>

Multiple Linear Regression

After consultation with a statistician at the Colorado Biostatistics Consortium at the University of Colorado Denver, it was determined that multiple linear regression is an appropriate alternative method of analysis since the dependent variable (quality of magnetic resonance image) is measured on a 5-point scale and as such can be considered a continuous variable (Sullivan & Artino, 2013). Visual inspection of a histogram indicated that the variable (i.e., quality of magnetic resonance image) was normally distributed. Therefore, an
unadjusted and adjusted multiple linear regression model was estimated to investigate Hypothesis #1.

First, the assumptions of multiple linear regression were evaluated. The assumption of normality was met, as assessed by P-P Plot. There was a linear relationship between covariates and quality of magnetic resonance image as assessed by visual inspection of a scatterplot. Independence of residuals was confirmed, as assessed by a Durbin-Watson statistic of 1.580 (unadjusted) and 1.602 (adjusted). The assumption of homoscedasticity was met, as assessed by visual inspection of a plot of studentized residuals versus unstandardized predicted values. There was no evidence of multicollinearity, as no tolerance values were greater than 0.1 or VIF greater than 10. There were no influential data points worth checking for validity as there were no values for Cook's distance above 1.

Both the unadjusted (Model 1) and adjusted (Model 2) multiple regression models indicate that the Intervention group had lower quality of magnetic resonance images compared to the Standard Care Sedation/GA group, with an adjusted value of 0.418 per unit increase on the dependent variable, quality of magnetic resonance image. The unadjusted model accounted for 2% of the overall variance while the adjusted model accounted for 20% of the overall variance in magnetic resonance image quality, $F(12, 4597) = 97.975, p < 0.0005$, $R^2 = 0.20$. All correlated predictor variables were entered in the adjusted model. Only gender, age, and body area of the MRI exam variables, however, added significantly to the prediction, $p < 0.0005$.

Hypothesis #1 was not supported as written. Results of the regression model indicate that the Intervention group as compared to the Standard Care Sedation/GA group had a significantly lower magnetic resonance image quality. Further analysis revealed, however,
that within the Intervention group, there were only three patients (2.3%) out of 132 who had unacceptable magnetic image quality and one patient (< 1.0%) who was unable to complete the scan. While statistically the Intervention group’s magnetic resonance image quality was lower than the Standard Care Sedation/GA group, there is appreciable clinical importance in that 95.5% of the total number of magnetic resonance images in the Intervention group were deemed of acceptable-to-excellent quality. Additionally, it is important to note that 97% of the children in the Intervention group had magnetic resonance images that were deemed acceptable to excellent. Regression coefficients, standard errors, and significant values for unadjusted (Model 1) and adjusted (Model 2) can be found in Table 16 below.

Table 16 - Summary of Multiple Linear Regression Analysis (Constant = Study Group 4, Standard Care Sedation/GA)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model 1 (Unadjusted)</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td>SEβ</td>
<td>β</td>
<td>p</td>
<td>B</td>
<td>SEβ</td>
<td>β</td>
<td>p</td>
<td>B</td>
<td>SEβ</td>
<td>β</td>
<td>p</td>
<td></td>
</tr>
<tr>
<td>Study Group 1 (Intervention)</td>
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<td>.055</td>
<td>.104</td>
<td>.000</td>
<td>.418</td>
<td>.051</td>
<td>.118</td>
<td>.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender Female</td>
<td>- .087</td>
<td>.019</td>
<td>-.060</td>
<td>.000</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Age</td>
<td>-.042</td>
<td>.003</td>
<td>-.235</td>
<td>.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*MRI (Thorax, Pelvis, Upper Extremity)</td>
<td>.466</td>
<td>.022</td>
<td>.322</td>
<td>.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>*MRI (Lower Extremity)</td>
<td>-.464</td>
<td>.043</td>
<td>-.150</td>
<td>.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of MRI Scans per Encounter</td>
<td>-.004</td>
<td>.009</td>
<td>-.006</td>
<td>.678</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*Diagnosis Sickle Cell</td>
<td>-.022</td>
<td>.129</td>
<td>-.002</td>
<td>.864</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*Diagnosis (Autistic, Attention Defect Disorder)</td>
<td>.140</td>
<td>.146</td>
<td>.013</td>
<td>.335</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*Diagnosis (Epilepsy)</td>
<td>-.098</td>
<td>.064</td>
<td>-.020</td>
<td>.129</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*Prior Experience</td>
<td>.057</td>
<td>.043</td>
<td>.018</td>
<td>.179</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Dependent Variable, Quality of MRI Scan
Sample Size for Multiple Linear Regression, N = 4610
*Categorical variables that are dummy coded

Hypothesis #2

There is no difference in quality of magnetic resonance images between children who received the PFC-NP intervention compared to those who received CCLS preparation for sedation/GA.
Analysis of Covariance (ANCOVA)

An ANCOVA was conducted to investigate Hypothesis #2 to determine if there was a difference in magnetic resonance image quality scores between the PFC-NP Intervention and the CCLS Preparation for Sedation/GA groups. Assumptions of ANCOVA were analyzed. Standardized residuals were normally distributed as assessed by the Normal P-P Plot of Regression of Standardized Residuals. There was a linear relationship between covariates and quality of magnetic resonance image as assessed by visual inspection of a scatterplot. The assumption of Independence of Covariates and Treatment effects was violated as the covariates differed across the four groups ($p < 0.0005$). Additionally, there was no homogeneity of regression slopes as the Levene’s Test of Equality of Error Variances was statistically significant, $F(3, 4606) = 13.876, p < 0.0005$, and as such the null hypothesis was accepted, indicating that the test for homogeneity was violated. Although according to statistical references, this is a common finding in large sample sizes and not a cause of concern, ANCOVA results are reported, and additional analysis was conducted using the nonparametric test, Kruskal-Wallis, and followed by multiple linear regression unadjusted model and adjusted model controlling for covariates (Nordstokke & Zumbo, 2007).

An ANCOVA, unadjusted and adjusted for covariates and fixed factors, was conducted. An unadjusted ANCOVA statistic revealed a statistically significant difference in the mean scores for the quality of magnetic resonance images between the groups $F(3, 4606) = 31.593, p < 0.0005$, partial $\eta^2 = 0.020$. Post hoc analysis was performed with a Bonferroni adjustment. The magnetic resonance image quality scores were significantly higher in the PFC-NP Intervention group ($M = 2.297, SE = 0.050$) compared to the CCLS Preparation for Sedation/GA group ($M = 1.850, SE = 0.039$), with a statistically significant mean difference
of $M_{\text{diff}} = 0.45$, 95% CI [0.28, 0.62], $p < 0.0005$. This finding indicates that the quality of magnetic resonance images within the PFC-NP Intervention group were statistically significantly lower compared to the CCLS Preparation for Sedation/GA group.

After adjustment for all associated covariates and fixed factors, an ANCOVA statistic revealed that there was a statistically significant difference in the mean magnetic resonance image quality scores between the groups $F(3, 4597) = 66.676$, $p < 0.0005$, partial $\eta^2 = 0.042$. Post hoc analysis was performed with a Bonferroni adjustment. Findings revealed that magnetic resonance image quality scores were significantly higher (indicating a lower quality of scan) in the PFC-NP Intervention group ($M = 2.233$, $SE = 0.046$) compared to the CCLS Preparation for Sedation/GA group ($M = 1.740$, $SE = 0.037$), with a statistically significant mean difference of $M_{\text{diff}} = 0.492$, 95% CI [0.336, 0.648], $p < 0.0005$ (see Table 17).

Table 17 - Adjusted and Unadjusted Means for Quality of Magnetic Resonance Image Study Groups 1 & 2 with Age, Gender, Diagnosis, Prior Experience, Body Area of Exam, Number of Magnetic Resonance Images per Encounter as Covariates

<table>
<thead>
<tr>
<th></th>
<th>Unadjusted</th>
<th>Adjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$N$</td>
<td>$M$</td>
</tr>
<tr>
<td>Study Group 1 (Intervention)</td>
<td>202</td>
<td>2.30</td>
</tr>
<tr>
<td>Study Group 2 (CCLS Prep for Sedation/GA)</td>
<td>334</td>
<td>1.85</td>
</tr>
</tbody>
</table>

Note: $N =$ Number of MRIs, $M =$ Mean, $SD =$ Standard Deviation, $SE =$ Standard Error

Hypothesis #2 was not supported as stated. Results indicate that the Intervention group as compared to the CCLS Prep for Sedation/GA group had a significantly lower magnetic resonance image quality.

Kruskal-Wallis

Since the Levene’s Test for Homogeneity was found to be statistically significant, the nonparametric test Kruskal-Wallis was also conducted using an unadjusted model to investigate Hypothesis #2. The Kruskal-Wallis test also confirmed a statistically significantly difference in quality of magnetic resonance images between study groups $\chi^2(3) = 88.152$, $p <$
0.0005, with the PFC-NP Intervention group having the highest mean rank (indicating a lower quality of scan) and the CCLS Preparation for Sedation/GA group having the lowest mean rank in magnetic resonance image quality scores (see Table 18).

The hypothesis was not supported (no difference in magnetic resonance image quality between groups). The quality of magnetic resonance image unadjusted mean rank was greater in the PFC-NP Intervention group compared to the CCLS Preparation for Sedation/GA group.

Table 18 - Unadjusted Quality of Magnetic Resonance Image Study Group Mean Ranks

<table>
<thead>
<tr>
<th>Study Group 1 (Intervention)</th>
<th>N</th>
<th>Unadjusted Mean Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Group 2 (CCLS Prep for Sedation/GA)</td>
<td>334</td>
<td>1977.96</td>
</tr>
</tbody>
</table>

Multiple Linear Regression

The appropriateness of using a multiple linear regression to determine the effect of the intervention on the dependent variable (quality of magnetic resonance image) was presented previously. Unadjusted and adjusted multiple linear regression models were estimated to evaluate Hypothesis #2.

Assumptions of multiple linear regression were analyzed. The assumption of normality was met, as assessed by P-P Plot. There was a linear relationship between covariates and quality of magnetic resonance image as assessed by visual inspection of a scatterplot. There was independence of residuals, as assessed by a Durbin-Watson statistic of 1.580 (unadjusted) and 1.602 (adjusted). There was homoscedasticity, as assessed by visual inspection of a plot of studentized residuals versus unstandardized predicted values. There was no evidence of multicollinearity, as no tolerance values were greater than 0.1 or VIF greater than 10. There were no leverage values greater than 0.2 and values for Cook's
distance above 1. Both the unadjusted (Model 1) and adjusted (Model 2) multiple regression models indicated a statistically significant association between membership in the Intervention group and a lower quality of magnetic resonance images as compared to the CCLS Preparation for Sedation/GA, realizing a 0.492 per unit increase on the dependent variable, quality of magnetic resonance image. The adjusted model accounted for 20% of the overall variance, $F(12, 4597) = 97.975, p < 0.0005$, adj. $R^2 = 0.20$ in image quality. All covariates were entered in the adjusted model; however, only gender, age, and body area of the MRI Exam variables added significantly to the model, $p < 0.0005$.

Hypothesis #2 was not supported as written. Results of the regression model indicate that the Intervention group as compared to the CCLS Preparation for Sedation/GA group had a statistically significant lower quality of magnetic resonance images. As discussed with the results of Hypothesis #1, in the Intervention group, there were only three patients (2.3%) out of 132 who had unacceptable magnetic image quality and one patient (< 1.0%) who was unable to complete the scan. While statistically the Intervention group’s magnetic image quality was lower than the CCLS Preparation for Sedation/GA group, there is appreciable clinical importance in that 95.5% of the magnetic resonance images in the Intervention group were deemed of acceptable-to-excellent quality. Regression coefficients, standard errors, and significant values for unadjusted (Model 1) and adjusted (Model 2) can be found in Table 19 below.
Table 19 - Summary of Multiple Linear Regression Analysis (Constant = Study Group 2, CCLS Preparation for Sedation/GA)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model 1 (Unadjusted)</th>
<th>Model 2 (Adjusted)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td>SEβ</td>
</tr>
<tr>
<td>Study Group 1 (Intervention)</td>
<td>.447</td>
<td>.064</td>
</tr>
<tr>
<td>Gender Female</td>
<td>-.087</td>
<td>.019</td>
</tr>
<tr>
<td>Age</td>
<td>-.042</td>
<td>.003</td>
</tr>
<tr>
<td>*MRI (Thorax, Pelvis, Upper Extremity)</td>
<td>.466</td>
<td>.022</td>
</tr>
<tr>
<td>*MRI (Lower Extremity)</td>
<td>-.464</td>
<td>.043</td>
</tr>
<tr>
<td>Number of MRI Scans per Encounter</td>
<td>-.004</td>
<td>.009</td>
</tr>
<tr>
<td>*Diagnosis Sickle Cell</td>
<td>-.022</td>
<td>.129</td>
</tr>
<tr>
<td>*Diagnosis (Autistic, Attention Defect Disorder)</td>
<td>.140</td>
<td>.146</td>
</tr>
<tr>
<td>*Diagnosis (Epilepsy)</td>
<td>-.098</td>
<td>.064</td>
</tr>
<tr>
<td>*Prior Experience</td>
<td>.057</td>
<td>.043</td>
</tr>
</tbody>
</table>

Dependent Variable, Quality of MRI Scan
Sample Size for Multiple Linear Regression, N = 4610
*Categorical variables that are dummy coded

**Hypothesis #3**

Children who received the PFC-NP intervention will have better magnetic resonance images as compared to children who opted for no preparation and no sedation/GA and did not receive the intervention.

**Analysis of Covariance (ANCOVA)**

An ANCOVA was conducted to investigate Hypothesis #3 to determine the difference in scores between the PFC-NP Intervention and the No Preparation & No Sedation/GA groups for quality of magnetic resonance image. Assumptions of ANCOVA were analyzed. Standardized residuals were normally distributed as assessed by the Normal P-P Plot of Regression of Standardized Residuals. There was a linear relationship between covariates and quality of magnetic resonance image as assessed by visual inspection of a scatterplot. The assumption of Independence of Covariates and Treatment effects was violated as the covariates differed across the four groups (p < 0.0005). Additionally, there was no homogeneity of regression slopes as the Levene’s Test of Equality of Error Variances
was statistically significant, $F(3, 4606) = 13.876, p < 0.0005$, and as such the null hypothesis was accepted, indicating that the test for homogeneity was violated. Although according to statistical references this is a common finding in large sample sizes and not a cause of concern, ANCOVA results are reported and additional analyses were conducted using the nonparametric test, Kruskal-Wallis, and followed by multiple linear regression unadjusted model and adjusted model controlling for covariates (Nordstokke & Zumbo, 2007).

An ANCOVA was conducted unadjusted and adjusted for covariates. An unadjusted ANCOVA statistic revealed that there was a statistically significant difference in the mean scores for the quality of magnetic resonance images between the groups $F(3, 4606) = 31.593, p < 0.0005$, partial $\eta^2 = 0.020$. Post hoc analysis was performed with a Bonferroni adjustment. The quality of magnetic resonance images were lower in the PFC-NP Intervention group ($M = 2.297, SE = 0.050$) compared to the No Preparation and No Sedation/GA group ($M = 2.097, SE = 0.013$), with a statistically significant mean difference of $M_{\text{diff}} = 0.20, 95\% \text{ CI } [0.06, 0.34], p = 0.001$.

After adjustment for all covariates, an ANCOVA statistic revealed that there was a statistically significant difference in the mean scores for the quality of magnetic resonance images between the groups $F(3, 4597) = 66.676, p < 0.0005$, partial $\eta^2 = 0.042$. However, a post hoc analysis using a Bonferroni adjustment revealed no statistical difference in means for the quality of scans between PFC-NP Intervention group ($M = 2.297, SE = 0.050$) compared to the No Preparation and No Sedation/GA group ($M = 2.097, SE = 0.013$), with a mean difference of $M_{\text{diff}} = 0.074, 95\% \text{ CI } [-0.53, 0.201], p = 0.741$. 
Hypothesis #3 was not supported. Although the unadjusted model revealed a statistical difference in the quality of magnetic resonance images, when covariates were entered into the model, there was no statistical difference in mean scores (see Table 20).

Table 20 - Adjusted and Unadjusted Means for Quality of Magnetic Resonance Image Study Groups 1 & 3 with Age, Gender, Diagnosis, Prior Experience, Body Area of Exam, Number of Magnetic Resonance Images per Encounter as Covariates

<table>
<thead>
<tr>
<th></th>
<th>Unadjusted</th>
<th>Adjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$N$</td>
<td>$M$</td>
</tr>
<tr>
<td>Study Group 1 (Intervention)</td>
<td>202</td>
<td>2.30</td>
</tr>
<tr>
<td>Study Group 3 (No Prep &amp; No Sedation/GA)</td>
<td>2936</td>
<td>2.10</td>
</tr>
</tbody>
</table>

Note: $N = \text{Number of MRIs}$, $M = \text{Mean}$, $SD = \text{Standard Deviation}$, $SE = \text{Standard Error}$

Kruskal-Wallis

Since the Levene’s Test for Homogeneity was found to be statistically significant, the nonparametric test Kruskal-Wallis was also conducted using an unadjusted model to investigate Hypothesis #3. The Kruskal-Wallis test confirmed a statistically significant difference in quality of magnetic resonance images between study groups $\chi^2(3) = 88.152, p < 0.0005$, with the PFC-NP Intervention group having the highest mean rank, indicating significantly lower quality images (see Table 21).

In this model, Hypothesis #3 was not supported as the quality of magnetic resonance image unadjusted mean rank was significantly higher in the PFC-NP Intervention group compared to the No Preparation and No Sedation/GA group. However, caution must be taken when interpreting these results, as an adjusted model could not be tested to confirm the aforementioned results.

Table 21 - Unadjusted Quality of Magnetic Resonance Image Study Group Mean Ranks

<table>
<thead>
<tr>
<th></th>
<th>Unadjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$N$</td>
</tr>
<tr>
<td>Study Group 1 (Intervention)</td>
<td>202</td>
</tr>
<tr>
<td>Study Group 3 (No Prep &amp; No Sedation/GA)</td>
<td>2936</td>
</tr>
</tbody>
</table>
Multiple Linear Regression

The appropriateness of using a multiple linear regression to determine the effect of the intervention on the dependent variable (quality of magnetic resonance image) was presented previously. An unadjusted and adjusted multiple linear regression were estimated to evaluate Hypothesis #3.

First, the assumptions of multiple linear regression were analyzed. The assumption of normality was met, as assessed by P-P Plot. There was a linear relationship between covariates and quality of magnetic resonance image as assessed by visual inspection of a scatterplot. Independence of residuals was confirmed, as assessed by a Durbin-Watson statistic of 1.580 (unadjusted) and 1.602 (adjusted). The assumption of homoscedasticity was met, as assessed by visual inspection of a plot of studentized residuals versus unstandardized predicted values. There was no evidence of multicollinearity, as no tolerance values were greater than 0.1 or VIF greater than 10. There were no influential data points worth checking for validity as there were no values for Cook's distance above 1.

The unadjusted (Model 1) multiple regression model indicate that the Intervention group had lower quality of magnetic resonance images as compared to the No Preparation and No Sedation/GA group, with a 0.20 per unit increase on the dependent variable, quality of magnetic resonance image. The quality of magnetic resonance image was statistically significantly lower in the intervention group, and the model only accounted for 2% of the overall variance, $F(3, 4606) = 31.593, p < 0.0005$, adj. $R^2 = 0.020$.

After adjustment for covariates, the adjusted model (Model 2) became non-statistically significant. Although the Intervention group had lower quality of magnetic resonance images as compared to the No Preparation and No Sedation/GA group, when
controlling for covariates, the 0.074 per unit increase on the dependent variable, quality of magnetic resonance image, became non-statistically significant, \( p = 0.123 \). Only gender, age, and body area of the MRI Exam variables added statistical significance to the prediction, \( p < 0.0005 \).

Multiple regression confirmed that when controlling for covariates, although the quality of magnetic resonance images for the Intervention group was lower than the No Preparation and No Sedation/GA group, the difference was not significant. Thus, Hypothesis #3 was not supported. In this analysis, Hypothesis #3 regression coefficients, standard errors, and significant values for unadjusted (Model 1) and adjusted (Model 2) can be found in Table 22 below.

Table 22 - Summary of Multiple Linear Regression Analysis (Constant = Study Group 3, No Preparation & No Sedation/GA)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model 1 (Unadjusted)</th>
<th>Model 2 (Adjusted)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td>SEβ</td>
</tr>
<tr>
<td>Study Group 1 (Intervention)</td>
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<td>.052</td>
</tr>
<tr>
<td>Gender Female</td>
<td>-0.087</td>
<td>.019</td>
</tr>
<tr>
<td>Age</td>
<td>-0.042</td>
<td>.003</td>
</tr>
<tr>
<td>*MRI (Thorax, Pelvis, Upper Extremity)</td>
<td>.466</td>
<td>.022</td>
</tr>
<tr>
<td>*MRI (Lower Extremity)</td>
<td>-0.464</td>
<td>.043</td>
</tr>
<tr>
<td>Number of MRIs per Encounter</td>
<td>-0.004</td>
<td>.009</td>
</tr>
<tr>
<td>*Diagnosis Sickle Cell</td>
<td>-0.022</td>
<td>.129</td>
</tr>
<tr>
<td>*Diagnosis (Autistic, Attention Defect Disorder)</td>
<td>.140</td>
<td>.146</td>
</tr>
<tr>
<td>*Diagnosis (Epilepsy)</td>
<td>-0.098</td>
<td>.064</td>
</tr>
<tr>
<td>*Prior Experience</td>
<td>.057</td>
<td>.043</td>
</tr>
</tbody>
</table>

Dependent Variable, Quality of MRI
Sample Size for Multiple Linear Regression, N = 4610
*Categorical variables that are dummy coded

Hypothesis #4

The PFC-NP intervention reduces hospital costs associated with MRI as compared to those who received (a) standard care sedation/GA and those who received (b) CCLS preparation for sedation/GA or (c) no preparation and no sedation/GA.
Multiple Linear Regression

A multiple linear regression was estimated to investigate Hypothesis #4a. First, assumptions of multiple linear regression were evaluated. The assumption of normality was met, as assessed by P-P Plot. There was a linear relationship between covariates and hospital costs, as assessed by visual inspection of a scatterplot. There was independence of residuals confirmed, as assessed by a Durbin-Watson statistic of 1.863 (unadjusted) and 1.956 (adjusted). The assumption of homoscedasticity was met, as assessed by visual inspection of a plot of studentized residuals versus unstandardized predicted values. There was no evidence of multicollinearity as no tolerance values were greater than 0.1 or VIF greater than 10. There were no influential data points worth checking for validity as there were no values for Cook's distance above 1.

Both the unadjusted (Model 1) and adjusted (Model 2) multiple regression models indicate that the Intervention group had lower healthcare costs as compared to the Standard Care Sedation/GA group, with a -1848.90 per unit decrease on healthcare costs. The adjusted model accounted for 67% of the overall variance in healthcare costs, $F(12, 3237) = 551.248$, $p < 0.0005$, adj. $R^2 = 0.670$. All covariates were entered in the adjusted model. Only body area of the MRI exam (lower extremity as compared to all others), number of magnetic resonance images per encounter, and diagnosis of epilepsy (as compared to all others) variables added significantly to the model, $p < 0.0005$.

Hypothesis #4a was supported as written in that results of the regression model indicate that the healthcare costs associated with the Intervention group as compared to the Standard Care Sedation/GA group were significantly lower ($1848.90 lower) per encounter. Interpretation of these results supports the use of the intervention as a viable option to reduce
healthcare costs associated with standard care sedation/GA for children needing outpatient
MRI. Regression coefficients, standard errors, and significant values for unadjusted (Model
1) and adjusted (Model 2) can be found in Table 23 below.

Table 23 - Summary of Multiple Linear Regression Analysis (Constant = Study Group 4,
Standard Care Sedation/GA)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model 1 (Unadjusted)</th>
<th></th>
<th>Model 2 (Adjusted)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td>SEβ</td>
<td>β</td>
<td>p</td>
</tr>
<tr>
<td>Study Group 1 (Intervention)</td>
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<td>74.585</td>
<td>-296</td>
<td>.000</td>
</tr>
<tr>
<td>Gender Female</td>
<td>-31.214</td>
<td>24.377</td>
<td>-013</td>
<td>.200</td>
</tr>
<tr>
<td>Age</td>
<td>.729</td>
<td>3.713</td>
<td>.002</td>
<td>.844</td>
</tr>
<tr>
<td>*MRI (Thorax, Pelvis, Upper Extremity)</td>
<td>-44.724</td>
<td>27.562</td>
<td>-.018</td>
<td>.105</td>
</tr>
<tr>
<td>*MRI (Lower Extremity)</td>
<td>107.500</td>
<td>50.106</td>
<td>.023</td>
<td>.032</td>
</tr>
<tr>
<td>Number of MRIs per Encounter</td>
<td>491.273</td>
<td>16.045</td>
<td>.329</td>
<td>.000</td>
</tr>
<tr>
<td>*Diagnosis Sickle Cell</td>
<td>-372.650</td>
<td>200.561</td>
<td>-.019</td>
<td>.063</td>
</tr>
<tr>
<td>*Diagnosis (Autistic, Attention Defect Disorder)</td>
<td>-250.744</td>
<td>173.768</td>
<td>-.015</td>
<td>.149</td>
</tr>
<tr>
<td>*Diagnosis (Epilepsy)</td>
<td>-195.408</td>
<td>72.437</td>
<td>-.028</td>
<td>.007</td>
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<tr>
<td>*Prior Experience</td>
<td>60.881</td>
<td>33.217</td>
<td>.019</td>
<td>.067</td>
</tr>
</tbody>
</table>

Dependent Variable, Quality of MRI
Sample Size for Multiple Linear Regression, N = 3250
*Categorical variables that are dummy coded

A multiple linear regression was estimated to investigate Hypothesis #4b.

Assumptions of multiple linear regression were analyzed and were met as aforementioned.

Both the unadjusted (Model 1) and adjusted (Model 2) multiple regression models indicate
that the Intervention group had significantly lower healthcare costs as compared to the CCLS
Prep for Sedation/GA group, realizing a -1663.032 per unit decrease on the dependent
variable, healthcare cost. The adjusted model accounted for 67% of the overall variance in
healthcare costs, \( F(11, 3238) = 601.537, p < 0.0005, \) adj. \( R^2 = 0.670. \) All covariates were
entered in the adjusted model. Only body area of the MRI exam (lower extremity as
compared to all others), number of magnetic resonance images per encounter, and diagnosis
of epilepsy (as compared to all others) variables added significantly to the model, \( p < 0.0005. \)
Hypothesis #4b was supported as results of the regression model indicate that healthcare costs associated with the Intervention group as compared to the Standard Care Sedation/GA group were significantly lower ($1663.03 lower) per encounter. Interpretation of these results supports the use of the intervention as a viable option to reduce healthcare costs associated with CCLS prep for sedation/GA for children needing outpatient MRI. Regression coefficients, standard errors, and significant values for unadjusted (Model 1) and adjusted (Model 2) can be found in Table 24 below.

Table 24 - Summary of Multiple Linear Regression Analysis (Constant = Study Group 2, CCLS Preparation for Sedation/GA)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model 1 (Unadjusted)</th>
<th>Model 2 (Adjusted)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td>SEβ</td>
</tr>
<tr>
<td>Study Group 1 (Intervention)</td>
<td>-1669.309</td>
<td>86.981</td>
</tr>
<tr>
<td>Gender Female</td>
<td>-31.146</td>
<td>24.371</td>
</tr>
<tr>
<td>Age</td>
<td>.729</td>
<td>3.713</td>
</tr>
<tr>
<td>*MRI (Thorax, Pelvis, Upper Extremity)</td>
<td>-44.516</td>
<td>27.538</td>
</tr>
<tr>
<td>*MRI (Lower Extremity)</td>
<td>107.452</td>
<td>50.098</td>
</tr>
<tr>
<td>Number of MRIs per Encounter</td>
<td>491.335</td>
<td>16.039</td>
</tr>
<tr>
<td>*Diagnosis Sickle Cell</td>
<td>-373.059</td>
<td>200.521</td>
</tr>
<tr>
<td>*Diagnosis (Autistic, Attention Defect Disorder)</td>
<td>-249.969</td>
<td>173.698</td>
</tr>
<tr>
<td>*Diagnosis (Epilepsy)</td>
<td>-195.037</td>
<td>72.402</td>
</tr>
<tr>
<td>*Prior Experience</td>
<td>61.019</td>
<td>33.205</td>
</tr>
</tbody>
</table>

Dependent Variable, Quality of MRIs
Sample Size for Multiple Linear Regression, N = 3250
*Categorical variables that are dummy coded

A multiple linear regression was estimated to investigate Hypothesis #4c. Assumptions of multiple linear regression were evaluated. The assumption of normality was met, as assessed by P-P Plot. There was a linear relationship between covariates and hospital costs, as assessed by visual inspection of a scatterplot. Independence of residuals was confirmed, as assessed by a Durbin-Watson statistic of 1.863 (unadjusted) and 1.956 (adjusted). The assumption of homoscedasticity was met, as assessed by visual inspection of a plot of studentized residuals versus unstandardized predicted values. There was no
evidence of multicollinearity as no tolerance values were greater than 0.1 or VIF greater than 10. There were no influential data points worth checking for validity as there were no values for Cook's distance above 1.

The unadjusted (Model 1) multiple regression model indicates that the Intervention group had statistically significantly higher costs compared to the No Preparation and No Sedation group, a $184.42 per encounter increase, accounting for 56.3% of the variance. The adjusted model indicated no significant difference in healthcare costs, \( p = 0.055 \).

Hypothesis #4b was not supported as a result of the adjusted regression model. This multiple linear regression analysis revealed a statistically significant unadjusted increase in cost per encounter. However, when covariates were accounted for in the model, the adjusted model indicated a non-statistically significant increase of $121.20 in healthcare cost per encounter associated with the Intervention group as compared to the No Preparation and Sedation/GA group. Regression coefficients, standard errors, and significant values for unadjusted (Model 1) and adjusted (Model 2) can be found in Table 25 below.

Table 25 - Summary of Multiple Linear Regression Analysis (Constant = Study Group 3, No Preparation and No Sedation/GA)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model 1 (Unadjusted)</th>
<th>Model 2 (Adjusted)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>( B )</td>
<td>( SE_\beta )</td>
</tr>
<tr>
<td>Study Group 1 (Intervention)</td>
<td>184.422</td>
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</tr>
<tr>
<td>Gender Female</td>
<td>-31.214</td>
<td>24.377</td>
</tr>
<tr>
<td>Age</td>
<td>.729</td>
<td>.713</td>
</tr>
<tr>
<td>*MRI (Thorax, Pelvis, Upper Extremity)</td>
<td>-44.724</td>
<td>27.562</td>
</tr>
<tr>
<td>*MRI (Lower Extremity)</td>
<td>107.500</td>
<td>50.106</td>
</tr>
<tr>
<td>Number of MRIs per Encounter</td>
<td>491.273</td>
<td>16.045</td>
</tr>
<tr>
<td>*Diagnosis Sickle Cell</td>
<td>-372.650</td>
<td>200.561</td>
</tr>
<tr>
<td>*Diagnosis (Autistic, Attention Defect Disorder)</td>
<td>-250.744</td>
<td>173.768</td>
</tr>
<tr>
<td>*Diagnosis (Epilepsy)</td>
<td>-195.408</td>
<td>72.437</td>
</tr>
<tr>
<td>*Prior Experience</td>
<td>60.881</td>
<td>33.217</td>
</tr>
</tbody>
</table>

Dependent Variable, Quality of MRI
Sample Size for Multiple Linear Regression, \( N = 3250 \)
*Categorical variables that are dummy coded
Hypothesis #5

Children who received the PFC-NP intervention have reduced procedural turnaround time as compared to patients who received standard care sedation/GA.

Multiple Linear Regression

A multiple linear regression was estimated to investigate Hypothesis #5. First, assumptions of multiple linear regression were evaluated. The assumption of normality was met, as assessed by P-P Plot. There was a linear relationship between covariates and procedural time, as assessed by visual inspection of a scatterplot. Independence of residuals was confirmed, as assessed by a Durbin-Watson statistic of 1.881 (unadjusted) and 1.913 (adjusted). The assumption of homoscedasticity was met, as assessed by visual inspection of a plot of studentized residuals versus unstandardized predicted values. There was no evidence of multicollinearity as no tolerance values were greater than 0.1 or VIF greater than 10. There were no influential data points worth checking for validity as there were no values for Cook's distance above 1.

Both the unadjusted (Model 1) and adjusted (Model 2) multiple regression models indicate that the Intervention group had shorter procedural times as compared to the Standard Care Sedation/GA group. The unadjusted model estimated a 32.86-minutes-per-unit decrease, and the adjusted model estimated a 31.83-minutes-per-unit decrease on the dependent variable, procedural time. The adjusted model accounted for 14% of the overall variance, $F(12, 3234) = 45.007, p < 0.0005$, adj. $R^2 = 0.140$. All covariates were entered in the adjusted model; however, only body area of the MRI exam (lower extremity as compared to all others), number of magnetic resonance images per encounter, diagnosis of epilepsy (as
compared to all others), and prior experience variables added significantly to the model, \( p < 0.0005 \).

Hypothesis #5 was supported in that results of the regression model indicate that the procedural time with the Intervention group as compared to the Standard Care Sedation/GA group was significantly shorter, -31.83 minutes per encounter. Interpretation of these results supports the use of the PFC-NP intervention as a viable option to reduce procedural times associated with standard care sedation/GA for children needing outpatient MRI. Regression coefficients, standard errors, and significant values for unadjusted (Model 1) and adjusted (Model 2) can be found in Table 26 below.

Table 26 - Summary of Multiple Linear Regression Analysis (Constant = Study Group 4, Standard Care Sedation/GA)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model 1 (Unadjusted)</th>
<th>Model 2 (Adjusted)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>( B )</td>
<td>SE( \beta )</td>
</tr>
<tr>
<td>Study Group 1 (Intervention)</td>
<td>32.860</td>
<td>4.547</td>
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<tr>
<td>Gender Female</td>
<td>.077</td>
<td>1.640</td>
</tr>
<tr>
<td>Age</td>
<td>-.123</td>
<td>.250</td>
</tr>
<tr>
<td>*MRI (Thorax, Pelvis, Upper Extremity)</td>
<td>.424</td>
<td>1.855</td>
</tr>
<tr>
<td>*MRI (Lower Extremity)</td>
<td>-9.872</td>
<td>3.369</td>
</tr>
<tr>
<td>Number of MRIs per Encounter</td>
<td>15.695</td>
<td>1.079</td>
</tr>
<tr>
<td>*Diagnosis Sickle Cell</td>
<td>-16.577</td>
<td>13.485</td>
</tr>
<tr>
<td>*Diagnosis (Autistic, Attention Defect Disorder)</td>
<td>3.386</td>
<td>11.683</td>
</tr>
<tr>
<td>*Diagnosis (Epilepsy)</td>
<td>-27.432</td>
<td>4.807</td>
</tr>
<tr>
<td>*Prior Experience</td>
<td>-6.446</td>
<td>2.236</td>
</tr>
</tbody>
</table>

Dependent Variable, Quality of MRIs
Sample Size for Multiple Linear Regression, N = 3247
* Categorical variables that are dummy coded

**Hypothesis #6**

Patients who received the PFC-NP intervention will have reduced procedural turnaround time as compared to patients who received CCLS preparation for sedation/GA.
Multiple Linear Regression

A multiple linear regression was estimated to answer Hypothesis #6. First, assumptions of multiple linear regression were evaluated. The assumption of normality was met, as assessed by P-P Plot. There was a linear relationship between covariates and procedural time, as assessed by visual inspection of a scatterplot. Independence of residuals was confirmed, as assessed by a Durbin-Watson statistic of 1.881 (unadjusted) and 1.913 (adjusted). The assumption of homoscedasticity was met, as assessed by visual inspection of a plot of studentized residuals versus unstandardized predicted values. There was no evidence of multicollinearity as no tolerance values were greater than 0.1 or VIF greater than 10. There were no influential data points worth checking for validity as there were no values for Cook's distance above 1.

Both the unadjusted (Model 1) and adjusted (Model 2) multiple regression models indicate that the Intervention group had significantly shorter procedural times as compared to the CCLS Preparation for Sedation/GA group. The unadjusted model estimated a 25.90-minutes-per-unit decrease, and the adjusted model estimated a 24.74-minutes-per-unit decrease on the dependent variable, procedural time. The adjusted model accounted for 14% of the overall variance, $F(12, 3234) = 45.007, p < 0.0005$, adj. $R^2 = 0.140$. All covariates were entered in the adjusted model; however, only body area of the MRI exam (lower extremity as compared to all others), number of magnetic resonance images per encounter, diagnosis of epilepsy (as compared to all others), and prior experience variables added statistically significantly to the model, $p < 0.0005$.

Hypothesis #6 was supported as statistical significance was reached and results of the regression model indicated that the procedural time with the Intervention group as compared
to the CCLS Preparation for Sedation/GA group was 24.74 minutes shorter per encounter.

Interpretation of these results supports the use of the intervention as a viable option to reduce procedural times associated with CCLS preparation for sedation/GA for children needing outpatient MRI. Regression coefficients, standard errors, and significant values for unadjusted (Model 1) and adjusted (Model 2) can be found in Table 27 below.

Table 27 - Summary of Multiple Linear Regression Analysis (Constant = Study Group 2, CCLS Preparation for Sedation/GA)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model 1 (Unadjusted)</th>
<th>Model 2 (Adjusted)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td>SEβ</td>
</tr>
<tr>
<td>Study Group 1 (Intervention)</td>
<td>25.897</td>
<td>5.302</td>
</tr>
<tr>
<td>Gender Female</td>
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<td>1.640</td>
</tr>
<tr>
<td>Age</td>
<td>-.123</td>
<td>.250</td>
</tr>
<tr>
<td>*MRI (Thorax, Pelvis, Upper Extremity)</td>
<td>.424</td>
<td>1.855</td>
</tr>
<tr>
<td>*MRI (Lower Extremity)</td>
<td>-9.872</td>
<td>3.369</td>
</tr>
<tr>
<td>Number of MRIs per Encounter</td>
<td>15.695</td>
<td>1.079</td>
</tr>
<tr>
<td>*Diagnosis Sickle Cell</td>
<td>-16.577</td>
<td>13.485</td>
</tr>
<tr>
<td>*Diagnosis (Autistic, Attention Defect Disorder)</td>
<td>3.386</td>
<td>11.683</td>
</tr>
<tr>
<td>*Diagnosis (Epilepsy)</td>
<td>-27.432</td>
<td>4.807</td>
</tr>
<tr>
<td>*Prior Experience</td>
<td>-6.446</td>
<td>2.236</td>
</tr>
</tbody>
</table>

Dependent Variable, Quality of MRI
Sample Size for Multiple Linear Regression, N = 3247
*Categorical variables that are dummy coded

**Hypothesis #7**

Patients who received the PFC-NP intervention have reduced procedural turnaround time as compared to patients who opted to receive no preparation and no sedation/GA.

**Multiple Linear Regression**

A multiple linear regression was estimated to test Hypothesis #7. Assumptions of multiple linear regression were evaluated. The assumption of normality was met, as assessed by P-P Plot. There was a linear relationship between covariates and procedural time, as assessed by visual inspection of a scatterplot. Independence of residuals was confirmed, as assessed by a Durbin-Watson statistic of 1.881 (unadjusted) and 1.913 (adjusted). The
assumption of homoscedasticity was met, as assessed by visual inspection of a plot of
studentized residuals versus unstandardized predicted values. There was no evidence of
multicollinearity as no tolerance values were greater than 0.1 or VIF greater than 10. There
were no influential data points worth checking for validity as there were no values for Cook's
distance above 1.

Both the unadjusted (Model 1) and adjusted (Model 2) multiple regression models did
not indicate that the Intervention group had shorter procedural times as compared to the No
Preparation and No Sedation/GA group. The Intervention group did realize a 3.08-minute-
per-unit decrease on the dependent variable, procedural time; however, that decrease was not
statistically significant. The adjusted model accounted for 14% of the overall variance, $F(12,
3234) = 45.007, p < 0.0005$, adj. $R^2 = 0.140$. All correlated predictor variables were entered
in the adjusted model, but only body area of the MRI exam (lower extremity as compared to
all others), number of magnetic resonance images per encounter, diagnosis of epilepsy (as
compared to all others), and prior experience variables added statistically significantly to the
prediction, $p < 0.0005$.

Hypothesis #7 was not supported as no significant difference in procedural time was
found. Results of the regression model indicate that the procedural time with the Intervention
group as compared to the No Preparation and No Sedation/GA group was 3.08 minutes
shorter per encounter, but this difference was not found to be statistically significant.
Interpretation of these results suggest that the use of the intervention is another option for
children needing outpatient MRI as it does not increase the procedural time as compared to
patients with no preparation and no sedation. However, further evaluation of the
intervention’s effects on reducing anxiety or distress of the child requiring outpatient MRI
may provide more information about the intervention’s efficacy in reducing procedural time. Regression coefficients, standard errors, and significant values for unadjusted (Model 1) and adjusted (Model 2) can be found in Table 28 below.

Table 28 - Summary of Multiple Linear Regression Analysis (Constant = Study Group 3, No Preparation and No Sedation/GA)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model 1 (Unadjusted)</th>
<th>Model 2 (Adjusted)</th>
</tr>
</thead>
<tbody>
<tr>
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<td>B</td>
<td>SEβ</td>
</tr>
<tr>
<td>Study Group 1 (Intervention)</td>
<td>4.593</td>
<td>4.336</td>
</tr>
<tr>
<td>Gender Female</td>
<td>.077</td>
<td>1.640</td>
</tr>
<tr>
<td>Age</td>
<td>-.123</td>
<td>.250</td>
</tr>
<tr>
<td>*MRI (Thorax, Pelvis, Upper Extremity)</td>
<td>.424</td>
<td>1.855</td>
</tr>
<tr>
<td>*MRI (Lower Extremity)</td>
<td>-9.872</td>
<td>3.369</td>
</tr>
<tr>
<td>Number of MRIs per Encounter</td>
<td>15.695</td>
<td>1.079</td>
</tr>
<tr>
<td>*Diagnosis Sick Cell</td>
<td>-16.577</td>
<td>13.485</td>
</tr>
<tr>
<td>*Diagnosis (Autistic, Attention Defect Disorder)</td>
<td>3.386</td>
<td>11.683</td>
</tr>
<tr>
<td>*Diagnosis (Epilepsy)</td>
<td>-27.432</td>
<td>4.807</td>
</tr>
<tr>
<td>*Prior Experience</td>
<td>-6.446</td>
<td>2.236</td>
</tr>
</tbody>
</table>

Dependent Variable, Quality of MRI
Sample Size for Multiple Linear Regression, N = 3247
*Categorical variables that are dummy coded

Summary

Chapter IV provided results of the data analysis. The effectiveness of the PFC-NP intervention in reducing healthcare costs, improving procedural time, and ensuring good quality of magnetic resonance image as compared to three other groups was analyzed using multiple linear regression. In summary, Hypotheses #s1, 2, 3, 4c, and 7 were not supported. However, Hypotheses #s4a, 4b, 5, and 6 were supported.

After analysis of unadjusted and adjusted multiple linear regression models, the PFC-NP Intervention group as compared to Standard Care Sedation/GA group was found to have statistically significantly lower quality of magnetic resonance images with a 0.418-per-unit increase in quality ratings, lower healthcare costs by $1,848.90 per encounter, and shorter procedural times by 31.83 minutes.
When comparing the PFC-NP Intervention group to the CCLS Preparation for Sedation/GA group, the Intervention group had lower quality of magnetic resonance images with a 0.492-per-unit increase in quality ratings, lower healthcare cost by $1663.03 per encounter, and shorter procedural times by 24.74 minutes.

Comparing the PFC-NP Intervention group to the No Preparation and No Sedation/GA group on quality of scan, healthcare costs, and procedural time revealed no statistical difference, suggesting that the PFC-NP intervention is an alternative option.
CHAPTER V

DISCUSSION AND CONCLUSIONS

The purpose of Chapter V is to discuss findings of the study, application of those findings to the theoretical framework, potential limitations to the study, and implications of this study for policy, practice, and further and patient- and family-centered research.

Discussion of Study Findings

The primary rationale for the use of sedation/general anesthesia (GA) in magnetic resonance imaging (MRI) is to ensure that the child remains still for the duration of time while the scan is being conducted. However, the use of sedation/GA is not benign and has real physiological and biological side effects for children. The safety risks and side effects of anesthetic agents used for children requiring MRI include emergence delirium, respiratory depression, oxygenation, nausea, vomiting, agitation, and cardiovascular bradycardia. Of growing concern is the emerging literature exploring the effects of sedation/GA on the developing brain. The concern over these safety risks provides support to explore alternative options to sedation/GA for outpatient MRI for children. While there are many strategies being explored to lessen the side effects of anesthetic drug used for children undergoing MRI, the risks associated with sedation/GA remain.

The purpose of this study was to address the gap in the empirical literature by testing the theoretically supported relationships between a patient- and family-centered Non-Sedation/GA preparation (PFC-NP) intervention for pediatric MRI and its effects on (1) magnetic resonance image quality, (2) hospital costs, and (3) operational efficiency, described as procedural time.
Partnering with patients and families can lead to the reduction of the use of sedation/GA in children needing an outpatient MRI. The PFC-NP intervention is a new and innovative approach to care delivery and responds to the national call to action to embrace a patient-centered approach to care. The findings of this study provide support for the theoretical relationship between patient/family partnership and a safer, timelier, and more cost effective option compared to sedation/GA for children needing an outpatient MRI.

The PFC-NP intervention used a structured methodology to create an individualized patient-centered plan to prepare the child for magnetic resonance imaging. This methodology drew upon the personal knowledge of the child/family for the development of a personalized preparation plan to maximize the true potential of the child in successfully completing the MRI without sedation/GA. Individualized preparation and support during the MRI led to successful completion of the MRI, defined as magnetic resonance images that are deemed interpretable by the radiologist. This quasi-experimental study analyzed data from all children chronologically 3 through 17 years of age who underwent an outpatient MRI from January 2015 through September 2016 in an urban pediatric academic medical center in the United States. There were seven hypotheses tested in this study, all of which compared the outcome variables (1) quality of magnetic resonance image, (2) the healthcare cost, and (3) procedural times between the PFC-NP intervention and three different comparison groups.

**Hypothesis #1**

There is no difference in quality of magnetic resonance images between children who received the PFC-NP intervention compared to those who received standard care sedation/GA. This hypothesis was initially developed to ensure that there was no difference in the quality of magnetic resonance images between the Intervention group and the Standard
Care Sedation/GA group so that, at the very least, the two groups would have the same magnetic resonance image quality. This hypothesis was not supported as stated. The results of the regression model indicate that the PFC-NP Intervention group had significantly lower magnetic resonance image quality compared to the Standard Care Sedation/GA group. While statistically this hypothesis was not supported, these results have clinical relevance. In the Intervention group, there were only three patients (2.3%) out of 132 who had unacceptable magnetic image quality and one patient (<1.0%) who was unable to complete the scan. There is appreciable clinical importance in that 95.5% of the magnetic resonance images in the intervention group were deemed of acceptable to excellent quality for interpretation by a radiologist. This result suggests that if the child is prepared for an MRI in a way that is individualized to the child’s specific physiologic and developmental needs, the child is able to listen to directions and remain still for the MRI. Interpretation of these results supports the use of the intervention as a viable option over standard care sedation/GA for children needing outpatient MRI.

**Hypothesis #2**

There is no difference in quality of magnetic resonance images between children who received the PFC-NP intervention compared to those who received CCLS preparation for sedation/GA. As mentioned before, this hypothesis was developed to ensure that there were no differences in magnetic resonance image quality between groups. Hypothesis #2 was not supported as stated. Results indicate that the Intervention group had a significantly lower magnetic resonance image quality compared to the CCLS Prep for Sedation/GA group. As with Hypothesis #1, 95.5% of the magnetic resonance images in the Intervention group were deemed of acceptable to excellent quality. While there was a statistical difference found
between groups, clinically, these findings suggest that if the child is prepared for an MRI in a way that is individualized to the child’s specific physiologic and developmental needs, the child is able to listen to directions and remain still for the MRI. Interpretation of the results supports the use of the intervention as a viable option over CCLS preparation for sedation/GA for children needing outpatient MRI.

**Hypothesis #3**

Children who received the PFC-NP intervention will have better magnetic resonance images as compared to children who opted for no preparation and no sedation/GA and did not receive the intervention. The adjusted model indicated no statistical difference in the quality of magnetic resonance images for the Intervention group as compared to the No Preparation and No Sedation/GA group, and as such, the hypothesis was not supported. This result suggests that the PFC-NP intervention may be an alternative option for children in certain circumstances, but further research is needed.

**Hypothesis #4**

The PFC-NP intervention reduces hospital costs associated with MRI as compared to those who received (a) standard care sedation/GA and those who received (b) CCLS preparation for sedation/GA. Hypothesis #4a was supported as stated as statistical significance was reached. The results of the regression model indicated that the adjusted healthcare costs associated with the Intervention group were $1848.90 lower per encounter as compared to the Standard Care Sedation/GA group. Interpretation of these results supports the use of the intervention as a viable option in reducing healthcare costs associated with standard care sedation/GA for children needing outpatient MRI.
Additionally, Hypothesis #4b was supported as stated as statistical significance was reached. The results of the regression model indicated that healthcare costs associated with the Intervention group were $1663.03 lower per encounter as compared to the Standard Care Sedation/GA group. However, Hypothesis #4c was not supported as stated as statistical significance was not reached. Interpretation of these results supports the use of the intervention as a viable option to reduce healthcare costs associated with CCLS prep for sedation/GA for children needing outpatient MRI.

**Hypothesis #5**

Children who received the PFC-NP intervention have reduced procedural turnaround time as compared to patients who received standard care sedation/GA. Hypothesis #5 was supported as stated. The results of the regression model indicate that the Intervention group has a statistically significantly shorter procedural time as compared to the Standard Care Sedation/GA group. Interpretation of these results supports the use of the PFC-NP intervention as a viable option to reduce procedural times associated with standard care sedation/GA for children needing outpatient MRI.

**Hypothesis #6**

Patients who received the PFC-NP intervention have reduced procedural turnaround time as compared to patients who received CCLS preparation for sedation/GA. Hypothesis #6 was supported as stated. The results of the regression model indicate that the Intervention group had a statistically significantly shorter procedural time as compared to the CCLS Preparation for Sedation/GA group. Interpretation of these results supports the use of the intervention as a viable option to reduce procedural times associated with CCLS preparation for sedation/GA for children needing outpatient MRI.
Hypothesis #7

Patients who received the PFC-NP intervention have reduced procedural turnaround time as compared to patients who opted to receive no preparation and no sedation/GA. Hypothesis #7 was not supported, as statistical significance was not reached. Interpretation of these results suggest that the use of the PFC-NP intervention is another option for children needing outpatient MRI as it does not increase the procedural time as compared to patients with no preparation and no sedation. However, further evaluation of the intervention’s effects on reducing anxiety or distress of the child requiring outpatient MRI may provide more information about the efficacy of this intervention in reducing procedural time.

Summary

The effectiveness of the PFC-NP intervention in reducing healthcare costs, improving procedural time, and ensuring good quality of magnetic resonance images as compared to three other groups was analyzed using multiple linear regression. After analysis of unadjusted and adjusted multiple linear regression models, the PFC-NP Intervention group as compared to the Standard Care Sedation/GA group was found to have statistically significantly lower quality of magnetic resonance images, with a 0.418-per-unit increase in quality rating, lower healthcare costs by $1,848.90 per encounter, and shorter procedural times by 31.83 minutes. When comparing the PFC-NP Intervention group to the CCLS Preparation for Sedation/GA group, the Intervention group had lower quality of magnetic resonance images with a 0.492-per-unit increase, lower healthcare cost by $1663.03 per encounter, and shorter procedural times by 24.74 minutes. Although it was found that, statistically, patients that are sedated have a better quality of scan image, the PFC-NP
Intervention remains a viable option to sedation as an overwhelming number of these scans (95.5%) were of acceptable-to-excellent quality.

Comparing the PFC-NP Intervention group to the No Preparation and No Sedation/GA group on healthcare costs and procedural time revealed no statistical difference in the adjusted model. This suggests further research is needed to explore the effects of the PFC-NP intervention on magnetic imaging quality in differing patient characteristics such as developmental age groups and certain diagnosis.

**Application of Findings to Theoretical Framework**

As discussed in Chapter II, the PFCC theoretical framework (Mastro et al., 2014) proposes that the development of a caring and trusting relationship and leveling of power leads to the empowerment of the patient/family to participate as full partners in care and posits seven relational outcome propositions. In this study, the PFC-NP intervention was considered patient- and family-centered as the parent was offered the choice for preparation for non-sedation/GA and was empowered to participate in the development of the individualized preparation plan. The individualized plan was developed in collaboration and partnership with the parent and was created based on shared knowledge of the child. For this study, three of the seven proposed outcome propositions associated with the PFCC Theoretical Framework were tested.

Findings support the relational propositions of an inverse relationship between patient and family partnership and healthcare costs. The healthcare costs for those patients who received the PFC-NP intervention ranged from $1,663.03-$1,848.90 less per encounter than for those patients who did not receive a patient- and family-centered intervention and received sedation/GA ($p < 0.0005)
The second relational outcome proposition tested supports a positive relationship between patient- and family-centered partnerships and operational efficiency. Patients who received the PFC-NP intervention had 24.72-31.83 minutes shorter procedural times than those patients who received sedation/GA without patient and family-centered preparation ($p < 0.0005$).

A positive relationship with safety was defined as no use of sedation/GA. In each sedation/GA study group comparison, the results of a multiple linear regression revealed that the quality of the MRI scan was lower in the PFC-NP Intervention group ($p < 0.0005$). Although the PFC-NP Intervention group patients had statistically significantly lower quality of magnetic resonance images than those that received sedation/GA, 95.5% of the images were of acceptable-to-excellent quality in 97.7% of the patients ($B = 0.418-0.492$, $p < 0.0005$), thus supporting the relational proposition of a positive relationship between patient- and family-centered partnerships and patient safety.

**Summary**

This research supported the proposed relational propositions between patient partnership and lower healthcare costs, higher operational efficiencies, and safer care.

**Study Limitations**

There were several limitations to this study. The sample, while adequate, was not representative of the entire United States (only one hospital in the Northeast), and as such, caution should be taken in generalizing the results outside of the size, population, and demographics of this specific healthcare organization. Furthermore, this study was limited to those patients who spoke English. Caution should be taken in generalizing to patients who speak languages other than English. Additionally, this was a quasi-experimental study.
exploring retrospective data, and as such, participation in groups was not randomly assigned. As a result, the external validity for this study was limited to facilities of similar size, population, and demographics. Although there were seven covariates significantly associated with the outcome variables and controlled in the analysis, there may have been other pre-existing factors and other influences may not have been accounted for and therefore not controlled for in the analysis. This causes a potential threat to the internal validity of the analysis.

**Policy and Practice Implications**

Findings of this study help to inform policy and practice guidelines regarding best and safest practices for the preparation and conduction of pediatric MRIs. The PFC-NP intervention has shown that children ages 3 through 17 have the ability to successfully complete a MRI without sedation/GA. More importantly, the quality of an overwhelming number of the magnetic resonance images for those children who received the PFC-NP intervention was found to be acceptable to excellent. These results suggest that the PFC-NP intervention is an acceptable option for parents, radiologists, and other providers when determining the safest, most cost effective, and most efficient method in obtaining a MRI. As such, the PFC-NP intervention should be incorporated into practice and clinical policy within this healthcare organization. The historical reason for the practice of using sedation/GA was to ensure the child remained still in order to obtain a magnetic resonance image with high enough quality for interpretation. However, the results of this study bring this standard practice under scrutiny. This study supports the proposition that healthcare providers should no longer assume young patients need sedation/GA to remain still enough to obtain an acceptable quality magnetic resonance image. This newly defined and tested intervention
needs to be further tested in various settings throughout the US. Additionally, policy-related practice guidelines should reflect a patient- and family-centered approach to individualized preparation and support for children needing MRI so as to avoid sedation/GA and promote the safest, timeliest, and most cost effective and care practices.

This study also exemplifies nursing’s important role in design, implementation, and evaluation of patient- and family-centered care practices and serves as a model for nurse leaders in other organizations. The findings of this study inform the activities of pediatric nurse leaders in their efforts to enhance child safety and operational efficiencies during MRI procedures.

To influence practice policy change, these findings will be disseminated in partnership with leaders in child life, anesthesia (medical doctor and certified registered nurse anesthetists), and radiology. A manuscript will be submitted for publication consideration to the *Journal of the American College of Radiology*, a peer-reviewed journal for radiology that focuses on clinical practice, practice management, health services and policy, and education and training of radiologists. A follow-up manuscript will also be developed and submitted to the *Journal of Nursing Administration* to encourage nurse executives to advance and test patient-centered care practice in their organizations. This study will also be submitted for presentation at several national conferences such as the Children’s Hospital Association, American College of Radiology annual meeting, American Society of Anesthesiologists annual meeting, and at the American Academy of Pediatrics Advisory Board meeting. Additionally, the published manuscript will be shared with the leadership and faculty of the Institute for Patient- and Family-Centered Care. The results of
this study will be presented to the Hugs for Brady Board of Directors in hopes they will continue to support patient- and family-centered research.

**Implications for Further Nursing Research**

This study begins to fill a gap in the literature and adds to the growing body of patient- and family-centered research. However, replication of this study and the effects of the PFC-NP intervention in different healthcare settings throughout the US should be explored. Considering the findings of this study and the national support for research focused on patient-centered care, the following are additional potential research questions needing further exploration.

**PFC-NP Intervention-Specific Research Questions**

1. Does the PFC-NP intervention for children diagnosed with sickle cell (a) improve the utilization of MRI in young sickle cell patients and (b) uncover subclinical findings that would have been missed if the patient did not have a MRI?
2. Does the PFC-NP intervention reduce anxiety and stress of the child needing a MRI as compared to those who do not receive the intervention?
3. Are patients/families who receive the PFC-NP intervention more satisfied with care and more likely to return for future care than those patients who receive sedation/GA?
4. Does the PFC-NP intervention reduce healthcare costs and overall length of stay for admitted patients needing MRI?
5. Does the PFC-NP intervention reduce cost, improve procedural time, and have better magnetic resonance imaging quality across multiple healthcare sites in the United States?
6. Can the PFC-NP intervention reduce sedation/GA use, anxiety, and stress in adult patients needing MRI?

**Patient- and Family-Centered Research Questions**

1. What is the relationship between patient- and family-centered care and patient safety as evidenced by medication errors and mortality rates?

2. Does partnership with patients using a patient- and family-centered approach to care impact nursing quality indicators such as falls, pressure ulcers, and hospital acquired infections defined as catheter-associated urinary tract infections, ventilator-associated pneumonia, and central line blood stream infections?

3. Is there an association between patients/parents who partner in care and their ability to care for themselves or their children at home?

4. Does a patient- and family-centered approach to care result in a decrease in hospital readmission rates?

**Conclusions**

The findings from this study have provided the first evidence that supports a safer, more cost effective, and more efficient alternative to sedation/GA use in children needing a diagnostic MRI. The results of this research reveal that taking a patient- and family-centered approach to care reduces the use of sedation/GA in children needing outpatient MRI, thus improving the safety of care for this population. Additionally, the PFC-NP intervention supports the theoretical proposition that a patient- and family-centered approach to care reduces healthcare costs, improves operational efficiencies, and improves the safety of the care. While additional research is needed to further support these findings and broader application of patient- and family-centered care practices, the findings of this study help to
inform design of strategies for improving patient- and family-centered care practices that focus on improving safety, reducing healthcare cost, and improving healthcare system efficiencies.
REFERENCES


scanner training protocol results in high quality structural and functional MRI scans.


Institute for Healthcare Improvement. (2011). Retrieved from

Institute of Medicine. (2001). Retrieved from

Institute for Patient and Family Centered Care. (2013). Retrieved from
http://www.ipfcc.org/faq.html


APPENDIX A

Release of Copyright, Journal of Nursing Administration

From: Karen Hill <jonaeditor@gmail.com>

Subject: permission to use your JONA article in your dissertation

Date: September 3, 2014 6:59:00 PM EDT

To: Kari Mastro <kari.mastro@icloud.com>

Kari, you have permission to publish your JONA article:

Patient- and Family-Centered Care: A Call to Action for New Knowledge and Innovation

"Mastro, Kari A.; Flynn, Linda; Preuster, Christa; Journal of Nursing Administration.


Sincerely,

Karen S. Hill

--

Karen S. Hill, DNP, RN, NEA-BC, FACHE, FAAN

Editor-in-Chief, The Journal of Nursing Administration
APPENDIX B

Columbia University Human Subjects Protocol Data Sheet, Initial

Columbia University Human Subjects Protocol Data Sheet

General Information

Protocol: AAAQ7510(M00Y01)  Protocol Status: Approved
Effective Date: 03/08/2016  Expiration Date: 03/07/2017
Originating Department Code: NUR Nursing General (800100X)
Principal Investigator: Mastro, Kari (km2916)
From what Columbia campus does this research originate:
Title: The Effectiveness of a Patient and Family Centered Intervention to decrease Anesthesia Use in Children Undergoing MRI
Protocol Version #: PFC-NP
Abbreviated Title: PFC-NP
Was this protocol previously assigned a number by an IRB: No

Is the purpose of this submission to obtain a "Not Human Subjects Research" determination?
No

IRB Expedited Determination

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnoses).

Attributes

Special review type: Check all that apply or check "None of the Above" box.
[ ] Review for 45 CFR 46.118 Determination (involvement of human subjects is anticipated but is not yet defined)
[ ] Funding review for Administrative IRB approval (such as for Center or Training Grants)
[ ] None of the above

IRB of record information: Will a Columbia IRB be the IRB that is responsible for providing review, approval, and oversight for this study?
Yes
Select the most appropriate response:
Columbia will be the IRB of record for the study procedures conducted by Columbia researchers (Note: this response will apply to most submissions).

Is this research part of a multicenter study?
No

Please indicate if any of the following University resources are utilized:
[ ] Cancer Center Clinical Protocol Data Management Compliance Core (CPDM)
[ ] CTSA-Irving Institute Clinical Research Resource (CRR)
[ ] CTSA- Irving Institute Columbia Community Partnership for Health (CCPH)
[ ] None of the above
To obtain approval for a waiver or alteration of the HIPAA privacy authorization, the research project must meet the criteria listed below. Please describe how your study meets the criteria.

1. There is an adequate plan to protect subject identifiers from improper use and disclosure.

To ensure privacy, confidentiality, and protect the safety of electronic research data, the electronic data extracted will be stored in an electronic file for the purpose of data analysis. A coding system will be used for data entry to computer. The electronic file will be password protected and stored on the hospital’s password protected and networked computer.

The file will only be accessible to the researcher (PI). Once all data is collected, the PI will de-identified the data by eliminating the medical record number thus making the data set anonymous.

2. There is 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.

Once the study is completed, the electronic file will be permanently deleted from the computer.

3. Protected health information (PHI) will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which use or disclosure of PHI would be permitted under HIPAA regulations.

There will not be any reuse of PHI as once all data is collected, the PI will de-identified the data by eliminating the medical record number thus making the data set anonymous.

4. The research could not practicably be conducted without the waiver or alteration.

This study is entirely retrospective and absolutely no data will be collected prospectively.

5. The research could not practicably be conducted without access to and use of PHI.
APPENDIX D

Columbia University Human Subjects Protocol Data Sheet, Renewal

Columbia University Human Subjects Protocol Data Sheet

General Information

Protocol: AAAQ7510(M00Y02)  Protocol Status: Approved
Effective Date: 01/10/2017  Expiration Date: 01/09/2018
Originating Department Code: NUR Nursing General (800100X)
Principal Investigator: Mastro, Kari (km2916)
From what Columbia campus does this research originate: Medical Center
Title: The Effectiveness of a Patient and Family Centered Intervention to decrease Anesthesia Use in Children Undergoing MRI
Protocol Version #: Abbreviated Title: PFC-NP
Was this protocol previously assigned a number by an IRB: No

Is the purpose of this submission to obtain a "Not Human Subjects Research" determination?
No

IRB Expedited Determination

9. Continuing review of research not conducted under an investigational new drug application or investigational device exemption where categories (listed above) do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Renewal Information

Enrollment status:
Open to enrollment or ongoing review of records/specimens
Provide any additional information necessary to explain the study status:
Currently analyzing data
Since the last renewal:
Have there been any changes in the relevant literature that would affect the study design or procedures?
No
Have there been any interim findings associated with this study?
No
Have there been any publications resulting from this study?
No
Have any participants been enrolled using the Short Form process?
No
Is there a Data Monitoring Committee (DMC), Data Safety Monitoring Board (DSMB), or other monitoring entity for this study?
No
Is an annual Progress Report required by the funding organization or coordinating center for this study?
No
Does this submission include a modification?
No

IRB-AAAQ7510
APPENDIX E

COMIRB Protocol, Certificate of Exemption

University of Colorado Hospital
Denver Health Medical Center
Veteran's Administration Medical Center
Children's Hospital Colorado
University of Colorado Denver
Colorado Prevention Center

Certificate of Exemption

22-Jun-2016

Investigator:  Kari Mastro
Subject:  COMIRB Protocol 16-0844 Initial Application
Review Date:  16-Jun-2016
Effective Date:  16-Jun-2016
Anticipated Completion Date:  15-Jun-2019
Sponsor(s):  None
Title:  The Effectiveness of a Patient- and Family-Centered Non-Sedation Program to decrease Anesthesia Use in Children Undergoing MRI
Exempt Category:  4

Submission ID: APP001-2

SUBMISSION DESCRIPTION:

APP001-2: Initial Exempt submission (Response to Minor Modifications)
HIP001-1 submitted concurrently

Your COMIRB Initial submission APP001-2 has been APPROVED FOR EXEMPTION. Periodic continuing review is not required. For the duration of your protocol, any change in the experimental design/content/personnel of this study must be approved by COMIRB before implementation of the changes.

The anticipated completion date of this protocol is 15-Jun-2019. COMIRB will administratively close this project on this date.
APPENDIX F

COMIRB Certificate of HIPAA Compliance

University of Colorado Hospital
Denver Health Medical Center
Veteran's Administration Medical Center
Children's Hospital Colorado
University of Colorado Denver
Colorado Prevention Center

Certificate of HIPAA Compliance

22-Jun-2016

Investigator: Kari Mastro
Sponsor(s): None
Subject: COMIRB Protocol 16-0844 HIPAA
Effective Date: 16-Jun-2016
Title: The Effectiveness of a Patient- and Family-Centered Non-Sedation Program to decrease Anesthesia Use in Children Undergoing MRI

Based upon information submitted to COMIRB, this protocol meets the requirements for HIPAA Compliance in its use of:

Submission ID: HIP001-1
Attachment O: Full Waiver of HIPAA Authorization—Determined to meet criteria for full waiver of HIPAA authorization

Please note that COMIRB will no longer be E-mailing approved documents. Stamped, approved documents can be retrieved in the eRA (InfoEd) system. Please click here to access instructions on finding these approved documents.

Sincerely,

UCD Panel C
## APPENDIX G

### Data Collection Sheet

<table>
<thead>
<tr>
<th>Encounter Number</th>
<th>Patient Number</th>
<th>Gender</th>
<th>Age at Scan in Years</th>
<th>Body Area of Exam</th>
<th>Number of Scans per Encounter</th>
<th>Diagnosis</th>
<th>Ethnicity</th>
<th>Primary Language</th>
<th>Insurance Type</th>
<th>Total MRI Time</th>
<th>Total Sedation/CA Time</th>
<th>In-MRI Time Variance between Expected &amp; Actual</th>
<th>Total Change</th>
<th>Quality of MRI</th>
<th>Study Group (1,2,4)</th>
<th>Any prior experience at all</th>
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