Parents' Impressions of Their Child's Minor Surgical Procedure with Nitrous Oxide

Tina Shapiro-Stoler

University of Miami, tinashapirosa@yahoo.com

Follow this and additional works at: https://scholarlyrepository.miami.edu/oa_dissertations

Recommended Citation
https://scholarlyrepository.miami.edu/oa_dissertations/331

This Open access is brought to you for free and open access by the Electronic Theses and Dissertations at Scholarly Repository. It has been accepted for inclusion in Open Access Dissertations by an authorized administrator of Scholarly Repository. For more information, please contact repository.library@miami.edu.
UNIVERSITY OF MIAMI

PARENTS’ IMPRESSIONS OF THEIR CHILD’S MINOR SURGICAL PROCEDURE WITH NITROUS OXIDE

By

Tina Shapiro-Stoler

A DISSERTATION

Submitted to the Faculty of the University of Miami in partial fulfillment of the requirements for the degree of Doctor of Philosophy

Coral Gables, Florida

December 2009
A dissertation submitted in partial fulfillment of
the requirements for the degree of
Doctor of Philosophy

PARENTS’ IMPRESSIONS OF THEIR CHILD’S MINOR SURGICAL PROCEDURE
WITH NITROUS OXIDE

Tina Shapiro-Stoler

Approved:

Elias P. Vasquez, Ph.D.
Associate Professor of Nursing

Terri A. Scandura, Ph.D.
Dean of the Graduate School

Joseph De Santis, Ph.D.
Assistant Professor of Nursing

Kandyce M. Richards, Ph.D.
Assistant Professor of Nursing

Frank Wang, M.D.
Clinical Assistant Professor of
Anesthesiology and Perioperative Medicine
Invasive procedures are often painful and distressing for children and disturbing for their parents. The purpose of this study was to develop a substantive theory of parental perceptions of their school-aged child’s responses to an outpatient minor surgical procedure with nitrous oxide. The sample included 22 parents of 21 children who underwent a nitrous procedure. Participants were recruited from the pediatric surgery department at a children’s hospital. Semi-structured, audio-recorded interviews were conducted with each participant. Grounded theory method was used to simultaneously collect and analyze the data using the constant comparative method.

The findings of the study revealed parental impressions involving a process of various emotions and behaviors. The identified process began at procedural scheduling, progressing through the procedure, and terminated going home. The core category derived from the data was *Weathering the Storm before the Calm by Securing Connections*. This core category describes the complexity of parental impressions and all categories subsumed by the core category. Six major categories and seven subcategories derived from the data represent parental impressions. Parental feelings of anxiety and fear arose during initial phases of the process. Parents attempted to deal with these stormy feelings in several ways. Parents experienced a sense of calmness after the procedure upon realizing their child was safe. The theme that weaves through the entire process is the parental-child connection and parental presence during the nitrous procedure. Parents
also identified barriers and facilitators they faced during this process. The substantive theory that emerged provides nurses with an understanding of the stormy and subsequent calm phases parents endured.

This information offers clinicians unique interventions to help parents get through this process. Future research needs extension to other settings such as radiology and other specialties such as plastic surgery and urology. Further research warrants investigating children’s perceptions to their procedure with nitrous oxide.
Dedication

To all the parents who generously contributed their time for this study. Their willingness to share their impressions made this dissertation possible and…

To all the children who have and will go through the experience of invasive procedures with nitrous oxide and…

To all the nurses who assist them to weather the storm into calmness.
Acknowledgments

The completion of this dissertation was accomplished with the help of many invaluable individuals who assisted directly or indirectly. First, I would like to express my sincerest appreciation to my dissertation committee members for their scholarly guidance through this long and rewarding journey. I want to extend my deepest gratitude to Dr. Elias Vasquez, my committee chairperson, who gave me the tools, showed me the way, and allowed me to succeed. Thank you very much to my other committee members, Dr. Joseph De Santis, Dr. Kandyce Richards, and Dr. Frank Wang who provided their support and mentoring in making this work possible.

I most gratefully acknowledge the pediatric surgeons at Miami Children’s Hospital: Dr. Steven Stylianos, Dr. Cathy Burnweit, Dr. Leopoldo Malvezzi, and Dr. Colin Knight whose constant support and encouragement greatly facilitated the successful completion of this study.

I would like to extend a heartfelt thank you to my recruiters, Jeannette Diana-Zerpa and Raquel Pasaron for generously giving their valuable time. Without their ongoing assistance during participant recruitment, this project would not have been possible. A special thank you goes to Maria Neyra for alerting the recruiters to potential participants. I wish to thank the outpatient center nurses, Frances Valdes, Elizabeth Roman, and Nancy Perdomo for support and providing rooms for participant interviews. Thank you to Jeannette Galano and Maggie Alemany for all their hard work and timely return of precisely transcribed interviews.

To my fellow doctoral student, Mary Anne Milone, who kept my life in perspective and kept me smiling and sane. She always knew when a night at The Titanic was needed for extra studying. She never let the lights go out on my dream of completing this work.
A warm thank you goes out to Dr. Lee Schmidt and Dr. Gail McCain for giving their time so willingly. Their invaluable mentorship is much appreciated. Thanks to Gersom Manresa for his technical assistance and being available at a moment’s notice.

Thank you from the bottom of my heart to my very good friends, Jeannette and Carlos Zerpa and Dr. Patricia Messmer for giving me shelter and food. Their endless generosity and support will never be forgotten.

My heartfelt gratitude goes out to my best friend, Sue Nettis. Her encouragement, understanding, and late night long phone calls pulled me through this arduous journey. I am privileged to have her as my friend.

Thank you to my family, mother, and late father who nurtured, encouraged and supported me. My mother, Jackie Shapiro told me that I can always have whatever I wanted. Based on her influence, the perceived impossible dream just became a reality: the pursuit of my doctoral degree in nursing. Sadly, my father, Hy Shapiro, oldest brother, Ralph Shapiro, and sister-in-law, Mary Anne Shapiro passed away before seeing my dream come true.

I thank my husband, Gabriel Stoler for his support and sacrifices made throughout my dissertation process. Due to his patience and belief in me, I remained on the path to successfully ending this journey despite all of the obstacles. Although we were separated by thousands of miles, his love and encouragement were always a constant presence.

Thank you to all who assisted me in any way to complete this dissertation. Words alone cannot express my gratitude.

This study was partly supported by grants from the American Pediatric Surgical Nurses Association and the Frida Hill Beck fund from Miami Children’s Hospital.
# TABLE OF CONTENTS

| LIST OF FIGURES | ix |
| LIST OF TABLES | x |

## Chapter

1. **THE PROBLEM**
   - Background of the Problem: 2
   - Purpose: 4
   - Significance of this Study: 4
   - Definition of Terms: 4
   - Definition of Responses to Invasive Procedures: 6
   - Diagram of Relationships among Variables: 9

2. **REVIEW OF LITERATURE**
   - Literature Reviewing Grounded Theory: 10
   - Consequences of Acute Pain in Children: 12
   - Cognitive Development of Children: 13
   - Preoperational Stage: 14
   - Concrete Operational Stage: 14
   - Concrete Operational Stage and Pain Behavior: 15
   - Formal Operational Stage: 17
   - Parental Involvement, Responses, and Perception: 17
   - Benefits of Nitrous Oxide/Oxygen Analgesia: 20
   - Adverse Effects and Contraindications of Nitrous Oxide: 22
   - Conscious Sedation: 25
   - Moderate Sedation Techniques: 27
   - Outpatient Minor Surgical Procedures: 28
   - Children’s Responses to Procedures: 28
   - Summary: 29

3. **METHOD**
   - Study Design: 31
   - Grounded Theory Methodology: 31
   - Aims and Features of Grounded Theory: 33
   - Grounded Theory Key Characteristics: 33
   - Theoretical Sensitivity: 34
   - Sampling and Selection of Participants: 34
   - Constant Comparative Analysis: 37
   - Coding and Categorizing Data: 37
   - Open Coding: 38
   - Selective Coding: 38
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theoretical Memos and Diagrams</td>
<td>38</td>
</tr>
<tr>
<td>Literature as Data Source</td>
<td>39</td>
</tr>
<tr>
<td>Integration of Theory</td>
<td>39</td>
</tr>
<tr>
<td>Trustworthiness in Qualitative Research</td>
<td>40</td>
</tr>
<tr>
<td>Credibility</td>
<td>41</td>
</tr>
<tr>
<td>Transferability</td>
<td>42</td>
</tr>
<tr>
<td>Dependability</td>
<td>42</td>
</tr>
<tr>
<td>Confirmability</td>
<td>43</td>
</tr>
<tr>
<td>Protection of Human Subjects</td>
<td>44</td>
</tr>
<tr>
<td>Sample</td>
<td>46</td>
</tr>
<tr>
<td>Inclusion Criteria</td>
<td>48</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>48</td>
</tr>
<tr>
<td>Setting and Procedure</td>
<td>49</td>
</tr>
<tr>
<td>Data Collection</td>
<td>51</td>
</tr>
<tr>
<td>Demographics</td>
<td>51</td>
</tr>
<tr>
<td>Interview Process</td>
<td>51</td>
</tr>
<tr>
<td>Data Analysis</td>
<td>54</td>
</tr>
<tr>
<td>Trustworthiness Strategies for This Study</td>
<td>56</td>
</tr>
<tr>
<td>Audit Trails</td>
<td>56</td>
</tr>
<tr>
<td>Peer Review</td>
<td>57</td>
</tr>
<tr>
<td>Summary</td>
<td>58</td>
</tr>
<tr>
<td>4 RESULTS</td>
<td>60</td>
</tr>
<tr>
<td>Description of the Sample</td>
<td>60</td>
</tr>
<tr>
<td>The Core Category and Basic Social Process</td>
<td>65</td>
</tr>
<tr>
<td>Categories within the Process</td>
<td>67</td>
</tr>
<tr>
<td>Knowing what to Expect</td>
<td>69</td>
</tr>
<tr>
<td>Reflecting on Past Experiences</td>
<td>69</td>
</tr>
<tr>
<td>Searching for Information</td>
<td>70</td>
</tr>
<tr>
<td>Having Expectations</td>
<td>72</td>
</tr>
<tr>
<td>Having to Wait</td>
<td>73</td>
</tr>
<tr>
<td>Participating in Pre-induction</td>
<td>75</td>
</tr>
<tr>
<td>Using Distracters</td>
<td>76</td>
</tr>
<tr>
<td>Assisting the Team</td>
<td>77</td>
</tr>
<tr>
<td>Watching the Procedure</td>
<td>80</td>
</tr>
<tr>
<td>Parental Responses</td>
<td>80</td>
</tr>
<tr>
<td>Child’s Responses</td>
<td>83</td>
</tr>
<tr>
<td>Feeling Relief</td>
<td>86</td>
</tr>
<tr>
<td>Going Home</td>
<td>88</td>
</tr>
<tr>
<td>Summary</td>
<td>89</td>
</tr>
<tr>
<td>5 DISCUSSION</td>
<td>90</td>
</tr>
<tr>
<td>Relation to Other Studies</td>
<td>92</td>
</tr>
<tr>
<td>Significance to Nursing Theory, Research, and Practice</td>
<td>106</td>
</tr>
<tr>
<td>Implications for Nursing Practice</td>
<td>106</td>
</tr>
<tr>
<td>Implications for Nursing Education</td>
<td>109</td>
</tr>
<tr>
<td>Recommendations for Future Research</td>
<td>110</td>
</tr>
</tbody>
</table>
LIST OF FIGURES

Figures

1.1 Diagram of proposed relationships among study variables…………………..9

4.1 Diagram of core category: Weathering the storm before the calm by securing connections ………………………………………………………..66
LIST OF TABLES

Table

<table>
<thead>
<tr>
<th>Tables</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1 Parent demographic data</td>
<td>62</td>
</tr>
<tr>
<td>4.2 Child demographic data</td>
<td>64</td>
</tr>
<tr>
<td>4.3 Taxonomy of categories</td>
<td>68</td>
</tr>
</tbody>
</table>
Chapter 1

The Problem

Many studies have shown that nitrous oxide is a safe, efficacious, and cost-effective analgesia compared to general anesthesia for minor surgical painful procedures in children (Burnweit et al., 2004; Frampton, Browne, Lan, Cooper, & Lane, 2003; Kanagasundaram, Lane, Cavalletto, Keneally, & Cooper, 2001; O’Sullivan & Benger, 2003). Most of these studies, however, used only children's self-report to evaluate the child’s pain. Since nitrous oxide possesses amnesic effects (Burnweit et al., 2004; Luhmann, Schootman, Luhmann, & Kennedy, 2006) accuracy and reliability of the child's pain scores must be questioned.

The criteria for examining interventions to improve children’s procedural pain control are expanding from efficacy and safety towards a more thorough analysis of parental evaluations (McCarthy et al., 2005). Parental perceptions would provide additional perspectives such as satisfaction, dissatisfaction, or early observation of adverse effects related to achieving children’s pain control associated with invasive procedures using nitrous oxide.

There are a few studies that address parental perceptions of their children’s responses to invasive procedures using various sedations. Schechter and colleagues (1991) found that some parents were excellent predictors of their children's reactions to procedural pain. Thus, parents may be considered as valuable resources by health care providers in developing a plan for pain management.

Empirical studies are limited about parents’ perceptions of their children's distress related to invasive procedures. Parents are very cognizant of their child’s pain and how he or she reacts to pain. Watt-Watson, Everndern, and Lawson (1990) examined parents’
perceptions of their children’s acute pain experience and found that parents were able to identify the non-verbal cues which indicated that their child was in pain. In addition, a study conducted by Schneider and LoBiando-Wood (1992) found that pain assessments from the parent were correlated with the child’s perception, and therefore could be useful. Pain ratings by children and nurses were noted to be significantly different. Parents are often the primary source of information about how their child shows pain and should be encouraged to contribute to the assessment of pain. Koolen and Perduijn (1991) found that nurses utilized parental input for assessing and managing pain in especially young children.

**Background of the Problem**

Procedure-related pain is a major source of distress to many of these children and their families (Jay, Ozolins, Elliott, & Caldwell, 1983; Kazak, Penati, Brophy, & Himelstein, 1998). Increasingly, parents participate more fully in the care of their children in the hospital (Chapados, Pineault, Tourigny, & Vandal, 2002; Polkki, Vehvilainen-Julkunen, & Pietila, 2002). Caregivers are typically present during their child’s painful invasive procedures. There is limited data on the perception of children’s responses by parents despite the considerable attention on reducing pain and anxiety in children undergoing procedures utilizing pharmacological interventions (Kennedy & Luhmann, 2001; Krauss, 2001) and non-pharmacological interventions (Kleiber & Harper, 1999; Uman, Chambers, McGrath, & Kisely, 2006). The social response system is an external individual behavior system that includes all elements of the social context within which pain is experienced (Sullivan, 2008). Feelings of empathy or sympathy stimulated by the observation of others’ experience of pain encourage supportive or care-giving behavior (Craig, 2004; Goubert et al., 2005; Williams, 2002). Current studies suggest that
individuals are not only able to express pain, but are also “equipped” to respond to others’ pain (Goubert et al., 2005). Research on the neuroanatomic correlates of pain infers that mechanisms involved in the pain experience are also implicated in the perception of pain in others (Botvinik et al., 2005; Jackson, Meltzoff, & Decety, 2005; Singer et al., 2004).

Parents can provide essential baseline data for the nurse to use in decision-making for effective pain control (Eland, 1985). In order to broadly assess parent satisfaction and clinical ways in which nitrous oxide helps or does not benefit their children, a qualitative study using grounded theory (GT) methodology investigating parents’ perceptions of their children’s responses was conducted.

Minor invasive procedures in children need adequate pain control with the reduction of anxiety and limited movement. Protective airway reflexes may be lost with certain conscious sedation techniques. Nitrous oxide however, when inhaled at levels below 50% maintains protective reflexes and does not require fasting or post-procedural monitoring (Burnweit et al., 2004).

Currently, no studies have been found exploring parent’s perceptions of their child’s responses undergoing elective outpatient minor surgical procedures with nitrous oxide. Pain assessments may not be accurate when utilizing self-report of children since nitrous oxide possesses an amnesic effect. An alternative method for evaluating how children respond to an outpatient minor surgical procedure with nitrous oxide is to have their parents evaluate their responses. Parents are in a unique position to evaluate their child’s response because parents know their child best and parents can be a valuable asset for the nurses in signaling pain sooner.
Purpose

Researchers found that parents can reliably evaluate their children's pain (Schecter, Bernstein, Beck, Hart, & Scherzer, 1991; Schneider & LoBiando-Wood, 1992; Watt-Watson, Evernden, & Lawson, 1990). Therefore, the focus of this study is to investigate parent’s perceptions to adequately assess their child's responses during outpatient minor surgical procedures using nitrous oxide.

Using GT methodology, the purpose of this study is to develop a substantive theory of parental perceptions of their school-aged child’s responses to an outpatient minor surgical procedure with nitrous oxide. GT methodology will be used to simultaneously collect and analyze the data using the constant comparative method.

Significance of This Study

The data obtained from this study provides insight into the parent’s perspectives of their school-aged child’s responses to a scheduled outpatient minor surgical procedure with nitrous oxide. The substantive theory that emerged can promote a better understanding from the parent’s perspective of their child’s responses to the invasive procedure which may enhance parental support. Furthermore, the data obtained from this study can help design interventions to improve the child’s experience of an invasive procedure using nitrous oxide.

Definition of Terms

The terms pertinent to this study are nitrous oxide/oxygen analgesia, elective minor surgical outpatient procedures; pain, fear, and anxiety (probable responses to invasive procedures). In addition, parent perception (to child’s pain) will also be defined. The definitions of these terms are described below.
Nitrous oxide/oxygen analgesia. Nitrous oxide/oxygen analgesia (also known as *laughing gas*) is an inhalational anesthetic, colorless, and tasteless gas containing a mixture of nitrous oxide and oxygen. Nitrous oxide while practically an odorless gas has a faint, sweet aroma (American Academy of Pediatric Dentistry, 2005) which has analgesic, amnesic, and anxiolytic properties. This gas is used for pediatric procedural sedation. The equipment that was used to administer nitrous oxide included a flow meter, scavenger, oxygen and nitrous oxide tanks, and an appropriate sized nasal scented hood. This apparatus is a portable delivery system that blends nitrous oxide and oxygen. For safety reasons, these inhalation gases are delivered from two separate color-coded portable cylinders. Nitrous oxide is stored in a blue cylinder and oxygen is kept in a green cylinder to avoid confusing the two gases.

Nitrous oxide and oxygen cause central nervous system depression and euphoria with hardly any effect on the pulmonary system (Paterson & Tahmassebi, 2003). These gases provide short-term pain relief and relaxation for a number of painful procedures (O’Sullivan & Benger, 2003; Pediani, 2003). Before the procedure, the certified nurse practitioner administered 100% oxygen for one to two minutes followed by blended nitrous oxide and oxygen titrated from 20% to 50% via scented nasal hood.

Elective minor surgical outpatient procedures. This term is referred to as scheduled invasive procedures performed in an outpatient center (OPC) that does not require general anesthesia but usually require topical and/or injectable local anesthetic. Some examples of minor elective outpatient procedures are excision of a cyst, ganglion aspiration or frenulectomy. These types of procedures were considered non-painful to the child prior to interventional treatment.
**Child responses to minor surgical procedures.** According to previous research studies, children respond to minor invasive procedures in a variety of behaviors such as pain, anxiety, and fear (Jacobsen et al., 1990; Jay, Elliot, Ozolins, Olson, & Pruitt, 1985; Maligalig, 1994). These behavioral responses include verbalizations such as refusal, crying, and/or yelling. The physical behavioral responses include withdrawal, pushing, or kicking. Biological responses to painful procedures consist of sweating and/or changes in the heart rate or cortisol levels. Behavioral responses of pain, fear, and anxiety are operationally defined below.

**Definition of Responses to Invasive Procedures**

**Pain.** According to the International Association of Pain, the term **pain** is defined as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage” (Mersky & Boyduk, 1994). For this study, the definition proposed by Price (1999) will be used to help understand the child’s pain experience: “Pain is a somatic perception containing a bodily sensation with qualities like those reported during tissue damaging stimulation, an experienced threat associated with this sensation, and a feeling of unpleasantness or other negative emotions based on this experienced threat.” The bodily sensation is the invasive procedure (such as an excision of a nevus) that the child experiences. For the purposes of this study, the term “pain behavior” is used to refer to specific body movement shown during the invasive procedural experience. Such movement include facial or postural configuration, such as grimacing or wincing, actions oriented toward protection of the affected body part (e.g., guarding, withdrawal), and vocal pain expressions (e.g., pain words, grunts, moans) (Craig, 2004; Deyo, Prkachin, & Mercer, 2004; Williams, 2002).
Behavioral responses to an invasive procedure are operationally defined for this study as crying, vocalizations, and facial expressions. Physiological responses to an invasive procedure include changes in heart rate, respirations, blood pressure, and O₂ saturation.

**Anxiety.** Anxiety is referred to as a nonspecific feeling of apprehension, worry, uneasiness, or dread and the source may be vague or unknown (Thomas, 1997). For this study, the operational definition of anxiety is the subjective and objective anxiety responses of the child and parent to the invasive procedure. Subjective responses include but not limited to focus on self, nonspecific fright, and/or rising apprehension. The objective responses are jitteriness, restlessness, trembling, voice quivering, and cardiovascular excitation (Bay & Algase, 2002).

**Fear.** For this study, fear is defined as a feeling of fright or dread related to an identifiable source (e.g., invasive procedure or injection) recognized by the individual such as the child or parent (Thomas, 1997) wherein a single threat guides behavior. The subjective responses of fear are self-reporting, apprehension, feeling frightened (Charney, Grillon, & Bremner, 1998). For this study, objective fear responses of the child include crying, clinging, sweating, syncope, refusal to cooperate, silence, and/or obsessive talking (Bay & Algase, 2002).

Parents as observers of their child’s response to an invasive procedure can provide their perceptions of their child’s experience (McCarthy & Kleiber, 2006). Since this study explores parents’ perceptions of the children’s responses to invasive procedures, it is important to define the term perception.

**Perception.** The term, perception, indicates a person’s observation of something external to the self. Perception is defined as an impression of an object obtained by the
use of the senses (Merriam-Webster’s Collegiate Dictionary, 2005). For this study, perception refers to an active information process, which allows the parent to organize, interpret, and act upon sensory data coming from the outside world (parents observing their child’s invasive procedure).

The correlation between parent anxiety and child distress is not well documented in the literature. Some researchers have reported positive relationships between child distress and parental trait anxiety (Jacobsen et al., 1990; Jay et al., 1983). Frank et al. (1995) found that maternal anxiety did not significantly contribute to children’s distress behavior during routine immunization.

Some parental responses to children’s invasive procedures include monitoring and comforting of the child (Woodgate & Kristjanson, 1996). For this study, monitoring refers to supervising the child’s pain experience during the invasive procedure. Monitoring will include observing for signs of pain. Comforting relates to behaviors associated with giving physical and psychological support to the child by the parent. Comforting includes holding or rubbing a body part, talking to the child in a reassuring tone, and distracting the child from pain (e.g., singing).
Diagram of Relationships among Variables

The following diagram depicts the chronological order and relationships among the study variables. Although a qualitative methodology is chosen for this study, a model is important to help understand and visualize how these variables relate to one another in an orderly fashion.

Figure 1.1

Diagram of Proposed Relationships Among Study Variables
Chapter 2

Review of Literature

Procedural pain in children is distressing for the individual, their parents, and health care providers (Smalley, 1999). Exposure to painful procedures does not desensitize children but increases their sensitivity to pain, with increased anxiety heightening the pain experience (McCaffery, 1972). Invasive procedures are often painful and distressing for children and disturbing for their parents. Therefore, it is important to determine from parental perceptions whether the use of nitrous oxide for invasive procedures is helpful to minimize the physical and psychological trauma caused to children and decrease parental apprehension.

Parental presence during invasive procedures has become relatively commonplace over the last decade (Astuto et al., 2006; Egemen, Ikizoglu, Karapnar, Cosur, & Karapnar, 2006; Fulbrook, Latour, & Albarran, 2007; Melhuish & Payne, 2006). Astuto and colleagues (2006) reported that parental presence minimized fear and avoided separation in both the child and parents during anesthesia induction. In addition, the need for pre-procedural sedatives was reduced and improvement of the child's compliance during anesthesia induction was demonstrated.

Literature Reviewing in Grounded Theory

One of the current issues in GT methodology approach is when the literature should be reviewed. In quantitative studies, researchers thoroughly review the literature on the topic of interest before conducting the work. In GT, however, the place of literature review is debatable. There are some researchers who advise initial review of the literature because it facilitates readers to recognize the researcher’s viewpoint as the study commences and affords justification for embarking on the GT study (McGhee, Marland & Atkinson,
2007). At this point, the feasibility of bracketing and its relationship to GT may arise. Bracketing refers to the process of setting aside or suspending presuppositions surrounding a specific phenomenon (Gearing, 2004). Bracketing is the process of the researcher becoming self-aware and reflecting on the research process and own assumptions (Jacelon & O’Dell, 2005). The purpose of bracketing is to avoid the possibility that the data and data analysis become a reflection of the researcher’s preconceived ideas and values (Mariano, 1995). Thus, the researcher may need to separate preconceptions and personal experiences when reviewing the literature a priori. Subsequently, the researcher reviews the literature for a second time to link extant research and theory with the concept of the new theory (Hutchinson, 1993).

Glaser and Strauss, the originators of GT, disagreed over the necessity to conduct an initial literature review. Glaser (1978, 1992) strongly suggests against any type of literature review before the study is undertaken. Glaser (1992) advises not to examine the literature until the researcher is in the field and codes and categories begin to emerge to prevent generating a focus from the literature rather than from the emerging data.

In his later writing with Corbin, Strauss disagreed with Glaser and supported examining the literature early in the research. This strategy was used to stimulate theoretical sensitivity, to provide a secondary data source, to direct theoretical sampling and to provide supplementary validity (Strauss & Corbin, 1990).

An overview of the literature was conducted to provide justification for this qualitative study, to meet the requirements of local research ethics and university committees, to discover established knowledge and assess if GT is an appropriate method for this study’s purpose. The literature search and review will be ongoing for this study. The literature will become another source for data in the main body of the study where it will be guided
by the emerging categories (Strauss & Corbin, 1998). The researcher will compare and contrast the findings with those of similar research results reported in the scientific literature.

**Consequences of Acute Pain in Children**

Acute procedural pain in children can result in short and long-term psychological and physiological effects that are an ethical and economic burden on the health care system and society. Inadequate pain relief is not only unpleasant, but can also cause neural, immune, and genetic changes that can result in chronic pain. Research has also shown that unrelieved pain may also exacerbate illness or injury, prevent wound healing, and lead to infection (Engel & Kartin, 2004). Unrelieved pain has many undesirable physiological consequences such as rapid, shallow breathing which can lead to alkalosis; inadequate expansion of lungs, inadequate cough; increased heart rate and tissue ischemia; and increased perspiration. Research studies indicate that children remember their experience of invasive procedures quite accurately (Chen, Zeltzer, Craske, & Katz, 2000; Merritt, Ornstein, & Spicker, 1994; Saywitz, Goodman, Nicholas, & Moan; 1991). Distress at the time of the procedure can exaggerate negative memories of the procedure, which in turn can increase distress at subsequent procedures (Chen et al, 2000). Psychological consequences due to inadequate pain relief in children have resulted in nightmares and have increased anxiety. In addition, studies have shown that children are less cooperative for future procedures (Eland, 1990). Painful procedures can be the cause of increased psychological and emotional distress in children and may affect the short and long term physical and mental well-being of children and their families, possibly affecting their future neurological development (Jacobsen et al., 1990; Sclare & Waring, 1995).
Cognitive Development of Children

The ability to give meaning to pain and perception seems to be related to a child’s cognitive development (Engel & Kartin, 2004). Therefore, healthcare professionals must recognize the child’s cognitive level of development. Children perceive the world differently than adults. According to Jean Piaget (1973), a Swiss developmental psychologist, boundaries between reality and fantasy are blurred in childhood. Piaget developed a cognitive development model with four successive stages. These four consecutive stages are: sensory motor stage (birth to two years old), pre-operational stage (two to seven years old), concrete operational stage (seven to eleven years old), and the formal operational stage (11 to 15 years old) (Piaget, 1973). Piaget’s theory of cognitive development purports that as children grow and mature so do their cognitive abilities progressing through stages defined by specific operations (Piaget & Inhelder, 1969).

Children’s thinking eventually changes from concrete to abstract as they progress through the developmental stages. Children develop the ability to replace overt actions by mental representations, egocentrism, and centration lessens (Piaget, 1973). Centration is the tendency to focus on one aspect of a situation and neglect others. This term was introduced by Piaget (1973) to refer to the tendency of young children to focus attention on only one salient aspect of an object situation, or problem at a time, to the exclusion of other potentially relevant aspects. The process of cognitive development by which a child develops from centration to a more objective way of perceiving the world is decentration. The child’s ability to decenter refers focusing on more than one feature of a problem or
task at a time. The individual is able to shift from a single perspective to multiple points of view.

The ages of the participants’ children for this study are between four years and eighteen years old. Thus, a description of the cognitive developmental stages for these age groups is important to briefly review.

**Preoperational stage.** Children in the preoperational stage are usually between the ages of two and seven years old. During this stage, the development of language occurs at a rapid pace. Children learn how to interact with their environment through the use of words and images. This stage is marked by egocentrism which is the child’s belief that everyone sees the world the same way that the child does (Piaget, 1973). Research appears to show younger children as being more anxious than older children. Piaget’s theory of cognitive development may help explain the increase in anxiety. Children in the preoperational stage of development are not able to think logically. They focus on magical thinking and are less able to distinguish reality from fantasy (Piaget, 1973).

**Concrete operational stage.** As children get older and enter into the concrete operational stage, their cognitive abilities mature. School-aged children between the ages of six years to 12 years old are typically in the cognitive developmental stage of concrete operations. At this level they are beginning to understand abstract phenomena. Many children during this stage develop the ability to conserve number, length, and liquid volume. Conservation refers to the idea that a quantity remains the same despite changes in appearance. When referring to the concrete operations stage, the term, *operations*, means logical operations or principles we use when solving problems. During this period, the child uses symbols and manipulates these symbols logically. Children perform these operations within the context of concrete situations in this stage. Children’s information
processing capacities increase and problem solving becomes more advanced. These children are able to reason more logically and understand a view other than their own. Children are able to rationally think through the surgery process step by step. This logical progression may enable children to develop coping behaviors to help deal with the stress of surgery, thereby reducing anxiety.

**Concrete operational stage and pain behavior.** Growth and development stage as well as cognitive processes influence the physiological, psychological, and experiential pain components of children (Stevens, Hunsberger, & Browne, 1987). Thus, the health care provider must assess the child’s cognitive developmental stage prior to any invasive procedure and choice of pain management interventions.

Most children require sedation and analgesia for brief procedures that are painful or anxiety provoking. The cognitive developmental level of children will affect the way they perceive painful events. Therefore, clinicians need to individualize the preparation and sedation techniques depending on the child’s developmental stage.

Empirical literature suggests an association exists between childhood fears and pain. Savedra, Gibbons, Tessler, Ward, and Wegner (1982) investigated pain-related feelings of children between the ages of nine to twelve years old and discovered that hospitalized children often reported feeling nervous, tense, and scared when in pain. A study performed by Alex and Ritchie (1992) examined the intensity of pain after surgical procedures in school-age children that focused on the affective, cognitive, and sensory interpretation of the children’s pain experiences. This study found that fear of mutilation and concerns about body integrity were clearly stimulated or exaggerated by pain. Pain is
viewed as occurring inside and outside of the body. Therefore, children in the concrete stage of development would be ideal candidates to describe their pain and anxiety experiences.

There are some studies that have addressed older children’s ability to describe their pain and the methods of relieving it (Abu-Saad, 1994; Ely, 1992; Engel, 1996; Harbeck & Peterson, 1992; Polkki, Pietila, & Rissanen, 1999). Despite this substantive evidence, clinicians sometimes assess a child’s pain from an adult perspective and disregard or misinterpret the child’s perspective.

Research literature supports strong evidence of the ability of school-aged children and adolescents to give clinicians accurate cross-modality estimations of their pain intensity experience. LeFleur (1999) studied children’s and adolescents’ perceptions of the descriptors hurt, ache, and pain. The results give strong evidence of children’s and adolescents’ ability to use language to communicate pain experiences in a meaningful way.

Children in the concrete operation stages of development are better able to conceptualize and quantify abstract phenomenon (Piaget, 1969). These children are able to reason more logically and understand a view other than their own. Therefore, children in the concrete stage of development would be ideal candidates to describe their pain and anxiety experiences.

During the concrete operational phase, a child is able to understand the need for performing the procedures that are anxiety alleviating (e.g., increased body control, decreased vocal protest) and therefore the procedures caused them less distress (Engel & Kartin, 2004). For some children, concrete thinking affords a logical and realistic
understanding of the need for invasive procedures, and this knowledge is comforting. For other children, this knowledge may result in regression (Engel, 1988).

**Formal Operational Stage**

In the final stage of cognitive development from 12 years of age and beyond, children begin to develop a more abstract view of the world. They are able to apply reversibility and conservation to both real and imagined situations (Piaget, 1969). They also develop an increased understanding of the world and the idea of cause and effect. Children in this stage want to behave in a socially acceptable manner and show a controlled behavioral response when reacting to painful stimuli (Ball & Bindler, 2003). Adolescents usually have more sophisticated descriptions as experience is gained.

**Parental Involvement, Responses, and Perception**

Parents play an important role in efforts to promote children’s coping during painful procedures (Varni, Blount, Waldron, & Smith, 1996). Parents usually prefer to be present when their children undergo invasive procedures (Boie, Moore, Brummett, & Nelson, 1999). The parent can provide support, encouragement, reinforcement, and coaching the child in the use of coping strategies (Blount, Powers, Cotter, Swan, & Free, 1994). Parent anxiety during the procedure may also affect the level of distress the child presents (Jacobsen et al., 1990).

Parental perception is a very important aspect of children’s pain assessment undergoing nitrous oxide analgesia. Since this inhalational gas has an amnesic quality (Burnweit et al., 2004; Clark & Brunick, 1999; Gregory & Sullivan, 1996) children may not be very reliable in reporting their experience with nitrous oxide during outpatient minor surgical procedures. Since one parent usually accompanies the child during these procedures, parental perception of their children’s responses can be very useful in order to
analyze if this pain control using nitrous oxide analgesia is satisfactory and efficacious for their child.

Williams, Riley, Rayner, and Richardson (2006) reported satisfaction of nitrous oxide use by children, their parents, and clinicians involved with the painful procedure. The researchers found that repeated procedures carried out to the child were far less traumatic for the child’s parents and the professionals. Williams and colleagues (2006) reported that some of the parents’ comments were: “less stressful for the both of us,” “highly recommended,” “he cooperated,” and “can we use it next time?”

There is limited knowledge about how a child’s experience of pain affects his or her parents. Using a vignette methodology, a study by Goubert, Vervoort, Sullivan, Verhoeven, and Crombez (2008) examined emotional responses of school children’s parents to imagine different painful situations that their child might experience. This study found that the impact of parents catastrophizing about their child’s pain was most pronounced for parental distress, probably reflecting the increased threat value they attribute to their child’s pain. Catastrophizing generally refers to a negative cognitive process of exaggerated negative rumination and worry (Asmundson, Vlaeyen, & Crombez, 2004).

Other research studies supported findings that parents have unmet information needs and only passive involvement in pain care for their children (Simons, Franck, & Roberson, 2001; Woodgate & Kristjanson, 1996). A qualitative study was undertaken by Woodgate and Kristjanson (1996) to describe how parents and nurses respond to hospitalized young children experiencing pain from surgical interventions. This study sought to describe children’s responses to pain and examine the effect of others on children’s pain experiences. Parents’ actions showed that the parents played a crucial role
in the children’s care. The two major categories identified were the monitoring and comforting by the caregivers. In addition, subcategories emerged in regards to feelings experienced by parents and nurses as they coped with the children’s pain. Strategies influencing the caregivers’ behaviors were revealed. The findings revealed that parents were the bridge between nurses and children, especially during periods of severe pain (Woodgate & Kristjanson, 1996).

The observational assessment focusing on children has resulted in clinical recommendations regarding nurse and parent behavior for invasive pediatric procedures. There are few studies, however, that evaluate responses of parent behavior and child distress. Some studies reported that parents found distraction and soothing behaviors effective during their child’s painful procedures (Craig, McMahon, Morison, & Zaskow, 1984; Lewis & Ramsay, 1999). Parents’ most frequent responses to their child’s invasive procedure were verbal reassurance and physical comfort (Cohen, Bernard, & MacLaren, 2005). This study correlates with a prior investigation with preschoolers showing that reassurance is the most common parent behavioral response (Blount et al., 1989). A conflicting study suggests that a causal relationship exists between adult reassurance and child medical distress (Manimala, Blount, & Cohen, 2000). Manimale and colleagues found that reassurance produced increases in child distress relative to either the typical medical care control condition or the distraction condition. In light of these contradictory findings and a lack of theoretical basis for the studies, more investigation of factors influencing parental perceptions to their child’s stressful procedures is needed.

Nurses utilize parents as a useful source of information in assessing and managing pain in children. Parents know their children best. Therefore, parents can be a valuable asset for nurses to indicate when the child’s pain begins. In contrast, Hamers, Abu-Saad,
Halfens, & Schumacher (1994) found that information obtained from parents may not always be reliable because this information is usually verified by the nurse. In addition, Caty, Tourigny, and Koren (1995) found nurses to rely less on the parents when deciding to alleviate the child’s pain.

**Benefits of Nitrous Oxide/Oxygen Analgesia**

Numerous studies have shown the benefits and safety of nitrous oxide/oxygen analgesia administration for the management of pain and anxiety reduction in children undergoing minor surgical outpatient procedures (Annequin et al., 2000; Burnweit et al., 2004; Clark & Brunick, 1999; Cleary et al., 2002; Frampton, Browne, Lam, Cooper, & Lane, 2003; Kanagasundaram et al., 2001; Luhmann, Kennedy, Jaffè, & McAllister, 1999). These investigations addressed the efficacy, technical aspects, and/or the cost-effectiveness of nitrous oxide analgesia. Limited attention, however, has been given to parental perceptions of their child’s responses to determine effectiveness and satisfaction of nitrous oxide analgesia for the invasive procedure.

Since the study’s initial focus was on parents’ perceptions of their child’s responses undergoing an invasive procedure using nitrous oxide, it is important to review the literature on the efficacy and safety of this inhalational gas. The mixture of nitrous oxide and oxygen is an anesthetic gas with analgesic, anxiolytic, and amnesic properties. This inhalation gas was discovered over 200 years ago. The anxiety and pain associated with common painful minor procedures (such as incision and drainage of an abscess) has proved challenging to effectively minimize pain in young children. The ideal procedural sedation analgesia for young children is noninvasive, effective, rapid onset, brief duration, quick recovery, and safe and nitrous oxide fits all these qualities. Nitrous oxide sedation has a rapid onset of action (less than 30 seconds) with peak effects occurring in less than
five minutes. Complete recovery of inhalational nitrous oxide/oxygen is within a three to five minute period after termination of the drug. Another advantage of nitrous oxide is that titration is very easily accomplished. Titration is the process of administering a drug incrementally to a specific level or endpoint of sedation (Clark & Brunick, 1999).

The use of nitrous oxide for procedure-related pain control was found to be superior in regards to shorter recovery times, greater clinician satisfaction, and fewer side effects when compared to conventional treatment such as general anesthesia (Burnweit et al., 2004; Cleary et al., 2002; Luhmann, Kennedy, & Jaffee, 1999). Nitrous oxide has the ability to manage both pain and fear in children. In fact, a mixture of 20% of nitrous oxide and 80% of oxygen has the same analgesic equipotence as 15 milligrams of morphine sulfate (Chapman, Arrowood, & Beecher, 1943; Clark & Brunick, 1999) but without the risks of adverse effects.

Clinical studies focusing on the analgesic properties of nitrous oxide in children have shown consistent patterns of moderate to good pain relief undergoing minor procedures. Ninety children (one to eleven years old) who underwent repeated painful procedures such as lumbar punctures or bone marrow biopsies were given nitrous oxide. These children all experienced a short recovery time, amnesia of the painful event, and a lower level of distress (Kanagasundaran et al., 2001).

Cleary and colleagues (2002) evaluated the efficacy and safety of nitrous oxide for children undergoing intra-articular cortico-steroid injection. Child, nurse, and parent pain scores were compared using a 0-10 centimeter visual analogue scale immediately after the procedure. The mean rank child score was 2.12 which was greater than the nurse score (1.97), which was greater than the parent score (1.91). In a small number of cases there
appears to be differences between children’s, nurses’, and parents’ perception of procedure-related pain (Burnweit et al., 2004).

In summary, nitrous oxide facilitates outpatient minor surgical procedures by decreasing suffering of the child and stabilizing the “moving target” for the health care providers. This inhalational agent is efficacious, decreases the time needed to subdue a child, and eliminates costly operating room visits and hospital admissions (Burnweit et al., 2004). Most importantly, nitrous oxide provides adequate comfort for the child experiencing anxiety and pain for minor surgical outpatient procedures.

**Adverse Effects and Contraindications of Nitrous Oxide**

Nitrous oxide/oxygen analgesia, like all pediatric procedural sedation, presents certain risks. The American Academy of Pediatrics (AAP) warns that greater than 50% of nitrous oxide may increase the chances of deep sedation (AAP & AAP Dentistry, 2008). The low incidence of over-sedation reveals that nitrous oxide is safe if used at lower concentrations (below 50%) as previously reported (American Society of Anesthesiologists, 2002; Farrell, Drake, Rucker, Finkelstein, & Zier, 2008; Frampton et al., 2003; Kanagasundaram, et al., 2001).

The effect of nitrous oxide on the developing brain has recently become a very controversial issue. Human brain development continues quickly after birth and for several years. During synaptogenesis, neurons are rearranged in the brain to develop their synaptic connections as well as some unnecessary neurons that will undergo apoptosis (Schmitt & Baum, 2008). The term, apoptosis, or programmed cell death, is a normal component of the development of multicellular organisms. Cells expire that is triggered by a wide variety of stimuli. During apoptosis, cells die in a controlled way (Lockshin & Zakeri, 2001). Excessive apoptosis causes hypertrophy, such as ischemic damage,
whereas an insufficient amount, results in uncontrolled cell proliferation, such as cancer (Ameisen, 2002).

Some anesthetic agents such as nitrous oxide, propofol, ketamine, and halothane all increased apoptic neurogeneration in developing rat brain which may lead to neurotoxicity (Jevtovic-Todorovic, 2005; Zou et al., 2008). Interestingly, these researchers found a greater nitrous oxide and ketamine neurotoxicity in the adult compared to the infant rat, via another mechanism of cell death (Davidson & Soriano, 2004).

In a study conducted by Jevtovic-Todorovic and colleagues (2003), researchers found that nitrous oxide and midazolam alone caused no apoptosis, whereas isoflurane produced significant apoptosis. It must be noted that the rats in the study, as compared to humans, were not adequately monitored and there was no indication that cerebral perfusion and oxygenation was maintained (Davidson & Soriano, 2004; Jevtovic-Todorovic et al., 2003). It is important to realize that rat brains develop over two weeks as compared to a human brain which develops over several years. Therefore, if an average neonatal anesthetic were one to two hours long, this would be equivalent to less than a minute in a rat. Based on current available studies, it is difficult to positively determine if nitrous oxide harms the developing brain until more research is conducted to assess the risk of this inhalational agent.

Some studies have shown that nitrous oxide administered in therapeutic concentrations affects hematopoietic and neural cells by irreversibly oxidizing the cobalt atom of vitamin B$_{12}$ from an active to inactive state (Ahn & Brown, 2005; Guttormsen, Refsum, & Uleland, 1994; Nunn & Sharer, 1982; Pema, Horak, & Wyatt, 1998). Cobalamin (vitamin B$_{12}$) deficiency may result from inactivation by chemical reaction with the inhaled
anesthetic nitrous oxide (Ahn & Brown, 2005; Guttormesen, Refsum, & Uleland, 1994). Nitrous oxide irreversibly changes the cobalt component of the coenzyme, altering the functional reduced form to the inactive, oxidized form (Guttormsen, Refsum, & Uleland, 1994). This inhibits methionine synthetase and prevents the conversion of methyl-tetrahydrofolate to tetrahydrofolate, which is needed for deoxyribonucleic acid (DNA) synthesis, building of the myelin sheath, and methyl substitutions in neurotransmitters (Singer, Lazaridis, Nations, & Wolfe, 2008). Impairment of DNA synthesis in rapidly dividing cells of the bone marrow and gastrointestinal mucosa leads to megaloblastic anemia, glossitis, and diarrhea (Green & Kinsella, 1995). Individuals with subclinical vitamin B$_{12}$ deficiency may be more prone to develop deficits after more limited exposure to nitrous oxide (Singer et al., 2008). Prognosis tends to be good with prompt recognition, withdrawal of exposure, and vitamin B$_{12}$ supplementation (Green & Kinsella, 1995; Singer et al., 2008).

Vomiting is another adverse effect of the administration of nitrous oxide/oxygen analgesia (Clark & Brunick, 1999; Luhmann, Kennedy, Jaffe, & McAllister, 1999; Luhmann, Schootman, Luhmann, & Kennedy, 2006). The incidence of post-procedural nausea and vomiting occurred more in children than adults (Watcha & White, 1992). Nitrous oxide may cause nausea and vomiting by stimulating the sympathetic nervous system with catecholamine release, changes in middle ear pressure with stimulation of the vestibular system, and increased distension of the gastrointestinal tract (Clark & Brunick, 1999; Scholz & Steinfath, 1999).

Diffusion hypoxia is another potential adverse effect of nitrous oxide. During this phenomenon, it is postulated to occur at the end of inhalation sedation, when the flow of nitrous oxide is terminated. Nitrous oxide diffuses out of the blood in large volumes,
diluting oxygen in lung alveoli and reducing alveolar oxygen tension, which then produces hypoxia (Jeske, Whitmire, Freels, & Fuentes, 2004). Nitrous oxide exits the body faster than the nitrogen that replaces it, thereby diluting the oxygen supply and thus, reducing the oxygen blood saturation (Clark & Brunick, 1999). Some researchers hypothesized that headache, nausea, and lethargy may occur due to the decreased oxygen saturation blood levels caused by the fast exit of nitrous oxide upon its termination (Dunn-Russell, Adair, Sams, Russell, & Baren, 1993; Papageorge, Hunter, Norris, & Rosenberg, 1992). The administration of 100% oxygen for the first three to five minutes after nitrous oxide termination has been recommended to prevent diffusion hypoxia (Clark & Brunick, 1999). When systematically studied, however, diffusion hypoxia generally appears to be unfounded. Some researchers reported that the occurrence of hypoxia was not observed using breathing room air instead of 100% of oxygen in healthy participants following administration of nitrous oxide and oxygen (Jeske et al., 2004).

Nitrous oxide is contraindicated in children with bowel obstruction and intrathoracic injuries with the risk of pneumothorax. This inhalational agent diffuses into air filled spaces and thus increases the volume of space (Deshpande & Tobias, 1996). Since nitrous oxide increases intracranial pressure by the rapid replacement of nitrogen with nitrous oxide in air spaces, it is contraindicated in children with closed head injury and altered intracranial compliance (Clark & Brunick, 1999).

**Conscious Sedation**

Nitrous oxide/oxygen analgesia is categorized as a conscious sedation technique. Conscious sedation is defined as “a stage of sedation that permits appropriate response by the patient to physical stimulation or verbal command (AAP, 1992, p. 1112). At this level
of sedation, the patient should have a decreased level of consciousness but is able to be
aroused easily (American Society of Anesthesiologists Task Force, 2002).

The 2001 revised Joint Commission on Accreditation of Healthcare Organizations
(JCAHO) Sedation Care Standards replaced the term conscious sedation with “moderate
sedation/analgesia” (JCAHO, Sedation and Anesthesia Care Standards, 2001) and
provided clearer definitions of this term as well as other sedation levels. Moderate
sedation is defined as a “drug-induced depression of consciousness during which patients
respond purposefully to verbal commands either alone or accompanied by light tactile
stimulation. No interventions are required to maintain a patent airway, spontaneous
ventilation is adequate, and cardiovascular function is maintained” (AAP, AAP Dentistry,
Cote & Wilson, 2008, p.9).

Procedural sedation has been defined by the American College of Emergency
Physicians (1998) as a “technique of administering sedatives or dissociative agents with
or without analgesics to induce a state that allows the patient to tolerate unpleasant
procedures while maintaining cardio-respiratory function (p. 664).”

According to the AAP (AAP, American Academy of Pediatric Dentistry, Cote, Wilson,
& The Work Group on Sedation, 2006), the goals of sedation in children for diagnostic
and therapeutic procedures are to: (a) guard the child’s safety and welfare, (b) minimize
physical discomfort and pain, (c) control anxiety, minimize psychological trauma, and
maximize the potential for amnesia, (d) control behavior and/or movement to allow the
safe completion of the procedure, and (e) return the child to a state in which safe
discharge from medical supervision, as determined by recognized criteria is possible.
Discharge criteria include: (a) cardiovascular function and airway patency are satisfactory
and stable, (b) easily arousable and protective reflexes are intact, (c) child can talk, (d) can sit up unaided, and (e) state of hydration is adequate.

Moderate sedation in a pediatric setting is indicated when other means to overcome a child’s fears fail, but a major problem in this situation is that there is no route for quick sedation. Traditionally, oral and rectal routes have been used for drugs like chloral hydrate or diazepam, but these drugs are not ideal because of the slow onset of action, long effect, and a variable uptake (Ljungman, Kreuger, Andreasson, Gordh & Sorensen, 2000). An ideal sedative drug should provide rapid onset, be efficacious, have short recovery time, possess minimum side effects, cost-effective, and be safe and easy to administer. Nitrous oxide has all of these qualities. This inhalational gas has a short onset time, a relatively rapid redistribution phase, short half-life, and well suited for use in children.

**Moderate Sedation Techniques**

Nitrous oxide/oxygen inhalational analgesia is considered to be a moderate sedation technique. This sedation has many advantages over other pain and anxiety management options for children (Clark & Brunick, 1999). Nitrous oxide has a faster onset (about five minutes or less) than other moderate sedation medications (such as ketamine or midazolam). Children that receive nitrous oxide, quickly recover after cessation of treatment and are able to be immediately discharged (Burnweit et al., 2004).

Alternate methods commonly used for moderate sedation with children’s invasive procedures include, but not limited to are benzodiazepines (Singh, Manu, & Singh, 2005), opioids (Yaster, Nichols, Deshpande, & Wetzel, 1990), ketamine (Alfonzo-Echeverri, Berg, Wild & Glass, 1993; Tobias, Phipps, Smith & Mulhern, 1992), fentanyl (Schultz, 1993), and chloral hydrate (Buck, 2005). These pharmacotherapeutics are usually
efficacious in pain and reducing anxiety, however, they do have many adverse effects. Some negative effects of these drugs include oxygen desaturation, respiratory depression, airway obstruction, prolonged drowsiness, and lethargy (Bartolome, Lopez-Herce Cid, & Freddi, 2007; Buck, 2005).

**Outpatient Minor Surgical Procedures**

Previous studies in pediatric settings have documented the effects of control-related coping during scheduled minor invasive procedures. Planned procedures allow the child to learn about the procedure beforehand and to prepare for it (Langer, Chen, & Luhmann, 2005; Weisz, McCabe, & Dennig, 1994). Preparation includes the provision of detailed information on the events to follow and modeling and behavioral rehearsal of the upcoming procedure. The level of information provided during preparation must be tailored to the developmental level of the child as well as parents’ capabilities of comprehension.

Minor surgical procedures are painful and frightening for most children. Children are less likely than adults to understand the rationale for a given procedure, how long it may take, or how much discomfort may be involved (Butler, Symons, Henderson, Shortliffe, & Spiegel, 2005). Therefore, appropriate preparation before the planned procedure is essential to minimize emotional trauma for the involved child and parent.

**Children’s Responses to Procedures**

Anticipation of pain, separation from parents, loss of control, and fear of the unknown are some of the factors associated with increased anxiety during minor surgical outpatient procedures among children (Maligalig, 1994). Most children undergoing treatment for invasive procedures endure pain and anxiety (Jay, Elliott, Ozolins, Olson, & Pruitt, 1985).
During these procedures, children often respond by crying, screaming, groaning, muscle tension, and verbalizations of anxiety and pain (Jacobsen et al., 1990).

Some empirical studies found a significant relationship between children’s age, quantity, and type of distress behavior in response to pain (Jay et al., 1983; LeBaron & Zelter, 1984). For example, younger children (less than seven years old) were apt to express their behavior in a more intense, overt, and movement-oriented way than older children. Older children demonstrated greater control and fewer emotional outbursts. The investigators explained these differences by reasoning that younger children are less inhibited in their behavioral expressions of anxiety and that perhaps older children have a greater understanding of medical procedures.

**Summary**

Overview of the literature was reviewed regarding procedural pain in children and parental presence during invasive procedures. The use of literature in GT methodology approach prior to data collection was briefly debated.

Various scientific studies of the consequences of acute pain in children were provided. Researchers reported that unrelieved pain may intensify illness/injury, avert wound healing, and lead to infection (Engel & Kartin, 2004). Thus, the importance of providing adequate pain relief in children undergoing a minor surgical procedure should be a major priority for all health care professionals. Reports of the risks and benefits of the use of nitrous oxide for procedural sedation were discussed. In addition, moderate sedation techniques were briefly reviewed.

Piaget's theory of cognitive development of children was briefly reviewed (Piaget, 1973). There are four distinct stages but the concrete operational stage (six to twelve years old) was focused upon since the majority of children undergoing invasive
procedures for this study were in this age range. Piaget (1973) asserts that during the concrete stage, children can begin to understand some abstract phenomena (such as pain). Thus, children at this developmental stage are ideal candidates to describe their pain and anxiety experiences.

There were several quantitative studies reviewed reporting the safety and efficacy of nitrous oxide for children undergoing minor outpatient procedures. There is a gap in the literature, however, exploring parental behaviors to their child’s responses during invasive procedures.

Furthermore, empirical literature is scarce reporting parental perceptions of their child’s responses undergoing a minor outpatient surgical procedure. Soliciting parental perceptions provided additional perspectives in the acceptability and satisfaction for procedural pain relief and anxiety reduction using nitrous oxide analgesia in children.
Chapter 3

Method

This chapter includes a description of the study design, data collection, data analysis, and protection of human subjects. In addition, explanations of GT methodology and establishment of trustworthiness are provided.

Study Design

An exploratory, qualitative design was selected because the intent of the study was to make the phenomenon (parental perception of their child’s responses) understandable and to identify the perceptions of a particular group (parents of school-aged children undergoing a minor surgical procedure using nitrous oxide). The study design is qualitative with a GT approach. A qualitative, GT approach was required to explore the reality of parents’ perspectives in a context that could not be obtained through a quantitative design.

A GT approach was chosen to explore the parental perception of their school-aged child’s responses to an outpatient minor surgical procedure with nitrous oxide (N₂O) analgesia. This approach is most suited to the study’s purpose, considering the complex, subjective nature of the parent’s perceptions of their child’s responses to an invasive procedure using N₂O. In addition, a qualitative approach best facilitates the description of the process whereby parents reveal their perception of their child’s responses to the invasive procedure.

Grounded Theory Methodology

The GT approach is both a way to do qualitative research and a method to develop inductive theory. This approach was developed in the 1960s by two sociologists: Barney
Glaser and Anselm Strauss, the primary founders of GT. Glaser and Strauss “discovered” GT as a way to help reveal how people manage the problematic situations in their lives. GT guides the researcher through the simultaneous collection and analysis of data for the purpose of explicating the theory that lies within it (Glaser & Strauss, 1967).

GT approach is often used when little is known about a subject or problem area (McCann, 2003; Morse, 1991). GT may also be used when there is already some knowledge about the research phenomenon, but a new perspective is sought (Backman & Kyngas, 1999; Smith & Biley, 1997). In this study, the new knowledge being sought was the parent’s perception of their child’s responses undergoing a minor procedure with N₂O. Researchers already have shown that N₂O is safe and efficacious for children during minor procedures (Burnweit et al., 2004; Kanagasundaram et al., 2001; Luhmann, Kennedy, Jaffe, & McAllister, 1999). Scientific literature was scant however, focusing on the parental perceptions whose child was receiving N₂O for a minor procedure. Currently, there are no theories pertaining to the parental perceptions of their child’s responses undergoing an outpatient minor surgical procedure with N₂O analgesia. Due to the lack of data, an inductive methodology, GT was implemented for this study.

GT is a qualitative research approach suited to the purpose of theory development (Glaser, 1995; Strauss & Corbin, 1990). GT consists of the discovery and development of a theory based on information that is collected and analyzed simultaneously, comparatively, and systematically (Glaser & Strauss, 1967).

Essentially, GT is a qualitative research methodological approach that seeks to understand the meaning of the phenomenon or event from the participant’s perspective.
Glaser and Strauss (1967) emphasized that the theory is grounded in the data and not predetermined by any theoretical perspectives, assumptions, or speculations.

**Aims and features of grounded theory.** The central aim of GT is generation of theory from the data. GT is aimed at developing theory that is grounded in the actions, interactions, and processes of the everyday world. Researchers begin with an area of interest, collect the data and permit pertinent ideas to develop without preconceived theories and hypotheses to be tested for confirmation. Glaser and Strauss (1967) asserted that rigid preconceived assumptions prevent development of the research. They emphasized that imposing a framework might block the awareness of major concepts emerging from the data. Since this study was using a GT approach, no theoretical framework or hypothesis is provided before the study is conducted.

The GT qualitative research approach is suited to areas that have not been previously explored (Glaser & Strauss, 1967). This approach allows the emergence of theory from the data. Grounded theory is an inductive method for generating hypotheses and models emerging from data. Grounded theory can shed light on people’s experiences and how they perceive situations.

**Grounded theory key characteristics.** According to Glaser (1978), the following characteristics are necessary for GT: (a) theoretical sensitivity, (b) theoretical sampling, (c) constant comparative analysis, (d) coding and categorizing the data, (e) theoretical memos and diagrams, (f) literature as a source of data, and (g) integration of theory.

GT processes do not always follow in chronological order. Data collection and analysis are connected from the beginning of the study, proceed in parallel and interact continuously. This means that the collection of data becomes more focused as the process develops. The GT key characteristics are described below.
**Theoretical Sensitivity**

Theoretical sensitivity and awareness of the researcher, a concept developed by Glaser (1978), refers to finding meaning in the data. This term means that researchers can differentiate between significant and less important data and have insight into their meanings. Some of the sources for theoretical sensitivity are professional and personal experiences (Holloway & Wheeler, 2002) and preliminary review of the literature (Carpenter, 1999).

Strauss and Corbin (1998) claim that theoretical sensitivity increases when researchers interact with the data because they think about emerging ideas, ask further questions and see these ideas as provisional until they have been examined over time and are finally confirmed by the data.

**Sampling and Selection of Participants**

In the qualitative research approach, the participants are not acted upon, but rather are active participants of the study. The participants help to better inform and understand their perspective of the phenomenon of interest (Streubert & Carpenter, 1995). In quantitative research, participants are chosen randomly and the sample size must be sufficient to establish significance.

For this qualitative research study, participants were selected to participate in the research based on their firsthand experience of the phenomenon of interest (perception of their school-age child’s responses to a minor surgical outpatient procedure with N₂O). The researcher interviewed as many individuals as possible to obtain a clear understanding of the parental perspective. Lincoln and Guba (1985) refer to this type of sampling as purposeful. Purposeful sampling is the dominant strategy in qualitative
research. This type of sampling uses predetermined criteria, for example, gender, age, or specific diagnosis. Purposeful sampling seeks information-rich cases which can be studied in depth (Patton, 1990). The selection of participants, settings, or units of time are criterion-based (certain criteria applied), and the sample is chosen accordingly (Holloway & Wheeler, 2002). Sampling units are selected for a specific purpose on which the researcher decides. Thus, the term ‘purposeful’ sampling is used.

In GT, theoretical sampling refers to sampling which proceeds on the basis of emerging, relevant concepts and is guided by developing theory. Grounded theorists use theoretical sampling which is the process of simultaneously collecting, coding, and analyzing data to generate theory. Theoretical sampling is a complex, dynamic process that shifts as the categories develop and the theory emerges (Glaser & Strauss, 1967). Thus, the researcher can only plan in advance the initial sampling for data collection. Glaser and Strauss (1967) affirm that the sampling process is entirely controlled by the emerging theory. For this study, the researcher selected the sample based on the concepts and theoretical issues that arose during the research study.

One of the main differences between theoretical sampling and other sampling types is time and continuance. For example, theoretical sampling in GT continued throughout the study and was not planned beforehand. Researchers select their sample on the basis of concepts and theoretical issues that arise during the research. The theoretical ideas control the collection of data; therefore researchers have to justify the inclusion of particular sampling units (Holloway & Wheeler, 2002).

As initial data are collected and analyzed, further decisions about participants, sample size, settings, and the type of data to be collected were based on the emerging theory (Glaser, 1978; Schreiber, 2001). Theoretical sampling occurred when the investigator
collected new data to compare emerging categories and established conceptual boundaries that were related to the evolving theory (Strauss & Corbin, 1990). The goal of the developed theory was to illustrate the basic social processes (BSP) engaged in by the participants in a particular setting. People sharing common circumstances as well as experience shared meaning and behaviors that constitute the substance of GT (Hutchinson, 1993). Participants are not chosen on the basis of their representativeness, but because of their expert knowledge of the phenomena under scrutiny. For this study, the phenomena under scrutiny are the participant’s (parental) perception and perspective of their child’s response to an invasive procedure using N₂O. In other words, all shared a common experience and thus, a selective sample was used. The participants were chosen before the data collection. This method of sampling is called theoretical sampling. This sampling technique was used to increase the probability of describing the full scope of the studied phenomenon (Lincoln & Guba, 1985).

Sampling continued until theoretical saturation occurs. This was reached when no new data emerged relevant to certain categories and subcategories (Glaser, 1978). The quality of the data is more important in theoretical saturation than the frequency with which it recurs. Morse (1995) suggests that researchers can recognize when saturation has been achieved by the quality of the theory that has been developed. For this study, saturation was met with 12 participants. The researcher proceeded to interview participants to see if new data emerged. After saturation was ensured, data collection was terminated after 22 participant interviews.

People who share common experiences are considered useful informants. Morse (1991) identified good informants as those willing to share their experience with the interviewer.
Since this is a qualitative study, it was essential that the researcher selected a sample that could articulate their thoughts and experiences and thus enhanced the researcher’s understanding of the concept (Appleton, 1995).

**Constant Comparative Analysis**

Continuous comparison methods as described by Glaser and Strauss (1967) were used for this study. Constant comparative analysis is where the investigator compares each section of the data with every other datum throughout the study for likenesses, differences, and connections. This is the principal approach to data analysis in the development of a GT (Benton, 2000). Data collection and analysis take place simultaneously (Blaikie, 1993). Glaser and Strauss (1967) identified four stages in the constant comparative method. The first stage is comparing incidents applicable to each category. The second stage is integrating categories and their properties. The third stage consists of delimiting the theory. Finally, the fourth stage comprises writing the theory. The constant comparison process continued until a theory with sufficient detail was generated. Each stage is described below.

**Coding and Categorizing Data**

The first stage is coding and categorizing that continues throughout the research study. Coding initiates the process of theory development (Charmaz, 2000). In GT, coding is the process by which concepts or themes are identified and labeled during the analysis. Data are transformed and reduced to build categories. A category is a group of concepts and ideas with similar characteristics that form a unit of analysis (Holloway & Wheeler, 2002). The analyst groups concepts together and develops categories. Through the emergence of these categories theory can be evolved and integrated. There are different levels of coding: open and selective. These coding levels are briefly described below.
Open Coding

Open coding, also known as first-level or substantive coding, is the process of breaking down the data into discrete parts in order to conceptualize and categorize them. The researcher conducts open coding by carefully reading through the transcript or other document, examining the data, and selecting phases, words, or stories that, taken individually contain a single unit of meaning (Schreiber & Stern, 2001). The researcher tries to use the words of the participant in labeling the unit.

Selective Coding

Selective coding aims to identify a core category, and attempts to establish connections between this and other categories (Charmaz, 1990). These constructs contain developing theoretical ideas and themes. The researcher formulates hypotheses and confirms them through further data collection and analysis, moving back and forth between inductive and deductive thinking.

For an emerging theory to be integrated, a core category must be present (Hutchinson, 1993). The core category is broad in range and is able to explain the relationship between the other categories that emerge in the data. According to Strauss (1987), there are six criteria for assessing a core category. The criteria is as follows: (a) it appears frequently in the data, (b) it helps explain most of the variation in the data, (c) it links easily with other categories, (d) when identified in a substantive study, it has implications for a general or formal theory, (e) as it emerges from the data, the theory is able to progress forward, and (f) it permits maximum variation in the analysis.

Theoretical Memos and Diagrams

The researcher writes field notes and memos throughout the research process. Memos are simply notes and ideas that the investigator makes during data collection and analysis
in order to record and explicate the theory as it is developed (Smith & Biley, 1997). Memos should be dated and detailed. Memo writing is an excellent way to focus on the emerging concepts and their interrelationships. The grounded theorist may carry a Dictaphone or notebook to record these memos. Diagrams in the memos can help to remind the analyst and structure the study. Diagramming is an invaluable tool to help the researcher reflect on and understand the relationships between and among emerging categories. Even using sketchy diagrams, the researcher can sometimes see what is missing from the emerging theory (Schreiber & Stern, 2001). Memos and diagrams provide ‘density’ for the research and guide the researcher to base abstract ideas in the reality of the data (Holloway & Wheeler, 2002).

**Literature as Data Source**

In GT, a preliminary brief literature review is done before data collection and analysis to justify the need for the study, develop sensitizing concepts and provide a background to the study (McCann & Clark, 2003). The second literature review establishes a vital connection between theory and reality (Hutchinson, 1993).

The literature actually becomes a source of data. When categories have been found, analysts search the literature for confirmation or denial of these newly discovered categories. Strauss and Corbin (1998) assert that there are five main benefits for reviewing the literature. The benefits are: (a) preliminary review enhances theoretical sensitivity, (b) useful secondary source of data, (c) questions arise about the data, (d) important means of theoretical sampling, and (e) approach to validating the theory.

**Integration of Theory**

Throughout the inductive theory process in GT, there is interaction with the data, and the researcher uses memos to assist with conceptualization of the theory. Categories
should be linked with each other and connected tightly to the data. Glaser (1978) asserts that three key strategies are used to develop and add substance to the emerging theory. The first strategy is category reduction where a large number of categories are identified. Subsequently, clustering categories within bigger categories can lessen these. The second strategy is selective sampling of the literature where the literature is integrated in the emerging theory and categories. Finally, the third strategy is selective sampling of the data. This is where more data is collected from the field in order to develop and generate theory.

**Trustworthiness in Qualitative Research**

Trustworthiness in qualitative research is similar to validity in a quantitative study. Validity in quantitative research determines whether the research truly measures what it was intended to measure or how truthful the research results are (Golafshani, 2003). Validity is established through ensuring rigor in the process of data collection and analysis. Trustworthiness in qualitative research means methodological soundness and adequacy (Holloway & Wheeler, 2002). Establishing trustworthiness ensures the quality of the findings. This study was guided by Lincoln and Guba’s (1985) criteria to establish trustworthiness in qualitative inquiry. Lincoln and Guba (1985), emphasized that the qualitative researcher must persuade the readers that the study findings are indeed valid. Lincoln and Guba (1985) identified a set of criteria to ensure trustworthiness in qualitative research. They compared these qualitative criteria with quantitative research. The criteria for judging the quality of qualitative research are: credibility, transferability, dependability, and confirmability. These principles are established through the processes of data collection and analysis. Lincoln & Guba (1985) posit that trustworthiness of a
research study is important in evaluating its worth. The criteria of trustworthiness will be described separately, but are indeed interrelated.

**Credibility.** The first criterion of trustworthiness is credibility which refers to confidence in the truth of the findings. Guba and Lincoln (1981) suggest that the truth value of a qualitative study be evaluated by its credibility instead of internal validity as in quantitative research methods. Furthermore, the authors state that the determination of credibility can be accomplished only taking data and interpretations to the sources from which they were drawn and asking people whether they believe or find the results plausible (Guba & Lincoln, 1981). Thus, a qualitative study is deemed credible if it reveals accurate descriptions of participants’ experiences and that of the people having that experience would immediately recognize it from those descriptions as their own (Sandelowski, 1986).

Credibility in qualitative research corresponds to internal validity in quantitative research (Lincoln & Guba, 1985). With quantitative inquiry, internal validity refers to the extent to which the findings accurately describe reality. Credibility depends on the richness of the data gathered and on the analytical abilities of the researcher rather than on sample size (Patton, 1990). This means that the participants recognize the meaning that they themselves give to a situation and the truth of the findings in their own social context. The researcher’s findings are compatible with the perceptions of the participants (Holloway & Wheeler, 2002).

One technique for establishing credibility includes making segments of the raw data available for others to analyze, and the use of “member checks,” in which respondents are asked to corroborate the findings (Lincoln & Guba, 1985). Member checking is defined as the checking and verification of the data or interpretations by the participants.
(Holloway & Wheeler, 2002). Subsequently, they ask if the participants feel that the interpretation is a true and fair representation of their perspective. According to Holloway and Wheeler (2002), the purposes of member checks are to: (a) detect if the participant’s viewpoint is accurately presented, (b) give opportunities for participants to change errors which they feel they might have made, (c) assess the researcher’s understanding and interpretation of the data, and (d) provide the participants the opportunity to challenge the researcher’s ideas. Feedback from others ensures the trustworthiness of the research, and a member check is one of the strategies for achieving this (Holloway & Wheeler, 2002).

**Transferability.** Lincoln and Guba (1985) use transferability instead of generalizability. Transferability refers to showing that the findings have applicability in other contexts. The descriptive interpretation which results from this analysis should apply to other parents’ perspectives of their school-aged children’s responses in similar situations.

In quantitative research, external validity refers to the ability to generalize findings across different settings (Hoepfl, 1997). In the naturalistic paradigm, the transferability of a working hypothesis to other situations depends on the degree of similarity between the original situation and the situation to which it is transferred. Lincoln and Guba (1985) assert that the researcher cannot specify the transferability of findings; the researcher can only provide sufficient data that can then be used by the reader to determine whether the findings are applicable to the new situation.

**Dependability.** Another aspect of trustworthiness is dependability. Lincoln and Guba (1985) use the term dependability instead of reliability which corresponds to quantitative research. Dependability refers to showing that the findings are consistent and could be repeated. Lincoln and Guba (1985) assert that if the study findings are dependable, these
findings should be consistent and accurate. This means that the audience will be able to evaluate the adequacy of the analysis through following the decision-making process of the researcher (Holloway & Wheeler, 2002).

In quantitative research, there are three types of reliability (Kirk & Miller, 1986) which relates to the: (a) degree to which a measurement, given repeatedly, remains the same, (b) stability of a measurement over time, and (c) similarity of measurements within a given time period.

Lincoln and Guba (1985) use audit trail to enhance the dependability of qualitative work. An audit trail is a detailed explanation of the decision-making process of the researcher to demonstrate the logic and development of the research path (Holloway & Wheeler, 2002). This helps readers follow the researcher’s path and shows how the researcher achieved their conclusions.

**Confirmability.** Finally, confirmability is another important aspect in establishing trustworthiness. Confirmability refers to a degree of neutrality or the extent to which the findings of a study are shaped by the respondents and not researcher bias, motivation, or interest. Confirmability is the degree to which the results could be confirmed or corroborated by others. In qualitative inquiry, confirmability has replaced the term objectivity. Conventional research relies on quantitative measures to define a situation relatively value-free, and thus, objective. On the contrary, qualitative research which relies on interpretations and is value-bound is considered to be subjective. In quantitative research, subjectivity leads to results that are unreliable and invalid (Holloway & Wheeler, 2002). As the research is judged by the way in which the findings and conclusions achieve their aim and are not the result of the researcher’s prior assumptions and preconceptions, Lincoln and Guba demand ‘confirmability.’ Lincoln and Guba (1985)
question the true objectivity of statistical measures and the possibility of ever attaining pure objectivity at all. Lincoln and Guba (1985) refer to “confirmability” of the research when the researcher can demonstrate the neutrality of the research interpretations through a “confirmability audit.” This is where readers can trace the data to their participants. This means providing an audit trail consisting of: (a) raw data, (b) analysis notes, (c) reconstruction and synthesis products, (d) process notes, and (e) preliminary developmental information (pp. 320-321). Guba and Lincoln (1981) proposed that in qualitative research, confirmability is achieved by establishing auditability, applicability and truth value by which neutrality is judged.

Protection of Human Subjects

The human rights of the participants were protected according to the guidelines set by the University of Miami Human Subjects Committee and the Western Institutional Review Board. In addition, permission to conduct the study was obtained from the children’s hospital where the study participants were recruited. Institutional Review Board (IRB) approvals were obtained prior to the implementation of the research. Informed written or verbal consent was obtained from all participants. As required by the University of Miami IRB, the mandatory elements were included in this informed consent. The eight required elements which, unless waived by the IRB, were included in the informed consent: (a) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental, (b) a description of any reasonably foreseeable risks or discomforts to the subjects, (c) a description of any benefits to the subjects or to others which may reasonably be expected from the research, (d) a disclosure of appropriate alternative
procedures or courses of treatment, if any, that might be advantageous to the subjects, (e) a statement about how confidentiality of the subjects will be maintained, (f) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, and where further information may be obtained, (g) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subjects, and (h) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subjects is otherwise entitled, and the subjects may discontinue participation at any time without penalty or loss of benefits to which the subjects is otherwise entitled.

In addition to the eight required elements, federal regulations include six additional elements of informed consent. When appropriate, one or more of these elements of information were provided to each subject. These elements included: (a) a statement that the particular treatment or procedure may involve risks to the subjects (or to the embryo or fetus, if the subjects is or may become pregnant) which are currently unforeseeable, (b) anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent, (c) any additional costs to the subjects that may result from participation in the research, (d) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subjects, (e) a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject, and (f) the approximate number of subjects involved in the study.
All pediatric surgeons at the children’s hospital were approached to request access and written permission to allow their patients’ parents to participate in the study. The researcher attained approval by the surgeons and chief nursing officer of the hospital prior to conducting the study.

The investigator ensured the confidentiality of every participant. Confidentiality is the right of an individual to have personal, identifiable information kept private. Each participant was assured confidentiality by assignment of a code number to all interviews and reported findings. Pseudonyms or initials were also assigned in transcripts. All research data were kept confidential and locked in the researcher’s office. In order to protect the participants’ confidentiality, the demographic data forms were separated from the transcribed interviews. This data was accessible only to the investigator. The audiotapes and transcriptions of the interviews will be retained for five years after completion of this study and then will be destroyed.

Sample

An exact determination of the size of the population for a qualitative study cannot be established a priori (Morse, 2000; Sandelowski, 1995a). The number of participants is not predetermined and remains unknown until the data are collected. Typically, the more widespread and varied the data, the larger the data set must be to reach theoretical saturation; however, the researcher must remember that variation is needed for theory development (Schreiber & Stern, 2001). For this GT study, the sample size was guided by the principle of “saturation,” a process by which investigators collect and analyze data until no new themes are generated (Glaser & Strauss, 1967). Researchers suggest that saturation may be reached between twelve and twenty participants (Kuzel, 1992).
Purposeful sampling was undertaken on the basis that participants had experience of the phenomena being studied and could articulate this experience (Holloway & Wheeler, 2002). A purposeful sample of parents of school-aged children was obtained from the pediatric surgery department located at a children’s hospital in southeastern Florida, United States. Since a GT approach was used, the sample size was determined after theoretical saturation occurred. The sample consisted of parents or legal guardians of healthy school-aged children that underwent scheduled minor surgical outpatient procedures with N₂O analgesia.

Sample recruitment originally took place at the pediatric surgeons’ office. The surgical scheduler informed the investigator and two outside key personnel all pre-planned elective procedures with administration of N₂O for children between the ages of four years and eighteen years old. Key personnel included two pediatric surgical nurse practitioners at the research site location. Children and parents who fit the study criteria were potentially included in the research. Key personnel invited the parent for study participation at the time of procedure scheduling or at the outpatient center (OPC) prior to the procedure. If the parent or guardian agreed to participate in the study, the investigator was subsequently notified and the consent was obtained. There was an incentive given to participants for this study. For compensation of the participants’ time, the incentive was a $20 gift card to a toy store after completion of the interview.

Based on previous statistical analysis, the researcher anticipated more children to be scheduled for N₂O procedures since the onset of the study. The pediatric surgery office manager postulated that since the economy had sharply declined, many parents and children do not have health insurance and are delaying elective procedures. The researcher made an amendment to access participants retrospectively in order to increase
sample size. Parents were recruited by telephone into the study if their child underwent a scheduled N₂O procedure between January 2008 and February 2009. Therefore, the study protocol included recruiting participants retrospectively as well as prospectively.

**Inclusion Criteria**

Inclusion criteria for this study were: (a) parents who had a healthy male or female child between the ages of four years and eighteen years old, (b) parents able to speak and understand English, (c) at least one parent or legal guardian in attendance with the child during the procedure, (d) child scheduled for an elective, non-urgent, outpatient minor surgical procedure (e.g., excision of a nevus), (e) a topical and/or injectable local anesthetic applied to the affected site if indicated prior to the procedure, and (f) N₂O/O₂ analgesia ordered for the scheduled outpatient minor surgical procedure.

**Exclusion Criteria**

Exclusion criteria included children with a(n): (a) chronic illness or disease process (e.g., sickle cell disease, diabetes), (b) acute illness process (e.g., otitis media, bowel obstruction, altered mental status from drugs or injury, hemodynamic instability, or pneumothorax), (c) American Society of Anesthesia (ASA) risk score greater than two, and/or (d) mental, psychological or emotional illness. Additional exclusion criteria were any parent unwilling to accompany their child during the procedure or reported confirmation or possibility that the child’s mother is pregnant at time of the procedure. Studies of female health care workers exposed to chronic amounts of N₂O have reported adverse effects such as spontaneous abortion and reduced fertility (Rowland, Bard, Shore, Weinberg, Savitz, & Wilcox 1995; Szymanska, 2001). Animal studies using
approximately 60% N₂O for 24 hours on pregnant rats produced miscarriage and teratogenicities (Fujinagra, Baden, & Mazze, 1989).

**Setting and Procedure**

The scheduled outpatient minor surgical procedure took place in the small operating room located in the OPC at the research site. The informed consent was obtained by the principal investigator at the time of procedure scheduling, on the day of the procedure in the OPC, at the surgeon’s office, or by telephone. The nurse, doctor, or parent applied a topical anesthetic if indicated to the child’s affected site one hour to three hours before the procedure began. The nurse practitioner (NP) performed a brief history and physical to determine if the child was safe to receive N₂O analgesia. In addition, the NP assessed the ASA classification for medical risk on the child prior to the invasive procedure. The ASA score was developed to estimate the anesthesia risk of a patient before a surgical procedure. The ASA (1963) established the following parameters for this classification system: (a) ASA I: a normal healthy patient that pose no risk to inhalation sedation. These patients do not have any physiological or psychiatric abnormalities. (b) ASA II: a patient with mild systemic disease, such as well-controlled asthma. These patients usually pose no risk to N₂O sedation. (c) ASA III: A patient with severe systemic disease that cannot tolerate exertion and stress such as cystic fibrosis or cardiac disease. Medical consultation is recommended for these patients prior to administration of N₂O. (d) ASA IV: a patient with severe systemic disease that threatens life and unstable health problems. N₂O is usually not indicated except in emergency situations. (e) ASA V: a moribund patient who is not expected to survive more than 24 hours. (f) ASA VI: a patient that is clinically brain dead but being maintained for organ harvest. There is no indication for N₂O.
After determination that the child and parent fit all inclusion study criteria, a short teaching session on N\textsubscript{2}O administration was performed by the NP who administered the inhalational gas. The parent or nurse offered the child a small snack and drink prior to the procedure. The child and parent remained together before, during, and after the elective procedure. The nurse obtained the child’s baseline vital signs, weight, and O\textsubscript{2} saturation before the procedure. Both child and parent were escorted to the minor operating room. The child was placed on the provided stretcher and the parent was seated on a chair near the child’s head. All parents were instructed to hold the N\textsubscript{2}O mask over the child’s nose and speak to their child in a soothing tone throughout the procedure. Children were informed not to speak while the nasal hood was in place since this diminishes the effect of N\textsubscript{2}O. The certified NP administered O\textsubscript{2} for two to five minutes prior to giving N\textsubscript{2}O to the child. N\textsubscript{2}O mixed with O\textsubscript{2} was titrated until the child’s pulse rate decreased and moderate sedation achieved. The NP monitored and recorded the child’s pulse, respiratory rate, and O\textsubscript{2} saturations every five minutes. In addition, the O\textsubscript{2} and N\textsubscript{2}O percentages administered were also documented every five minutes. The surgeon administered an injectable anesthetic to the affected site if it was indicated. Afterwards, the surgeon began performing the procedure. Once the procedure was complete, N\textsubscript{2}O was turned off and pure O\textsubscript{2} was given to the child for five minutes. The scented nasal hood was then removed and given to the child or parent as a souvenir. The parent and child were then escorted to a private room in the OPC for the interview to take place. Parents were
interviewed by telephone if their child already underwent a scheduled procedure with N₂O.

**Data Collection**

**Demographics**

After obtaining written or telephone consent, the researcher collected data that included demographic information and semi-structured audio recorded interviews with each participant. Demographic background information was completed prior to the interview. Demographic questionnaires included the participant’s age, gender, marital status, occupation, education, race, ethnicity, language, and telephone number. Additional data included participants’ child’s age, gender, diagnosis, type of procedure, medications, history of prior hospitalizations and/or procedures/surgeries. Demographic data were analyzed using summary statistics (as shown in Tables 1 and 2). A total of 21 interviews consisting of 22 participants were completed. Participants included 16 mothers, three fathers, one grandmother (legal guardian); and one set of parents (one mother and one father) that were interviewed together.

**Interview Process**

Individual interviews were completed in person with parents who were recruited prospectively. For participants accessed retrospectively, telephone interviews were conducted. There were seven face-to-face participant interviews conducted immediately after the child’s procedure in the OPC. Fourteen telephone interviews were completed with parents whose child underwent a procedure using N₂O within one year ago. The researcher conducted all interviews between January 2009 and April 2009. The duration of each interview lasted between 45 minutes to one hour. Audio recordings of the
interviews were professionally transcribed verbatim and reviewed by the researcher in their entirety. The total sample included sixteen mothers, three fathers, and one grandparent. In addition, one set of parents were interviewed together (one mother and one father) since both were with their child during the procedure. Each participant was interviewed individually with the exception of one set of parents.

The investigator interviewed the participant(s) face to face in a quiet, private room at a children’s hospital OPC either immediately after the minor procedure or at a later date by telephone. After the procedure, the child remained with the parent during the face to face interview. The child was distracted by activities (i.e., playing games, watching television, or reading) to divert attention from focusing on the interview. The child was invited to participate in distracting activities provided by either a child life therapist or the nurse while the parent was telling their story to the researcher. Parents whose children underwent previous N₂O procedures were interviewed by telephone on an individual basis.

Data were collected through semi-structured interviews, in which participants told their stories about the procedural event from beginning to end. This approach was based on the premise that data are more valid when the participants, rather than the investigator, describe their world (Faux, Walsh, & Deatrick, 1990). These one-to-one interviews took place in person or via telephone either immediately after the procedure or at a later date. A semi-structured interview with open-ended questions facilitated responses from the parent’s viewpoint and frame of reference that more adequately reflected the parent’s perceptions about their child’s responses to the invasive minor surgical procedure as well as the entire experience from scheduling until termination of the procedure (which occurred on separate days). Each interview lasted between 30 to 60 minutes depending
upon the information the participant wanted to share. The researcher asked the parent to “describe how you think your child responded to the procedure with laughing gas.” Questions evolving from the first set of interviews helped guide subsequent interviews.

“Probing” was used to encourage longer, more in-depth responses. The term probing refers to prompts used during interviews to assist participants in answering the interview questions. Probes tended to be open-ended or specific to the participant’s comments rather than to a pre-existing theory. One example of probing that was used for this study is “can you tell me more about that?”

When used during GT, probing can be an invaluable tool for ensuring reliability of the data. Probing ensures reliability of the data by: (a) allowing for the clarification of interesting and relevant issues raised by the participants (Hutchinson & Skodal-Wilson, 1992), eliciting valuable and complete information (Barnball & While, 1994), enabling the interviewer to explore and clarify inconsistencies within participants’ accounts, and helping participants recall information for questions involving memory (Smith, 1992). Appendix D is a list of probe questions asked to the study participants. Some examples of probes that were used in this study were: (a) Is this how you expected your child to respond to the procedure? Please explain. (b) Is there anything you wish the nurse/doctor had done to help you or your child? If yes, what are your suggestions? (c) Is there anything else at all that you would like to tell me about your experience that is important for me to know?

The researcher was solely responsible for the data collection. The parents were audio-recorded during face-to-face or telephone interviews. All interviews were conducted by the researcher with one participant at a time. The participant’s satisfaction or dissatisfaction was addressed regarding the procedure utilizing N₂O analgesia.
All data were coded, filed, and locked appropriately in the researcher’s office. Within one week of data collection, all data were transcribed and analyzed. Field notes and memos were reviewed and added to previous notes and impressions.

**Data Analysis**

Using guidelines based on the work by Glaser and Strauss (1967) data were collected and analyzed simultaneously. In this study, data included demographic questionnaires, field notes, memos, audio-recorded interviews, and transcriptions of the taped interviews. Transcripts are considered the raw data of a qualitative study (Sandelowski, 1995b). An inductive method was used to analyze the data and to identify concepts, shared meanings, and linkages (Lincoln & Guba, 1985).

All audio-recorded interviews were transcribed verbatim by a hired transcriptionist. The researcher reviewed and analyzed all transcribed interviews in entirety. A hard copy of the transcript was read entirely by the researcher during a second review of the tape to fill in any missing information. These transcripts were repeatedly reviewed. Numbered transcripts was then coded by hand identifying data units small enough to stand alone and representing some understanding action of the parental evaluation. Initial coding was done by writing codes in the margins. Codes that emerged from this initial hand coding process were based on the participant’s own words. According to Glaser and Strauss (1967), initial or open coding begins with the examination of each data line or set of lines, naming the action or events found within. Codes were evaluated for similarities and then condensed into categories. All participant’s words and phrases from the interview data were cut and pasted onto an easel pad and formed into categories. Words, phrases, and
sentences were analyzed by the researcher and three research advisors to identify concepts.

Throughout the study, the researcher recorded field notes on participants such as observations of aspects of the unit context, impressions of informal interactions with participants, personal feelings or concerns about the progress of the study, and decisions made when changes from the original planned methods were necessary.

During data analysis, memos were constantly written. Memoing was then analyzed and interpreted. Memos included a sentence, a paragraph, or a few pages that raised data to a conceptual level and began locating the emerging theory. Memoing was used in data analysis to capture thoughts and ideas about aspects of data coding while in the clinical setting and reflections on the data.

The constant comparative analysis technique was employed for this research. Contrasting data, first against itself, then against extant theories facilitated the emergence of knowledge that provided relevant predictions, explanations, interpretations, and applications (Glaser & Strauss, 1967). The data was coded, categorized and constantly compared to produce concepts grounded in the data. Grounded in the data refers to data that is systematically “grounded” or obtained from the research. “Grounded” refers to the development of theory from data, and this resulting theory must remain linked to those data (Schreiber & Stern, 2001). Categories and themes were identified and named during the analysis. Data were transformed and reduced to build categories. Through the emergence of these categories, a substantive theory was generated and integrated. Through theoretical sampling, theoretical concepts that pertain to the emerging theory were developed. Comparison with the data and sampling of empirical studies in the literature were continued until saturation occurred and no new data of relevance emerged.
Theoretical saturation occurred when the properties of a category are delimited and no new properties emerge (Glaser, 1998). Forty categories were collapsed to the core category, six main categories, and seven subcategories. There were four categories that did not reach theoretical saturation and thus were discarded.

The last stage in the data analysis was sorting of the categories and memos. This step permitted the investigator to determine how the categories related theoretically and substantively to each other (Glaser, 1998). The investigator developed a taxonomy and diagram to visualize how the categories and subcategories fit together with the emerging substantive theory.

**Trustworthiness Strategies for this Study**

In qualitative research, trustworthiness refers to methodological accuracy and validity. There are several strategies to ensure rigor during the data collection and analysis processes. The most common strategies are member checking, peer review, and the audit trail (Lincoln & Guba, 1985). For this study, the researcher employed audit trails and peer checks to ensure trustworthiness and authenticity of the data.

**Audit Trails.** One of the strategies to ensure trustworthiness and dependability for this study was an audit trail. Lincoln and Guba (1985) regarded audit trails as one of the principal techniques for establishing the ‘confirmability’ of qualitative findings. Audit trails refer to having a researcher not involved in the research process who examines both the process and product of the research study. The term *audit trail* is defined as the detailed explanation of the decisions made before and during the research to show the consistency, logic, and development of the research procedures (Holloway & Wheeler, 2002). The purpose of the audit trail was to provide a critical appraisal of the qualitative methods of this research study.
Records of participants, interview transcripts, field notes, research procedures, and the analysis process were secured. Two selected clinical pediatric nurse practitioners examined the interview transcripts, coding sheets, and a synopsis of the study findings for substantiation of interpretation and analysis. These two health care professionals audited the research process of this study. Both examiners are pediatric surgical nurse practitioners with expertise in qualitative research analysis. In addition, these examiners are certified and have expertise in administering N₂O analgesia to children for minor procedures. All categories were independently reviewed by these two examiners to confirm the classification, organization, and relationships of derived properties and categories. For a categorization or data analysis decision to be confirmed, all reviewers were required to agree (Woodgate & Kristjanson, 1995). The purpose was to evaluate the accuracy and evaluate whether or not the findings, interpretations and conclusions were supported by the data. Both examiners confirmed and agreed on the organization and relationships of the categories as well as the data analysis for this study.

**Peer Review.** A peer review is a valuable strategy for enhancing the quality of qualitative research (Ely et al., 1991; Lincoln & Guba, 1985). Colleagues, who are competent in qualitative research process, review and re-analyze the raw data throughout the research development. The peer researchers comment on transcripts of participant observation and interviews, listen to the researcher’s concerns and provide a forum for discussing the researcher’s ideas (Jacelon & O’Dell, 2005).

For this study, the researcher selected three nurse researchers for peer review. One researcher was a pediatric nurse practitioner proficient in the qualitative research process. The second researcher chosen has expertise in GT methodology and conducting qualitative research. The third peer selected is a seasoned nurse researcher with pediatric
nursing and qualitative research methodology expertise. This strategy was used to help detect bias and try other explanations of the investigator’s working propositions and alert against the attempt to ‘fit’ interpretations that cannot be validated by the data. Peer review also helps support the credibility of the data analysis. The reviewers made some suggestions to strengthen the presentation of the themes and were satisfied with the data analysis. The three selected researchers all agreed with the conclusions developed by the investigator of this study.

Summary. This chapter described the GT method used for this study. This method was chosen as the best approach to conceptualize the theoretical basis for comprehending the parental perceptions of their child’s responses to a minor surgical outpatient procedure with N₂O. The characteristics of the study participants and recruitment were described and the procedures taken to ensure the protection of human subjects were delineated.

The GT approach has been used in nursing research since the 1970s. Many of these studies investigated nursing practice and patients’ experiences (Murdaugh, 1989; Villanueva, 1999; Woodgate & Kristjanson, 1996). Using the GT approach, it is possible to study the meanings of events for people. Since this study’s focus is on parents’ perception of their child’s responses to invasive minor surgical procedures with N₂O analgesia, GT was the most suitable methodology to examine this phenomenon. GT is a preferred approach in nursing because researchers take the study findings into account and act on them after having identified the ground of informants’ experiences (Wuest, 1995). The ground of the informants’ experiences refers to the participants’ interpretations of their experiences which are rooted in the data obtained from the research. Once theory is generated from the data, nurses have the opportunity to implement these findings into
practice in order to improve patient care. GT is used for a richer and deeper understanding of limited or unknown knowledge and to generate theory in a practice profession particularly when a focused concept is abstract and difficult to measure.

GT aims to generate theory that is grounded completely in the data. GT is a useful approach in the nursing discipline due to the systematic and structured way in which the data are collected and analyzed. In fact, this process is very similar to the nursing process. GT best answers questions that focus on the participants’ experiences, documenting their responses through an event. It is particularly useful when limited research has been done in a specific area, problem of inquiry, or a new and exciting outlook is needed in a familiar setting. Since there have been no research investigating parental perceptions on their children’s responses of invasive procedures using N₂O analgesia, a GT approach for this study provided a useful framework for guiding data collection and analysis.

In order to verify credibility of findings, trustworthiness is essential to establish when evaluating qualitative study findings. Lincoln’s and Guba’s (1985) trustworthiness criteria were described. Peer review and audit trail were implemented for this study and are considered effective strategies for nurse researchers in the challenging area of maintaining rigor in qualitative research.
Chapter 4

Results

This chapter describes the results of the data obtained from transcribed parent interviews. The constant comparative method was used for data analysis. The purpose of this study was to develop a substantive theory of parental perceptions of their child’s responses to an outpatient minor surgical procedure with N₂O. The substantive theory that emerged from this study promotes a better understanding from the parent’s perspective of their child’s N₂O procedural experience that can enhance improved parental-child support. The basic social process (BSP), core category, and subcategories that emerged from the data will be presented based on parental impressions of their child’s N₂O procedural experience. A conceptual model and substantive theory were thereby generated on the basis of the core category: *Weathering the Storm before the Calm by Securing Connections*. Definitions of categories and a conceptual framework of six developmental phases of the core category are discussed. All of the reported findings were derived inductively from the parents’ interviews. The identified process is described from the parent’s perspective using selective interview quotations to help support each category.

Description of the Sample

A demographic questionnaire was used to obtain information about the study participants and their children. The participants were parents of children who underwent a scheduled outpatient minor surgical procedure with N₂O analgesia. The parents were recruited both prospectively and retrospectively.
A purposive sample of 22 individuals participated in this study. The total sample included 16 mothers (72.7%), three fathers (13.7%), one mother-father dyad (9.1%), and one grandparent (4.5%). The participants ranged in age from 27 to 65 years with a mean age of 39.8 years. Participants’ were predominantly between 36 to 44 years old (63.6%), Hispanic (63.6%), married (63.6%), had a college degree (45.5%), and spoke English and Spanish fluently (63.7%). Table 4.1 summarizes parental demographics.

Children of parent participants ranged in age from five years to eighteen years (mean age = 8.2 years). There were a total of 21 children (11 males, 10 females) who underwent scheduled outpatient minor surgical procedures with N₂O analgesia. Procedure types included removal of various lesions (62%), implant insertion (9.5%), frenulotomy (9.5%), pilonidal cyst excision (9.5%), ganglion cyst aspiration (4.8%), and lysis of adhesions (4.8%). Prior to the scheduled minor surgery, 81% of the participant’s children never received N₂O or had undergone a minor procedure. Table 4.2 portrays the summary of the child demographic data.

There were 23 participants who were not included in the study due to the following reasons: thirteen parents did not speak English, five parents’ telephone numbers were incorrect, four parents did not answer their given telephone number, and one child had N₂O aborted mid-procedure due to inability to cooperate.
## Table 4.1

### Parent Demographic Data

<table>
<thead>
<tr>
<th>Variable</th>
<th>Characteristic</th>
<th>N</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parent or legal guardian</td>
<td>Mother</td>
<td>16</td>
<td>72.7</td>
</tr>
<tr>
<td></td>
<td>Father</td>
<td>3</td>
<td>13.7</td>
</tr>
<tr>
<td></td>
<td>Both parents</td>
<td>2</td>
<td>9.1</td>
</tr>
<tr>
<td></td>
<td>Grandparent</td>
<td>1</td>
<td>4.5</td>
</tr>
<tr>
<td>Age (years)</td>
<td>27-34</td>
<td>4</td>
<td>18.2</td>
</tr>
<tr>
<td></td>
<td>36-44</td>
<td>14</td>
<td>63.6</td>
</tr>
<tr>
<td></td>
<td>45-65</td>
<td>4</td>
<td>18.2</td>
</tr>
<tr>
<td>Education level completed</td>
<td>Some high school</td>
<td>1</td>
<td>4.5</td>
</tr>
<tr>
<td></td>
<td>Grade12/GED</td>
<td>4</td>
<td>18.2</td>
</tr>
<tr>
<td></td>
<td>Technical or vocational school</td>
<td>1</td>
<td>4.5</td>
</tr>
<tr>
<td></td>
<td>Some college</td>
<td>2</td>
<td>9.1</td>
</tr>
<tr>
<td></td>
<td>College</td>
<td>10</td>
<td>45.5</td>
</tr>
<tr>
<td></td>
<td>Graduate school</td>
<td>4</td>
<td>18.2</td>
</tr>
<tr>
<td>Marital status</td>
<td>Single</td>
<td>4</td>
<td>18.2</td>
</tr>
<tr>
<td></td>
<td>Married</td>
<td>14</td>
<td>63.6</td>
</tr>
<tr>
<td></td>
<td>Separated</td>
<td>2</td>
<td>9.1</td>
</tr>
<tr>
<td></td>
<td>Divorced</td>
<td>2</td>
<td>9.1</td>
</tr>
<tr>
<td>Occupation</td>
<td>Professional</td>
<td>7</td>
<td>31.85</td>
</tr>
<tr>
<td></td>
<td>Management</td>
<td>7</td>
<td>31.85</td>
</tr>
<tr>
<td></td>
<td>Secretarial or technical</td>
<td>6</td>
<td>27.3</td>
</tr>
<tr>
<td></td>
<td>Housewife</td>
<td>1</td>
<td>4.5</td>
</tr>
<tr>
<td></td>
<td>Disabled</td>
<td>1</td>
<td>4.5</td>
</tr>
<tr>
<td>Race</td>
<td>Hispanic</td>
<td>14</td>
<td>63.6</td>
</tr>
<tr>
<td></td>
<td>Caucasian</td>
<td>4</td>
<td>18.2</td>
</tr>
<tr>
<td></td>
<td>African American</td>
<td>3</td>
<td>13.7</td>
</tr>
<tr>
<td></td>
<td>Asian</td>
<td>1</td>
<td>4.5</td>
</tr>
<tr>
<td>Religion</td>
<td>Catholic</td>
<td>17</td>
<td>77.3</td>
</tr>
<tr>
<td></td>
<td>Baptist</td>
<td>1</td>
<td>4.5</td>
</tr>
<tr>
<td></td>
<td>Jewish</td>
<td>1</td>
<td>4.5</td>
</tr>
<tr>
<td></td>
<td>No answer</td>
<td>3</td>
<td>13.7</td>
</tr>
<tr>
<td>Language(s)</td>
<td>English</td>
<td>7</td>
<td>31.85</td>
</tr>
<tr>
<td></td>
<td>English &amp; Spanish</td>
<td>14</td>
<td>63.65</td>
</tr>
<tr>
<td></td>
<td>Spanish, French, Creole, &amp; English</td>
<td>1</td>
<td>4.5</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Hispanic</td>
<td>4</td>
<td>18.2</td>
</tr>
<tr>
<td></td>
<td>American</td>
<td>4</td>
<td>18.2</td>
</tr>
<tr>
<td></td>
<td>South American</td>
<td>4</td>
<td>18.2</td>
</tr>
<tr>
<td></td>
<td>Cuban</td>
<td>3</td>
<td>13.62</td>
</tr>
<tr>
<td></td>
<td>Puerto Rican</td>
<td>3</td>
<td>13.62</td>
</tr>
<tr>
<td></td>
<td>Nicaraguan</td>
<td>1</td>
<td>4.5</td>
</tr>
<tr>
<td></td>
<td>Haitian</td>
<td>1</td>
<td>4.5</td>
</tr>
<tr>
<td></td>
<td>African American</td>
<td>1</td>
<td>4.5</td>
</tr>
<tr>
<td></td>
<td>Asian</td>
<td>1</td>
<td>4.5</td>
</tr>
</tbody>
</table>
Table 4.1

Note. GED = General Equivalency Diploma; South American = Columbian (2), Argentine (1), Venezuelan (1)
Table 4.2

**Child Demographic Data**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Characteristic</th>
<th>N</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Male</td>
<td>11</td>
<td>52.4</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>10</td>
<td>47.6</td>
</tr>
<tr>
<td>Age (years)</td>
<td>5-8</td>
<td>13</td>
<td>62.0</td>
</tr>
<tr>
<td></td>
<td>9-12</td>
<td>5</td>
<td>23.8</td>
</tr>
<tr>
<td></td>
<td>13-18</td>
<td>3</td>
<td>14.3</td>
</tr>
<tr>
<td>Grade</td>
<td>Pre-K-3&lt;sup&gt;rd&lt;/sup&gt;</td>
<td>13</td>
<td>62.0</td>
</tr>
<tr>
<td></td>
<td>4&lt;sup&gt;th&lt;/sup&gt;-8&lt;sup&gt;th&lt;/sup&gt;</td>
<td>5</td>
<td>23.8</td>
</tr>
<tr>
<td></td>
<td>9&lt;sup&gt;th&lt;/sup&gt;-12&lt;sup&gt;th&lt;/sup&gt;</td>
<td>3</td>
<td>14.3</td>
</tr>
<tr>
<td>Medical conditions</td>
<td>Esophagitis</td>
<td>1</td>
<td>4.8</td>
</tr>
<tr>
<td></td>
<td>Precocious puberty</td>
<td>2</td>
<td>9.5</td>
</tr>
<tr>
<td></td>
<td>Asthma</td>
<td>2</td>
<td>9.5</td>
</tr>
<tr>
<td></td>
<td>ADHD</td>
<td>2</td>
<td>9.5</td>
</tr>
<tr>
<td></td>
<td>Obesity</td>
<td>1</td>
<td>4.8</td>
</tr>
<tr>
<td></td>
<td>None</td>
<td>13</td>
<td>62.0</td>
</tr>
<tr>
<td>Past minor procedures</td>
<td>Endoscopy</td>
<td>1</td>
<td>4.8</td>
</tr>
<tr>
<td></td>
<td>Supprelin implant</td>
<td>1</td>
<td>4.8</td>
</tr>
<tr>
<td></td>
<td>Pilonidal excision</td>
<td>1</td>
<td>4.8</td>
</tr>
<tr>
<td></td>
<td>Nevus excision</td>
<td>1</td>
<td>4.8</td>
</tr>
<tr>
<td></td>
<td>Cast</td>
<td>1</td>
<td>4.8</td>
</tr>
<tr>
<td></td>
<td>None</td>
<td>16</td>
<td>76.2</td>
</tr>
<tr>
<td>Previous N₂O</td>
<td>Yes</td>
<td>4</td>
<td>19.0</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>17</td>
<td>81.0</td>
</tr>
<tr>
<td>Medications</td>
<td>Prevacid</td>
<td>1</td>
<td>4.8</td>
</tr>
<tr>
<td></td>
<td>Singulair</td>
<td>2</td>
<td>9.5</td>
</tr>
<tr>
<td></td>
<td>For ADHD</td>
<td>1</td>
<td>4.8</td>
</tr>
<tr>
<td></td>
<td>None</td>
<td>17</td>
<td>81.0</td>
</tr>
<tr>
<td>Past hospitalizations</td>
<td>Yes</td>
<td>3</td>
<td>14.3</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>18</td>
<td>85.7</td>
</tr>
<tr>
<td>Procedure type</td>
<td>Lesion excision</td>
<td>13</td>
<td>62.0</td>
</tr>
<tr>
<td></td>
<td>Implant insertion</td>
<td>2</td>
<td>9.5</td>
</tr>
<tr>
<td></td>
<td>Frenulotomy</td>
<td>2</td>
<td>9.5</td>
</tr>
<tr>
<td></td>
<td>Pilonidal cyst excision</td>
<td>2</td>
<td>9.5</td>
</tr>
<tr>
<td></td>
<td>Ganglion aspiration</td>
<td>1</td>
<td>4.8</td>
</tr>
<tr>
<td></td>
<td>Lysis of adhesions</td>
<td>1</td>
<td>4.8</td>
</tr>
</tbody>
</table>

*Note.* ADHD = attention deficit hyperactivity disorder.
The Core Category and Basic Social Process

The analysis revealed a process of *Weathering the Storm before the Calm by Securing Connections* which is presented in a model illustrating the substantive theory (Figure 4.1). The theoretical model that emerged from the data illustrates six main categories: *Knowing What to Expect, Having to Wait, Participating in Pre-induction, Watching the Procedure, Feeling Relief, and Going Home*. The BSP accounts for process, change and movement over time (Glaser, 1978). Parents consistently identified the rough and smooth spots of each step of the process. The BSP or core category that integrated the six major categories and describes the focus of this research was *Weathering the Storm before the Calm by Securing Connections*. The core category appeared frequently in the data and answered the question: what BSP helps parents move through their child’s N₂O procedure experience?
The process emerged as parents described their experiences of having their child undergo an outpatient minor surgical procedure with N₂O. The parents expanded their focus from their child’s responses of the N₂O to the pre- and post-procedural experiences. Definition of the core category is necessary for the understanding of the theoretical model. *Weathering the Storm before the Calm by Securing Connections* is referred to as the unpredictability and unchartered course parents faced during the initial phases of the process. Parents expressed feelings of anxiety, nervousness, and fear when scheduling their child’s procedure. Parents attempted to deal with these *stormy* feelings in a variety of ways that are described in the categories and subcategories. The subsequent *calm* feeling was experienced when the parent observed their child’s response to the N₂O and procedure. For this study, *calmness* is defined as a feeling of relaxation, peacefulness,
tranquility, and a sense of relief. All parents described the importance of a *connection* with their child which resulted in a sense of calmness and security for both. The theme that weaves through the entire process is the parental-child connection and parental presence during the procedure with N₂O. Parents expressed a need to be present and strong for their child as described by the parent-child connection (physically and emotionally) throughout the N₂O procedure experience. The core category describes parental impressions and all categories subsumed by the core category. The process of parents weathering the stormy phases to achieve calmness by securing physical and emotional connections with their child emerged as the main phenomenon of the study.

**Categories within the process.** The core category, *Weathering the Storm before the Calm by Securing Connections* was based on six main categories and seven subcategories. This core category comprises what happens in the time span from onset of the surgeon’s office visit until discharge from the OPC after the N₂O procedure. The procedure usually occurs about one to two weeks after the office visit.

Parents progressed through all phases of the process in a consecutive linear fashion. The duration of each phase, however, varied with each parent depending upon the parent’s previous experiences and knowledge, waiting time, and procedure type.

All main categories were originated from the data and represent the parents’ impressions during this process. These categories and its subcategories are described within the sections that follow and listed in Table 4.3. Direct quotations from the
interview transcripts appear as excerpts (indented paragraphs), in which square brackets ([ ] ) indicate information added by the researcher and ellipses (...) signify items omitted for conciseness.

Table 4.3

*Taxonomy of categories*

<table>
<thead>
<tr>
<th>Weathering the Storm before the Calm by Securing Connections</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Knowing What to Expect</strong></td>
</tr>
<tr>
<td>Reflecting on Past Experiences</td>
</tr>
<tr>
<td>Searching for Information</td>
</tr>
<tr>
<td>Having Expectations</td>
</tr>
<tr>
<td><strong>Having to Wait</strong></td>
</tr>
<tr>
<td><strong>Participating in Pre-induction</strong></td>
</tr>
<tr>
<td>Using Distracters</td>
</tr>
<tr>
<td>Assisting the Team</td>
</tr>
<tr>
<td><strong>Watching the Procedure</strong></td>
</tr>
<tr>
<td>Parental Responses</td>
</tr>
<tr>
<td>Child’s Responses</td>
</tr>
<tr>
<td><strong>Feeling Relief</strong></td>
</tr>
<tr>
<td><strong>Going Home</strong></td>
</tr>
</tbody>
</table>
Knowing what to expect. This phase was the first main category of the process. Knowing What to Expect began upon scheduling the child’s procedure during the surgeon’s office visit. This visit took place about one to two weeks prior to the scheduled procedure. This category emerged from descriptions of parental expectations and comments about the child’s upcoming procedure scheduled with N₂O analgesia.

Based on previous surgical experiences, occupation, knowledge, child’s history and baseline characteristics, parents had a variety of expectations and concerns regarding their child’s upcoming procedure with N₂O. The category, Knowing What to Expect consists of three subcategories that occurred simultaneously: Reflecting on Past Experiences, Searching for Information, and Having Expectations. This phase continued until the onset of the scheduled procedure and intensified during Having to Wait phase.

Reflecting on past experiences. After the child’s procedure was scheduled, parents began to recall previous surgery experiences. They reflected on personal, family members’, and/or their own children’s past procedures. Some parents described their past experiences and concerns of general and local anesthesia. In addition, there were some parents who recalled their own experiences with N₂O analgesia.

I don’t remember being up [with having N₂O].

(…) going to be the same experience as the first one that he had.

I’ve been through it already; knew what to expect.

I don’t remember anything that they did to me while I was under laughing gas.

I’m in the medical field (…) ; not really familiar with nitrous oxide (…) ; comfortable with giving the [general] anesthesia part.

I assumed every procedure that you not participate in it.
The lack of past experience with surgery, anesthesia and/or N\textsubscript{2}O was also described by some participants.

I’ve never been in an operation.

First time parents who have never experienced this type of procedure with the gas.

No, no, this was the first time, that’s why I was kind of worried at the beginning. I thought it would be something bad; but it was fine and this was my first time.

**Searching for information.** When the participant’s child was scheduled for an outpatient minor surgical procedure with N\textsubscript{2}O, the surgeon provided explanations to the parent and child. Many parents were unfamiliar with medical terminology and had a lack of knowledge of the child’s procedure and N\textsubscript{2}O. The phase, *Searching for Information* refers to the parental desire for more education about the upcoming procedure and N\textsubscript{2}O. This phase began upon confirmation of the child’s diagnosis and scheduling of procedure during the surgeon’s office visit. Many parents who were not familiar with surgical procedures or anesthesia wanted thorough explanations not only about the procedure but the N\textsubscript{2}O analgesia as well. In addition to the explanations provided by the surgeon, there were some parents who searched for information from outside sources (e.g., internet) on their own accord due to confusion and desiring supplemental information. Some participants were surprised that they were not informed that they will be active participants during their child’s procedure. These parents wished they were made aware during the office visit so they knew what to expect and could have been better prepared.

Explain the procedure better; the fact that I was going to be there with him, that I was going to be holding the mask.

Good to let the parents know that here, you’re going to be doing this, and this.
If I get a pamphlet, I’ll actually read it; would’ve known exactly.

I looked it up on the internet.

Many parents lacked knowledge about different types of anesthesia (such as local vs. general). Some parents wished that specific information was provided about the N₂O during the office visit.

I’m not too familiarized with it [N₂O].

The parent who hasn’t had it [N₂O], I think if they made some literature, you know, these are the 3 types of anesthetics, this is what it involves; I think it would just help the parent be more informed as opposed to have to, you know, go on the internet and find out because most of the parents nowadays do that (…)

To understand the difference between this [N₂O] and a local anesthetic; why is one needed and not the other. Just to understand the two differences.

Most parents moved through this phase with ease and confidence based on the clinician’s explanations. In fact, some parents were impressed that the choice of words used was appropriate for their child to understand.

They explained everything really good.

(…) they explained the procedure in kid language which made him feel comfortable.

Told her exactly what they were going to do to her.

There were some parents however, that felt too much information about the upcoming procedure was given to their child. These parents would have preferred for the doctor to speak to the child after discussing the procedure with an adult first.

(…) procedure should have been discussed to an adult and then let the parent decide to involve the child.

I wouldn’t mind explaining to the child in front of her with the doctor in different terms. So I would’ve preferred first, adults talk and then it’s like how are we going to explain it to her and then take it from there.
When the doctor was explaining to me the procedure, I would’ve preferred first for him, to have myself and the doctor for us two to talk about it first without her present and then come in, and then talk about it in a more simpler way. Because he discussed the whole procedure, snip, snip, tuck, tuck, you know, and right in front of her.

I would like to explain it [to my child].

On the other hand, some parents wanted the staff to provide as much information as possible. Furthermore, some parents thought that it would be confusing for their child to wait outside the room while having a private conversation with the surgeon.

If a child stays outside until I speak with the doctor, going to be more confusing for her. Because if something is going on, why don’t they want to tell me?

No matter how hard it is, the truth is always better.

I think it’s better to give more information you have, the better you are prepared.

This phase continued until the child’s actual procedure took place. In fact, some parents continued their search upon hospital arrival by requesting more information from the staff about the child’s procedure and N₂O.

**Having expectations.** This phase began upon confirmation of the child’s diagnosis and surgical recommendation for the minor procedure with N₂O. *Having Expectations* refers to how parents expected their child to respond to the N₂O procedure. Many parents were surprised to learn that their child may be partially awake and responsive during the procedure. These parents were basing their expectations on previous personal experiences with N₂O as to how they thought their child would respond.

I thought once she had the gas, she would be out of it and just totally relaxed (…) didn’t know she’d be so with it, that she would be able to cry and kick and pick her head up.

I thought that he would be maybe dazed, not talking, not moving, just looking up in the sky.
I thought it was going into his system so I didn’t know whether or not he was going to reject it or accept it, yeah, I just didn’t know what type or reaction he was going to have.

Even the adults, you’re going in for a procedure and don’t exactly know what to expect, it’s nerve-wracking.

Some parents expressed concern about the possible reactions to the N₂O while others were more focused on their child’s behavioral and sensory responses to the procedure. Most parents expected their child to remain calm and have minimal pain during the procedure with N₂O. Many parents focused on the procedural outcome and expected it to be successful.

I thought she was going to pass out.

(... that her surgery would come out as expected.

My main concern was any allergy reaction.

My main concern before the procedure started, how he was going to take it; how he was going to respond.

When they say laughing gas, I thought she was going to start laughing.

Having Expectations extends beyond the initial surgical office visit. For most parents, this phase continued until after the child’s procedure was terminated. Parents realized how their child responded to the procedure and N₂O and thus no longer had any expectations.

**Having to wait.** Upon arrival to the OPC, all parents were required to wait for their child’s procedure to take place. Having to Wait began at registration until entrance into the minor procedure room. The duration of Having to Wait varied for each parent and child depending upon the availability of the surgeon, nurse practitioner, and topical anesthetic application. Once the registration process was completed, the parent and child
were placed in a small private examination room in the OPC to wait for the procedure. Each examination room is equipped with a small television, stretcher, two straight back chairs, one recliner, and over bed table.

Many participants described their wait as upsetting, anxiety-provoking and highly stressful. Many parents expressed that their child also became restless, bored, and agitated during the excessively lengthy waiting period. Parents described feeling more fearful and anxious the longer they were made to wait for the procedure to occur.

If we can reduce the waiting time, it will be less stressful for the kid and at the same time for the parent.

Waiting time was too much for a child to wait.

For me, it was too long because she was nervous; was like two hours waiting for five minutes [procedure] that she was here. (…) asking me when they’re coming, when is this going to be over.

To just sit and wait for me, it’s torture.

One of the worst things to do is wait because then the anticipation and the thoughts going through your mind. That’s the worst thing.

A few of the parents did not find the waiting time duration as too excessive. In fact some parents expected to wait and did not describe being disturbed or anxious before the procedure while in the examination room. In addition, some parents were impressed how quickly they went through the registration process.

We were able to go into the room with him. They had the TV on and we were able to go in and out and maybe go get a snack or drink or something, so I think for me, it was fine.

What I liked a lot that is different to other hospitals, that the registration is really fast, just like a couple of questions, sign two papers.

I don’t know if it’s because I had an appointment so probably we had priority, was pretty easy (registration process).
Few parents commented that the staff did not make themselves visible during the long endured wait. In fact some parents felt like they were being avoided. 

(...), just being visible.

People were hiding.

There were some parents who made suggestions how to pass the wait for children to decrease boredom and anxiety.

Good to have them watch cartoons, entertain them for awhile.

I don’t know if you guys have a playroom or something that maybe you know, there’s toys and there’s a TV and maybe video games, so like that they can interact with other kids. Things that you guys are doing in the individual rooms but do it in a centralized area where there are other kids and they can just socialize and get their mind off things.

**Participating in pre-induction.** All scheduled minor surgical procedures with N₂O took place in the outpatient treatment room. One parent was required to stay with their child and actively participate during the entire procedure. Parent participation included holding their child’s N₂O scented nasal mask and providing distraction techniques during the pre-induction and procedural periods. This phase commenced when the child was placed on the stretcher and the parent was seated next to the child’s head in the treatment room. Prior to the procedure, the certified nurse practitioner or physician assistant instructed the parent to hold the nasal mask over the child’s nose before the O₂ and N₂O were administered. The parent was required to hold the child’s mask until the inhalational gases were turned off. This phase includes two subcategories: *Using Distracters* and *Assisting the Team*. These two components occurred simultaneously. **Participating in Pre-induction** ended when the inhalational gases were discontinued.
Most parents believed that their presence during the N₂O induction and procedure helped their child as well as helped themselves. Parents strongly agreed that being able to be present provided them peace of mind, to ensure “things” were being done correctly, and to make their child felt more secure.

**Using distracters.** During Pre-induction, the nurse turned off the lights with the exception of the surgeon’s examination lamp and x-ray wall light in the treatment room. All noise was kept to a minimum when the parent placed the mask over the child’s nose. The staff instructed the parent to divert the child’s attention from the procedure during pre-induction of N₂O. Parents were encouraged to use distraction techniques such as storytelling, reading, or just talking. The child was advised not to speak while the N₂O was being administered to ensure efficacy of the inhalational gas. Parents were advised to avoid distraction techniques that required the child’s verbal response. The staff encouraged the parent to talk about the day the child was born. There were a few parents however, that felt sharing this story may not be the best distracter at this time. Using various techniques, the nurses and doctors often participated in distracting the child during the procedure. Some parents expressed that most distracting techniques used were effective to lessen the child’s anxiety and fear.

He [child] was talking to the guy who was giving him the anesthesia (…) man was making him laugh.

Hard for me to come up with a story (…) wanted to pay attention to what was going on.

What they (nurses and doctors) did was a good thing, keeping him distracted by talking and asking him questions.
Most parents agreed that music and singing are effective distracters during the child’s invasive procedure. Parents stressed that the choice of music according to the child’s age was important.

I guess music would help. Because it was just us really talking. I guess some sort of children’s music or even like a show that is in the background because they would just be listening to it.

(... the background music or kiddy songs, or maybe a children’s show that they can associate with.

As soon as she was concentrating on the music, she started like she forget about what was going on.

They started singing to him and he enjoyed that.

Many participants agreed that the parent speaking to their child is the best distracter due to the familiar voice. Moreover, parents emphasized what is said to their child during pre-induction and the actual procedure is of utmost importance. Most parents felt it was imperative to speak about happy memories or pleasant vacations instead of talking about the procedure.

Parent’s voice would be the best assurance that a child would have.

Read a book. Talk about where to go afterwards, mainly just talking. Just don’t talk about the procedure. Just get their mind off the procedure. Talk to them about something else, like reading. Remember a family vacation that they went to. Remember we went here and you like this and you did that. Happy memories.

**Assisting the team.** Participants were given the responsibility of securing the child’s mask during administration of the N₂O for the procedure. *Assisting the Team* began when the parent held their child’s nasal mask during the N₂O administration and helped secure their child’s head or extremities for increased movement. In addition, this phase included providing reassurance to the child by the parent. This phase overlapped with *Using
Distracters. Parents that were using distracting techniques on their child were in essence assisting the team.

Most parents wished they would have known in advance that they needed to be active participants during their child’s procedure. Parents wanted to know what they were expected to do to help their child and staff. Some of the parents felt that they had to be strong for their child to get through the procedure.

Just let us know what we’re going to do and what they’re going to do so that …we can be strong for them and just, you know, be prepared.

Had no idea that they were going to put laughing gas on her until they asked me to come into the room.

(…) a little surprised I kind of had to hold it [mask] for him.

When I went in the room and the doctor told me put the mask and sit down just next to her and I thought I was in the middle, you know, like I’m going to bother him and I’m trying to move and he said no, no, no, don’t move, stay there, you don’t bother me, he said.

My husband had to hold her arms down. I had to hold her feet down (…) very anxious (…) the minute it was over, she was fine.

Some parents felt their child became anxious and frightened upon the mask application while in the supine position on the stretcher. The children that showed signs of anxiety during induction were less than eight years old. Parents believed their child’s anxiety and fear resulted from losing a sense of control being in a vulnerable position. Parents expressed that their child who occasionally received aerosol treatments, did not display signs of agitation upon mask placement.

A few parents recommended putting the child’s mask on while the child is in the sitting position. When the child begins to feel the effects from the N₂O, then the child can be placed in the appropriate position on the stretcher as suggested by some parents.
He did get frightened somewhat when the mask was put on him and I was holding the mask and he got a little bit frightened.

If you just sit them up, they’re okay with it, but if you put them to lie down that’s when they start to cry.

(…) put the mask and then let them sit for awhile when they’re comfortable, let them lie down.

When we start, put the mask first, sit him with the mask seeing that he’s laughing or doing something crazy, then let’s lay him down because they easily move.

Furthermore, some parents would have preferred to be given the choice whether or not to hold their child’s mask during the procedure. There were some parents who actually wanted to see the child’s procedure instead of worrying about the proper positioning of the mask.

Don’t want to be in there holding a mask and not being able to see [procedure].

(…) that they [parents] have to hold the mask or if they don’t want to hold the mask, they have to be given the choice to hold the mask or not.

The team included the surgeon, outpatient nurse, and nurse practitioner/physician assistant. The surgeon performed the minor procedure on the child while the outpatient nurse assisted. The certified nurse practitioner or physician assistant administered the N₂O to the child before and during the procedure. During this phase, most parents remarked about the nurses’ and doctors’ proficiencies and attributes who were participating in the procedure. Many parents were impressed how child-oriented and competent the nurses and doctors were carrying out their child’s procedure.

The nurses (…) very knowledgeable, very child-oriented.

How the doctors and nurses acted. That’s pretty much I would say that would be the standard to perform, especially when dealing with kids.

The people who were there made him feel real confident and calmed down better than I could.
Kind of flawless the procedure they did.

I told her [participant’s wife] how comfortable I felt with the doctors and nurses.

They made everything look so routine and so smooth that if there were any complications, I didn’t notice.

I saw what he [doctor] was doing. Not that I would ever do it [laughing] because they don’t pay for that and that’s not my line of apples. But I saw what he was doing and I tell you what, it takes a special breed of people to do things like that.

**Watching the procedure.** This phase describes parents’ impressions watching their child’s procedure. Most parents did not expect that they would be able to watch their child’s procedure. Due to positioning, some parents however, were unable to watch the procedure being performed on their child. Some of these parents who did not see their child’s procedure wished that they were given the opportunity to observe.

A few parents had the opportunity to watch the procedure but purposefully chose not to see. These parents were thrilled just to be with their child to provide security and saw no benefits to observe the procedure. *Watching the Procedure* began upon onset of the procedure and included two subcategories: *Parental Responses* and *Child’s Responses*. These two components overlapped and occurred simultaneously. This phase ended when the child’s procedure and N₂O were terminated.

**Parental responses.** During the child’s procedure, parents were faced with unfamiliar technical components. *Parental Responses* specifically describe parents’ responses to their child’s N₂O procedure. Most parents described their own reactions in response to their child’s procedure. Some parents became emotional or physically overwhelmed resulting from watching this event take place.
I was the one that tensed up.

When I took a look, I got a little queasy…had to give me a little bit of smelling salt.

I felt teary-eyed because you don’t want to see your child in pain.

Little bit shocked, surprised that when they cut with the scissors that he didn’t move.

Despite some participants’ fears and concerns, many parents expressed the need to be strong in order to support their child. Many parents tried to hide their emotions because they felt it would negatively affect their child’s behavior for the procedure.

Give myself a mental thing that you got to deal with it. Afterwards you want to cry about it, lock yourself up in the bathroom and you cry.

I need to be strong. I need to support my daughter.

I have to pass my strength onto her.

When I saw the needle to numb the area, I had to be strong for him.

The parent has to be calm because if the parent is freaking out, that’s not going to help the child at all.

Technical aspects such as positioning of the child and themselves, N\textsubscript{2}O mask and apparatus, O\textsubscript{2} saturation monitor, and the minor surgical procedure posed a challenge to some parents. In fact, some parents faced conflicting issues: focus on their child’s mask versus watching the procedure.

I wanted her to be relaxed so I had to just keep her mask on but in the back of my mind, I wanted to see what was being done.

I would’ve liked to have been told beforehand that sounds could be coming out of that [O\textsubscript{2} saturation monitor] and that’s due to the fact that your child does A, B, or C but don’t worry, it’s okay, instead of hearing the sounds and thinking, my God, what’s wrong.
Wondering why he needed to be laid face down on this procedure which was on the right elbow, then face down with the face right on top of part of the mask, on the hose.

A common theme amongst all phases with special emphasis on Parental Responses was the satisfaction of parental presence and ongoing connection with their child throughout the procedure. Parents strongly agreed that this physical and emotional connection gave the feeling of security and comfort to themselves and their child.

Me being there, he was going to be okay and comfortable, and not too scared.

What made me happy was that I was able to go in with him.

I believe a parent should be next to a son or daughter at the time of anything being done to them.

Even though they don’t see you because they are under the influence, you’re there.

Interestingly, many parents preferred to observe their child’s procedure. Some parents felt that they would be less anxious knowing what was occurring as opposed to having to be absent and waiting outside.

I would much rather be in there looking at what’s going on than being outside worried about it.

I loved being there. I prefer to be in there with him watching what’s going on than to be outside and be worried, and concerned while waiting.

Parents need to know what’s happening.

Furthermore, several parents expressed that it would be helpful to watch the procedure to better understand the child’s diagnosis and after care. Some parents claimed they were just plain curious and wanted to ensure that everything was being performed correctly.

I wanted to see what was being done. I would’ve liked to have known what was going on rather than seeing her after.
It would have been very helpful to me to see what was going on, to see what was done. I guess for me, because what I see now is just the tape. I saw the suture being done and the doctor instructed me as to the steri strips staying there but as to how it was removed or how it was done, I wanted to see that, what was taken out.

If I am going to be in there and it’s okay germ-wise that I’m there, then I might as well see what you’re doing because then I can understand my son better.

I would’ve liked to see the procedure. To see what they’re doing to him, done correctly.

Child’s responses. The process of the Child’s Responses to their child’s procedure with N₂O was met with anticipation, fear, and anxiety by the participant. Child’s Responses refer to parental perceptions of their child’s responses to the N₂O procedure. Parental descriptions include the perception of their child’s physical, behavioral, and sensory responses (such as movement, laughter, pain) to the procedure with N₂O. Many parents were concerned how their child was going to react not only to the procedure but also to the N₂O analgesia. Most parents feared the potential pain and discomfort their child may endure due to the injection and procedure.

I didn’t ever see her flinch the initial time that the doctor was putting that injection in her.

Cool, calm, and collective.

To see your own child crying, so anxious, it breaks your heart.

Most parents expressed their extreme satisfaction with their child’s responses to the N₂O and procedure. Parents were closely monitoring their child for any painful behaviors relating to the procedure. Children’s behavioral responses to the N₂O procedure perceived by parents included but not limited to facial expressions, verbalizations, crying, and limb movements.
Clenching her feet, but then later on, she was relaxed.

Kicking, crying, screaming, and carrying on [during procedure].

Felt something but I definitely think it was more anxiety.

I know she wasn’t in pain because she wasn’t flinching, her eyes were like relaxed.

I was looking at him for any kind of facial expressions to see if he felt any pain or anything like that. He didn’t reveal any at all, whatsoever, just laughing once in awhile.

The following quotations help illustrate parental perceptions of their child’s sensory responses to the invasive procedure. Most parents perceived that their children had minimal pain during the procedure with N₂O based on their child’s non-verbal behaviors and self-report.

I didn’t ever see her flinch the initial time that the doctor was putting that injection in her.

But she just laid there. She had four injections.

He was fine. He had no complaints.

Some parents felt their child responded to the N₂O with a feeling of euphoria. This feeling was described as totally foreign to the child as perceived by the parents.

Lightheadedness that he never felt before.

That euphoric feeling that he got that was foreign to him. It scared him at first because he didn’t know what that was.

I wouldn’t call it hallucinating but he said I felt like I was on a cloud and that was kind of funny.

There were a few parents however, who perceived their child to experience some discomfort during the procedure based on their child’s self-report, movements and/or facial expressions.

He felt pain which I did not think he would because when they pinched him, we all sang in there to try and have him think of something else, but he flinched.
She told me she remembered that it hurt a little bit.

He said he felt pain, but I don’t know if he actually did.

There were several parents who described their child’s physiological responses to the N₂O procedure. Many parents remarked on their child’s level of consciousness. From the previous phase, Having Expectations, many parents were concerned about the child’s response to N₂O and wondered if they will remain awake or stay asleep.

Glad to see he was awake the whole time.

Maybe she was feeling it but then she slept right back.

This time he had a tendency of falling asleep more [child had previous procedure with N₂O].

When indicated, children had a topical anesthetic cream (EMLA®, AstraZeneca, Wilmington, DE) applied to their affected site several hours prior to the procedure. EMLA® cream was indicated to prevent or diminish pain resulting from the injection. Several parents expressed dissatisfaction and lengthy time with its effectiveness of this cream and wished there was another modality that worked better. Furthermore, other parents felt the EMLA® cream was applied on the child’s pertinent site for too long resulting in minimal efficaciousness.

Better numbing cream because he flinched.

You put the cream on. You have to wait for a long time for it to take effect, then he got pricked anyway and he still felt it.

I think the stuff was starting to wear off because it was way past the three hour mark.

I thought she waited too long because she felt when they were doing the incision; was very painful. She was crying.
Some parents wished that the practitioners administering the N₂O had more patience when delivering the inhalational gas to the child. These parents felt that their child needed more time and the correct amount for the N₂O to take effect before starting the procedure.

(...) waited until the gas kicked in a little bit.

Make sure that it’s the right amount so that he doesn’t feel the pain because I wouldn’t want that to happen to him again.

Nurses need to have a little more patience.

Weren’t even there 10 minutes and it was poom, poom, poom, poom and didn’t give it a chance [for N₂O to take effect].

Some parents perceived that their child’s responses indicated they may have experienced discomfort during the injection or procedure. Many children had little or no recollection of the procedural event and/or injection. The majority of participants were quite surprised and satisfied with the N₂O amnesic effects.

He doesn’t remember anything that happened after that.

She doesn’t remember the rest of the conversation.

She was laughing and then touched her ear and that’s when she pointed to me that there was something in her ear which signified to me that she didn’t remember anything.

**Feeling relief.** This phase began after the inhalational gases were turned off and included the parental perceptions during their child’s recovery period. Parents described a range of experiences relating to the child’s recovery phase. The process of *Feeling Relief* after the N₂O procedure was met with surprise, excitement, and calmness. Most parents described a sense of relief because their child did not experience or recall any pain. In
addition, parents felt an easing of distress after the procedure was safely accomplished and saw that their child was in no imminent danger.

I felt more relaxed because I wasn’t worried once I’d seen that the laughing gas had made calm down a lot.

I’m glad it’s over and everything came out good.

Keep the laughing gas going because the laughing gas I think is the best that you can give kids for minor surgeries. Nothing else. Leave it like that. It’s the best.

Oxygen was administered to the child for five minutes after the N₂O was discontinued to prevent a headache from occurring. Parents expressed relief that the procedure was over and surprised how quickly their child recovered from the N₂O. Most children did not remember details of the procedure and had no recollection of the injection received. This amnesic quality of N₂O both dismayed and pleased the parents. Participants felt relief that their child did not need further monitoring. Moreover, parents were very satisfied they were able to leave immediately after the procedure. Participants were very satisfied about their child’s quick recovery and ability to resume normal functions effortlessly.

Like nothing ever happened.

She was herself almost immediately.

I was happy to see that once they took it [N₂O] out, he was back to normal peacefully.

He came out of the drowsiness pretty quick.

(…) it was nice that he is up and walking and we can leave.

Summing up the whole experience, parents expressed their confidence and appreciation of the staff’s care. For some children, this was their second procedure receiving N₂O. The following quotes help portray the parents’ feelings of relief and satisfaction with the N₂O procedure and staff.
I loved it. I would like that all the doctors do exactly the same that they did this time with her.

I got excellent treatment.

They pretty much have it down to an art.

I had a positive experience twice.

Some parents even remarked how impressed they were with the hospital and its services catering to children.

They have everything set up in the hospital is fine.

Everybody knows about [this hospital]. It’s like the best place to bring the kids because that’s the reason why they’re open to make them feel comfortable.

Children’s hospital is A1 when it comes to treating kids.

**Going home.** The final phase *Going Home* refers to the preparation for discharge when the parent learned the after care. This process included the balance of the parent’s cognitive, affective, and psychological abilities to provide post-procedure care for their child. Some parents felt more secure of their capabilities to take care of their child because of watching the surgeon perform the procedure. Parents relied upon the nurses and doctors to provide accurate instructions for home care.

The doctor told me everything that needed to be done.

And seeing what he did, let me know what I’m capable of doing.

There were some parents who requested return demonstrations to ensure proper understanding of their child’s after care. This phase ended when the child was fully recovered and parents felt confident and knowledgeable about their child’s post-procedure care.

Teach us how to clean but basically not teaching us, physically teaching us how to do it. How to clean the operation, you know, how to take care of it after, once they get home.
Doing it while the doctor is seeing or the nurse seeing how I do it so they can correct me if I’m doing it wrong.

Summary. *Weathering the Storm before the Calm by Securing Connections* was determined to be the central process in this study. This process emerged from the data as parents described their impressions of having their child undergo an outpatient minor surgical procedure with N₂O.

The core category derived from the data gives an overall description of how parents view the progression through their impressions. The core category led to the BSP where parents consistently identified the rough and smooth spots of each step of the process which led to the substantive theory. This theory occurred in six phases which included: *Knowing What to Expect, Having to Wait, Participating in Pre-induction, Watching the Procedure, Feeling Relief, and Going Home*. These phases were represented by interactional processes that illuminate a pattern of progressive movement from scheduling the N₂O procedure to going home after the procedure. This theory depicts how parents described their process through having expectations before the procedure, waiting for the procedure, watching the procedure, feeling relief, and finally going home. This theory also identifies parents’ main concerns and what helps and impedes them through this process.
Chapter 5

Discussion

In this chapter, the data results and substantive theory that was derived from the conceptual findings of this study are discussed. Literature that relates to the generated substantive theory, study limitations, and recommendations for future research are identified. In addition, the discussion of the study’s implications for nursing theory, practice, and education are provided.

Grounded theory methodology requires the necessity to conduct a literature search for studies related to emerged concepts from data analysis. Glaser (1998) points out, as discovery and emergence are at the core of the GT method, related literature cannot be known at this stage. Focused reading should only occur when the emergent theory is well formulated. The core category for this study, *Weathering the Storm before the Calm by Securing Connections* was not anticipated prior to data collection. For this study, the researcher initially focused on the parents’ perceptions of their child’s responses to the \( \text{N}_2\text{O} \) procedure. As the study progressed and data emerged, the focus expanded from parental perceptions of the child’s responses to parental impressions incorporating the entire procedural process. The following discussion includes a selected literature review centered on themes that emerged from the data.

The purpose of this study was to develop a substantive theory of parental perceptions of their school-aged child’s responses to an outpatient minor surgical procedure with \( \text{N}_2\text{O} \). Prior to conducting the study, this nursing phenomenon had not been researched using a qualitative approach. The substantive theory derived from this study, *Weathering the Storm before the Calm by Securing Connections* was identified as the core category
and portrays the unchartered stormy course followed by the sense of calmness parents endured during this process. As described in the findings, the themes that developed through the data analysis process led to six main categories that characterize the nature of parental impressions of *Weathering the Storm before the Calm by Securing Connections*. These categories include: *Knowing What to Expect, Having to Wait, Participating in Pre-induction, Watching the Procedure, Feeling Relief, and Going Home*.

The categories that emerged from this GT study supported, enhanced, and refuted findings discussed in extant literature related to children’s procedures using sedation. There is a gap in the literature however, using GT to describe the complex and dynamic process of parental impressions of their child undergoing an outpatient minor surgical procedure specifically with N₂O. This study imparts the exclusive nature of what parents face by citing descriptive explanations in the parents’ own words.

As was discovered in this study, parental impressions do not begin upon entry into the outpatient treatment room on the day of the scheduled N₂O procedure. This unique process actually begins during the surgeon’s office visit when the parent’s child is scheduled for the outpatient minor surgical procedure with N₂O.

The realization by the parent that the child will be scheduled for an outpatient minor surgical procedure with N₂O brings to mind past surgical and anesthesia memories. Subsequently, parents had multiple expectations about the scheduled procedure and concerns how their child may respond. Parents’ expectations are inextricably linked to what was previously remembered. *Knowing What to Expect* was therefore identified as the onset of the process and the first category subsumed under the core category.
Parents verbalized the presence of anxiety and fear as they initially moved through this process. Their main concern was constantly being with their child for security and comfort purposes during the procedural experience. By exploring and discovering this real human experience, the challenge that these parents faced has been acknowledged and a better understanding of what they were going through has been gained.

**Relation to Other Studies**

The first category, *Knowing What to Expect* portrays what parents want to know and expect about the upcoming procedure and N₂O. This phase began during examination of the parent’s child and subsequent procedure scheduling in the surgeon’s office. The first subcategory, *Reflecting on Past Experiences* is directly linked with *Knowing What to Expect* for the future procedure. Parents who had previous knowledge and experience with surgical procedures and/or N₂O had a baseline on what to expect for their child’s procedure. Many parents compared their personal procedural experiences with how their child may respond to the N₂O and minor surgical procedure. Although there are many ways in defining the term “expectations” in this context, a commonly used definition is beliefs about upcoming clinical occurrences (Kravitz, 2001). Research is scarce examining parents’ previous experiences and expectations for future clinical occurrences on their child who will receive N₂O for a minor procedure. Oliver (1993) suggests that the experienced performance (such as past surgical experience) has a direct influence on satisfaction, and that priorities and discrepancy between expectation and experienced performance may also influence satisfaction. Other variables with influence on expectations and satisfaction are parent characteristics, other experiences, and the effects of these experiences on the individual (Thompson & Sunol, 1995). These studies support
that parents’ prior experiences correlate with how they expect their child to respond to the future procedure.

The category, *Searching for Information* described the parents’ challenge to learn as much as possible about their child’s upcoming procedure and N₂O. The findings from this current study suggest that a majority of parents believed it would have been helpful to receive information about the procedure and N₂O in written or video format in addition to the provided verbal instructions. In fact, some parents used outside sources (such as the internet) to supplement procedural information that was provided by the surgeon. Prior research shows that the majority of patients believe pre-procedural information is of value (Watts, 1997). In fact a number of studies have shown that adequate pre-procedural preparation can reduce anxiety and procedural pain for a range of medical events, such as venipuncture (Kolk, van Hoof, & Riedeldij, 2000; Nelson & Allen, 1999). For this study, most parents expressed that education for themselves and their child as well as the rapport established between them and the health care provider was essential. Parents agreed that proper pre-procedural education would make themselves and the child less anxious during the pre- and peri-procedural period and be able to deal with post-procedural care more easily. These findings were duplicated with Jawahar’s and Scarisbrick’s study (2009) suggesting a need for pre-operative and pre-admission education that allows parents to be more involved in their child’s care. McGraw (1994) found that education for the patient and family was necessary pre-operatively. These findings were supported by Margolis and colleagues (1998) who found that use of an age-appropriate interactive booklet used by the parent and child diminished the child’s anxiety postoperatively and met the parent’s satisfaction. Moreover, Lynch (1994) reported that preoperative
education for the parent and child resulted in decreased emotional distress as compared to when there was no formal instruction given. In this current study, several parents felt that more sufficient information should have been provided pre-procedurally. A qualitative study by Gilmartin (2004) identified that 80% of the sample felt there was insufficient information about the forthcoming procedure. This finding confirms parents’ request for more adequate procedural information. Furthermore, information deficits were also found in research conducted by Rhodes et al. (2006). Bradshaw et al. (1999) identified specific information deficits involving pain management and misuse of appropriate terminology. According to Costa (2001), appropriate and timely provision of preoperative information is necessary. Mitchell (2001) suggests that the level of information people need and how they retain it varies, thus providing information should be tailored individually.

Finally, Kehlet and Wilmore (2008) found that understanding peri-operative pathophysiology and care regimens accelerates post-operative recovery and increases patient satisfaction after discharge. It is important to note that pre-procedural education for each child and parent must be individualized. In this study, there were a few parents who wanted to filter the procedural information provided by the surgeon. These parents thought that the surgeon was too blunt with descriptions and too much information initially was given to the child. Subsequently, these parents wanted to choose what their child needed to know about the scheduled procedure. One study was found that supported this finding to individually tailor information given to parents and children about the planned procedure (Justus et al., 2006). This research conducted by Justus and colleagues (2006) suggests that parents have different concerns according to their background. Therefore, the practitioners need to personalize the way parents and their children are
educated about the procedure. Although there are numerous reports investigating
preparation for various medical events and hospitalization, there is a gap in the literature
examining preparation for pediatric outpatient minor surgical procedures using N₂O as
sedation.

The category Having Expectations refers to the parental concerns relating to the
planned procedure. Depending upon parents’ past experiences or lack of knowledge
directly influenced their expectations and concerns. Some of these concerns include not
knowing what to expect and the outcome of the procedure. There is evidence in the
literature suggesting that parental expectations and fulfillment of expectations were
important influences in perception of satisfaction in their child’s care. Furthermore,
research has shown that having confidence in the doctors was identified as one of the
most important determinants of satisfaction (Ammentorp, Mainz, & Sabroe, 2006). These
findings correlated with this current study. Parents expressed having extreme confidence
with the nurses and doctors which directly influenced their positive expectations and
satisfaction.

Ross, Frommelt, Hazelwood, and Chang (1987) suggest that priorities may be a
missing link in the expectation-satisfaction relationship. In other words, what does the
patient want? What does the patient expect? What patients value in a specific service, can
be described as their expectations and priorities. In this study, parents clearly had a
variety of expectations for their child’s planned procedure with N₂O. Most parents clearly
based their expectations on past experiences and prior knowledge. Research has reflected
confusion about the definition of patients’ and parents’ expectations.
Increased feelings of anxiety, nervousness, and boredom experienced by the parents were worsened as a direct result of prolonged waiting time for the procedure. These findings were also recognized by Gilmartin and Wright (2008). For the parents, the critical moments of the journey are interrupted by waiting time and lack of information about delays. Similar findings in relation to excessive pre-procedural waiting time and abandonment experienced by patients have been noted (Malsters et al., 1998; Williams et al., 2003). The unexpected long wait highlighted in this study, three hours in some cases, left parents feeling fearful, tense, and bored.

Using distracters to divert children’s attention during painful procedures is well recognized in the literature (Fanurik, Koh, & Schmitz, 2000; Uman, Chambers, McGrath, & Kisely, 2007; Winskill & Andrews, 2008). A key to managing procedure-related pain and anxiety in children is for health care professionals to anticipate situations that may create pain and anxiety (AAP, 2001; Broome, Bates, Lillis, & McGahee, 1994; Winskill & Andrews, 2008). Coupled with N₂O inhalation, distraction techniques were usually quite useful to manage procedural pain and anxiety in the children.

Distraction is one example of the multiple non-pharmacological strategies available to lessen pain and anxiety experienced by children (Almond, 1999; Fanurik, Koh, & Schmitz, 2000; Uman et al., 2007). Distraction diverts the child’s attention away from a negative experience—namely the procedure—to a more positive focus, usually an object or activity (such as singing or watching a video). The aim of distraction is to diminish the child’s anxiety, encourage relaxation and elicit a higher level of cooperation from the child (Schecter et al., 2007; Windich-Biermeir, Sjoberg, Dale, Eshelman, & Guzzetta, 2007). Using distracting techniques, parents, staff, and the child may be less distressed about the procedure and related pain (Almond, 1999; AAP, 2001). In this study, parents
were instructed to distract their child during the N₂O induction and until the procedure was terminated. Interestingly, children who were less than eight years old, most parents reported successful use of particular distraction techniques such as talking, reading, and singing. When asked, parents thought certain distraction techniques may not be appropriate or successful for children older than eight years old (such as storytelling and singing songs). This finding was supported by studies and reviews (Fanurik, et al, 2000; Royal Australasian College of Physicians, 2005) which indicated that distraction is most effective for children less than seven years old. Kleiber and McCarthy (1999) conducted a study on parent behavior and child distress during urethral catheterization. Their findings suggest that parental reassurance did not decrease distress behavior in most children. Some techniques that have been successful in young children include listening to music, counting objects in the room, bubble blowing, reading I Spy® books, and using distraction boxes (Schecter et al., 2007; Winskill & Andrews, 2008).

When children are undergoing anesthesia, it is usually an anxious time for both parent and child (Bevan et al., 1990; Cameron, Bond, & Pointer, 1996; Chundamala, Wright, & Kemp, 2009). The category Participating in Pre-induction describes a two-stage simultaneous process that the parents experienced before their child underwent the N₂O induction. Parents unanimously expressed satisfaction that they were able to be present with their child during this process. These parents believed that their presence during the pre-induction and entire procedure made their child feel more secure and comfortable. There were conflicting findings evaluating parental presence effectiveness and children’s anxiety during anesthesia induction and medical procedures. While it was once assumed that children were reassured by having their parents present during anesthesia induction
and medical procedures, numerous scientific studies of parental presence have not produced any consistent conclusion (Chambers, 2003). Currently, research focuses on the relationship between specific parent behaviors and children’s coping and distress (Blount, Bunke, Cohen, & Forbes, 2001; Blount et al., 1997).

Although one would expect parental presence to be beneficial, Chundamala’s and colleagues’ (2009) review found otherwise. Their review examined 14 studies evaluating children being inducted with general anesthesia and/or given a pre-medication sedative (midazolam). This review did not find parental presence to be more effective than no parental presence, midazolam or parental presence plus midazolam when evaluating children’s and parental anxiety. Chundamala’s study suggests that parental presence does not seem to decrease parents and children’s anxiety. In many cases, midazolam or distraction techniques appear to be a suitable substitute.

There is a gap in the literature evaluating parental/children’s anxiety and parental presence during N₂O induction. The only studies available were evaluating parental presence and children’s anxiety during general anesthesia induction or procedures. In many cases, parental presence may not make any measurable difference for anxiety. For example, pre-medications (such as midazolam) may decrease children’s anxiety and subsequently, parental presence may be of no added benefit to these children. In this study, children received N₂O below 50% without hypnotic sedatives. Therefore, the child undergoing the procedure was fully conscious prior to induction of N₂O and aware of their parent’s presence.

The category, Assisting the Team provides a unique view of processes that occur when parents are required to assist the nurses and doctors before and during the child’s
procedure. Parents were instructed to hold their child’s mask during the entire NO₂/O₂ administration. In addition, parents were directed to distract their child before and during the entire child’s procedure. For some children that had increased bodily movements, parents assisted to restrain the child’s head or limbs when needed. Parents generally preferred to actively participate and be involved during the procedure by distracting, coaching, and soothing their child rather than to just observe. This finding is consistent with Jones’ and colleagues’ study (2005) where parents wanted to be active participants in their child’s painful medical procedures. It is important to note in this study that some parents would have preferred to be informed in advance of their responsibilities during the child’s procedure in order to be better prepared. Nurses and doctors must realize there is a clear subset of parents who want to be present but do not wish to actively participate mainly because they are either too nervous or want to watch the child’s procedure.

Assisting the Team also included the parents’ impressions of the staff’s characteristics and competencies during the N₂O procedure experience. Most parents expressed that the nurses and doctors were very child-centered and were generally satisfied with the care received. Parents described nurses and doctors as being very competent resulting in having much confidence in the staff. This study’s finding of competent practice in the healthcare profession is consistent with requirements of professional associations. O’Neil (1999) asserted that certification and licensing of health professionals of the future must be linked to demonstration of continuing competence. The professional expectation of nursing serves as the foundation for remaining current and competent in nursing practice throughout one’s nursing career. External regulatory bodies such as Joint Commission on Accreditation of Healthcare Organizations (JCAHO) maintain and assess competence
within each healthcare organization. The JCAHO standards related to competence assessment address how organizations ensure healthcare providers are competent based on the services provided (JCAHO, 2005). Arcand and Neumann (2005) established a successful centralized nursing competency assessment program in a large hospital. The practitioner’s competence not only is essential to safety but makes a positive impact on parents ensuring confidence in their child’s well-being.

The category, *Watching the Procedure* provides a unique perspective of what processes occur when parents are required to attend their child’s N₂O procedure. Most parents expressed a desire to watch the procedure while they were in the room with their child. Some parents who were unable to see their child’s procedure (due to limited view) wished they could have observed. In contrast, a few parents were content just being with their child and had no desire to see the procedure.

One of the most interesting findings of this study relate to parents observing their child’s procedure. These findings are explained in the category of *Watching the Procedure* and two subcategories of *Parental and Child’s Responses*. Most parents unintentionally saw their child’s procedure since they were required to be active participants. Previous research suggests most parents want to be present for their child’s painful procedures (Mangurten et al., 2005; Meyers et al., 2000; Powers & Rubenstein, 1999). Research is limited however, describing parents’ desire, request, and reason to watch their child’s procedure.

Parents have a unique opportunity to stay with their child during the entire N₂O procedure. The stages of *Parental Responses and Child’s Responses* occur simultaneously. The category, *Parental Responses* describes parents’ impressions during their child’s N₂O procedure. Parental impressions include descriptions of the exposed
technical components of the N₂O apparatus, monitors, surgical procedure, and child positioning. Parental responses were directly related to the child’s reaction to the N₂O, procedure and their own past experiences.

The effect of parental responses during anesthesia induction on parental anxiety and satisfaction were previously studied (Blesch & Fisher, 1996). Findings suggested that parents who were present for induction expressed satisfaction with having clear explanations given to them and having interactions with anesthesia care providers. The emotional reactions of parents of children ages one to ten years who chose to be present for their child’s anesthesia induction were investigated in another study (Ryder & Spargo, 1991). In rating of parents’ emotional response: 55.4% were calm, 40.3% were anxious, 29% were very anxious, and 1.4% were terrified. Another group of researchers conducted a study to examine parental physiological and behavioral manifestations of stress during their child’s anesthesia induction (Kain et al., 2003). Parents had an increase in heart rate and skin conductance until the child entered the operating room for anesthesia induction. There were no significant rhythm abnormalities or ST changes noted on their electrocardiograms. Increased heart rate and skin conductance are associated with high anxiety levels. It is important to realize that these studies on parental responses are with children undergoing general anesthesia. Furthermore, these parents were not present for their child’s procedure and thus parental responses were not examined during this event. There is a scarcity of studies in the scientific literature reporting parental responses to their child’s procedure with N₂O analgesia. Parental responses to the N₂O induction and watching their child’s procedure may produce different manifestations.
Parents described their perceptions of their child’s responses to the N\textsubscript{2}O and procedure. These findings provide a clear understanding of parents’ impressions about how they think their child responded to the inhalational gas and procedure. Interestingly, parents who perceived their child demonstrated painful behaviors in response to the procedure and/or injection, these children scored very low or zero on the Pain Scale. In addition, these children did not have any recollection of the procedure or injection. This finding supports a previous study examining the safety and efficacy of N\textsubscript{2}O in children for minor surgical outpatient procedures (Burnweit et al., 2004).

Parents’ perceptions of their child’s responses to the invasive procedure with N\textsubscript{2}O were described as behavioral and sensory reactions. Most parents perceived their child experienced minimal pain and discomfort during the procedure as a result of the N\textsubscript{2}O. Some parents were quite surprised and satisfied that their child appeared very comfortable and cooperative during the invasive procedure. These findings support the results of a study conducted by Williams et al. (2006). Williams and colleagues (2006) conducted a survey and discovered the use of N\textsubscript{2}O is helpful in minimizing the psychological trauma caused to children, parents, and professionals involved during painful procedures undertaken.

Several parents expressed dissatisfaction with the effectiveness of the topical anesthetic (EMLA) used prior to the child’s procedure. Furthermore, the delayed onset of action (greater than one hour) was fraught with frustration which extended the waiting time for the procedure. Topical anesthetics have demonstrated reduction of pain for subcutaneous and intramuscular injections, despite their limited skin penetration. The
anesthetic most studied for use with injections, such as immunizations, is EMLA ® (eutectic mixture of local anesthetics) cream (Cassidy et al., 2001; Halperin, McGrath, Smith, & Houston, 2000). When indicated, EMLA® cream was applied to children’s surgical site one to three hours before the procedure. The success of EMLA in reducing injection pain is likely attributed to a decrease in pain as the needle penetrates the skin and a reduction in the underlying muscle spasm associated with this pain (Schecter et al., 2007). EMLA is used to alleviate pain for procedures involving needles. EMLA is applied to intact skin one to four hours in advance of a procedure and the onset of action is approximately one hour. Based on reports by verbal children, studies support the effectiveness of the cream in preventing the sensation of pain (Taddio, Nulman, Goldbach, Ipp, & Koren, 1994). A study conducted by McGrath and McAlpine (1993) showed that the effectiveness of EMLA alone may be difficult to assess owing to the anxiety of a needle and of other stressors of a procedure.

Researchers evaluated the effectiveness of EMLA cream and inhaled N₂O for infants and young children undergoing an injection (Carbajal et al., 2008). EMLA and N₂O were more effective than either EMLA alone or N₂O alone in reducing pain that is induced by injections. As shown in the literature, there seems to be conflicting findings of EMLA cream for its effectiveness in diminishing pain to the affected site. This current study also shows mixed results for EMLA’s efficaciousness as described by parents.

For this study, parents who believed that EMLA was not effective during injection, these children did not recall the needle and/or had low pain scores. Similar results were found by Burnweit et al. (2004) where 84% of children who had prior EMLA application,
denied receiving a needle despite flinching during the injection. The memory loss may be attributed to the excellent amnesic quality of N₂O.

Several researchers have studied parental perceptions of their child’s responses to invasive procedures. There is limited research, however examining parents’ perceptions of their child’s responses to N₂O, EMLA and an invasive procedure.

The category, *Feeling Relief* described the sensation parents experienced during and after the child’s procedure. This sensation was described as a feeling of relief, calmness and reduction of anxiety. This feeling was a direct result due to the successful and positive experience of the child’s procedure as described by all parents. The parental feeling of relief immediately after their child’s procedure has not been well documented in the literature. In fact, there were no studies found which specifically examined parents’ post-procedural feelings. There were studies, however, that assessed the effects of parental presence in the pediatric treatment room on the child, parent, and health professional outcomes. Parental outcomes included feelings of less distress and more satisfaction due to being present for their child’s invasive procedure (Haimi-Cohen, Amir, Harel, Straussberg, & Varsano, 1996; Piira, Sugiura, Champion, Donnelly, & Cole, 2005). These findings were similar to parents’ outcomes for this study.

The category, *Going Home* is the final phase of this process. This phase refers to the discharge preparation for the parents which included learning the after-care. There is evidence in the literature that preparing parents educationally for discharge helps to improve compliance and patient outcomes. The parents in this study generally felt that the discharge teaching was adequate and understandable. With this study, discharge teaching included verbal and written instructions for the child’s post-procedural care. There were a
few parents however, that would have liked a return demonstration in order to know if they were performing the care correctly (such as changing a dressing or cleaning a wound).

Previous research has identified that the competencies of pediatric nurses providing discharge teaching to parents of hospitalized children is essential to promote feelings of readiness for discharge and the transition to care for the child at home (Weiss et al., 2008). Weiss and colleagues measured parent educational preparation for discharge using the Quality of Discharge Teaching Scale. Findings clearly delineate hospital discharge as a transitional process for parents that can be positively influenced by nurses’ skills in providing discharge teaching. Most of the reported studies for discharge teaching assess parent education for hospitalized children. Health care practitioners are challenged to successfully provide discharge teaching to parents in an acute outpatient clinic setting. Constraints of time usually pose the biggest challenge to ensure adequate parental discharge education and understanding.

Results of this current study have strong implications for clinicians caring for children and their parents. In summary, the literature remains largely inadequate in attempting to explain the process that parents go through when their child undergoes an invasive procedure with N₂O. This study adds to existing research examining parents’ perceptions of their child’s responses to an invasive procedure with sedation.

This study captures the uniqueness of the entire process that parents encounter from scheduling until the termination of their child’s N₂O procedure. This newly developed substantive theory recognizes the process that parents move through while *Weathering the*
Storm before the Calm by Securing Connections. This theory can guide clinicians to help parents support their child undergoing an invasive procedure with N₂O.

Significance to Nursing Theory, Research and Practice

The findings of this study make a significant contribution to nursing theory, research and practice. The substantive theory that emerged from this study is grounded in parental impressions and can be used to guide nursing practice in the population where it was derived. This theory, Weathering the Storm before the Calm by Securing Connections adds to the scientific knowledge base of the nursing discipline by describing the unique impressions of parents whose children underwent outpatient minor surgical procedures with N₂O. This theory provides nurses with a better understanding of the consecutive stormy and calm phases that parents endured during this process. In addition, this theory describes the barriers and facilitators that parents recognized during their experience. This new-found knowledge offers clinicians unique interventions that can assist parents through this process.

Implications for Nursing Practice

The findings from this study offer several practical applications. Understanding what parents go through when their child is scheduled and undergoes a minor procedure with N₂O can help clinicians intervene and support parents more effectively during this process.

Parents in this study identified several facilitators and barriers that helped or hindered them and their child during this process. Changes in practice can be developed to
augment the items parents identified as facilitators and diminish the incidence of barriers that hindered their experience.

The procedural experience can be stressful and traumatic for children and their families. Parents are faced with a disruption in their routines. Findings from this study clearly show that parents expect understandable information about their child’s upcoming procedure and N₂O. Allowing parents to take an active role in their child’s preparation, procedure, and care can help decrease their stress levels. Developing informational pamphlets, videos, or activities on the procedure and N₂O that parents can share with their child may prove worthwhile. Supplying parents with a pamphlet or video describing the upcoming procedure with N₂O can help continue the preparation process at home with their child.

Nurses and doctors should consider addressing each parental concern individually. For example, if parents want procedure explanations provided without the child present, clinicians should respect their wishes but explore the reason for this request. Moreover, clinicians should provide pre-procedural education for both the child and parent.

Parents and children should also be given an opportunity to visualize the setting where the future procedure will take place. If possible, nurses should incorporate child life therapists for play techniques and pre-procedural education. This strategy will familiarize children and parents with the hospital setting, technical aspects, and their procedures, thereby lessening fears of the unknown. Parents and children must be given an opportunity to express their concerns and needs to the scheduled procedure by speaking with professional staff. In addition, interested families should be encouraged to network with other parents with previous experience.
Education should include that one parent will be an active participant during their child’s procedure. Preparing and allowing parents to be present and active participants for N₂O induction can alleviate stress for the parent and child. In addition, advise parents that they will also be using distracting techniques to help divert their child’s attention during the procedure. This will give parents adequate time to prepare an effective technique to be used for their child. Parents should be advised to bring their child’s favorite toys, music, or books to help distract their child during the procedure.

Some parents felt ignored while waiting for the procedure. Therefore, it may be helpful that nurses are more visible and provide updates with accurate information in an empathetic manner when interacting with parents. The nurse’s ability to respond sensitively is essential to meet the psychological needs of the parent and child.

Having the family arrive one hour (instead of three hours) before the procedure can diminish the level of anxiety for the parent and child. During the procedure scheduling, advise the parent to bring the child’s favorite toy, game, book, and/or music to help prevent boredom and decrease fear. In addition, suggest to parents to also bring a book, computer, or activity for themselves to help decrease their own anxiety and boredom. If possible, provide a centralized play area for the children to make the wait more tolerable.

If requested, nurses should help develop sitting positions that promote comfort for the child before their parent applies the N₂O mask. This strategy may encourage children better cooperate and maintain a sense of control. When the N₂O analgesia becomes effective, the parent can assist the child to assume the appropriate position for the procedure. The positions of comfort also lessen the chance that the procedure will fail and subsequently having the N₂O aborted.
Some parents felt their child should have been more relaxed before the surgeon performed the procedure. The clinician administering the N₂O should consider incorporating parental impressions of their child’s comfort level into decision-making when to have the procedure begin.

When possible, parents should have the opportunity to demonstrate required discharge care. This approach ensures care is being done correctly and may help increase compliance.

**Implications for Nursing Education**

The results of this study have important implications for the education of future and current nurses caring for parents and children in an outpatient setting. Education about caring for children and parents in an outpatient setting undergoing procedures with sedation should begin in nursing school. This knowledge should not happen by chance. Nursing students must possess a basic knowledge of common childhood diagnoses and management encountered in an outpatient setting. Furthermore, education on moderate sedations and its effects on children should be incorporated in nursing programs. Equally as important, therapeutic communication strategies will help the novice nurse provide optimal support of the parent-child dyad. Instruction must include communication skills for developing optimal relationships between the nurse and parents. Even though the scheduled procedure is classified as minor, parents still perceive this as major when it concerns their child. Nurses should recognize signs of parental anxiety in order to help support them in their time of need.

Routine in-service opportunities must be provided to continually inform and educate nurses on the most current interventions and skills related to N₂O and other sedation
methods used for minor procedures in children. Staff training in N₂O sedation techniques, pharmacology, as well as the use of non-pharmacologic techniques is vital to the enhancement of parental support and success of N₂O programs provided by nurse practitioners.

**Recommendations for Future Research**

Future research should comprise a more diverse sample of participants including additional fathers and a wider range of ethnic and educational backgrounds. In addition, future studies are needed to examine the impressions of parents whose child previously underwent a minor procedure without N₂O and compare the difference when the same child has N₂O with the current procedure.

This study was conducted in an outpatient setting that included parents of children who underwent scheduled, non-urgent minor surgical procedures using N₂O analgesia. Since these procedures were all scheduled, most parents and children had the time to educationally and emotionally prepare for the upcoming event. Recommendation for further research is warranted to study parents of children for non-scheduled, urgent minor procedures (e.g., incision and drainage of an abscess) with N₂O. The findings of these two studies would be interesting to compare with each other. The latter group does not have time to prepare for the procedure because of the urgency and the child’s enduring pain.

The use of N₂O/O₂ analgesia has spread into many areas including radiology and in a variety of hospital settings for the alleviation of procedure-related pain and anxiety in children. This study was limited to only the pediatric surgery outpatient setting. Future research needs to extend in other settings such as in-hospital units, plastic surgery and hematology-oncology services to name a few. Many reported studies have already
established that N₂O is safe and efficacious for various pediatric procedures in a variety of settings. There is a gap in the literature however, using a qualitative approach analyzing parental impressions of their children who underwent minor procedures with N₂O analgesia in any setting.

Parents’ pain scores for their children when undergoing procedures have been previously compared with those of their children. This warrants further investigation correlating children’s and parent’s assessments of procedural pain with N₂O.

This study was limited to parents’ perceptions of their child’s responses to a N₂O procedure. Another area needed for further research is to study the child’s perception of pain when undergoing an outpatient minor surgical procedure with N₂O. Several scientific reports were found reporting children’s perception of procedural pain. There is paucity in the literature however, that assesses children’s perceptions to procedural pain using N₂O analgesia in an outpatient setting. The experience of what it is like to undergo a procedure with N₂O from the child’s perspective has not been previously studied using a qualitative methodology. Conducting a GT study describing the experiences of children in their own words who undergo procedures with N₂O may generate significant knowledge to enhance the pre-, intra-, and post-procedure care they receive.

Limitations of the Study

The present study may have been limited because of a select sample of parents. Parents in this sample were predominantly mothers, married, between the ages of 36 to 44 years old, Hispanic, college-educated, and professionals. Furthermore, children’s N₂O cases were all scheduled and considered non-painful prior to the procedure. Therefore, generalization of these findings is limited to parents of children undergoing an outpatient
minor surgical procedure with N\textsubscript{2}O. Finally, this research was limited to exploring parental impressions of their child’s N\textsubscript{2}O minor surgical procedure in an outpatient setting. By extending the scope of the study to in-hospital and various pediatric specialties may increase generalization of findings to other settings.

**Summary**

This is the first study to provide a comprehensive description and substantive theory of parental impressions of their child undergoing N\textsubscript{2}O for a scheduled outpatient minor surgical procedure. Study findings, pertinent literature relating to the generated substantive theory and limitations were discussed. The implications for nursing theory, research, education, and practice were presented.

The theory of *Weathering the Storm before the Calm by Securing Connections* signifies the impressions parents face in attempting to *weather* unchartered territory and maintain their coping mechanisms to achieve the *calmness*. The parental feelings of calmness and relief were directly related to being able to stay physically and emotionally connected to their child for the entire procedure. The study findings not only focused on the parental perceptions of the child’s responses to the N\textsubscript{2}O but also encompassed their impressions from scheduling the case until termination of the procedure.

To conclude, it is critical to acknowledge that a number of troublesome issues were expressed by the parents in this study. These findings have clear implications for practitioners and can be useful to pediatric nurses and surgeons to be more alert to the potential and current needs of parents. Findings from this study will help fill the gap in knowledge of parental impressions when their child is scheduled and undergoes an outpatient minor surgical procedure using N\textsubscript{2}O. These study results can be used by
pediatric nurses and other health care providers to help parents *weather the storm into calmness* by securing connections to their child.
References


Appendix A

Parent Recruitment Letter

University of Miami

Parental Perceptions of Their School-aged Child’s Responses to a Minor Surgical Outpatient Procedure with Nitrous Oxide Analgesia

**VOLUNTEERS Wanted for a Research Study**

The focus of this research is to study parents’ perceptions of their school-aged child's responses to a minor surgical outpatient procedure using nitrous oxide.

The information gained from this study may help promote a better understanding from the parent’s perspective of their child’s responses to the outpatient procedure with nitrous oxide. In the future, this information may be used to help improve children’s experiences with an outpatient procedure with nitrous oxide and may provide better parental support.

You may be able to participate in this research study if:

- your child is scheduled for a minor surgical outpatient procedure with nitrous oxide,
- your child is healthy and between the ages four years and eighteen years old,
- you are able to speak and understand English, and
- you will be in attendance with your child during the scheduled procedure

There will be no charge to you. For compensation of your time, a $20 gift card to Toys R Us® will be provided to you after your participation.

The research study will take place at Miami Children’s Hospital Outpatient Center. Your child’s procedure will also take place in the outpatient center.

To learn more about this research, please call Tina Shapiro-Stoler at 561 809 2804.

This research is conducted under the direction of Dr. Elias Vasquez, University of Miami, School of Nursing and Health Studies.

Thank you very much in advance for your time and participation.
Appendix B

Demographics Questionnaire

Code Name_________ Code Number_________

1. Are you Male or Female?
2. What is your age?
3. What is the highest level of education you have completed?
4. What is your occupation?
5. What is your current marital status?
6. What is your religious affiliation?
7. What is your race?
8. What is your ethnicity? (for example, Jamaican, Puerto Rican)
9. What language(s) do you speak?
10. What is your telephone number?

Please answer the following questions about your child who is undergoing a procedure using nitrous oxide:

1. Is your child male or female?
2. What is your child’s age?
3. What grade in school is your child in?
4. What type of procedure is your child having? (for example, removal of a mole)
5. Does your child have any medical conditions?
   a. If yes, what conditions?
6. Has your child ever had a minor procedure before?
7. Has your child ever had nitrous oxide (laughing gas)?
   a. If yes, for what reason?
8. Does your child take any medication?
   a. If yes, what medications?
9. Has your child ever stayed in a hospital overnight?
   a. If yes, why and how many days?
10. Has your child ever had surgery?
    a. If yes, what type?
Appendix C

Informed Consent – Miami Children’s Hospital

RESEARCH SUBJECT INFORMATION AND CONSENT FORM
Miami Children’s Hospital

TITLE: Parental Perceptions of Their School-aged Child’s Responses to a Minor Surgical Outpatient Procedure with Nitrous Oxide

PROTOCOL NO.: None
WIRB Protocol #20082204
0000770899

SPONSOR: Tina Shapiro-Stoler, BSN, M.S.N.
Miami, Florida
United States

INVESTIGATOR: Tina Shapiro-Stoler, BSN, M.S.N.
3100 Southwest 62nd Avenue
Miami, Florida 33155
United States

SITE(S): Miami Children’s Hospital
3100 Southwest 62nd Avenue
Miami, Florida 33155
United States

STUDY-RELATED PHONE NUMBER(S): Tina Shapiro-Stoler,
561-809-2804 (24 hours)
305-286-8751 (24 hour pager)

This consent form may contain words that you do not understand. Please ask the researcher or the study staff to explain any words or information that you do not clearly understand. You may have an unsigned copy of this consent form to consider or discuss with family or friends before making your decision to allow your child to participate. In this consent form the word “parent” will also represent the child’s legal guardian.

SUMMARY

- You are being asked to be in a research study.
- Your decision is voluntary.

134
• If you decide to be in this study and then change your mind, you can leave the study at any time without any consequences.
• You will be interviewed in this study for about 60 minutes and have no planned study visits.
• If you agree to be in this research study, your child’s medical records will become part of this research. They may be looked at or copied by the sponsor of this study.
• You will not give up any of your/your child’s rights by signing this consent form.

SOURCE OF FUNDING

The researcher (and/or) Miami Children’s Hospital will not be paid for your enrollment in this study. There will be no compensation for the researcher.

You may ask the researcher how she or others may benefit from your participation in this study.

PURPOSE OF THE STUDY

The purpose of this research study is to talk to parents about how their child responded to the use of nitrous oxide (laughing gas) that was given during an outpatient surgical procedure. This will take place during an interview with parents after their child has had the procedure.

Parents are in the best position to evaluate how their child responded to the nitrous oxide. They can determine whether they were satisfied that it helped to relieve pain for their child and whether or not their child had any bad reactions. This information from parents may be a valuable asset for health care professionals in signaling pain sooner.

You will be in this study for about 60 minutes. Approximately 15 parents will participate in this study.

PROCEDURES

The study interview will take place either immediately after or within one year of your child having the surgical procedure using the nitrous oxide. The following information concerns the use of nitrous oxide during the procedure.

In the outpatient center exam room, the nurse practitioner (NP) will perform a screening to determine if your child is safe to receive nitrous oxide (laughing gas). If indicated, the nurse or you will apply a topical numbing cream to your child’s affected site 30 to 60 minutes before the procedure. If the NP determines that it is safe for your child to receive nitrous oxide, a short teaching session will be given. The nurse will offer your child a small snack and drink before the procedure. You and your child will remain together before, during, and after the minor surgical outpatient procedure. The nurse will take your child’s vital signs, weight, and oxygen saturation before the procedure. The nurse
will escort you and your child to the minor outpatient operating room where the procedure will take place. Your child will be placed on the provided stretcher and you will be seated on a chair near your child’s head. You will be instructed to hold your child’s nitrous scented nasal mask and speak to your child in a soothing tone throughout the procedure. Your child will be instructed not to speak while the nasal mask is in place since speaking decreases the effect of nitrous oxide. The NP will give oxygen for two to five minutes before giving nitrous oxide to your child. Nitrous oxide mixed with oxygen will gradually be adjusted until your child’s pulse rate and excitement decrease. The NP will continue monitoring and recording your child’s pulse, respiratory rate, and oxygen saturations every five minutes. If indicated, the surgeon will administer an anesthetic injection (shot) to the affected site.

Afterwards, the surgeon will start the procedure. Once the procedure is over, nitrous oxide will be turned off and oxygen given for about five minutes. The nasal mask will then be removed and given to your child as a souvenir. Afterwards, your child will be given a short test to score pain at different times (pre-procedure, at injection, during procedure, and post-procedure).

INTERVIEW PROCESS

You and your child will be escorted to a private room in the outpatient center for the interview to take place or the interview may take place by telephone or at an agreed location. The researcher will conduct audio-taped interviews with you which will last for about one hour or less. Some background information (such as your age, gender, race, your child’s diagnosis and procedure, etc.) will be collected for this study. You are free to decline to answer any particular question(s) that make you uncomfortable.

RISKS AND DISCOMFORTS

Risks of Study Procedures
There is a risk of loss of confidentiality of your personal information in this study.

If you are a woman who could be pregnant, you need to be aware there are risks to an unborn child from exposure to nitrous oxide in the operating room. Please ask the researcher about these risks.

NEW INFORMATION

If significant new information is discovered during this research that the study researcher believes might change your decision to be in this study, you will be given this information.

BENEFITS

This is not a treatment study. You or your child is not expected to receive any direct medical benefits from participation in the study.
The information from this research study may lead to a better experience in the future for children that undergo minor surgical outpatient procedures with nitrous oxide.

**COSTS**

All study-related costs associated with you being in this study will be paid by the sponsor. You or your child’s insurance company will be billed for the costs of your child’s routine care (the care your child would have received if you were not in this study). Your child’s health insurance company may not pay for these charges because your child is in a research study.

**PAYMENT FOR PARTICIPATION**

You will be given a $20 gift card to Toys “R” Us® if you complete the study interview. If you leave the study early, you will not be paid for the study.

**ALTERNATIVES**

This is not a treatment study. Your alternative is to not participate in this study.

**AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES**

Federal regulations give you certain rights related to your child’s health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify your child.

**What information may be used and given to others?**

If you choose to be in this study, the researcher will get personal information about you and your child. This may include information that might identify your child. The researcher may also get information about your child’s health including:

- Past and present medical records
- Research records
- Records about your child’s study visits
- Information (obtained during this research or already included in your child’s records) about
  - HIV / AIDS
  - Hepatitis infection
  - Sexually transmitted diseases
  - Other reportable infection diseases
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Diaries and questionnaires
• The diagnosis and treatment of a mental health condition

Who may use and give out information about your child?
Information about your child’s health may be used and given to others by the researcher and staff. They might see the research information during and after the study.

Information about your child and your child’s health which might identify your child may be given to:

• The U.S. Food and Drug Administration (FDA)
• Department of Health and Human Services (DHHS) agencies
• Governmental agencies in other countries
• Governmental agencies to whom certain diseases (reportable diseases) must be reported
• Miami Children’s Hospital
• The Western Institutional Review Board® (WIRB®)

Why will this information be used and/or given to others?
Information about your child and your child’s health that might identify your child may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your child’s information for this purpose.

The results of this research may be published in scientific journals or presented at medical meetings, but your child’s identity will not be disclosed.

The information may be reviewed by Western Institutional Review Board (WIRB). WIRB is a group of people who perform independent review of research as required by regulations.

What if I decide not to give permission to use and give out my child’s health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you decide not to give permission, your child will not be able to be in this research.

May I review or copy the information obtained from my child or created about my child?
You have the right to review and copy your child’s health information.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will be good until the end of this research study (recommended) or will not expire.

You may withdraw or take away your permission to use and disclose your child’s health
information at any time. You do this by sending written notice to the researcher. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you or your child will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my child’s health information protected after it has been given to others?
If you give permission to give your child’s identifiable health information to a person or business, the information may no longer be protected. There is a risk that you and your child’s information will be shared with others.

COMPENSATION FOR INJURY

The study is an interview only. There will be no medical treatment for research related injury since this is not a treatment study.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

If you do not take part in or withdraw from this study, your child will continue to receive care.

Your participation in this study may be stopped at any time by the researcher without your consent.
If you leave the study before the final regularly scheduled visit, you may be asked by the study doctor to make a final visit for some of the end-of-study procedures.

QUESTIONS

If you have any questions about this study or your participation in this study, contact Tina Shapiro-Stoler at Phone 561 809 2804 (24 hours) or 305-286-8751 (24 hour pager).

For more information concerning this study, study-related risks or injuries, and information regarding research subjects’ rights you may contact Christian C. Patrick, M.D., Ph.D., Senior Vice President for Medical Affairs/Chief of Staff at 305-666-6511, ext. 2023. You can also call this number if the research staff could not be reached, or if you wish to talk to someone other than the research staff.

Or

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
WIRB is a group of people who perform independent review of research.

For questions regarding accountability and disclosure (sharing) of your child’s protected health information, you may also wish to contact Karen Silliter, Privacy Officer at Miami Children’s Hospital at 1-800-521-8803.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

**PERMISSION TO PROCEED**

Please do not sign anything until the person obtaining informed consent (the study doctor, or research coordinator) is with you.

I have read (or have had read to me) the information in this consent form and associated information.

I have been given the opportunity to ask questions about this study. I freely agree to participate.

I authorize the use and disclosure of my/my child’s health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not waived any of the legal rights which I or my child otherwise would have as a subject in a research study.

<table>
<thead>
<tr>
<th>Name of Subject (Typed or printed)</th>
<th>Signature of Subject</th>
<th>Date</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Name of Principal Investigator (Typed or printed)</th>
<th>Signature of Principal Investigator</th>
<th>Date</th>
</tr>
</thead>
</table>

-------------------------- Use the following only if applicable --------------------------------

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely
consented to participate in the research study.

______________________________    ______________________
Signature of Impartial Witness     Date Signed

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.
Appendix D

Study Questions

eProst ID: 20080938
( Text Box comment WIRB 20082204 #6527657.0 )
Approval Date: 03/25/2009

Probe Interview Questions

Some examples of probe questions that may be used in this study are:

1. Describe what it was like to see your child undergo the procedure with laughing gas.

2. Describe how you think your child responded to the procedure with the laughing gas.

3. Is this how you expected your child to respond to the procedure? Please explain.

4. What was your main concern before/during/ and after the nitrous procedure?

5. Give a brief description how you think your child responded during the injection.

6. What did your child express regarding the nitrous procedure before coming to the hospital?
   • Have you (or your children) had any previous experience with nitrous oxide? If yes, how was this experience similar or different from your previous encounter with nitrous?

7. What do you wish the nurse/doctor would have done to help you or child before, during, and/or after the procedure?
   • Some parents suggested distraction (e.g., talking to child) as helping the child during the nitrous procedure. What forms of distraction do you think would help your child during the nitrous procedure?

8. If your child had to undergo another minor procedure, would you choose to have nitrous oxide given again? Why or why not?

9. Is there anything else at all that you would like to tell me about your experience that is important for me to know?
VITA

Tina Jill Shapiro-Stoler was born in Brooklyn, New York on March 30, 1959 and spent her childhood living in Long Island, New York. Her parents are Hy Shapiro (deceased) and Jackie Hahn Shapiro. She received her elementary education at Robbins Lane Elementary School and her secondary education at Syosset High School. In August 1977 she entered the School of Nursing at the University of Miami, Coral Gables, Florida from which she was graduated with a Bachelor of Science in Nursing in May 1982. In August 1985 she was admitted to the Graduate School of Nursing at the University of Miami where she was graduated with a Master of Science in Nursing in May 1989.

She practiced pediatric nursing and specialized in pediatric surgery. She held many positions in her professional nursing career. She was a staff nurse, associate nurse manager, clinical nurse specialist, and advanced registered nurse practitioner. She also practiced and taught nursing in South Africa.

In August 2002 she was admitted to the Graduate School at the University of Miami. In December 2009 she was granted the degree of Doctor of Philosophy in Nursing.

Permanent Address: 10391 Sunset Bend Drive, Boca Raton, Florida 33428