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Development of a Program Proposal for a Nitrous Oxide Program in Pediatrics

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This is to certify that the doctoral study by

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has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

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2016

Abstract

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MSN, Walden University, 2013

BSN, University of Wisconsin-Green Bay, 2009

Project Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Nursing Practice

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Abstract

When pediatric patients are admitted to the inpatient or outpatient hospital setting they potentially have to endure procedures that cause pain, fear, and anxiety which can have a lifelong impact on the child's response to future healthcare needs. The purpose of this project was to create a comprehensive program proposal for a nitrous oxide sedation program to minimize those perceptions towards medical procedures. The project utilized a systematic review of literature and secondary data to address the most important indicators for developing a comprehensive program proposal to present to the pediatric leadership team. Multiple studies have shown nitrous oxide having an excellent safety profile in the pediatric population while providing an almost pain and anxiety free procedure. The program proposal will be used to improve pain and anxiety management for pediatric patients requiring procedures such as intravenous access, venipuncture, voiding cystourethrograms, lumbar puncture, bone marrow biopsy, port-a-cath access, PICC line insertion, dressing changes, chest tubes, and wound care. Key stakeholders and content experts were brought together to create the nitrous oxide program proposal which included a new practice guideline, a comprehensive policy and procedure for nitrous oxide administration, and an education plan. The program proposal included other key components necessary for a safe and efficient program such as a pre-assessment to determine if the child is a candidate, monitoring and documentation of nitrous oxide administration, and education for the child/parent(s). The nitrous oxide program for pediatrics was designed as a minimal sedation method to minimize procedural pain, fear, and anxiety in children where medical procedures are a necessary part of treatment.

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Dedication

I dedicate this project to my husband, Kevin, for his unconditional support while I continued my studies. Also, for proofreading my papers even though he knew nothing about the topics. To my children, Kamden and Haleigh, who are the best children a mother could ask for. Their smiles and hugs kept me going. I have no doubt that without their love and support through my doctorate studies; I would not be where I am today. I also dedicate this work to my parents, Jerry and Cindy, who have taught me perseverance and that I can do anything I set my mind on.

Acknowledgement

The last 18 months has been an intense learning experience both academically and personally. This project has had a big impact on me, and I want to thank everyone involved who has supported and guided me through this journey. I would like to express my gratitude to my project committee, Dr. Oscar Lee, Dr. Catherine Garner, and Dr. Francisca Farrar. Your guidance, contributions, and feedback at each level of my project have been invaluable.

I would also like to thank the pediatric leaders, Kim Kostichka RN, Lori Vertz, RN, and Drs. Taylor and Ament for all of your help and guidance in completing my work and for helping me grow as a scholar, practitioner, and a leader. Your continued support and encouragement has been priceless. I am indebted to the knowledge and expertise you each provided as I developed my work. A very special thanks goes out to my practicum mentor and Executive Director of Pediatrics, Heidi Warpinski MS, RN, CPNP, for her willingness to help with this project and for her continued enthusiasm and support. I am entirely grateful for all the teamwork, dedication, and support from the pediatric leaders that was needed to complete my work and for guiding me every step of the way.

Table of Contents

List of Figures

Section 1: Overview of the Evidence-Based Project

Introduction and Background

Pediatrics is defined as a field of medicine that is concerned with the health of infants, children, and adolescents: their growth and development and the conditions that allow them to achieve full potential as adults (American Academy of Pediatrics [AAP], n.d.). According to the United States Census Bureau's 2011 data, there are 74 million children who live in the United States (U.S. Census Bureau, 2014). There were 25.5 million under the age of six, 24.9 million aged six to 11 years, and 23.8 million aged 12-17 years (U.S. Census Bureau, 2014). The percentage of the total population under the age of 18 is projected to decrease from 23% to 20% between 2014 and 2060 (Colby & Ortman, 2015).

Hospital admissions can be very stressful for children and their parents. Hospitalizations can cause a great deal of emotional stress, especially in children, where the anxiety from being away from their home environment can be traumatic (Macías et al., 2015). Children will often miss their normal routines, interactions with their peers, their families, and even their pets. Stress in children is usually caused by experiences that are unfamiliar or unpredictable. These situations may present unclear expectations that cause a fear of failing, or create anticipation of something unpleasant (Washington, 2009). Children often demonstrate negative reactions, including aggressive behaviors, withdrawal from caregivers or family, becoming uncooperative, and showing difficulty coping with and/or recovering from procedures performed in the hospital or outpatient settings. These types of distress can interfere with the delivery of needed medical attention (Rodriguez, Clough, Gowda, & Tucker, 2012). Barkley and Stephens (2000)

found that when anxiety is decreased, children are able to approach medical situations with a sense of comfort, achievement, and control. A suggested method to help alleviate pain, anxiety, or fear associated with medical procedures in children is the use of inhaled nitrous oxide.

Factors such as fear, anxiety, coping difficulties, and lack of social support can further exaggerate the physical pain in children (Verghese & Hannallah, 2010). The use of basic ethical principles can help nurses make evidence-based decisions that provide optimal pain treatment for the pediatric patient (Bernhofer, 2011). Pediatric patients are patients at a high risk for inadequate pain management. Pain assessments may be complex due to the subjective nature of information received from the patient. Utilizing ethical principles of autonomy, beneficence**,** nonmaleficence, and justice may help the nurse advocate for the patient's pain relief needs. Nitrous oxide sedation for anxiolysis is a method providers can suggest to the patient/parent(s) to use to reduce pain, fear, and anxiety associated with noninvasive, minimally invasive, and invasive procedures during hospitalizations in the pediatric departments and in the outpatient pediatric hematology/oncology clinic. Figure 1 describes the categorization of procedures.

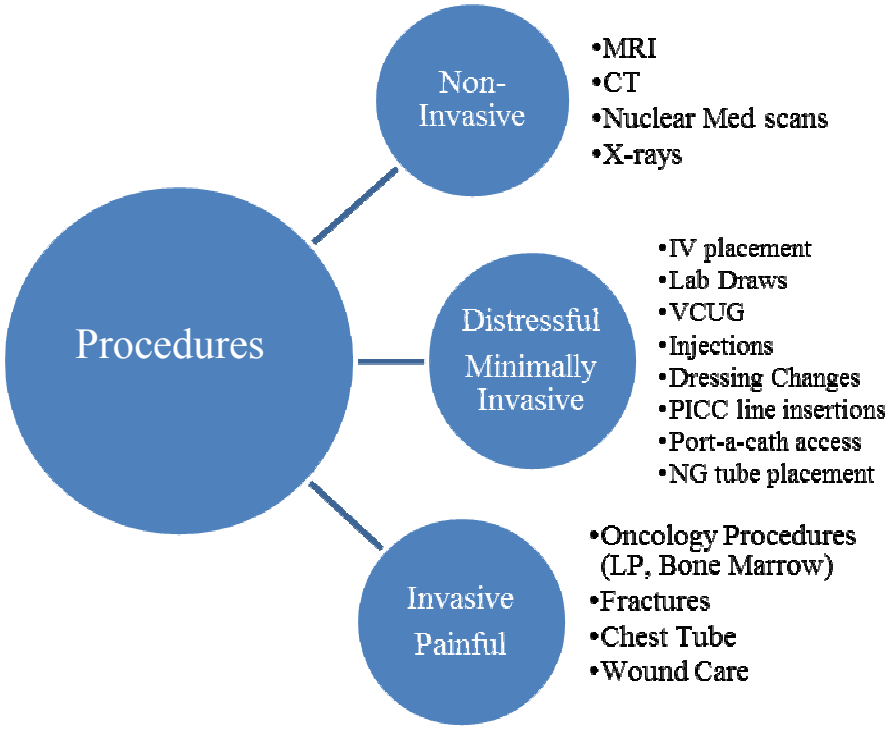

Figure 1. Categorization of procedures

Nitrous oxide sedation has been proven to be a safe and effective method of reducing pain and anxiety in patients and has been around for over 200 years. Nitrous oxide was discovered in the late 1770s by Sir Joseph Priestley. Priestly discovered N_2O through experiments on nitrous air which was a mixture of iron filings, sulfur, and water (Clark & Brunick, 2015). Humphrey Davy went on to experiment with N_2O and found the gas provided the sensation of pleasure, joy, and euphoria, and he felt like laughing (Clark & Brunick, 2015). During Davy's experiments, he experienced pain relief of a toothache from the N_2O gas; it was at that point where he began to believe that the gas could have some anesthetic properties (Clark & Brunick, 2015). Over the next few decades, others continued to experiment with N_2O; however, the anesthetic properties of

the gas were not pursued. It wasn't until the 1840s that the anesthetic value of N_2O was considered again. Dr. Horace Wells, a dentist, began using the gas for tooth extractions in his dental office after he breathed the gas himself and had a colleague extract one of his own teeth (Clark & Brunick, 2015; Ellis, 2015). Wells was recognized by the American Dental Association (ADA) as the primary discoverer of anesthesia (Clark & Brunick, 2015).

Nitrous oxide has remained in continuous use longer than any other drug and has never been replaced by something different; it continues to be used during procedural sedation for pain and anxiety relief in patients undergoing invasive procedures, and it has a remarkable safety record (Clark & Brunick, 2015). Nitrous oxide has been primarily used in dentistry but has also been used in emergency medicine, podiatry, labor and delivery, radiology, and as a sedation treatment for procedures not requiring general anesthesia (Farrell et al., 2008). Over the years, procedural sedation and analgesia have grown and have been further advanced by new drugs and monitoring technologies, expanded practitioner skills, the need to shift procedural work to outpatient settings, and widespread acceptance of the ethical guidelines to treat pain and anxiety in children (Krauss & Green, 2006).

Problem Statement

Healthcare professionals who work with children frequently claim that "children are not little adults" and have special physiologic and developmental needs; however, this is often ignored when it comes to pain and sedation management in children. According to the AAP and the American Pain Society (APS, 2001), there is much evidence that pain and distress in hospitalized children is undermanaged. This may be particularly true for

many “routine” nursing procedures, including venipunctures, IV starts, and bladder catheterizations. Many such procedures are capable of producing a state of panic in children (Herd, 2008). Distress and anxiety can actually increase the child’s perception of pain (Rodriguez, Clough, Gowda, & Tucker, 2012). According to Zempsky (2008), pediatric patients report IV placement as the leading cause of procedure-related pain in the hospital. One study discussed by Kennedy, Luhmann, and Zempsky (2008) surveyed 2,188 pediatric, emergency, and infusion nurses and found that children were physically restrained during IV insertion 74% of the time. Although topical anesthetics such as lidocaine 2.5%/prilocaine 2.5% (EMLA) and intervention by the child life specialists are valuable tools in this practice area, they are not always enough to gain the cooperation of a frightened child (Ekbom, Jakobsson, & Marcus, 2005).

Nitrous oxide is a clear, odorless gas with sedative, amnestic, and mild analgesic properties (Farrell et al., 2008). It has been used safely to provide conscious sedation without loss of verbal contact with the child in a number of settings and for a variety of procedures. The goal of this project was to develop an evidence-based N_2O program for pediatric and pediatric hematology/oncology patients for inpatient and outpatient procedures. The proposed plan is to expand the pediatric sedation program with the addition of N_2O as a single sedative agent for anxiolysis/analgesia use in the sedation program. The administration of minimal, moderate, and deep sedation is an integral part of pediatric hematology/oncology practice. Procedural sedation is the technique of administering sedatives or dissociative agents with or without analgesics to put the patient in a state where they are able to tolerate painful or unpleasant procedures while continuing to maintain cardiorespiratory function (Mace et al., 2008).

Nitrous oxide is an analgesic that is administered for the pediatric population to reduce fear, anxiety, and pain response during minor invasive procedures. Nitrous oxide administration would be a very beneficial addition to the sedation program for patients in a pediatric setting. A majority of the children in the pediatric department are oncology patients. Children who are diagnosed with cancer go through procedures such as lumbar punctures, bone marrow biopsy and aspirations, placement of a central line at the beginning of treatment and removing it at the end of treatment, dressing changes, port access for chemotherapy and other medications, and/or IV starts during the course of their treatment. Nitrous oxide administration provides for an almost pain and anxiety-free procedure, requires neither an intravenous line nor postprocedure monitoring, and minimizes any unpleasant memories the child may have (Burnweit et al., 2004).

Context

The environment selected for the nitrous oxide program proposal is the HSHS St. Vincent Children's Hospital which is located within HSHS St. Vincent Hospital. The population of patients for the DNP Project will be pediatric patients undergoing painful and anxiety provoking procedures, specifically in the inpatient pediatric department, the pediatric intensive care unit, and the outpatient pediatric hematology/oncology clinic. Children admitted to HSHS St. Vincent Children's Hospital are cared for in one of two pediatric locations within the 24-bed Children's Hospital inpatient units, not including the neonatal intensive care unit (NICU), depending on the severity of illness or injury. The pediatric intermediate care unit (PIMCU) cares for general admissions and those patients requiring closer observation. The pediatric intensive care unit (PICU) is reserved for children with very severe or life-threatening illnesses where care is provided by pediatric

intensivists. The pediatric department and the PICU are located on the same floor, making the transition from one unit to another easier for both patients and their families. HSHS St. Vincent Children's Hospital also includes an outpatient pediatric hematology/oncology clinic that provides care to children who have cancer or blood disorders. The clinic is located in a different area of the host hospital; however it is an easy transition for children who are admitted for chemotherapy treatments, illness or complications due to chemotherapy, and children needing treatment for bleeding disorders. The HSHS St. Vincent Children's Hospital is also affiliated with Prevea Health Care where pediatric patients can be seen by their regular pediatrician for well-child checks or referred to other providers.

The total inpatient days for pediatrics, PICU, and NICU during the 2015 fiscal year was 10,371. This excludes the routine newborn population, since that population is part of the women's center. The number of pediatric ambulatory/short stay visits for the 2015 fiscal year was 1,075. There were 768 patients from the pediatric hematology/oncology clinic during the fiscal year; however this number does not include nonprovider visits. The nonprovider visits are nurse-only visits which include routine lab checks, blood or platelet transfusions, intravenous immunoglobulin (IVIG) infusions, or port-a-cath needle changes or flushes. The pediatric gastrointestinal clinic saw 570 patients (this is partial year data). The pediatric subspecialty clinics saw 4,369 patients during the fiscal year and the Prevea Health pediatric primary clinics saw a total of 50,096 patients in the 2015 fiscal year.

The HSHS St. Vincent Children's Hospital also has a pediatric procedural sedation program. The program has made it easier and safer for pediatric patients

undergoing both inpatient and outpatient procedures such as MRIs and CT scans, lumbar punctures, and bone marrow biopsies and aspirations. Children requiring such procedures usually are admitted in the morning, undergo the procedure, and are discharged the same day. A pediatric intensivist and a PICU nurse attend to the patient throughout the procedure, and the child is monitored until full recovery, usually in the PIMCU. The same process occurs in the pediatric hematology/oncology clinic. The nurses in the pediatric hematology/oncology clinic are trained to monitor patients receiving moderate sedation as well as recover patients receiving moderate or deep sedation.

Over the last two years (11/1/2013-12/1/15) the pediatric procedural sedation team has performed 833 cases. A majority of the sedation cases were done for children who had cardiovascular disorders, developmental delays, infections, leukemia, seizure disorders, hematology/oncology disorders, and neurological disorders. The top primary problems were leukemia (217 cases), seizure disorders (117 cases), hematology/oncology disorders other than leukemia (129 cases), and neurological disorders (213 cases). The pediatric intensivists performed 725 cases and 106 cases were performed by pediatric subspecialists (e.g., RN staff in the pediatric hematology/oncology clinic). The procedures performed included bone marrow biopsies (43), Botox injections (7), bronchoscopies (5), cardiac echocardiograms(19), CT scans (28), EEGs (68), EMGs (8), joint injections (6), lumbar punctures for diagnostic or therapeutic reasons (48), lumbar punctures for chemotherapy administration (196), MRIs (366), PICC line placement (20), renal or bone scans (19), voiding cystourethrograms (14), radiology tests (25), and other painful procedures not specified (69). The medications used for the procedures include the intravenous medications midazolam (143 instances), propofol (699 instances),

fentanyl (194 instances), morphine (110 instances), and lidocaine as well as 471 instances of the topical anesthetic 2.5% lidocaine/2.5% prilocaine (EMLA). Many of the procedures used either deep sedation or moderate sedation depending on the child's developmental age, anxiety towards the procedure, or parental request. The pediatric sedation program does not have a minimal sedation method. The above procedures can be performed utilizing N_2O (minimal sedation) because they are relatively short procedures. Nitrous oxide can be used effectively for short procedures and has a shorter recovery time than both moderate and deep sedation methods.

There were minimal side effects or complications seen with the sedation cases, which involved airway obstruction (18 cases), apnea >15 seconds (2 cases), coughing (14 cases), desaturation/hypoxia (15 cases), IV related complications (3 cases), requirement of emergent airway intervention (3 cases), snoring/partial obstruction (25 cases), stridor (3 cases), and unexpected change in heart rate or blood pressure >30% (2 cases). There were 769 cases without any side effects or complications.

HSHS St. Vincent Hospital is an acute care hospital within the Hospital Sisters Health System, which is a multi-institutional health care system comprised of 14 hospitals and is the host hospital for the HSHS St. Vincent Children's Hospital. HSHS St. Vincent is a 255 bed hospital including adult intensive care, cardiovascular (heart center), emergency, gynecology, hospice/palliative care, neurology, obstetrics (women's center), oncology, orthopedics, pulmonary, rehabilitation/physical medicine, trauma, urology/nephrology, palliative care, dialysis, and a stroke center (HSHS St. Vincent Hospital, 2015).

Purpose Statement

The purpose of developing a N_2O program for pediatrics is to provide anxiolysis and analgesia via an inhaled N_2O delivery system for pediatric patients undergoing painful procedures or procedures that cause anxiety or fear. Statistics show that nearly 35 million people in the United States avoid procedures because of fear and anxiety (Clark & Brunick, 2011). Fear of pain can be a huge obstacle to overcome, especially in the pediatric patient. Invasive diagnostic and minor surgical procedures on pediatric patients outside the traditional operating room setting have increased in the last decade and as a consequence, the need for sedation for procedures in physician offices, dental offices, subspecialty procedure suites, imaging facilities, emergency departments, and ambulatory surgery centers has also significantly increased (Cote & Wilson, 2008).

Nitrous oxide sedation has primarily been used in dental practices. When used for dental procedures in children, N_2O is typically used in longer dental procedures to provide analgesia/anxiolysis to expedite the completion of procedures that are not comfortable for the child (American Academy of Pediatric Dentistry [AAPD] Council on Clinical Affairs, 2013). Using N_2O for the pediatric patient may allow the patient to tolerate an uncomfortable dental procedure by relieving anxiety, fear, discomfort, or pain (AAPD Council on Clinical Affairs, 2013). According to Krall (2011), nitrous oxide can be administered in procedures such as diagnostics (x-ray films, clinical exams), minor procedures (impressions, placement of orthodontic bands, suture removal), periodontal (probing, scaling, root planning), restorative (fillings, crown, bridge), and surgical (periodontal, oral surgery, endodontic, implant placement).

Project Premise.

The premise of the project included development of a comprehensive program proposal for an alternative method for pain and anxiety management in pediatric patients to be used to inform the interprofessional Pediatric Policy Committee. A question addressed by the project premise was: Will administering N_2O to pediatric patients provide a safe, effective, comparable option to moderate sedation in reducing anxiety and assessed or reported pain scores during invasive, potentially painful procedures?.

Program Objectives

The outcomes addressed for the N_2O program are:

1. Provide a comprehensive program proposal with recommended policies and procedures.
2. Provide patient/family education materials that would inform families of nitrous oxide use.
3. Present the Nitrous Oxide Program Proposal Project packet to the decision-making body, which would include the leaders within the pediatric departments and the pediatric intensivists.

Using N_2O as an analgesic in a sedation program provides for an almost pain and anxiety-free procedure, and it can minimize any unpleasant memories the child may have with the procedure (Burnweit et al., 2004). Rather than a moderate or deep sedation method, N_2O can be used for many different pediatric procedures, including lumbar punctures, bone marrow aspirations, dressing changes, IV starts, port-a-cath access, or wound care and it has been established world-wide as an analgesic method for painful procedures (Kanagasundaram, Lane, Cavalletto, Kenally, & Cooper, 2001). The length of

stay would be reduced for patients and their families because the recovery from N_2O is about 5 minutes versus 1 hour or longer for moderate or deep sedation (Clark & Brunick, 2015). Nitrous oxide administration has been proven to be safe minimal sedation option as compared to moderate or deep sedation. Treatment with N_2O is a well-established method for pain alleviation in children (Burton, Auble, & Fuchs, 1998; Cleary et al., 2002; Annequin et al., 2000; Krause & Green, 2006) and has been used with good results, in particular in children who fear the dentist (AAPD, 2013). Nitrous oxide has an excellent safety record, has a relative ease of use, and has minimal effect on a patient's physiological function, making it a very versatile and safe sedative agent (Krall, 2011).

New policies and procedures, administration guidelines, documentation and monitoring tools, fasting guidelines, patient and family education information packets for staff, plan for staff training, and preprocedure, during procedure, and postprocedure pain/anxiety assessment tools were incorporated into a comprehensive protocol proposal for an evidence-based N_2O program for the HSHS St. Vincent Children's Hospital. New practice strategies created from this project could be placed into the pediatric department's strategic plan for the future, and budgets could be planned to maintain equipment, training, and gas needed for nitrous administration.

The DNP project for developing a proposal package for the N_2O program will reflect objectives from the Essentials of Doctoral Education for Advanced Nursing Practice from the American Association of Colleges for Nursing (AACN): (a) underpinnings for practice, (b) organizational and systems leadership for quality improvement and systems thinking, (c) scholarship and analytical methods for evidence-

based practice (EBP), (d) information systems and technology, (e) policy for advocacy, (f) and inter-professional collaboration (AACN, 2006).

Significance to Practice

Sedation for children is very different from sedation of adults due to physiology and age-related developmental factors. When sedation is administered in the pediatric patient, it is usually done to control behavior to safely complete the procedure. A child's ability to control his or her behavior and cooperate for a procedure depends both on chronologic and developmental age (AAPD, 2013). Children younger than six years and those with developmental delay may require a deep level of sedation to control their behavior for the procedure (AAPD, 2013).

An alternative sedation method is the administration of inhaled N_2O. Nitrous oxide has rapid onset (30–60 seconds), maximum effect after about 5 minutes, and rapid recovery upon discontinuation (Krauss & Green, 2006). Children who have received minimal sedation (N_2O) may not require more than observation and intermittent assessment of their level of sedation during administration (AAPD, 2008). The pediatric patient is able to maintain verbal communication throughout the procedure when N_2O is used along with the balance of oxygen and without any other sedatives, narcotics, or other depressant drugs before or along with the N_2O gas (AAPD, 2008). Nitrous oxide administration may be useful in a pediatric oncology setting for sedation in children undergoing basic procedures such as a lumbar puncture, bone marrow biopsy and aspiration, placing a port-a-cath at the beginning of treatment and removing it at the end of treatment, dressing changes, peripheral lab draws, or IV starts if needed. Using nitrous oxide has been shown to have a significant reduction in pain, allow for a shorter recovery

time, and helps children experience less anxiety or distress during the procedures (Alai, 2014). Nitrous oxide use in these situations may create a less traumatic experience for the pediatric patient as well as their families.

Nitrous oxide delivery is not intended to replace any of the current sedation methods being used. It would be used to expand the pediatric sedation program by using nitrous oxide as an analgesic/anxiolytic. The administration of minimal, moderate, and deep sedation is an integral part of pediatric hematology/oncology practice, as well as general pediatrics. Procedural sedation is the technique of administering sedatives or dissociative agents with or without analgesics to put patients in a state where they are able to tolerate painful or unpleasant procedures while continuing to maintain cardiorespiratory function (Mace et al., 2008). Creation of a nitrous oxide program can increase the child and family's access to the sedative/analgesic agent (Farrell et al., 2008).

Implications for Social Change

Pain management is an essential nursing and physician responsibility. Physicians and nurses are very important aspects of patient and family experience. Pediatric patients need to have positive experiences with receiving medical care, as these experiences may influence their future feelings about their care and seeking treatment. Adequate pain management reduces child and parent anxiety and increases compliance and cooperation (Zempsky & Shechter, 2003). Assessment, management, and reassessment of pain are part of the Joint Commission standards for pain. Healthcare providers and nursing staff need to address the patient's pain level and if the patient is experiencing pain, appropriate care should be made available (Joint Commission, 2015). Providers and nurses

understand that some medical procedures can cause pain and distress. They are able to assess the pediatric patient's level pain and anxiety and take action to prevent it, while keeping the patient comfortable. It is their role to minimize pain using pharmacologic and nonpharmacologic methods to alleviate pain and anxiety related to medical procedures.

The N_2O program may provide a less traumatic experience for painful and anxiety provoking procedures in pediatric patients and provide an additional option for use in the pediatric sedation program. Adding the N_2O as a new modality to the pediatric sedation program offers a safe method of sedation that provides pain control and anxiety relief quickly (Clark & Brunick, 2015). It can be easily reversed if needed by turning off the N_2O and delivering 100% oxygen for 3-5 minutes (Clark & Brunick, 2015).

Definition of Terms

The terms pertinent to this study are described below.

Nitrous oxide/oxygen analgesia: Nitrous oxide/oxygen analgesia (also known as laughing gas) is an inhalational anesthetic in the form of a colorless and tasteless gas containing a mixture of nitrous oxide and oxygen. Nitrous oxide, while practically an odorless gas, has a faint, sweet aroma and has analgesic, amnesic, and anxiolytic properties (AAPD, 2013; Farrell et al., 2008).

Levels of Sedation

Minimal sedation: A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination might be impaired, ventilatory and cardiovascular functions remain unaffected (American Society of Anesthesiologists, 2014).

Moderate sedation: A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Reflex withdrawal from a painful stimulus is not considered a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained (American Society of Anesthesiologists, 2014).

Deep sedation: A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function could be impaired. Patients might require assistance in maintaining a patent airway and spontaneous ventilation might be inadequate. Cardiovascular function is usually maintained (American Society of Anesthesiologists, 2014).

Procedural sedation: A technique of administering sedatives or dissociative agents with or without analgesics to induce a state that allows patients to tolerate unpleasant procedures while maintaining cardiorespiratory function (Adams & Dervay, 2012).

Additional Definitions

Anxiolytic: A drug that relieves anxiety.

Analgesia: A drug that relieves pain.

Anesthetic: A drug that causes anesthesia.

Amnesia: Loss of memory.

Pain: An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage (International Association for the Study of Pain, 2015).

Anxiety: An emotion characterized by feelings of tension, worried thoughts and physical changes (American Psychological Association, 2015).

Fear: An unpleasant emotion caused by being aware of danger (Merriam-Webster Dictionary, n.d).

Assumptions and Limitations

Assumptions of the project are that the literature review and secondary data provided the necessary information to address the most important indicators for developing a N_2O program proposal in the pediatric department and the pediatric hematology oncology clinic, since primary data cannot be obtained from the pediatric population.

I developed a comprehensive program proposal for consideration by the pediatric sedation team and department leaders. An assumption is that the N_2O program will be further developed based on the protocol package presented and that eventually the N_2O program will be implemented, though that may take several months beyond my program completion to work on a pilot of the program with patient contact; therefore, I will not monitor subsequent program elements. A potential limitation of the proposed program protocol may be that the supporting documents can take time to be accepted by the pediatric sedation team and department leaders. Another possible limitation is that it may take longer than expected to complete and/or revise the supporting documents for consideration by the pediatric sedation team and the department leaders.

Summary

This project focused on developing a comprehensive program proposal for a nitrous oxide program for consideration by HSHS St. Vincent Children's Hospital's decision making committee to expand the pediatric sedation program to include the use of N_2O. Nitrous Oxide sedation can be administered for the pediatric population to reduce fear, anxiety, and pain response during minor invasive procedures. Nitrous oxide in varying concentrations has been successfully used for many years to provide analgesia for a variety of painful procedures in children and appears to be well tolerated in the pediatric population with no major problems being reported with its use (Kanagasundaram et al., 2001; Cravero, 2010; Cote & Wilson, 2008). Research supports the safety and efficacy of N_2O in children to reduce fear, anxiety, and pain that are associated with painful procedures.

Section 2: Review of Scholarly Evidence

General Literature

Health care is constantly changing as new evidence and technologies surface that support a change in practice. Evidence based practice increases knowledge on new or changing health care needs. Nitrous oxide was introduced around 1771 by Sir Joseph Priestly (Clark & Brunick, 2015). Nitrous oxide is an inorganic inhalation agent that is colorless, odorless (or slightly sweet-smelling), nonirritating to the tissues, and nonflammable, though it can be combustible (Becker & Rosenberg, 2008). Nitrous oxide is used to provide pain control and anxiety relief and can be reversed very quickly after the procedure is completed with oxygen. The popularity of nitrous oxide and nitrous oxide/oxygen sedation has varied over the years as some practitioners prefer to use it and others do not view it as favorably (Clark & Brunick, 2015). However, N_2O has withstood the test of time and is an anxiolytic/analgesic gas option that has never been replaced.

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; Cleary et al., 2002; Frampton, Browne, & Lam, 2003; Burnweit et al., 2004; Clark & Brunick, 2015; Kanagasundaram et al., 2001; Luhman, Kennedy, Porter, Miller & Jaffe, 2001). Researchers have addressed the efficacy, technical aspects, and cost-effectiveness of N_2O analgesia (Burnweit et al., 2004; Clark & Brunick, 2015; Kanagasundaram et al., 2001). Nitrous oxide has some advantages as compared to other sedation modalities for many reasons. First of all, NPO (nothing by mouth) guidelines are not required, intravenous access is not necessary, and in most cases patients can be discharged home without an

escort because of the rapid washout of the gas (Clark & Brunick, 2015). The benefits of administering N_2O are the low cost and no hospitalization (Hjortholm, Jaddini, Halaburda, & Snarski, 2013). It has a quick induction and recovery because it enters and leaves the brain so quickly compared to the other drugs that are given with it (Weaver, 2013).

Nitrous oxide was primarily used in dentistry and it is now being brought in as a procedural sedation option or for minor surgical procedures. These invasive diagnostic and/or minor surgical procedures on pediatric patients occurring outside of the traditional operating room setting have increased markedly in the last decade (AAPD, 2002). Over the years, procedural sedation and analgesia have grown and have been further advanced by new drugs and monitoring technology, expanded practitioner skills, the need to shift procedural work to outpatient settings, and widespread acceptance of the ethical guidelines to treat pain and anxiety in children (Krauss & Green, 2006).

When sedation is administered in the pediatric patient, it is usually done to control behavior to safely complete the procedure being performed. Pediatric procedural sedation is common with pediatric patients due to the painful and anxiety provoking procedures that may be a part of their treatment plan. Some of the procedures include lumbar punctures, bone marrow biopsies/aspiration, IV starts, wound care, dressing changes, urinary catheterization, nasogastric tube placement, and placement of a central line. Sedative-analgesic medications can enhance the comfort and acceptance of diagnostic and therapeutic procedures in children (Hoffman, Nowakowski, Troshynski, Berens, & Weisman, 2002). There is a wide range of short-acting sedative and analgesic medications being used for pediatric procedural sedation which have multiple routes of

administration. The choice of drug is based upon the type of procedure, the anticipated degree of pain, the targeted depth of sedation, and the patient's underlying medical condition (Hoffman et al., 2002). Some procedures are not painful (CT, MRI, radiation, bone scans, etc.) can but create anxiety in the child or that the child will need to remain still during the test. Adding nitrous oxide to a procedural sedation program provides another method to help reduce pain and anxiety in children.

Specific Literature

Painful and Anxiety Provoking Procedures

Intravenous (IV) Access and Venipuncture. Statistics show that nearly 35 million people in the United States avoid procedures because of fear and anxiety (Clark & Brunick, 2011). Fear of pain can be a major obstacle to overcome, especially in the pediatric patient. Children who may require repeated invasive medical procedures have anxiety and fear over needles. It can be extreme enough where they develop a needle phobia. Fear of needles is very common in the pediatric population and could result in poor cooperation from the child. Due to poor cooperation, children may need to be restrained during venipuncture, resulting in negative experiences and memories for the child and those involved (Williams, Riley, Rayner, & Richardson, 2006; Thurgate & Heppell, 2005). An anxiety or fear response can be triggered in children when they are exposed to or are anticipating a venipuncture which is often expressed by crying, psychomotor agitation, freezing, or clinging to a parent or family member (Thurgate & Heppell, 2005).

Several studies suggest treatments that can be used to alleviate anxiety, fear, and pain related to IV access and venipuncture are N_2O and 2.5% lidocaine/2.5% prilocaine

(EMLA) cream. EMLA cream is similarly effective in providing pain relief from venipunctures in pediatric patients (Paut, Calméjane, Delorme, Lacroix, & Camboulives, 2001; Hee, Roy, & Ng, 2003). Even with the use of EMLA cream, school-aged children would be aware of the needle and could react by showing anxiety due to expected pain associated with venipuncture (Hee, Roy, & Ng, 2003). Application of EMLA cream can cause vasoconstriction, which may result in difficulty obtaining IV access (Furuya et al., 2009; Hee, Roy, & Ng, 2003). Nitrous oxide may be advantageous over EMLA cream in reducing pain-related fear and anxiety. Kanagasundaram et al. (2001) and Furuya et al. (2009) reported that 50% to 70% N_2O inhalation for three minutes was effective in reducing venipuncture pain in children. Carbajal et al. (2008) found that nitrous oxide was only slightly better than 2.5% lidocaine/2.5% prilocaine (EMLA) in controlling injection pain; however, the combination of the two was significantly better than either intervention alone with limited side effects (Abdelkefi et al., 2004). Similar studies also showed no difference in pain reduction between nitrous oxide and EMLA cream, but a statistically significant synergistic effect was found when combined (Abdelkefi et al., 2004; Hee, Roy, & Ng, 2003; Paut, Calméjane, Delorme, Lacroix, & Camboulives et al., 2001). Treatment with N_2O increases the quality of care by facilitating venipuncture/venous cannulation without prolonging the effective time and makes it possible to complete all procedures and examinations (Ekbom et al., 2005).

In summary, N_2O has been found to be a safe and effective conscious sedation agent for needle sticks across a variety of settings and in a number of different cultural groups. The quality of evidence in support of this is quite good overall. Nitrous oxide works at least as well as EMLA, particularly for children over the age of 4 years, and

may work better in some instances. In particular, for children with more difficult IV access, such as obese clients, N_2O may be more beneficial than EMLA. Distress from fear of the mask must be taken into consideration and weighed against the potential benefit of greater pain control in younger age groups. A combination of N_2O and EMLA has been shown to have a synergistic effect on pain control in several studies.

Voiding cystourethrograms. A voiding cystourethrogram (VCUG) is a radiologic imaging technique that is used in diagnosing and follow-up of a variety of childhood diseases, including urinary tract infection (UTI) in children under 1 year of age, older children with recurrent UTI, children with ureteric dilatation, terminal hematuria accompanied by symptoms of lower urinary tract disease, renal failure of undetermined cause, certain voiding problems, thick-walled bladder detected with ultrasonography, and infants with significant hydronephrosis detected via ultrasound prenatally (Akil et al., 2005). VCUG testing is considered to be an invasive procedure, mainly due to the uncomfortable experience of bladder catheterization (Akil et al., 2005). Bladder catheterization for radiologic imaging can cause a great deal of psychological distress, pain, and anxiety in children (Zier, Kvam, Kurachek, & Finkelstein, 2007; Zier, Drake, McCormick, Clinch, & Cornfield, 2007). Several studies suggested oral midazolam and 50% inhaled N_2O were comparable treatment methods to reduce pain and anxiety associated with bladder catheterization for VCUGs; however, N_2O has an excellent safety profile, a more rapid onset, shorter recovery time, and fewer side effects than oral midazolam (Keidan et al., 2005; Zier et al., 2007; Zier et al., 2007; Farrell et al., 2008).

In this limited number of studies, N_2O was found to be better at relieving distress compared with a control state (Zier et al., 2007), and to be at least as effective as oral midazolam for VCUGs (Keidan et al., 2005). Satisfaction data was not statistically different between N_2O and oral midazolam, but clinically significant for the individuals previously treated with oral midazolam (Farrell et al., 2008). In two studies with a relatively large number of combined participants, no serious adverse events were recorded with the most common side effect being nausea and vomiting (Zier et al., 2007; Zier et al., 2007).

Miscellaneous painful procedures. Many of the painful procedures described in the literature were a combination of medical and nursing procedures, including insertion of central venous catheters, facial lacerations, chest tube removal, intra-articular joint injections, fiberoptic bronchoscopy, otologic procedures, forearm fracture reductions, botulinum toxin A injections, lumbar punctures, bone marrow biopsies, wound care, and a wide variety of other procedures performed in an emergency or inpatient care area (Abdelkefi et al., 2004; Annequin et al., 2000; Bruce & Franck, 2000; Bruce, Franck, & Howard, 2006; Cleary et al., 2002; Fishman, Botzer, Marouani, & DeRowe, 2005; Frampton, Browne, & Lam, 2003). The use of N_2O 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 moderate, deep, or general anesthesia (Burnweit et al., 2004; Cleary et al., 2002; Luhmann, et al., 2001).

Overwhelmingly, across studies, N_2O was found to be efficacious and safe with high levels of patient, parent, and staff satisfaction. When physical restraint was

measured, it was required less often in children sedated with N_2O compared with typical rates of restraint (Abdelkefi et al., 2004; Annequin et al., 2000). Abdelkefi et al. (2004), Bruce et al., (2006), Cleary et al. (2002), and Fishman et al., (2005) reported low pain scores with use of N_2O. Nitrous oxide was found to be significantly more effective than standard care in several studies (Fauroux et al., 2004; Luhmann, et al., 2001).

Administration of N_2O was found to be superior to midazolam (Luhmann et al., 2001; Zier et al., 2007) and a combination of ketamine and midazolam (Luhmann, Schootman, Luhman, & Kennedy, 2006). Mixing N_2O with midazolam did not confer any additional benefit, but did increase the risk of adverse effects (Luhmann et al., 2001). Nitrous oxide was equally as effective as morphine with a faster recovery time for chest drain removal in a small randomized controlled pilot study (Bruce et al., 2006). A few studies reported N_2O to be less effective in younger age groups, usually defined as two to three years or younger (Annequin et al., 2000; Fauroux et al., 2004). Frampton et al., (2003) stated there were good results in younger children, but no specifics about efficacy or safety in this age group were provided. Kanagasundaram et al., (2001) discuss that administration of N_2O for painful procedures in children maintains low distress scores during the painful phase and its most appropriate application is for children over the age of 6 and for short procedures.

Adverse Events and Contraindications

Nitrous oxide/oxygen analgesia use in pediatric procedural sedation is not without risks. The American Academy of Pediatrics (AAP) warns that greater than 50% of N_2O may increase the chances of deep sedation (AAP & AAPD, 2008). The risk of over-

sedation is decreased when N_2O is used at lower concentrations (below 50%) (American Society of Anesthesiologists, 2002; Farrell et al., 2008; Frampton et al., 2003; Kanagasundaram, et al., 2001).

Nausea and vomiting are the most common side effect of N_2O. Administration of N_2O does not cause serious side effects (apnea and desaturation below 92%) and the incidence of mild adverse events (diaphoresis, nausea, vomiting) are low occurring in approximately 0.5-4% of patients (Zier et al., 2007; AAPD, 2013). A higher incidence is noted with longer administration of N_2O, fluctuations in nitrous oxide levels, and increased concentrations of N_2O (AAPD, 2013).

Overall, serious adverse events were extremely rare, and generally resolved upon discontinuation of the N_2O. One rare adverse event associated with N_2O is inactivation of vitamin B_{12}. Nitrous oxide inactivates vitamin B_{12}, inhibits the enzyme methionine synthase, and increases plasma total homocysteine with prolonged exposure to N_2O and can lead to neuropathy, spinal cord degeneration, and even death in children (Baum, Willschke, & Marciniak, 2012; Kanagasundaram et al., 2001). Individuals with subclinical vitamin B_{12} deficiency may be more prone to develop deficits after more limited exposure to N_2O (Singer, Lazaridis, Nations, & Wolfe, 2008; Clark & Brunick, 2015). Patients with B_{12} deficiency can experience post-procedure effects such as myelopathy and neuropathy (Clark & Brunick, 2015).

Inhaled N_2O provides pain relief, sedation, and alleviation of anxiety (Kanagasundaram et al., 2001). Oversedation in one study happened in about 2.9% of sedation episodes, occurring more frequently among children receiving 70% N_2O (Babl,

Oakley, Seaman, Barnett, & Sharwood, 2008). The majority of patients in these studies achieved a level of sedation consistent with conscious sedation without loss of verbal contact with the child (Babl et al., 2008; Zier, Tarrago, & Liu, 2010). No statistically significant differences were found in the incidence of adverse events in children receiving $\leq$ 50% N_2O and those receiving higher percentages (Babl et al., 2008; Zier et al., Liu 2010).

Nitrous oxide has an excellent safety profile; however, more children under three years of age had a higher risk of reaching deep sedation (Babl et al., 2008), a higher rate of adverse events in children less than one year of age (Gall et al., 2001), a higher rate of adverse events (Gall et al., 2001), and a deeper level of sedation (Zier et al., 2010) in children who had received additional sedation medications. Other studies did not find a difference in the rate of adverse events among different age groups (Zier, Tarrago, & Liu, 2010). Although N_2O has demonstrated an excellent safety profile, providers must be prepared for a deeper level of sedation than intended and potential adverse events, particularly in the younger age groups and in children receiving concomitant medications.

Across all studies, major adverse events were quite rare. There were rare reports of patients being more deeply sedated than intended (Burton et al., 1998), but these episodes resolved without further intervention upon discontinuation of the N_2O. Brief desaturations were noted in a few studies (Fauroux et al., 2004; Zier et al., 2007), but all resolved without intervention. Common side effects included euphoria, dizziness, headache, nausea and vomiting.

Nitrous oxide is contraindicated in children with bowel obstructions, pneumothorax, cystic fibrosis, suspected or known pernicious anemia or vitamin B_{12}

deficiency, cancer therapy using bleomycin, head injuries, inability to understand procedure or unwilling to provide consent, and intrathoracic injuries (Clark & Brunick, 2015). Nitrous oxide use should not be administered for patients with cystic fibrosis or a pneumothorax. When N_2O is given in patients with a pneumothorax, the expansive quality of the gas causes an increased expansion and size of the pneumothorax (Clark & Brunick, 2015). Administration of N_2O should also be avoided in children with cystic fibrosis. The expansive nature of the gas may cause bullae. Since nitrous oxide increases intracranial pressure by the rapid replacement of nitrogen with N_2O in air spaces, it is contraindicated in children with closed head injury and altered intracranial compliance (Clark & Brunick, 2015).

Patient and Parental Response

Several studies reported a high level of staff satisfaction with N_2O (Abdelkefi et al., 2004; Annequin et al., 2000; Luhmann et al., 2001). Annequin et al. (2000) reported that 93% of children who were able to answer the question said they would accept N_2O if another procedure was to be performed. Satisfaction immediately after and two hours after the procedure was higher in the N_2O group in another study (Fauroux et al., 2004). Zier et al. (2007) found that parents rated satisfaction with N_2O sedation higher than prior sedations with midazolam. In a study by Williams et al., (2006), parents and children were highly satisfied when N_2O was used for the procedure. Parents stated that the procedure was less stressful, their child did much better with the N_2O, and that they would highly recommend it (Williams et al., 2006). Children's comments included how it

made them feel sleepy, they forgot about the procedure, the procedure went very fast, and that it had a tingly, light feeling (Williams et al., 2006).

Distraction and positive incentives are strategies that have become an important part of the technique for nitrous oxide administration for procedural sedation. Distraction is a great technique that can be used prior to and while administering the N_2O. Distraction techniques are used to keep the child calm while wearing the mask which can be a source of anxiety. Offering incentives when the child completes the procedure is also a great method of distraction as it is something the child looks forward once they are finished. Parent variables that may influence the success of parent distraction coaching for the child include ethnicity, gender, previous experience, belief about their ability to use distraction, anxiety, and parenting style (Kleiber & McCarthy, 2006). Variables may affect a child's response to pain during procedures are age, sex, diagnosis, ethnicity, previous experience, temperament, anxiety, coping style, genotype, and ability to pay attention.

There is also relationship between parents' affective responses before and during treatments and children's responses to the treatment (Harper, Penner, Peterson, Albrecht, & Taub, 2012). Penner et al. (2008) found negative associations between parents' empathic concern and children's pain/distress; meaning, the more empathic concern parents experienced prior to treatments, the less pain/distress children were observed to experience during the treatments. Children vary greatly in their response to pain. An important factor in young children's reaction to pain is caregiver behavior at the time of the pain (Walsh, Symons, & McGrath, 2004). Some children are able to tolerate

procedures or treatments without any calming or distracting interventions, but others struggle despite any efforts made to help the child stay calm.

Education

With all new programs education is a priority. Education should contain evidence-based practices (EBP) to provide the most current information. Evidence-based practice is using the available evidence to make decisions about the care of the patient, and it combines information about research results, clinical expertise, patient concerns and patient preferences (Johansson, Fogelberg-Dahm, & Wadensten, 2010). The EBP information will be used to build on current knowledge.

Patient education. Benefits of patient education include reducing complications of treatment, enhance patient self-confidence, assist the education of health behaviors, promote improved function and recovery, elevating patients' potential to follow a plan of care, easing the understanding of their condition, and empowering patients to make their health care decisions (Patient Education Institute, 2013). Organization wide benefits include complying with regulatory standards, have a greater amount of informed patients, elevate customer satisfaction, and increase efficiency with cost-effective care (Patient Education Institute, 2013). A well informed, educated patient and/or family member are able to actively participate in their own care, improve their outcomes, help identify errors before they occur, and reduce the length of stay (Patient Education Institute, 2013).

Effective patient education can have a large impact on the quality of care given to the patient and family, patient safety, and can have improved patient/family satisfaction (Tamara-Lis, 2013). For education to be effective it needs to be provided at the literacy level or the patient and/or the primary learners. More than one-third of all American

adults lack sufficient health literacy to completely understand instructions given at, during, or after discharge from the hospital or in outpatient healthcare settings (Tamara-Lis, 2013). Providing a N_2O fact sheet that is easily understood at any health literacy level in combination with face-to-face education will help the patient and family member understand the use of N_2O, the side effects, and it's effectiveness for some painful and anxiety provoking procedures. Offering educational material will help the patient and family make an informed choice about the sedation method they would prefer for their child to receive during their procedure.

Nurse and provider. Education is important because it lays the groundwork and allows further advancement in healthcare. Healthcare is a rapidly changing environment. Changes in practice require education to properly implement the change. Proper education arms the nurses and providers with the knowledge, competency, and skills that promote safe and effective high quality care (The Society for Pediatric Sedation, n.d.). Staff training is necessary prior to administering N_2O for patient procedures. Governing boards and licensing agencies may require specific courses and training in N_2O use before providers can use it in their clinical practice settings (Clark & Brunick, 2015). The certification program should include didactic education designed to address the pharmacology, toxicity, and environmental safety of nitrous oxide as well as the equipment used for its delivery (Farrell et al., 2008). Organizations may require three to five monitored administrations before the practitioner can administer nitrous oxide on their own (Farrell et al., 2008). The pediatric intensivists will be key players in providing N_2O education for the staff. Once they complete the certification course and training,

they will be able to provide education to the staff in the pediatric department and in the pediatric hematology/oncology clinic. Education on how to use and set up the equipment will be provided by the product vendor. All pediatric staff currently have pediatric advanced life support (PALS) certification. The pediatric hematology/oncology and PICU staff have completed competencies for administering and monitoring of conscious sedation procedures. The PICU nurses and the pediatric hematology/oncology nurses will be the primary staff who will monitor the patient during and after administration of N_2O.

Change Management

Change is a constant in healthcare. Change management includes planning for, managing, and reinforcing change. Change management is the process, tools and techniques to manage the people-side of change to achieve the required outcomes (Prosci, 2015). Change management incorporates the organizational tools that can be utilized to help individuals make successful personal transitions resulting in the adoption and realization of change (Prosci, 2015). Slack (2011) states, in processing change we must identify the problem, agree there is a problem, have support and be able to implement a process to make changes. In addition, the involvement of nurses providing effective workforce planning, collaboration among necessary colleagues and use of previously collected data will gain policy agreement (Institute of Medicine, 2010).

Designing, implementing, and managing successful change depends on the quality of the management team, specifically how the team works to facilitate the change process. The key members of the N_2O program will be the executive director, the pediatric intensivists, pediatric and PICU department manager, the pediatric hematology/oncology manager, and assistance of the DNP student. Change management

requires wide range of resources including relational, operational and strategic competencies (Yukl, 2006; as cited in Macphee & Suryaprakash, 2012). The N_2O program will need to utilize resources from other disciplines to make the program a success. The leaders will work closely with anesthesia, biomed, clinical engineering, and finance during the program development.

Change management can be one of the most important and difficult leadership responsibilities (Yukl 2006; as cited in Macphee & Suryaprakash, 2012). Leading teams into a change process can be difficult. The change project needs involvement of key stakeholders and buy-in from the group where the change will be implemented. Without buy-in from the staff, there is a high likelihood the change process will fail. Organizational readiness for change is essential for implementation of a change to be successful. Organizational readiness can be present at the individual, group, unit, department, or the organizational levels (Weiner, 2009).

Leaders can drive change and help an organization cope with the change (White & Dudley-Brown, 2012). They also have the ability to influence others and drive outcomes. A leader must have a clear understanding of where the organization is today, the current health care climate, and the mission and vision of the organization (Elwell & Elikofer, 2015). Healthcare leaders must understand the value and critical importance of delivering a style of leadership that will ensure that their staff feels empowered and supported as they work through and implement changes (Delmatoff & Lazarus, 2014). Leaders who do not take into consideration the needs of their staff, the change may be met with resistance or confusion. Leaders may encounter many difficulties associated with change. If they foster an organizational culture of support, empathy, and shared

success the staff may be more receptive to the change (Delmatoff & Lazarus, 2014). The most important traits of a leader involved in change management includes setting goals so the team knows what they are working towards; discuss and present desired outcomes so the team can brainstorm ideas to gain buy-in (Elwell & Elikofer, 2015); honesty; ability to delegate tasks; maintain open communication; have confidence and commitment in the team and the work being done; to have a positive attitude; have creativity and intuition; and be able to inspire the team.

Conceptual Models or Frameworks

The American Academy of Pediatrics and the American Pain Society (2001) list the following barriers to treatment of pain in children (p. 793):

1. The myth that children do not feel pain the way adults do and that there are no negative consequences to pain in this age group.
2. Lack of assessment and reassessment for the presence of pain.
3. Misunderstanding of how to conceptualize and quantify a subjective experience.
4. Lack of knowledge of pain treatment.
5. The notion that addressing pain in children takes too much time and effort.
6. Fears of adverse effects of analgesic medications.

Because of these barriers, children's pain often goes undertreated.

In response to the undertreatment of children's pain, Huth and Moore (1998) proposed a prescriptive theory of acute pain management in infants and children. This middle-range theory that was developed from the Acute Pain Management Guidelines can be well-summarized in the following propositions (Huth &Moore, 1998, p. 26):

1. An initial assessment includes concepts of past and present pain history, developmental level, coping, and culture. This will lead to the choice of appropriate therapeutic interventions.
2. Therapeutic interventions include child-parent teaching, pharmacologic, and non-pharmacologic interventions.
3. Reassessment consists of regular assessment of pain by child or parent report, assessment of behavioral and physiological states, and assessment of side effects. Reassessment leads to identification of inadequate pain relief, behavioral distress, unacceptable physiological measures, and side effects, all of which contribute to the choice of appropriate therapeutic interventions.

The end result of this model is pain reduction that is satisfactory to child, parent, and nurse. This theory has the potential to help nurses ensure that infants and children suffer less and avoid the consequences of unmanaged pain (Huth & Moore, 1998).

This conceptual model can be adapted to incorporate pain and anxiety reduction in procedural sedation for children. A thorough initial assessment of previous experiences with pain and sedation and consideration of developmental level, individual coping strategies, and culture can lead to the selection of therapeutic interventions. In addition to child-parent teaching, pharmacologic agents, and non-pharmacologic agents, N_2O could be used to help provide pain and anxiety relief for procedural sedation. Regular assessment of pain, behavior, physiologic states, and side effects helps to identify inadequate pain and anxiety control, leading to the selection of additional therapeutic interventions. While N_2O is quite effective, it does not work for everyone or for every procedure, so nurses must be alert to the need for additional interventions to manage pain

and anxiety. The end result will be pain and anxiety reduction that is satisfactory to child, parent, and nurse.

The National Guideline Clearinghouse has developed a guideline titled, "Sedation in Children and Young People: Sedation for Diagnostic and Therapeutic Procedures in Children and Young People". The guideline discusses the scope, methodology, recommendations, provides evidence for the recommendations, the benefits and harms of implementing the guideline, recommendations, and implementation of the guideline. The objective of the guideline is to offer best practice advice on the care of children and young people under the age of 19 undergoing sedation for diagnostic or therapeutic procedures (National Institute for Health and Clinical Excellence, 2010). Major recommendations of the guideline include (National Institute for Health and Clinical Excellence. (2010):

- Pre-sedation Assessment, Communication, Patient Information, and Consent.
  - Suitability for sedation.
  - Choosing the most suitable sedation technique.
  - Enabling the child or young person and their parents or care giver to make an informed decision, offering them verbal and written information.
- Fasting prior to procedure.
- Psychological preparation for the child and their parents.
- Personnel and training for staff.
- Clinical environment and monitoring.
- Discharge criteria for the patient.

Each of the elements of the National Guideline Clearinghouse will be incorporated in the N_2O program proposal package to be presented to the Pediatric Sedation team and the department leaders.

Summary

The literature summarized here represents a wide variety of pediatric populations from across the world; a variety of inpatient, outpatient, and emergency settings; and a wide variety of painful or anxiety-provoking procedures. The amount of evidence supporting N_2O use is quite good overall, with several randomized controlled trials as well as large-scale observational studies demonstrating safety and efficacy. While N_2O may not be enough for extremely painful procedures and may provide less benefit compared to risk in younger age groups, it has demonstrated a high degree of efficacy with a wide safety profile in children. Such an agent has the potential as an intervention to improve pain and anxiety management for procedural sedation to assure it is satisfactory to the child, parent, and nurse.

Section 3: Approach

Project Design/Methods

Once the program protocol package is presented to the pediatric sedation team and department leaders, it can be finalized and certain elements such as patient/family education materials and the policy and procedure can be branded for the HSHS St. Vincent Children's Hospital. After approval of the program proposal and staff education, a pilot study can be performed by the pediatric intensivist and the nurses who monitor the patient during administration of nitrous oxide. The proposed pilot test may be performed on two groups: children who receive moderate sedation (morphine/versed) and children who receive nitrous oxide as an anxiolysis/analgesia agent. The providers will assess and select which patients will receive either the N_2O or moderate sedation option and consent will be obtained. As part of the proposed pilot study, questionnaires will be distributed to each patient/parent(s) to measure how the child fared with the designated method. The child and/or parent(s) will be asked to rate their experience with the treatment they received and note the child's level of pain and/or distress with the procedure. The data from the surveys will be compiled to determine if N_2O administration is an effective and safe, comparable option that can be used to reduce assessed and reported pain during the particular procedure. The results will be shared with the staff and providers. Pilot study and data collection will be performed by pediatric staff and providers once the nitrous oxide program has been developed by the staff.

Population and Sampling

The population chosen for this project proposal will be pediatric patients admitted to the hospital in the pediatric and PICU departments and pediatric patients in the

outpatient pediatric hematology/oncology clinic. Sampling will be data from the RNs, LPNs, NPs, MDs, and child life specialists from pediatrics and pediatric hematology/oncology.

Project Team

In addition to myself, the project team will include pediatric intensivists, the executive director, the pediatric/PICU department manager, and the pediatric hematology/oncology manager. This will be the core group working on developing the program. The core team has been chosen based on their leadership roles in the department. The project team will meet on a regular basis (at least monthly) to provide updates on the progress of the project and/or delegated tasks. Communications can also be done through e-mail and phone conversations. Once the proposal package is completed, the I will present it to the project team for necessary changes and feedback. Once approved, the departments can begin educate the staff on administration of nitrous oxide and begin utilizing it for painful and anxiety provoking procedures.

Key stakeholders in the process include RN staff (pediatric inpatient, PICU, and pediatric hematology/oncology clinic), anesthesia, purchasing, biomedical staff, finance/billing, and child life specialists. The patient and parents will also be involved once the pilot begins. The stakeholders will be brought into the team meetings when appropriate. The comprehensive program proposal will be presented to the team at the initial meeting. This will provide valuable feedback for the for me as I finish the program proposal. At initial meeting all of the background information and work will be discussed with the team and a timeline for developing the program will be created. Stakeholders outside of the department will be notified of the program development and that they may

be called upon to provide additional assistance. All members of the team work within the organization with the exception of the product vendor. I will facilitate team meetings, delegate tasks to appropriate team members, and assist with development of tools necessary for the program.

The department has already received grant money to purchase equipment and has planned for the program in the current year's budget. A product quote will be provided by the vendor. The team member from purchasing will be asked to attend a meeting to discuss purchasing the products chosen from the vendor. The pediatric hematology/oncology clinic was recently renovated and has nitrous oxide piped into the procedure rooms that are ready for use.

Data Collection

I propose a pilot study when the staff begins to implement the N_2O program. The documents created for the DNP project will be used for data collection during the pilot study. Data collection will be from staff in the pediatric units and the pediatric hematology/oncology clinic. This will be in the form of a needs assessment from the RNs, LPNs, NPs, MDs, and child life specialists created in SurveyMonkey and disseminated through e-mail that will determine educational needs. The IRB I received from the facility will need to be reevaluated to conduct the needs assessment. Data will also include the number of moderate sedations using morphine and versed for painful procedures. A questionnaire will be developed for the patient/parent(s) for data collection before, during, and after the procedure performed to gather information on how they felt the N_2O made the procedure tolerable; the effectiveness of N_2O; if they would recommend it for various types of procedures; and if they would use it for future

procedures. Staff involved in the procedure using N_2O will also complete a questionnaire to include the type of procedure, length of time gas is administered, any complications identified, ease of use, patient tolerance, patient pain levels before, during, and after the procedure, and if N_2O is recommended for future use.

The only archival data that may be included is a sedation report that identifies the number of sedations performed in pediatrics and in the pediatric hematology/oncology clinic. This report can be run by the pediatric intensivist and provided to me. The report contains no names and only lists the sedation method used and the procedure performed. Another source of data collection would be in the form of reported pain and anxiety. Pain assessment is a requirement of the Joint Commission. There are a variety of tools that can be used to assess pain and anxiety that are appropriate for the child's developmental age. A variety of tools can also be utilized for measurement of pain. Most are behavioral pain scales, acknowledged by some authors as a limitation that makes it difficult to separate pain from anxiety (Carbajal et al., 2008). Pain and anxiety are both outcomes of interest for this project. The reliability and validity of several of these scales such as the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) and Observational Scale of Behavioral Distress (OSBD) are well-established and are described in systematic reviews of such behavioral pain tools (Von Baeyer & Spagrud, 2007; Crellin, Sullivan, Babl, O'Sullivan, & Hutchinson, 2007). Often behavioral pain scales are combined with some type of visual analog scale rated by children, parents, and/or staff/observers. These scales include the numeric pain rating scale (Figure 2); Wong-Baker's FACES scale, which measures pain intensity "faces" that correspond to pain intensity (Figure 3), and the Faces

Legs Activity Cry Consolability Scale (FLACC) scale (Figure 4). Satisfaction on the part of the child, parent, and/or nurse was also a commonly investigated endpoint.

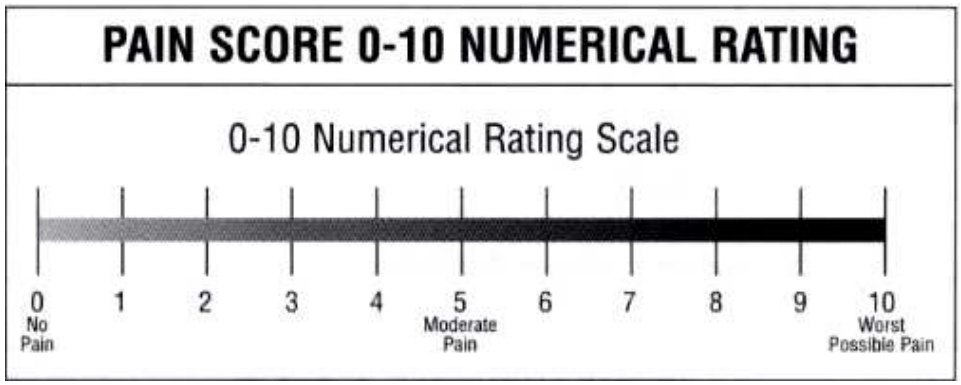

Figure 2. 0-10 Numeric pain rating scale

Figure 3. Wong-Baker FACES® Pain Rating Scale to assess pain in the pediatric patient. Permission granted from Wong-Baker Faces Foundation.

	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn disinterested	Frequent to constant frown, clenched jaw, quivering chin
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
Cry	No cry (awake or asleep)	Moans or whimpers, occasional complaint	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging or "talking to", distractible	Difficult to console or comfort

Figure 4. Faces, legs, activity, cry, consolability (FLACC) pain scale. Merkel, S., Voepel-Lewis, T., Shayevitz, J., & Malviya, S. (1997). Printed with permission, The Regents of the University of Michigan.

Reliability and Validity of Pain and Anxiety Assessment Tools. The 0-10 numeric rating scale is widely used to assess pain intensity in the pediatric population. It is generally used in children over the age of 8. Patients are asked to rate their pain on a scale from 0 to 10, where 0 represents "no pain" and 10 represents "the worst pain possible." Once the patient rates their pain, the nurse will ask the patient what his or her goals and expectations are with respect to the pain rating as a measure of satisfaction with the current pain relief method (Hartrick, Kovan, & Shapiro, 2003). The numeric pain scale has been validated in children 6 years and older and is a clinically meaningful tool to guide treatment (Pagé et al., 2012).

The Wong-Baker FACES scale is a popular method of pain severity assessment in pediatric populations. Faces scales use a series of facial expressions to illustrate a

spectrum of pain intensity (Garra, et al., 2010). The Wong-Baker FACES scale has proven to have content validity and has the potential to be an excellent measure of treatment in school-aged children and adolescents (Garra et al., 2010). The FACES pain scale is the most psychometrically sound self-report measure of pain in children between 4 and 12 years of age (Stinson, Kavanagh, Yamada, Gill, & Stevens, 2006; as cited in Noel, McCurty, Chambers, & McGrath, 2010).

The FLACC behavioral pain tool has excellent reliability and validity in assessing pain in critically ill adults and children (Voepel-Lewis, Zanotti, Dammeyer, & Merkel, 2010). The FLACC tool may offer an advantage as it can be used across populations and settings, and FLACC scores are comparable to scores obtained by using 0-to-10 number rating scales (Voepel-Lewis et al., 2010).

Data Analysis

The pilot study will be performed by the pediatric and pediatric hematology/oncology staff using the documents I created for the proposal package. Data analysis may include the data collected from the needs assessment to help guide staff education and determine a general knowledge base of what N_2O is and how it is used for painful and anxiety provoking procedures. Results from the staff and patient/family questionnaires will also be analyzed by the pediatric and pediatric hematology/oncology leaders to identify effectiveness of N_2O use and any recommendations. No new research will be done directly on the patients in both pediatric and the pediatric hematology/oncology clinic for the project.

A satisfaction survey that I created will be used by the staff to determine satisfaction from the parents and/or patient for N_2O administration for the procedure

being performed. Satisfaction data will be recorded from the patient and parental experience of receiving N_2O for painful procedures, fear of the procedure, and anxiety related to the procedure. Children will be able to rate their satisfaction with the pain and anxiety management when explained to them in a developmentally appropriate way. Additionally, parents and the sedation nurse will also be asked to rate their satisfaction with pain and anxiety management of the child before, during, and after the procedure. This data will be used to provide additional information of the overall effect of the intervention.

Project Evaluation Plan

Process evaluation for this project will include the following:

1. Documentation of IRB approval from the Walden University and HSHS St. Vincent Children's Hospital.
2. Development of needs assessment from the RNs, LPNs, NPs, MDs, and Child Life Specialists to be disseminated by the pediatric and pediatric hematology/oncology leaders.
3. Determination of scope of practice (RN delivery versus MD delivery).
4. Obtaining a quote and purchasing equipment needed to deliver nitrous oxide.
5. Development of proposed policies and procedures, documentation on the sedation record and sedation navigator in Epic, fasting protocol, and parent education brochure, RN and Parent procedure surveys.
6. Determine what education is required for staff and providers.
7. Documentation of and continued report to N_2O project team.

There are many processes that can help to evaluate the outcomes to determine if they have been met or need to be adjusted to meet the objectives. Research states that recovery from N_2O is approximately 5-10 minutes after the gas has been stopped and the patient is ready for discharge within 30 minutes after (Clark & Brunick, 2015). Moderate sedation requires a minimum of a one hour recovery which could take longer depending on the patient (J. Taylor, personal communication, August 3, 2015). Once nitrous use is implemented, length of stay can be tested and compared to that of moderate sedation.

Nitrous oxide administration may be useful in a pediatric oncology setting for sedation in children undergoing basic procedures such as a lumbar puncture, bone marrow biopsy and aspiration, placing a port-a-cath at the beginning of treatment and removing it at the end of treatment, dressing changes, or IV starts if needed. Nitrous oxide provides for an almost pain and anxiety-free procedure, requires neither an intravenous line nor post-procedure monitoring, and minimizes any unpleasant memories the child may have (Burnweit et al., 2004). To evaluate this outcome, a survey would be completed by the patient and/or parent for satisfaction and if the N2O was effective in reducing pain, anxiety, and/or fear during the procedure. Other evaluation criteria may include the type of patient and indication for N2O use, success of treatment, and behavior of the patient during the procedure, and any adverse effects noted (Collado et al., 2008).

The proposal package will include tools used to assist in developing new practice guidelines would include how the physician will assess whether or not the patient is a candidate to receive N_2O as well as consent; a monitoring tool for the sedation nurse to use during the procedure for documentation of vital signs, O_2 saturation, pain scores, and level of consciousness every five minutes while the gas is being administered; and a

patient/parent survey will be created to evaluate N_2O use as compared to moderate sedation using versed and morphine.

Since this is a brand new program, there are many elements that have to be developed such as a hospital policy, assessment tools (hard copy or in electronic medical record), guidelines, education, and staff/parent surveys. Along with implementing the use of N_2O, there will also be a need for patient and family education; therefore, if their child is a candidate, they are able to make an educated decision regarding which therapy they would like their child to receive. A parent education pamphlet will be developed to give to the parents when the procedure is scheduled so they understand what N_2O is, side effects related to the gas, how it is used, and information regarding its effectiveness and safety.

Proposal Package Documents

The proposal package for the N_2O program will include several components such as a proposed policy and procedure; changes to the sedation record to include nitrous oxide delivery that will be added to the Epic sedation navigator; proposed needs assessment for education and knowledge base of staff; RN and patient/family procedure surveys; sample MD order set; where providers will obtain education and who will be deemed a champion to education staff in the departments; fasting guidelines; and patient/family education materials. These documents will be presented to the pediatric leaders as part of the completion of the DNP project. Evidence-based research will be used to create the program proposal to provide the most current information regarding the safe administration of N_2O to the pediatric patients.

Summary

It should be noted that N_2O may not be effective or necessary for every child. Appropriate assessment should lead to the choice of effective pain management strategies. Some children may need pharmacologic intervention beyond N_2O and topical anesthetics to effectively manage distress. Providing a comprehensive program protocol package will assist in planning a successful project that meets the needs of the pediatric patient, their parents and family, and the pediatric staff and providers.

Section 4: Findings, Discussion, Implications

Introduction

The purpose of this project was to assess the need and gather support for development of a comprehensive program proposal for a nitrous oxide program in pediatrics. Nitrous oxide provides analgesia and anxiolysis. Administration of N_2O for procedures causing pain, fear, and/or anxiety allows for better cooperation from the pediatric patient for adequate completion of the procedure. Nitrous oxide has an excellent safety record and provides pain control and anxiety relief that is quickly and easily reversed (Clark & Brunick, 2015). The child remains calm and maintains verbal contact with the administering provider during the procedure.

The goal of the project was to develop a program proposal for a N_2O sedation program for the pediatric team to use during their development and implementation of the program. The N_2O program will be used to minimize pain and anxiety associated with some medical procedures. Children admitted to the pediatric department as well as the pediatric hematology/oncology clinic often go through procedures such as IV starts, urinary catheterization, lumbar punctures, bone marrow aspirations, central line insertions, port-a-cath access, nasogastric tube insertions, or gastrostomy tube changes. Each of these procedures can be pain, fear, or anxiety provoking. The goal of the nitrous oxide program is to minimize pain, fear, and anxiety associated with those procedures, which allows for completion of the procedure.

Discussion of Project Products

The scholarly products developed for the nitrous oxide protocol included a proposed policy and procedure; changes to the procedural sedation record and

documentation in the Epic Sedation Narrator to include nitrous oxide; a proposed needs assessment for education and knowledge base of staff; RN and patient/family procedure surveys; sample MD order set; education staff plan; fasting guidelines; patient/family education materials; and obtaining a quote for equipment. The scholarly products were presented to the pediatric leaders for review and approval.

Concept Map.

To begin the planning phase of the project, a concept map was created (Appendix A). Brainstorming ideas at the beginning of the project was valuable in determining what products would be necessary to present to the pediatric leaders to aid in their development and implementation of the nitrous oxide program in the inpatient departments and the pediatric hematology/oncology clinic. A concept map is a tool that shows the main idea, subconcepts, and cross-links and organizes the relationships between concepts (Noonan, 2011). The concept map included the stakeholders, safety, education, policy, scope of practice, finance, equipment, tools, regulatory issues, patient population, and the physician group. Each of these subconcepts is critical to planning a successful program.

Policy and procedure. As part of the program protocol package, a proposed nitrous oxide policy and procedure (Appendix B) was developed using current evidence-based practice. This policy was presented to the pediatric leaders for feedback to include revisions and approval of the policy to continue on in the process for approval by the organization. The pediatric medical director was a key stakeholder in developing the policy. The director's expertise and knowledge were very valuable in creating the policy.

Sample MD order set. The proposed physician order set included the concentration of N_2O/O_2 to initiate the procedure, the continued concentration throughout the procedure, the order to administer 100% O_2 for 3-5 minutes after discontinuing N_2O upon completion of the procedure, and a discharge order. An example of a physician order set can be found in Appendix C. The pediatric medical director has chosen to use the sample order set as a guide to developing the orders for N_2O administration. Another option may be to add N_2O to the existing procedural sedation order set.

Fasting guidelines. The pediatric sedation program has defined the fasting guidelines as nothing by mouth (NPO) for solids after midnight, clear liquids until 2 hours prior to the procedure, and then NPO. The guidelines will remain in place for planned procedures using N_2O. For unplanned procedures such as IV starts, difficult port-a-cath access, or lab draws, the physician may waive the fasting guidelines. The physician will ask the patient prior to administering N_2O what they ate or drank prior to the procedure. Typically, patients may eat a light meal no closer than 2 hours prior to the procedure (Clark & Brunick, 2015).

Sedation record. Documentation of a procedure of nitrous oxide will include the concentration of N_2O/O_2 administered; the start and stop times of the N_2O; vital signs every 5 minutes during the procedure; an Aldrete score preprocedure, postprocedure and every 15 minutes until the patient is fully recovered and back to baseline activity; ASA level documented in the physician's dictation note; and a Richmond Agitation and Sedation Scale (RASS) score during the procedure. The procedural sedation record was updated to include N_2O for documentation (Appendix D).

Proposed needs assessment/education plan. The proposed needs assessment may be used by the pediatric leaders during the development of the N_2O program to assess the knowledge base of the pediatric staff members (Appendix E). The data collected from the needs assessment may be used to guide staff education. The same needs assessment can be used after education to assess knowledge gained through education.

The proposed education plan is for a select group of staff to attend a didactic and hands-on education course offered by American Family Children's Hospital in Madison, Wisconsin. The course provided is taught by the assistant professor of pediatrics who is also the associate director of pediatric sedation. The group selected may include two of the pediatric intensivists, the managers of pediatric and pediatric hematology/oncology, child life specialists, a PICU RN, and a pediatric hematology/oncology RN. The pediatric intensivists will then be responsible for staff education in the departments.

The equipment vender will also be sending a clinical product specialist to do education on the Porter Sentry Sedate N_2O system. There will be six sessions over 2 days that are approximately one hour in length. There will also be a 15 minute video to show how to set up, use, and break down the equipment.

RN/family survey. Once the pediatric department and the pediatric hematology/oncology clinic begin the pilot program, surveys can be used to assess the level of pain, distress, and anxiety the patient has before, during, and after the procedure where N_2O is administered. The survey of the RN staff will be used to determine satisfaction of N_2O for the procedure (Appendix F). The parent survey will be used to determine their satisfaction with N_2O (Appendix G). The data collected from the surveys

will be used to assess the effectiveness of N_2O sedation from both the RN staff and the parent.

Patient and family education. Education is very important in any new program. Nitrous oxide sedation is a new concept and the patient and family will need education prior to choosing it for their child's procedure. Education materials developed for the program proposal includes a N_2O fact sheet (Appendix H) and an educational brochure (Appendix I). Information in the educational materials includes what N_2O is, how it will help the child during the procedure, how it is given, what the risks are, what the parent can do to help the child, and the role of the child life specialist.

Equipment quote. Grant money will be used to purchase the equipment necessary to deliver N_2O to the pediatric patient. The quote for the equipment was received and the department is planning to purchase the equipment in June, 2016 (Appendix J).

Implementation Plan

The products completed for the N_2O sedation program can be used by the pediatric leadership team to develop and implement the program in the pediatric departments. The leadership team can continue with development of the program by seeking hospital approval of the policy and procedure and then begin scheduling education for the pediatric intensivists as well as a select group of nursing staff. These individuals will be key members to provide education to the staff in pediatrics/PICU and the pediatric hematology/oncology outpatient clinic. The vendor will also be responsible for education on the set-up and break down of equipment. Once the N_2O program has been developed using the products created from the DNP project, the pediatric leadership

team can begin a pilot and collect data on the procedures using N_2O sedation. Data can be used to determine efficiency and satisfaction with N_2O use for medical procedures.

Implications

The program proposal for a N_2O sedation program in the pediatric/PICU inpatient departments and the pediatric hematology/oncology outpatient clinic included a hospital policy and procedure. The policy was presented to the pediatric leaders as well as the pediatric medical director for feedback and potential approval of the policy. The pediatric medical director was instrumental in developing the policy. The medical director has many years of experience in developing policies and is an expert in his field of medicine. The feedback received on the first draft of the policy helped to revise the content to create a solid policy for administering N_2O to the pediatric patient.

This project may pave the way for the pediatric staff to utilize a minimal sedation method that will minimize pain, fear, and anxiety associated with some medical procedures. The short acting and rapid recovery of N_2O can satisfy the needs of patient and family. Parents do not like to see their children in distress. Those situations causing pain, fear, and anxiety can set a negative tone for the child's hospitalization and potentially cause more trauma.

Strengths

A strength of the project was the effective interprofessional collaboration. An advantage in the development of this project group was that most of the individuals already worked closely together with a high degree of multidisciplinary collaboration. Adding a N_2O sedation to the pediatric sedation program was well received by the multidisciplinary work team. Using a minimal sedation technique to minimize pain, fear,

and anxiety associated to medical procedures is a priority in providing the very best care to the pediatric patient. The multidisciplinary team valued and respected each member's input, which contributed to excellent interprofessional collaboration and enthusiasm for this project.

Limitations

An anticipated limitation of the proposed program was involvement of the anesthesia department. This project involved is one of the first programs to use an inhalation agent outside of the operating room within the institution; it was believed that this could be seen as a "turf" issue with anesthesia. Input from the anesthesia department was needed for many aspects of the project. According to Rose (2011), sharing such disciplinary expertise can be perceived as threatening to an individual when that knowledge would enable other professionals to take on aspects of that individual's own role. Because of the deeper understanding of children and their unique pain and sedation needs, the director of anesthesia was approached for assistance with the N_2O program. When members of the project team explained what the goals of the project were, the anesthesiologists were very supportive of the program. By involving the anesthesia department in the program proposal, they we able to maintain some control of their identity and territory within this project.

Another limitation of the project was maintaining a meeting schedule with the key stakeholders in the project. Each of the individuals had very busy schedules and coordinating a time that worked for all of them was very difficult and it was rare that the team was able to sit down together to review the proposal of the program. Much of the communication occurred via email or sporadic individual meetings rather than the whole

group meeting. A plan for future projects would include planning regular meetings ahead of time to ensure the multidisciplinary team can meet as a whole group rather than individually as time permits. The meeting times would then be on the team members' schedule for better attendance and commitment to the project.

Analysis of Self

The past 18 months of doctoral education has expanded my engagement in a higher level of academic activities which include program planning and development. Prior to the doctoral education, I had minimal experience in these types of leadership activities. New knowledge about leadership responsibilities and activities necessary for change has been instrumental in improving confidence in leadership skills. Improved leadership skills will assist in future planning, organizing, and facilitating program development. Learning how to appropriately plan, implement, disseminate, and evaluate a program allows me to become more successful with future projects and job responsibilities as a leader.

Developing a program proposal for administration of N_2O in the pediatric patient has been a very valuable learning experience. Leading a multidisciplinary team in successful planning of the project was not without challenges. However, the whole team was able to come together to approve the proposal of the program. Using the products developed in the DNP project, the team can move forward with developing the N_2O program in the pediatric/PICU departments and the pediatric hematology/oncology clinic to provide the pediatric patients with a sedation method to minimize pain, fear, and anxiety. The N_2O program can eventually be rolled out to other areas within the

organization that serve pediatric patients such as radiology, GI lab, and the emergency department.

As a Scholar

The AACN (1999) defines scholarship as "activities that systematically advance the teaching, research, and practice of nursing through rigorous inquiry that 1) is significant to the profession, 2) is creative, 3) can be documented, 4) can be replicated or elaborated, and 5) can be peer-reviewed through various methods" (para. 1). This project provided me with the opportunity to develop skills through building an evidence-based program proposal for a N_2O program in the pediatric/PICU departments and the pediatric hematology/oncology clinic. Development of the policy, education plan, staff and family education, documentation to include N_2O for sedated procedures, staff and family surveys to present to the pediatric leaders was a valuable experience. Preparation of the program proposal provided me with the ability to comprehend, appraise, and interpret the literature surrounding the safety and efficacy of N_2O administration in pediatric patients. Through gaining an understanding of the literature surrounding N_2O I was able to apply the most current evidence-based information into creating the comprehensive program proposal to present to the pediatric leadership team for approval.

As a Practitioner

The doctorate preparation has provided me with better understanding of the leadership role. Leaders are effective in facilitating change. The N_2O program is a new program that will be implemented in the pediatric practice areas. Change is not always well received; however, this was not the case for this project. During the preparation of the project, there has been an overwhelming positive response from the pediatric staff for

the N_2O program. The knowledge and skills learned at the doctoral level have allowed me to achieve the outcomes of the project, develop a program proposal, and present it to leaders to use for development of the N_2O sedation program. Plans are in place by the pediatric leaders to use the proposed program prepared by through DNP project to develop and implement the N_2O program by August 2016.

As a Project Developer

The experience of developing N_2O program offered me the opportunity to identify an evidence-based project in the pediatric department at HSHS St. Vincent Children's Hospital. Experiences included working together with a multidisciplinary team to develop a program proposal of a new sedation method to minimize pain, fear, and anxiety in pediatric patients undergoing medical procedures, developing a comprehensive policy for administering N_2O, preparing patient, family, and staff education. Presenting the program proposal to the pediatric leadership team has given me improved confidence for future program development opportunities.

Summary

According to Taddio et al. (2009), pain relief is a basic human right, and reducing procedural pain in children demands prioritization by healthcare agencies, researchers, and parents. Safe methods to alleviate such pain are readily available and N_2O is one more method that can be used for pediatric patients. Greater distress during such procedures leads to more negative memories, which can have serious effects on compliance of treatment. Patients may avoid receiving necessary healthcare due to pain, fear, and anxiety associated with medical procedures

During this project, it has become clear that changing the culture to add N_2O has been well received by the pediatric leadership team and staff in the departments. Enthusiasm for the eventual implementation of N_2O program has spread throughout the pediatric departments and the staff members are looking forward to using it for future procedures. The pediatric leadership team may be utilizing the tools and resources created from this project to develop and implement the N_2O program.

Culture change takes time, but with better education of healthcare professionals on the importance and ethics of pediatric pain management, interventions like nitrous oxide could become the norm. Taddio et al. (2009), discussed that suboptimal implementation of comprehensive pain management programs can be attributed to a lack of knowledge about pain and effective pain prevention strategies, as well as the persistence of attitudes and beliefs about pain that impede clinical progress in this area. Projects such as this can educate and change the attitudes of healthcare providers so that children receive the basic human right of effective pain management.

Section 5: Scholarly Product

Introduction

The proposal of a comprehensive N_2O program for pediatrics was presented to the pediatric leadership team on March 21, 2016. The leaders were able to review the proposal and provide feedback. The policy and procedure was revised and returned to the pediatric medical director on March 28, 2016. The products of the proposal were approved by the pediatric leadership team and may be used for the future development of the N_2O program in pediatrics, PICU, and pediatric hematology/oncology clinic.

Problem

Pain in the pediatric patient is often undermanaged. Pain, fear, and anxiety can be associated to some medical procedures. Examples of routine procedures that cause these emotions include IV starts, lab draws, port-a-cath access, lumbar puncture, and urinary catheterization. Distress and anxiety can enhance the child's perception pf pain (Rodriguez, et al., 2012). Nitrous oxide is used to induce minimal sedation for these routine procedures to help alleviate pain, fear, and anxiety in the pediatric patient.

Purpose

The purpose of the DNP project was to create a comprehensive N_2O program proposal to present to the pediatric leadership team to move forward with their development of the N_2O sedation program. According to the executive director of pediatrics, adding a N_2O program was something the leaders and pediatric intensivists have talked about since 2013. The program proposal developed through the DNP project can enable the pediatric leaders to begin developing and implementing the N_2O sedation program.

Goals/Outcomes

The goals and outcomes of the DNP project were met by developing a comprehensive proposal of the N_2O program for pediatrics and presenting it to the pediatric leadership team. Patient and family education materials were developed to provide information on N_2O, which was also presented. The HSHS St. Vincent Children's Hospital is going through the planning process and has not selected a graphic icon to represent the hospital. Once the icon is chosen, the education materials can be submitted to the organization for approval and branding. After the proposal was presented to the pediatric leadership team, there was positive feedback; however, some of the components needed revisions or modifications. The requested changes were made and presented to the team a second time at which time they approved the materials and allowed me to proceed with portions of the proposal that the organization needed to approve. The procedural sedation record was approved by health information management and was loaded into Epic forms for staff to utilize. There has been a request to add N_2O to the Epic Sedation Narrator for documentation of the administration and concentration of N_2O used for the procedure. The policy and procedure will be moving forward to seek approval from the anesthesia department and then approval from the organization.

Significance to Practice

The products created for the N_2O sedation program may be used to assist in further development and eventual implementation of the program. Nitrous oxide sedation provides a minimal sedation option for the pediatric procedural sedation program. Nitrous oxide provides minimal sedation and has both rapid onset and recovery while minimizing

the child's pain, fear, and anxiety that may be associated with some medical procedures. Both pain and anxiety are managed with N_2O to help the child remain calm in order to facilitate completion of the procedure. The minimal sedation technique can reduce the need for restraining the child to complete the procedure and can minimize the number of needle stick for IV starts, port-a-cath access, and/or lab draws.

Literature and Evidence to Support Project

A systematic literature review was conducted using the simultaneous CINAHL/MEDLINE database with combinations of keywords including *pain, anxiety, fear, pediatric, nitrous oxide, child, developmental ages, intravenous catheterization, urinary catheterization, sedation,* and *conscious sedation*. Literature from the systematic review showed N_2O sedation having an excellent safety profile and that it can be effectively used to minimize pain, fear, and anxiety in children due to routine medical procedures. Nitrous oxide has anxiolytic, analgesic, and amnesic properties to help manage pain and keep the child calm during the procedure being performed.

Frameworks

Frameworks used for the DNP project include Huth and Moore's prescriptive theory of acute pain in children and the National Guideline Clearinghouse guideline for sedation in children and young people. Both frameworks discuss pain control in the pediatric patient. Minimizing pain, fear, and anxiety during hospital admissions and clinic visits is a priority in managing care in the pediatric patient. The frameworks discussed in the project were incorporated when developing the products for the proposal of a N_2O sedation program. These frameworks were used to develop the proposal which will be

used to reduce pain, fear, and anxiety for routine medical procedures and procedural sedation.

Summary

Input received and integrated from key stakeholders contributed to the success of this project. Their feedback was a valuable asset while creating the program proposal for a nitrous oxide program in pediatrics. The nitrous oxide program proposal was created to provide a minimal sedation option to add to the current pediatric sedation program. Managing procedural pain and anxiety in the pediatric patient is a top priority. Nitrous oxide has an excellent safety profile and will be used to minimize procedural pain, fear, and anxiety in children where medical procedures are necessary for treatment.

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Appendix A: Concept Map for Nitrous Oxide Program

Appendix B: Proposed Policy and Procedure for N_2O Administration

SUBJECT: Administration of Nitrous Oxide **Effective Date:**
Next Revision Due:

AREA: Pediatrics, PICU, Pediatric Hematology/Oncology

Policy#/Name: Nitrous Oxide for Anxiolysis

DEPARTMENTAL APPROVAL:

RECOMMENDED BY:

POLICY: Nitrous oxide use to produce minimal sedation for medical procedures in Pediatrics, PICU, and Pediatric Hematology/Oncology.

PURPOSE: To provide guidelines for pediatric patient management of all procedures requiring the use of nitrous oxide sedation by non-anesthesia personnel.

PROCEDURE:

I. Procedure:

A. Indications for use:

1. Nitrous oxide may be used as a minimal sedation agent for procedures that may cause pain or anxiety, including but not limited to:
   a. Insertion of intravenous catheter/port-a-cath access
   b. PICC line insertion
   c. Lumbar Puncture
   d. Insertion of urinary catheters
   e. Nasogastric tube insertion
   f. Injections
   g. Painful dressing changes
   h. Gastrointestinal tube changes
   i. Other minor procedures (MRI, CT, Nuclear Medicine, etc.)

B. Contraindications

1. Nitrous oxide will diffuse into a closed space or fluid filled space and expand air, causing increased pressure within the closed space. Nitrous oxide may also slightly increase intracranial pressure. The potential for teratogenicity and abuse exists.
   a. Pneumothorax/Pneumomediastinum
   b. Intestinal obstruction

c. Recent middle ear occlusion or tympanoplasty
d. Pulmonary bullae or severe bullous emphysema (e.g. caution with cystic fibrosis)
e. Air embolism
f. Decompression sickness
g. Maxillofacial injuries with potential for trapped gas
h. Intraocular surgery, penetrating injury to the globe, or increased intraocular pressure (past 10 weeks)
i. Recent myringoplasty
j. Pneumocephalus
k. Within 3 weeks following a craniotomy
l. Increased intracranial pressure
m. Pregnancy
n. Vitamin B12 deficiency
o. Impaired level of consciousness
p. History of bleomycin administration
q. Intoxication with drugs or alcohol
r. Current or recovering drug addiction

C. Qualifications of administering provider:
1. To administer nitrous oxide, providers must complete a nitrous oxide training course. Training includes didactic component and monitored hands-on training to include 3 supervised nitrous oxide administrations with an experienced mentor to establish competency.
2. The administering provider must be qualified to recover the patient from a level of sedation beyond that intended.

D. Qualifications of monitoring RN:
1. Nitrous oxide may only be ordered and administered by a medical provider specifically credentialed by the Medical Staff in the administration of nitrous oxide as a minimal sedation agent.
2. PALS certification required and established competency in monitoring sedations
3. Pregnant staff in the first trimester must not participate in nitrous oxide administration.

II. Equipment

A. Storage of equipment and Nitrous Oxide tanks must be in a designated locked area.
B. Replacement tanks will come from the Storeroom
C. Equipment check performed prior to sedation.
1. Oxygen and nitrous oxide tubings connected to appropriate tanks.
2. Flow appropriately set to 3-4 L/min

3. Nitrous Oxide auto-cutoff test: Start a minimal flow of nitrous oxide; turn off oxygen flow and be sure nitrous oxide flow also stops.
4. Confirm the absence of leaks at pressure connections.
5. Scavenging equipment intact and prepared to operate during nitrous oxide administration

III. Nitrous Oxide Pre-Anesthesia Assessment:

A. Current medical history including medications and allergies
B. Past medical history to include past anesthetic history to include problems with anesthesia or sedation
C. Focused physical exam to include:
   1. VS and weight
   2. Malampati Score
   3. Heart
   4. Lungs
   5. ASA Status
D. NPO Status
   1. Follow sedation NPO guidelines located in policy #100-22-001: Procedural Sedation (Appendix 6).
   2. NPO guidelines may be waived by the medical staff provider in special circumstances.
E. Patient/Family Preparation
   1. Educate patient, parent, and/or legal guardian regarding nitrous oxide administration.
   2. Use of topical anesthetic for IV starts is recommended even if nitrous oxide is used.
   3. Involve Child Life Specialists with procedure preparations to alleviate anxiety associated with procedure and mask.
F. Obtain informed consent
G. Perform Time Out and complete Time Out Checklist:
   1. Patient correctly identified for procedure using two identifiers.
   2. Patient evaluated for presence of contraindications to use of nitrous oxide
   3. Confirm that orders call for no less than 30% oxygen whenever nitrous oxide is administered.
   4. Emergency equipment available at bedside as per Policy #100-22-001: Procedural Sedation (Appendix 3).

IV. Intra-procedure Monitoring

1. Documentation of nitrous oxide concentration, pulse oximetry value, and level of sedation will be recorded at the onset of administration, with any changes in administered nitrous oxide concentration, and every 5 minutes thereafter on the patient record.
2. In addition to level of sedation and nitrous oxide concentration, the patient's heart rate, respiratory rate, blood pressure, and

pulse oximetry will be monitored every 5 minutes until patient returns to pre-sedation baseline, at which point VS may be discontinued.

3. Continuous direct observation by a qualified RN is mandatory throughout nitrous oxide administration.

V. Post-procedure Monitoring

1. Stop flow of nitrous oxide and administer 100% oxygen post procedure for 5 minutes to flush nitrous oxide from the patient's system and to avoid risk of diffusion hypoxia.
2. Pulse oximetry levels will be recorded until recovery is complete.
3. Monitor for nausea and vomiting
4. Adverse event such as emesis, vasovagal reaction, seizure, anaphylaxis or anaphylactoid reaction, cardiopulmonary impairment, or depth of sedation deeper than that intended, during the sedation period as well as interventions required will be documented.
5. May discharge per physician order once patient meets discharge criteria refer to Policy #100-22-001: Procedural Sedation.

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Appendix C: Proposed Physician Orders for N_2O Administration

Inpatient Observation Outpatient

Diagnosis: _____
Allergies: _____
Attending Physician: _____
Weight: _____

Please **CHECK** desired orders.

_____ 1. Complete nitrous oxide time out prior to initiation of sedation.

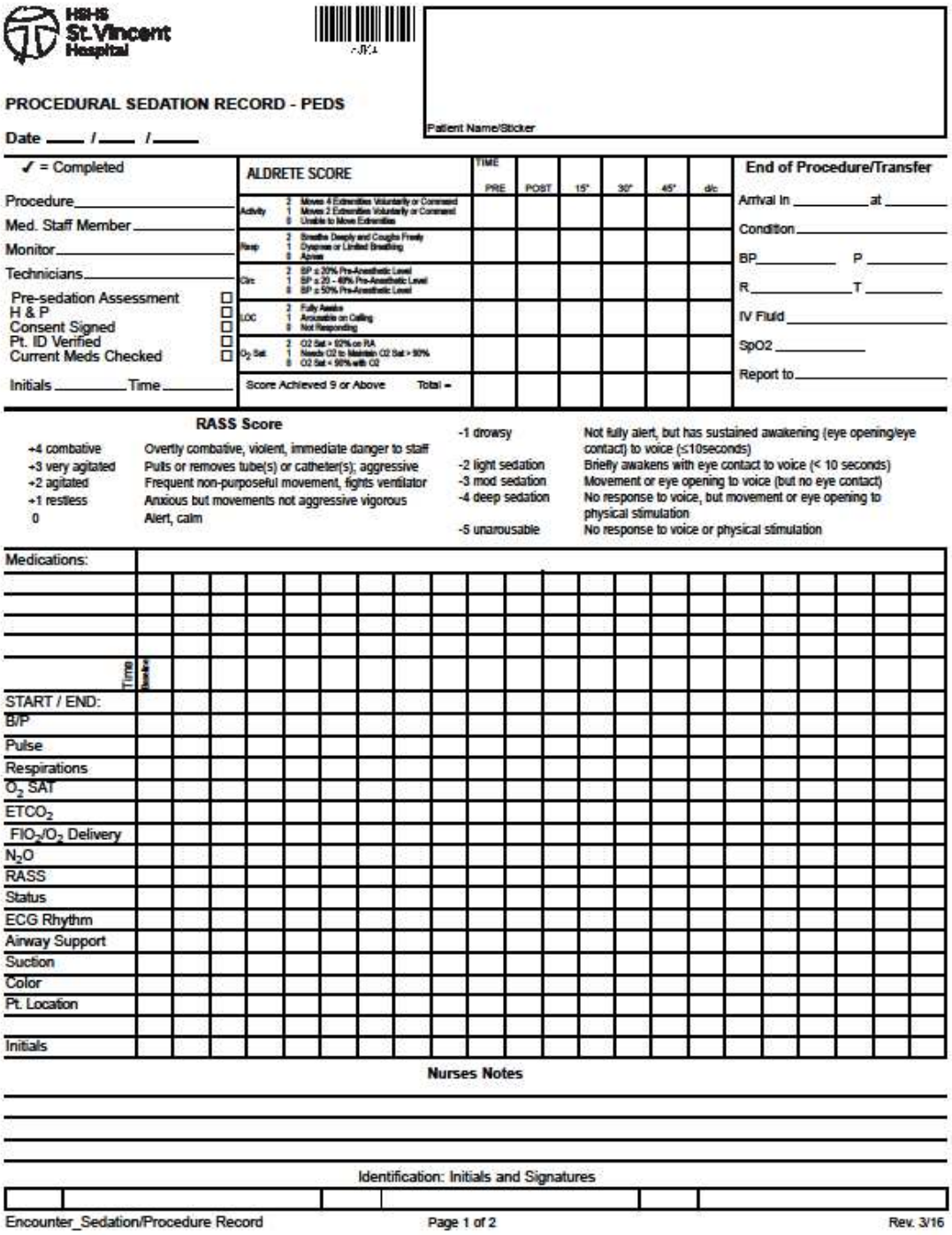
_____ 2. Initiate nitrous oxide at _____% (maximum 70%) x_____ minutes.

_____ 3. Continue administration at _____% to _____% (maximum 70%) for duration of procedure (maximum _____ minutes).

_____ 4. Upon discontinuation of nitrous oxide, administer 100% FiO2 x 5 minutes to prevent diffusion hypoxia.

Physician Signature:_____Date:_____ Time: _____

Appendix D: Procedural Sedation Record



HSHS St. Vincent Hospital

PROCEDURAL SEDATION RECORD - PEDS

Date ____ / ____ / ____

Patient Name/Sticker

✓ = Completed

Procedure _____

Med. Staff Member _____

Monitor _____

Technicians _____

Pre-sedation Assessment ☐
H & P ☐
Consent Signed ☐
Pt. ID Verified ☐
Current Meds Checked ☐

Initials _____ Time _____

ALDRETE SCORE		TIME PRE	POST	15'	30'	45'	d/c
Activity	2 Moves 4 Extremities Voluntarily or Command 1 Moves 2 Extremities Voluntarily or Command 0 Unable to Move Extremities						
Resp	2 Breathe Deeply and Coughs Freely 1 Dyspnea or Limited Breathing 0 Apnea						
Circ	2 BP ± 20% Pre-Anesthetic Level 1 BP ± 20 - 49% Pre-Anesthetic Level 0 BP ± 50% Pre-Anesthetic Level						
LOC	2 Fully Awake 1 Arousable on Calling 0 Not Responding						
O_2 Sat	2 O2 Sat > 92% on RA 1 Needs O2 to Maintain O2 Sat > 90% 0 O2 Sat < 90% with O2						
Score Achieved 9 or Above	Total =						

End of Procedure/Transfer

Arrival In _____ at _____

Condition _____

BP _____ P _____

R _____ T _____

IV Fluid _____

SpO2 _____

Report to _____

RASS Score

+4 combative	Overtly combative, violent, immediate danger to staff	-1 drowsy	Not fully alert, but has sustained awakening (eye opening/eye contact) to voice (≤10seconds)
+3 very agitated	Pulls or removes tube(s) or catheter(s); aggressive	-2 light sedation	Briefly awakens with eye contact to voice (< 10 seconds)
+2 agitated	Frequent non-purposeful movement, fights ventilator	-3 mod sedation	Movement or eye opening to voice (but no eye contact)
+1 restless	Anxious but movements not aggressive vigorous	-4 deep sedation	No response to voice, but movement or eye opening to physical stimulation
0	Alert, calm	-5 unarousable	No response to voice or physical stimulation

Medications:																							
Time / Name & Initials																							
START / END:																							
B/P																							
Pulse																							
Respirations																							
O_2 SAT																							
$ETCO_2$																							
FIO_2/O_2 Delivery																							
N_2O																							
RASS																							
Status																							
ECG Rhythm																							
Airway Support																							
Suction																							
Color																							
Pt. Location																							
Initials																							

Nurses Notes

Identification: Initials and Signatures

Encounter_Sedation/Procedure Record Page 1 of 2 Rev. 3/16

*Property of HSHS St. Vincent Hospital

Appendix E: Proposed Needs Assessment

Nitrous Oxide Needs Assessment

1.Please enter your Job Role

- RN
- LPN
- NP
- MD
- Child Life Specialist

2.I am satisfied with the current pain and anxiety management therapies offered for the following procedures for pediatric and pediatric hematology/oncology patients:

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	N/A
IV Starts						
Lab Draws						
Port Access						
Lumbar Puncture						
Urinary Catheterization						
Dressing Changes						
MRI						
CT scans						
NG Tube insertion						
Gastrostomy Tube Replacement						

Comments

3.Topical anesthetics (EMLA/LMX 4) are enough to gain cooperation of most children for lab draws and IV starts.

Comments

4.What percentage of the time would you estimate children are restrained to obtain:

	<10%	25%	50%	75%	>90%
IV Starts	○	○	○	○	○
Port Access	○	○	○	○	○
Lab Draws	○	○	○	○	○
Dressing Changes	○	○	○	○	○
Urinary Catheterization	○	○	○	○	○

Comments

5.Do you think adding a Nitrous Oxide Program to assist with procedures that cause fear, pain, and anxiety would be beneficial to the pediatric and pediatric hematology/oncology patients?

Comments

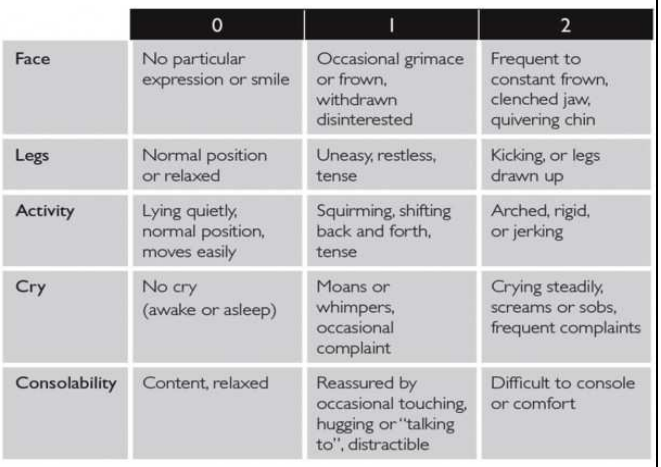
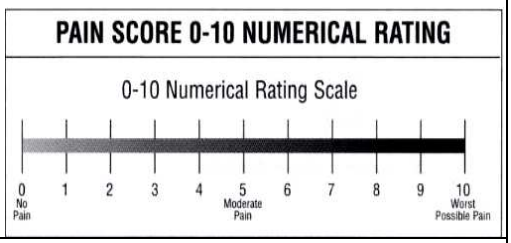
6.Is nitrous oxide a comparable method for sedated procedures to a morphine/versed sedation?

Appendix F: RN Satisfaction Survey

Patient Pain Assessment Data Collection Form during Nitrous Oxide Administration

Gender: □ Male □ Female	Date of Procedure: _____/_____/_____
Diagnosis:	
Procedure:	

Pain Assessment before Sedation: Patient Response

Nurse Completes FLACC (if child <3 years old)	Nurse Asks Child FACES Pain Rating (if child ≥3)
	 0-10 scale (for children <6) 
Nurse's Assessment of Patient's Pain	No Pain Worst Pain Possible 0 1 2 3 4 5 6 7 8 9 10

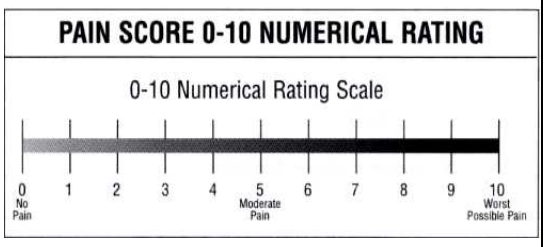
	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn disinterested	Frequent to constant frown, clenched jaw, quivering chin
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
Cry	No cry (awake or asleep)	Moans or whimpers, occasional complaint	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging or "talking to", distractible	Difficult to console or comfort

Pain Assessment during Procedure: Patient Response

Nurse Completes FLACC (if child <3 years old)	Nurse Asks Child FACES Pain Rating (if child ≥3)
	

	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn disinterested	Frequent to constant frown, clenched jaw, quivering chin
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
Cry	No cry (awake or asleep)	Moans or whimpers, occasional complaint	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging or "talking to", distractible	Difficult to console or comfort

0-10 scale (for children <6)



Nurse's Assessment pf Patient's Pain

No Pain Worst Pain Possible

0 1 2 3 4 5 6 7 8 9 10

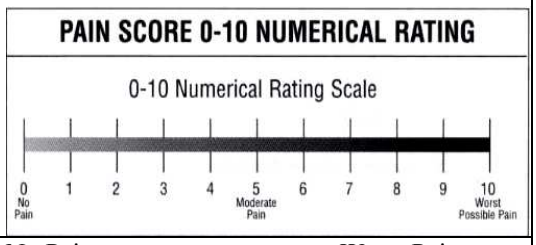
After Procedure (Prior to Discharge)

Nurse Completes FLACC (if child <3 years old)

	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn disinterested	Frequent to constant frown, clenched jaw, quivering chin
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
Cry	No cry (awake or asleep)	Moans or whimpers, occasional complaint	Crying steadily, screams or sobs, frequent complaint
Consolability	Content, relaxed	Reassured by occasional touching, hugging or "talking to", distractible	Difficult to console or comfort

Nurse Asks Child FACES Pain Rating (if child ≥3)

0-10 scale (for children <6)



Nurse's Assessment pf Patient's Pain

No Pain Worst Pain Possible

0 1 2 3 4 5 6 7 8 9 10

Nurse's Estimate of Ease of Procedure	□ Easy No Issues	□ Difficult Patient movement or resistance	□ Very Difficult Patient movement or resistance, traumatic procedure
Nurse Ask Patient	Can you tell me about your visit today?		
Non-pharmacological	□ Child Life Specialist		

Interventions (check all that apply)	□ Distraction (videos, music, etc.) □ Other (Specify): _____

Appendix G: Parent Satisfaction Survey

Form Completed By: □ Mother □ Father □ Other Guardian, specify:_____
Type of Procedure:_____

Please complete form to the best of your ability by circling one number for each of the questions below.

Before Sedation

Estimate your child's pain	No Pain … Worst Pain Possible 0 1 2 3 4 5 6 7 8 9 10
Estimate your child's distress	No Distress … Worst Distress Possible 0 1 2 3 4 5 6 7 8 9 10

During Procedure

Estimate your child's pain	No Pain … Worst Pain Possible 0 1 2 3 4 5 6 7 8 9 10
Estimate your child's distress	No Distress … Worst Distress Possible 0 1 2 3 4 5 6 7 8 9 10

After Procedure (before you leave the clinic)

Estimate your child's pain	No Pain … Worst Pain Possible 0 1 2 3 4 5 6 7 8 9 10
Estimate your child's distress	No Distress … Worst Distress Possible 0 1 2 3 4 5 6 7 8 9 10
Your Satisfaction with the sedation provided for this procedure	Extremely Satisfied … Extremely Dissatisfied 0 1 2 3 4 5 6 7 8 9 10
Your child's satisfaction with sedation provided for this procedure	Extremely Satisfied … Extremely Dissatisfied 0 1 2 3 4 5 6 7 8 9 10
Did your child have any problems with the procedure? Check all that apply.	Nausea □ Yes □ No Vomiting □ Yes □ No Combative behavior □ Yes □ No Unstableness when leaving for home □ Yes □ No
Was your child able to return back to normal activity before discharge?	□ Yes □ No
How would you compare this sedation experience to previous sedation experiences?	Please Check **one:** □ Better □ Same □ Worse

Do you have any comments or anything you would like to tell us to improve your care or experience?

Thank you very much for completing this survey!

Appendix H: Nitrous Oxide Fact Sheet

Nitrous Oxide

Key points to Remember
It helps to be near and to comfort your child during the use of nitrous oxide.
This gas is safe for use in children and there are no long term side effects.

What is nitrous oxide?
You may know this gas as happy gas or laughing gas. It is a sweet smelling, colorless gas used to ease pain and anxiety.

How will it help my child?
Your child may be offered nitrous oxide gas while the doctor or nurse carries out the procedure. The gas helps to ease the pain and anxiety your child may feel, but usually does not make them fall fully asleep.

When your child starts to breathe the nitrous oxide, they will feel drowsy within a couple of minutes. The gas will be continued until the procedure finishes and will wear off quickly when the gas is stopped. This means your child can quickly get back to their usual activities (playing, eating etc.).

How will it be given?
Nitrous oxide will be given by a doctor. Before it is given, your child will be assessed to make sure this is the best option. You will be asked to make sure your child stops eating and drinking for a certain time before they have the gas (usually at least 2 hours, but may be longer if other sedating medicines will be used with the nitrous oxide). This helps reduce the risk of vomiting.

Your child will be given a mask or a mouth piece attached to a machine through which they will breathe the gas. It can be helpful to look at, and play with the mask with your child before the procedure starts so your child is comfortable with it before it is placed on their face.

You are welcome to stay while your child is having the gas. The best thing you can do is to stay where your child can see you and hold their hand. The gas will be given a few minutes before the procedure starts and will continue until it is finished. The gas may make your child feel 'floaty', warm and tingly. Your child may or may not remember anything about the procedure.

When the nitrous oxide is stopped, your child will then be given oxygen through a mask to clear the gas from their lungs. After your child has had the oxygen and is awake and alert they will be able to eat and drink normally.

Are there any risks?
This gas is safe for use in children and there are no long term side effects from occasional use. Young children may not like having a mask on their face. They may feel angry or confused by the mask and gas and will need you to stay close and comfort them. The nurse or doctor may need to hold the mask firmly over your child's face at first until the gas starts to work and your child relaxes.

Other side effects may occur, but they are usually minor and get better quickly. Some children feel sick or vomit during nitrous oxide sedation. The staff looking after your child will know how to manage these problems if they occur.

What can I do to help?
Hospitals can be frightening places for children. If a child feels sick or is in pain, it can be upsetting to have nurses and doctors they don't know look after them. It helps if parents stay with their child to look after and comfort them during and after most procedures. If your child asks about the procedures being done, reassure them and explain in simple terms what is being done and why. Always tell the truth.

At times it is helpful to tell stories, talk about the family or anything else that may help to take their mind off the procedure. Remain calm; if you get upset so will your child. The staff is there to help you and your child. If you would like more information please ask the nurse or doctor caring for your child.

Child Life Specialists
A Child Life Specialist is trained in helping children and families to cope effectively with procedures while in the hospital. The CCLS will provide age appropriate teaching of procedures using medical dolls and age appropriate language to help the child to understand what will be happening during their stay. They will also provide distraction using toys, bubbles, soft music, and deep breathing throughout any procedures to keep their mind off of what the child may be going through.

Appendix I: Proposed Parent Education Brochure

Nitrous Oxide

Child Life Specialists

A Child Life Specialist is avalable to help your child stay comfortable during the procedure. The Child Life Specialist will provide age appropriate teaching of procedures using medical dolls and age appropriate language to help the child to understand what will be happening during their stay. They will also provide distraction using toys, bubbles, soft music, and deep breathing throughout any procedures to keep their mind off of what the child may be going through.

Questions

Be sure to ask your provider any questions or share concerns you may have about nitrous oxide sedation.

HSHS St. Vincent Children's Hospital
835 S. Van Buren
Green Bay, WI 54307
(920) 433-0111
www.stvincenthospital.org

Nitrous Oxide

What is Nitrous Oxide?

You may know nitrous oxide as "laughng gas" or "happy gas". It is a sweet smalling colorless gas used to ease pain and anxiety.

The gas is safe for use in children and there are no long term side effects.

How Can it Help Your Child?

The gas helps to ease pain and anxiety your child may feel, but usually does not make them completely fall asleep during the procedure.

When your child starts to breathe the nitrous oxide, they will feel drowsy within a few minutes. The gas is continued until the procedure is completed and then the gas is turned off. It wears off quickly and your child can return to their usual activities

How is it given?

Nitrous Oxide is given through a mask by your doctor. The gas is given for a few minutes before the procedure starts. It will make your child feel "floaty", warm, and tingly. Your child may not remember anything about the procedure.

Special Instructions

You should not to give your child any food or drinks in the 2 hours before the scheduled procedure.

Are There Any Risks?

Some children may feel sick or vomit during nitrous oxide sedation. The staff looking after your child will manage the side effects if they occur. Other side effects may occur, but are usually minor and resolve when the gas is turned off.

Your child may not like having the mask on their face. They may feel angry or confused by the mask and gas. You may need to stay close and comfort them when the gas is started.

Appendix J: N_2O Equipment Quote

PRAXAIR
HEALTHCARE SERVICES

QUOTATION FOR PORTER SENTRY SEDATE

Part Number	Description	Qty	Suggested Retail Price	Hospital Price	Total Price
Demand Flow System					
PAK SENTRY H34-AV	Porter Sentry Sedate MXR-1 Analog – Hospital Package	1	$9,750.00	$8,500.00	$8,500.00
Accessories					
PAK80010	O2 Hose – DISS/DISS Connect – 10ft	1	$231.00	$231.00	$231.00
PAK 5602-DISSVAC	Vacuum Quick Connect, DISS	1	$112.00	$112.00	$112.00
PAKA-3399-000	Replacement yoke washers	4	$2.00	$2.00	$8.00
Disposables					
PAKSACA120	Small Adult Full Facemask Breathing Circuit (box of 10)	2	$465.00	$290.00	$580.00
PAKPDCA130	Pediatric Full Facemask Breathing Circuit (box of 10)	2	$465.00	$290.00	$580.00
PAKYMCA140	Youth Medium Full Facemask Breathing Circuit (box of 10)	2	$465.00	$290.00	$580.00

Total Price Before Discount	$12,891.00
Total Price AFTER discount	**$10,591.00**
Savings	$2,300.00 18%

Comments:

Quotation Valid for 30 days
Shipping and applicable taxes will be added to all orders
Subject to Praxair's standard terms and conditions

Appendix K: Institutional Review Board Approval

Walden University granted Institutional Review Board (IRB) approval of the project on March 18, 2016. HSHS St. Vincent Hospital also granted approval of the project on April 11, 2016 (Appendix L). The IRB determined the project does not include the types of activities that require a traditional IRB review. This Confirmation of Ethical Standards (CES) has provided an IRB record number of 03-18-16-0302207.

Appendix L: IRB Approval HSHS St. Vincent Hospital

HSHS St. Vincent Hospital

Heidi Warpinski
HSHS St. Vincent Hospital
835 South Van Buren Street
Green Bay, WI 54301

RE: IRB16-01: Development of a Program Proposal for a Nitrous Oxide Program in Pediatrics

The Director of the HSHS St. Vincent Hospital Cancer Research Institute reviewed the above referenced study. The proposed activities were reviewed and approved in accordance with the federal definitions of "human subjects research". It has been determined that the proposed activities do not intend to conduct a systematic investigation pursuant to contribute to generalizable knowledge.

The following documents have been reviewed:

- Nitrous Oxide Proposal (January 5, 2016)
- Letter for Program Development (Signed February 14, 2016)
- Email from Walden University IRB (Dated March 18, 2016)

As currently constituted, the proposed activities do not warrant submission to the HSHS St. Vincent Hospital Institutional Review Board (IRB). **However, if there are any changes, it is possible that such changes will warrant official IRB Review. Please inform the IRB as soon as any changes are made to the proposed activities.** Furthermore, there will not be any annual follow-up, unless future changes to the proposed activities warrant.

Please maintain a copy of this letter in your files until they are destroyed.

Signed: Christina L Gilchrist **Date:** 4/11/16

Christina L. Gilchrist, PhD, CRA
Director, Clinical Programs
Cancer Research Institute

Cc: Sarah Oleson