Final Order No. DOH-13-2181-DS -MQA

FILED DATE - NOV 08 2013
Department of Health
By: Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF NURSING

IN RE: THE PETITION
FOR DECLARATORY
STATEMENT OF
LESLIE A. MELLIN, RN
_____/

FINAL ORDER

THIS CAUSE came before the Board of Nursing (hereinafter Board) pursuant to §120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code, at a duly-noticed meeting in Naples, Florida on October 3, 2013, for the purpose of considering the Petition for Declaratory Statement (attached as Exhibit A) filed on behalf of LESLIE A. MELLIN, RN (hereinafter Petitioner). Having considered the petition, the arguments submitted by counsel for Petitioner, and being otherwise fully advised in the premises, the Board makes the following findings and conclusions.

FINDINGS OF FACT

1. This petition was noticed by the Board in Vol. 39, No. 147, dated July 30, 2013 of the Florida Administrative Weekly.

2. Petitioner, LESLIE A. MELLIN, RN, is an nurse licensed to practice in the State of Florida. Petitioner did not supply her license number.

3. Petitioner is employed at St. Joseph's Children's Hospital in an outpatient unit.

4. The hospital is instituting a Nitrous-Oxide Program in the outpatient unit.

5. The hospital proposes to assign to registered nurses the initiation, administration and discontinuance of the Nitrous Oxide for identified procedures.

CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter pursuant to Section 120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code.

2. The petition filed in this cause is not in substantial compliance with the provisions of Section 120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code.

3. Section 120.565 provides for the issuance of declaratory statements to a substantially affected person regarding the applicability of a rule or statute to the *petitioner's particular set of circumstances.*

4. A declaratory statement may not take the place of a rule of general applicability to all licensees, and may not be issued concerning the proposed actions of persons other than the petitioner.

WHEREFORE, the Board hereby dismisses the petition for declaratory statement of Petitioner LESLIE A. MELLIN, RN.

DONE AND ORDERED this 1st day of May, 2013.

BOARD OF NURSING

Joe R. Baker, Jr., Executive Director
for Lavign Ann Kirkpatrick, BS, RN
Chair

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order

has been furnished by U.S. Mail to Petitioner LESLIE A. MELLIN, RN, St. Joseph's Children's Hospital, 3001 W. Dr. Martin Luther King Jr. Blvd, Tampa FL 33607 and by interoffice mail to Michele Bass, Paralegal Specialist, Department of Legal Affairs, PL-01 The Capitol, Tallahassee FL 32399-1050, this 8th day of November , 2013.

Angel Sanders

Deputy Agency Clerk

7012 3050 0001 9149 7559

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CLERK *Angel Sanders*
DATE JUN 10 2013

To: Department of Health's Agency Clerk's Office
4052 Bald Cypress Way
Bin # A02
Tallahassee, Fl 32399-1703

From: Leslie A. Mellin, RN
St. Joseph's Children's Hospital - Day Hospital
3001 W. Dr. Martin Luther King Jr. Blvd
Tampa, Fl 33607

Re: Petition for Declaratory Statement before the Florida Board of Nursing

A declaratory statement based on:

1. Rule # 64B9-8.005:

    a. States that a Registered Nurse may administer prescribed pharmacologic agents to mechanically ventilated and non-mechanically ventilated patients for the purpose of moderate sedation in anticipation of anxiety and or discomfort during a time-limited surgical, diagnostic or therapeutic procedure.

2. Rules # 64B5-14.001 – 14.004: Nitrous Oxide inhalation analgesia

    a. The administration by inhalation of a combination of nitrous-oxide and oxygen producing an altered level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command.

    b. The only agents that can be used for inhalation analgesia pursuant to Rule 64B5-14.003, below are nitrous- oxide and oxygen.

    c. A dentist may employ or use nitrous-oxide analgesia on an outpatient basis for dental patients provided such dentist:
        i. Has completed no less than a two-day course of training as described in the American Dental Association, "Guidelines for Teaching and Comprehensive Control of Pain and Anxiety in Dentistry."
        ii. Equipment with fail-safe features and a 25% minimum oxygen flow.

1701-172575

June 3, 2013

To Whom It May Concern,

I am a Registered Nurse at St. Joseph's Children's Hospital in Tampa, Florida. I work in an 11 bed outpatient unit that performs a variety of specialized, complex procedures and services. Some of the services we provide are as follows:

Voiding Cystourethrograms, Botox injections for patients' with Cerebral Palsy, sedated MRI's, sedated Echocardiograms, sedated EEG's, extensive hearing tests, sedated Lumbar Punctures for CSF and Intrathecal Chemo Administration, Growth Hormone Testing, Chemo and Chemo-like drug Infusions

Our hospital strives endlessly to provide a pain-free experience for our patients. In accordance with our pain-free mission, we are in the process of instituting a Nitrous-Oxide Program in our specialized outpatient unit. Currently, most of the services we provide require sedation. At present, our only means of providing moderate/deep sedation is through intravenous administration. Our goal is to be able to utilize Nitrous-Oxide, when deemed medically appropriate, to provide sedation with the benefit of a shorter recovery period. In doing so, the patient and parents benefit from a shorter hospital visit and return to their regular duties in a more expeditious, but safe manner.

Our Nitrous-Oxide Program will be Physician driven. The Physician will start the Nitrous-Oxide and establish the appropriate level. The credentialed Registered Nurse will monitor the administration and turn off at the completion of the procedure (Rule 64B5-14.004).

Our overall objective is to have a nurse- driven Nitrous-Oxide Program. The Physician would complete a patient assessment, prior to the procedure, and write the order for Nitrous administration. Subsequently, the credentialed Registered Nurse would initiate, administer and turn off the Nitrous-Oxide for the required procedure.

My question to the State Florida Board of Nursing is as follows:

May a qualified and sedation credentialed Registered Nurse administer Nitrous-Oxide once a sedation credentialed Physician has evaluated and placed an order for sedation using Nitrous-Oxide?

I have included an appendix that details our program and a copy of our Proposal to our facility.

I thank you for your time in reviewing this matter. I look forward to your expertise guidance and position regarding my petition.

Sincerely,

Leslie Mellin, RN
Leslie.mellin@baycare.org

Nitrous Oxide Overview

Nitrous oxide is a sweet-smelling, colorless gas that has provided mild sedative anxiolytic, analgesic and amnestic capabilities for over 160 years. The purpose of administering nitrous oxide is to produce an altered level of consciousness that retains the patient's ability to independently and continuously maintain their airway and respond appropriately to physical stimulation or verbal command.

Upon administration, clinical effects may be seen in less than 30 seconds, with peak effects usually occurring in less than 5 minutes. (Clark and Brunick, 2008-3rd Edition, Handbook for Nitrous Oxide and Oxygen Sedation) In addition, nitrous oxide can be easily titrated to an individual patient's need, outcome and response. Finally, nitrous has a rapid recovery time of 5 minutes (up to 10 minutes) when 100% 02 is administered during recovery.

Nitrous oxide is quickly eliminated in the lungs. It is not metabolized, therefore reducing any potential risks/difficulties with any drug interactions. Mild side effects that may indicate the need for a longer recovery period include lethargy, dizziness, confusion, headache and nausea.

Nitrous Oxide	Oral/IV Sedation
-rapid onset in less than 30 seconds	-onset is from 1-10 minutes (depending on drug)
-ability to titrate to desired effect	-inability to easily titrate
-minimal side effects	-risk of aspiration, respiratory depression/hypoxia and hypotension
-able to provide analgesic properties	-no analgesic properties
-painless administration	-IV administration requires a painful injection
-not metabolized	-metabolized by the liver
-rapid recovery in 5-10 minutes	-recovery time is 30-60+ minutes

General Indications for use in Pediatrics (our indications/purposes will be in **bold**)

IV start
PICC insertion
Botox injection
Voiding Cystourethrograms
Echocardiogram
EEG with/without long term monitoring application
ABR (2-3 hour extensive-sedated hearing tests)/BAER
Incision and drainage/dressing
Lab Draws
VEP
Laceration suturing
Joint Injections
Wound Debridement
Reduction of fracture/dislocations
Foreign body removal
Removal of cast/sutures
MRI/CT
Lumbar puncture
Gastrostomy tube change
Nasogastric tube insertion
Barium enema

Multidisciplinary Professional Workgroup

Anesthesia
Sedation credentialed Physicians (procedural and ER)
Nursing Administration (Director and Manager)
Nurse Practitioner
Education Specialist
Members of St. Joseph's Children's Hospital Pain Committee
Nursing (team members from procedural area)
Child Life Specialists
BioMedical/Engineering

Education and Training

In-Hospital Sedation Credentialing: Sedation and Analgesia by Non-Anesthesiologists 2012 (DVD) and post-test.

Nitrous Oxide Psycho-sedation: 2 day certification course.

Annual sedation competency for nurses

Complete and maintain a minimum of 4 hours of continuing education related to sedation every 2 years

ACLS (Advanced Cardiac Life Support)

PALS (Pediatric Advanced Life Support)

BLS (Basic Life Support)

Equipment and Regulatory Overview

Porter MXR E Stand Package: (Dental Portable System) BioMed has assisted in choosing the best and safest delivery system that meets hospital safety requirements and our delivery needs.

Nitrous Oxide Administration Policy in development (please see proposal document).

Nitrous Oxide Gas:	Portable e-cylinder to be managed and delivered by the Respiratory Therapy Department and gas will be ordered from Airgas.
Scavenging system:	BioMed has given their safety requirements and recommendations. Safety, Anesthesia Gas Scavenging Policy in place (please see proposal document).
Monitoring equipment:	This equipment is already in place due to current services that require oral and IV sedation.

Safety checks:

- •Nitrous oxide administration checklist.
- •Weekly scavenging checks from BioMed.
- •National Institute for Occupational Safety and Health.
- •Pregnant team members will not be present during administration and recovery.
- •Nitrous Oxide Order set in development.

Suction and Emergency Resuscitation Equipment:
This equipment is already in place due to current services that require oral and IV sedation.

Nitrous Oxide Administration Statistics

Safely used for over 160 years

Successful nurse-administered programs in Minnesota, Arizona, Oregon, Texas, Missouri, England and Australia.

Case Studies:

- •"A randomized clinical trial of continuous flow nitrous oxide and midazolam for sedation of young children during laceration repair." (Luhmann, Kennedy, Porter, Miller and Jaffe, Annals of Emergency Medicine, 37:1, January 2001). 204 pediatric patients were enrolled trialing the best sedative agents: midazolam with nitrous oxide, midazolam alone, nitrous oxide alone, lidocaine injection alone. The study concluded that patients that received nitrous oxide (alone or with midazolam) were found to have reduced distress and had fewer adverse effects and shorter recovery times than midazolam alone. (Please refer to Exhibit 1)

- •"Level of sedation with nitrous oxide for pediatric medical procedures." (Zier, Tarrago and Liu, Anesthesia & Analgesia, May 2010 vol. 110 no. 5 1399-1405). 1585 patients (younger than 18) were administered nitrous oxide with varying concentration levels to determine if there were any differences in the level of sedation and adverse effects related to the concentration. The study concluded that patients receiving a nitrous oxide concentration > 50% did not experience an increase in sedative or adverse effects. (Please refer to Exhibit 2)

- •"High-concentration nitrous oxide for procedural sedation in children: adverse events and depth of sedation." (Babl, Oakley, Seaman, Barnett and Sharwood, Pediatrics Digest, Vol. 121, No. 3, March1, 2008, p e528-e532). 762 pediatric patients (age 1 to 17 years) received nitrous oxide and different concentrations to record and examine any correlation between nitrous oxide concentration, adverse events, and depth of sedation. The study concluded that a high concentration (70 %) of nitrous oxide was found to be safe for procedural sedation and analgesia when administered within the safety parameters of a sedation program. (Please refer to Exhibit 3)

- •"Case-series of nurse-administered nitrous oxide for urinary catheterization in children." (Zier, Drake, McCormick, Clinch and Cornfield, Anesthesia & Analgesia, April 2007, Vol. 104, No. 4, p876-879). Nitrous oxide was administered on 1018 occasions to evaluate the safety of nurse-administered nitrous oxide for children sedated for urethral catheterization for urologic imaging. The study concluded that nitrous oxide sedation can be provided by a nurse-administered program for pediatric radiological exams and found that it may increase patient's access to this particular type of sedation and analgesic effect. (Please refer to Exhibit 4)

- "Nitrous oxide inhalation is a safe and effective way to facilitate procedures in pediatric outpatient departments." (Ekbom, Jakobsson and Marcus, Archives of Diseases in Childhood, January 2005, p 1073-1076). The study comprised of 70 children (ages 6-18) to evaluate the efficacy and safety of nitrous oxide in children for procedures in a pediatric outpatient department. The study concluded that the administration of nitrous oxide was a time effective and safe method for use in a pediatric outpatient setting to reduce pain, facilitate venous cannulation and subsequently reduced the number of costly procedures that were cancelled. (Please refer to Exhibit 5)

- "Nurse administered relative analgesia using high concentration nitrous oxide to facilitate minor procedures in children in an emergency department." (Frampton, Browne, Lam, Cooper and Lane, EMJOnline, May 22nd, 2003). The study collected data over a 12 month period to be able to describe the useage of high concentration nitrous oxide administered by nursing staff in children undergoing minor procedures in the emergency department. They collected and examined 224 cases in the 12 month period. The results of the study showed that nitrous oxide is a safe analgesic in children over the age of 1year undergoing painful or stressful procedures in their department. They concluded that a nitrous concentration of up to 70% was safely administered by nursing staff after appropriate training. (Please refer to Exhibit 6)

Quality Measurement Data and Tools (Please refer to Exhibit 7)

We will utilize a quality data collection tool to monitor, track and analyze positive and adverse effects, and usage. Data will be shared during appropriate hospital and departmental level meetings and during hospital Quality events and meetings as well.

Exhibit 1

A Randomized Clinical Trial of Continuous-Flow Nitrous Oxide and Midazolam for Sedation of Young Children During Laceration Repair

Jan D. Luhmann, MD*†
Robert M. Kennedy, MD*‡
Fran Lang Porter, PhD*‖
J. Philip Miller, AB§
David M. Jaffe, MD*‡

From the Division of Emergency Medicine, the Department of Psychology,† and the Division of Biostatistics,§ Washington University School of Medicine, and St. Louis Children's Hospital,‡ St. Louis, MO.*

Received for publication July 26, 1999. Revisions received March 27, 2000, July 27, 2000, and August 22, 2000. Accepted for publication September 29, 2000.

Presented at the Pediatric Academic Societies' annual meeting, New Orleans, LA, May 1998, and at the Society for Academic Emergency Medicine annual meeting, Chicago, IL, May 1998.

Address for reprints: *Jan D. Luhmann, MD, St. Louis Children's Hospital, One Children's Place, Room 4S50, St. Louis, MO 63110; 314-454-2341, fax 314-454-4345; E-mail luhmann_j@kids.wustl.edu.*

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47:1:112003
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See editorial, p. 61.

Study objective: To compare the efficacy and complication profile of oral midazolam therapy and continuous-flow 50% nitrous oxide in alleviating anxiety during laceration repair in children 2 to 6 years old.

Methods: We conducted a prospective, randomized clinical trial using 4 study groups who required laceration repair: (1) children who received standard care alone, which included comforting and topical anesthesia augmented with injected lidocaine if needed; (2) children who received standard care and oral midazolam; (3) children who received standard care and nitrous oxide; and (4) children who received standard care, oral midazolam, and nitrous oxide. Videotapes were blindly scored using the Observational Scale of Behavioral Distress-Revised (OSBD-R) to assess distress during baseline, wound cleaning, lidocaine injecting, suturing, and recovery. Adverse effects were noted during suturing and by parent questionnaires completed 24 hours after suturing and at suture removal. OSBD-R data were analyzed using repeated-measures analysis of variance. Adverse effect data were analyzed using categorical models.

Results: Two hundred four subjects were enrolled (midazolam plus nitrous oxide 52, midazolam 51, nitrous oxide 51, standard care 50; mean patient age was 4.1 years; 66% were boys). Mean OSBD-R scores were lower for groups that received nitrous oxide during wound cleaning by 2.2 points (95% confidence interval [CI] 1.1 to 3.2), lidocaine injecting by 2.5 points (95% CI 1.4 to 3.5), and suturing by 2.9 (95% CI 1.8 to 3.9). Adverse effects occurred more frequently, and recovery times were longer for groups that received midazolam.

Conclusion: For facial suturing in 2- to 6-year-old children, regimens including continuous-flow nitrous oxide were more effective in reducing distress, and had fewer adverse effects and shorter recovery times than midazolam.

[Luhmann JD, Kennedy RM, Porter FL, Miller JP, Jaffe DM. A randomized clinical trial of continuous-flow nitrous oxide and midazolam for sedation of young children during laceration repair. *Ann Emerg Med.* January 2001;37:20-27.]

INTRODUCTION

Lacerations requiring sutures contribute to as many as half of emergency department visits by injured children.[1] Even with the availability of tissue adhesives, many still require suturing. Successful management in the ED requires effective relief of pain and anxiety as these visits are often stressful for the patient, parent, and health care worker. Advances in analgesic regimens such as the use of topical and buffered injected anesthetics can make suturing almost painless.[2-4] However, anxiety during both wound preparation and suturing continues to be a significant problem, especially among young children and their parents.

Many agents for pharmacologic sedation during suturing in children have been studied.[5-12] Desirable characteristics include nonpainful routes of administration, predictable and titratable effects, lack of significant adverse effects, and rapid onset and recovery. Oral midazolam and inhaled nitrous oxide (N_2O) are 2 agents that meet most of these criteria and have commonly been used for outpatient procedures.[5-8,13-17] The purpose of this study was to compare the efficacy and complication profile of midazolam and continuous-flow N_2O in alleviating anxiety during laceration repair in young children. Our primary study hypotheses were (1) N_2O would produce more effective sedation than midazolam or standard care during wound preparation and suturing, and (2) differences in adverse effects between groups related to the known mechanisms of action would occur. In addition, our secondary hypotheses were (1) patients receiving N_2O would recover more rapidly from sedation than patients receiving midazolam, and (2) suturers would be more satisfied with N_2O sedations compared with midazolam or standard care.

MATERIALS AND METHODS

To compare the efficacy and complication profile of midazolam and continuous-flow N_2O, the following 4 treatment groups were defined: standard care alone, which includes comforting and topical anesthesia augmented with injected lidocaine if needed; standard care and oral midazolam; standard care and N_2O; and standard care and oral midazolam plus nitrous oxide. Children ages 2 through 6 years who presented to the ED at St. Louis Children's Hospital for repair of facial lacerations and met the American Society of Anesthesiologists (ASA) class I or II criteria[18] were invited to participate in the study between July 1, 1996, and September 1, 1997. Exclusion criteria were previous laceration repair; solid or liquid oral intake within 2 hours of evaluation[19]; abnormalities of airway, cardiac, hepatic, renal, or central nervous systems; bowel obstruction; otitis media; history of adverse reaction to the study drugs; or lacerations that would inhibit use of the mask for N_2O delivery (eg, nasal lacerations). Demographic data were recorded for patients who were eligible but not enrolled. Informed written consent was obtained from parents by the emergency physician before randomization. Research protocol, study design, and consent forms were approved by the institutional review board at Washington University School of Medicine.

Subjects were randomly assigned in blocks of 20 to receive standard care; standard care and oral midazolam; standard care and N_2O; or standard care, oral midazolam, and N_2O. Randomization sequences were predetermined by a random number generator and maintained in sealed envelopes until consent was obtained. For subject safety and because study medication delivery is easily distinguishable, physicians performing sedation were not blinded to the study regimens. Suturing and recovery were performed in an ED treatment room equipped for monitoring, resuscitation, and audiovisual recording.

Before and throughout sedation, levels of consciousness (A=alert, V=responsive to voice, P=responsive to pain, U=unresponsive),[20] heart rate, respiratory rate, blood pressure, and oxygen saturation were monitored continuously in all patients, and end-tidal N_2O levels were monitored continuously in the patients who received N_2O and both oral midazolam and N_2O using a Spacelabs model PC-2 monitor (Spacelabs Medical, Redmond, WA) and documented by the nurse at 5-minute intervals. After suturing, when cardiopulmonary functions were determined to be stable and adequate, documentation intervals were increased to 10 minutes until discharge. Also documented were subject age, weight, sex, race; location of laceration; ASA classification; allergies; time of last oral intake and presedation medications; study medication doses and administration times; and descriptions and times of adverse effects and interventions. Criteria for discharge were normal cardiopulmonary function, return to presedation level of responsiveness, and ability to talk, sit unaided, or walk with minimal assistance.[20] Recovery time was defined as

the time of placement of the last suture to the time of discharge.

All study medications were administered by 14 attending or fellow emergency physicians familiar with the medications and protocol. Sedators directly observed subjects throughout the procedure and until adequate cardiopulmonary functions were verified during recovery. Registered nurses remained with subjects throughout the procedure and recovery periods.

All patients received standard care, which included a topical anesthetic combination of lidocaine, epinephrine, tetracaine (LET),[2] supplemented after 20 minutes by injected buffered lidocaine[3,4] using a 30-gauge needle if needed as determined by the suturing physician. Parents or emergency staff provided age-appropriate comforting techniques, such as watching videotapes or reading books. Patients who received oral midazolam were given 0.5 mg/kg (maximum dose of 20 mg based on current practice in our institution) 20 minutes before suturing.[21,22] Patients who received N_2O were given a mixture of 50% N_2O/50% O_2 through a nasal mask just before wound preparation.

A customized continuous-circuit apparatus allowed continuous delivery of N_2O by emergency physicians, who were not involved with suturing.[23] This apparatus delivers a continuous flow of N_2O and is equipped with a valve that prohibits administration of N_2O flow unless oxygen delivery is at least 30% and has a scavenging system to minimize escaped gas exposure in health care personnel. An appropriately sized clear, disposable, cushioned nose mask scented with bubble gum, elbow connector with a gas sampling line, and a disposable Humidivent HME (heat moisture exchanger) filter (Airflow Developments Ltd, Buckinghamshire, England) to conserve exhaled heat and humidity and serve as a bacterial/viral filter[24] were connected to the respiratory circuit. A sidestream gas analyzer and Spacelabs Medical capnograph (model 90513) were used to measure O_2 and N_2O levels. The gas flow meter was set from 6 to 10 L/min and after achieving mask acceptance, the blender was dialed to 50% N_2O. The circuit and tanks were checked for proper functioning before each use. Routine room air sampling by the Environmental Safety department confirmed levels to be within standards established by the Occupational Safety and Health Administration.[25]

The primary outcome measure for efficacy was the Observational Scale of Behavioral Distress-Revised (OSBD-R),[26,27] which was scored from videotapes made during laceration repair. After informed consent was obtained, videotaping of subjects began and continued until discharge. The OSBD-R has been validated during procedures for children of ages within our sample range.[26] The presence of each of 8 behaviors (information seeking, cry, scream, restraint, verbal resistance, emotional support, verbal pain, and flail) was noted continuously every 15 seconds during the following intervals: baseline (3 minutes before intervention); local anesthetic injection, if needed; cleaning; suturing; and recovery. OSBD-R scores range from 0 to 23.5 per interval and higher scores indicate greater distress. Fifteen-second scores for each category were compiled, averaged, and weighted in a standard manner.[26] One of 2 trained observers who were blinded to study purpose and design scored the videotape of each subject. The scorers were not health care professionals and were instructed that various equipment and monitoring were being evaluated. Interrater reliability for each behavior of the OSBD-R was assessed by 2 trained observers before scoring study videotapes and midway during the scoring process.

Secondary outcome measures were visual analog scale (VAS) ratings completed by suturers. At the completion of suturing, suturers completed a 10-point VAS questionnaire to rate satisfaction with the sedation. The endpoints were "not satisfied" and "highly satisfied," with higher scores indicating greater satisfaction.

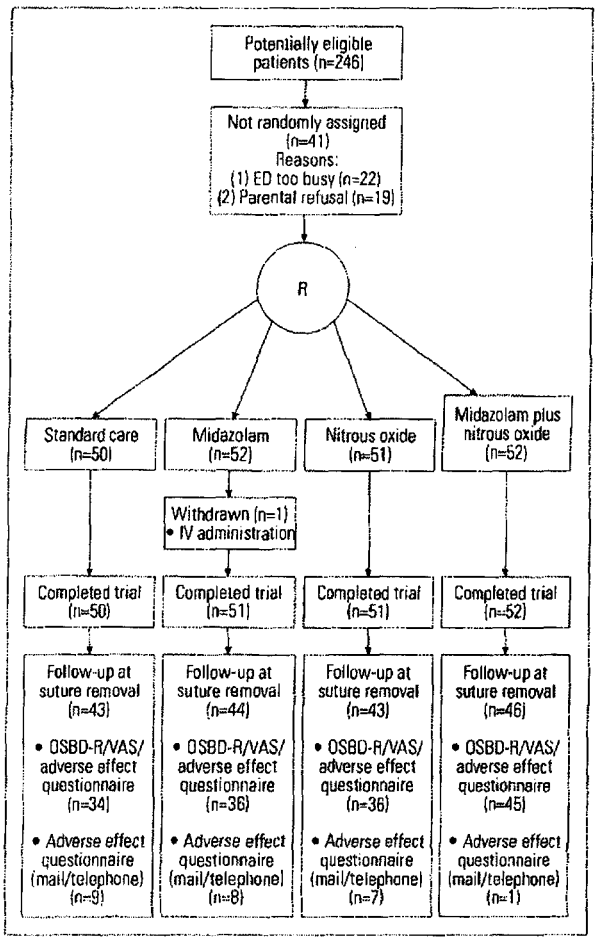
Primary outcome measures for adverse events were abnormalities in cardiopulmonary function as measured by oxygen saturation less than 93%, alterations in heart rate and blood pressure of more than 15% from baseline, clinical signs of hypoperfusion (eg, diminished peripheral pulses, cool and pale distal extremities, or delayed capillary refill), or need for supportive care, such as supplemental oxygen or positive-pressure ventilation.[28] Secondary measures of adverse events were frequency of adverse events, including vomiting, during sedation and recovery. Oversedation was defined as a level of consciousness of U (unresponsive) based on the nursing score. Parents completed questionnaires regarding adverse effects 1 day after suturing and at the time of suture removal. Parents who did not return to our institution for suture removal returned questionnaires by mail or were contacted by telephone.

Calculations of the anticipated power for the study were based on estimates of means and SDs. Assuming that the population mean OSBD-R was 1.75±1.85 OSBD units[26] with a power of 0.80 and α of .05, a change in the mean of 1.05 OSBD units could be detected by a t test with a sample of 50 children in each treatment group. Because no cardiopulmonary adverse effects associated with the use of 50% N_2O in large numbers of children

have been published, we did not conduct a formal power analysis for adverse effects and chose to evaluate comparative complication profiles of standard care with either oral midazolam or N_2O.

Descriptive statistics were used to examine the demographic data (sex, age, race, ASA class, laceration length, and number of sutures). Primary data analysis for efficacy compared mean OSBD-R scores for the 4 treatment groups using a repeated-measures analysis of variance (ANOVA) with oral midazolam and N_2O as the between-subjects factors. Suturer satisfaction scores and recovery times were also compared as a function of group assignment with 2-way ANOVA. Cardiorespiratory and other adverse effects were compared using an analogous categorical model using the weighted least square solution. Odds ratios and 95% confidence intervals (CIs) were computed from the estimated effects. All statistical analyses were performed using SAS software (version 8.0, SAS Institute, Inc, Cary, NC, 1996) with a value of P less than .05 as the criterion for statistical significance.

Figure 1.
Participant flow chart.



RESULTS

Two hundred five subjects (83% of eligible) were enrolled in the study (Figure 1). Patients eligible but not enrolled were similar to those enrolled in terms of age, sex, race, and laceration length. One subject enrolled was given midazolam intravenously and was excluded from analysis because of protocol violation. The mean patient age was 4.1 years; 66% were boys; 66% were black; and 92% were in ASA class I. There were no differences in age, sex, race, ASA classification, laceration length, or number of sutures between the groups (Table 1).

Mean OSBD-R scores were significantly lower for the groups that received N_2O during injecting lidocaine, cleaning, and suturing (Table 2, Figure 2). Although there was no similar systematic effect for midazolam, there were significant interactions for these periods. The general pattern of this interaction was for the midazolam group to have lower OSBD-R scores than the standard care group, but for the midazolam plus N_2O group to have no advan-

Table 1.
Subject characteristics.

Variable	Standard Care	Midazolam	N_2O	Midazolam+ N_2O
No.	50	51	51	52
Age, y (mean±SD)	4.0±1.4	4.2±1.4	4.2±1.4	4.0±1.4
Male sex, No. (%)	33 (66)	33 (65)	35 (69)	34 (65)
Race, No. (%)				
Black	35 (70)	37 (73)	34 (67)	29 (56)
White	15 (30)	14 (27)	17 (37)	23 (44)
ASA class, No. (%)				
I	46 (92)	44 (86)	47 (92)	50 (96)
II	4 (8)	7 (14)	4 (8)	2 (4)
Laceration				
Length (cm, mean±SD)*	1.5±0.9	1.7±1	1.5±0.9	1.5±0.7
No. of sutures (mean±SD)	5±3	6±3	5±2	5±2
Baseline OSBD-R score (mean±SD)	0.3±0.1	0.1±0.3	0.3±0.8	0.2±0.9

tage over the N_2O alone group. κ Coefficients of OSBD-R behaviors ranged from 0.66 (information seeking) to 1.0 (flail) on a sample of 5 randomly selected tapes at the midway point. Mean recovery times were longer for groups that received midazolam (Table 2), and suturer satisfaction VAS scores were higher for groups that received N_2O compared with midazolam (Table 2, Figure 3).

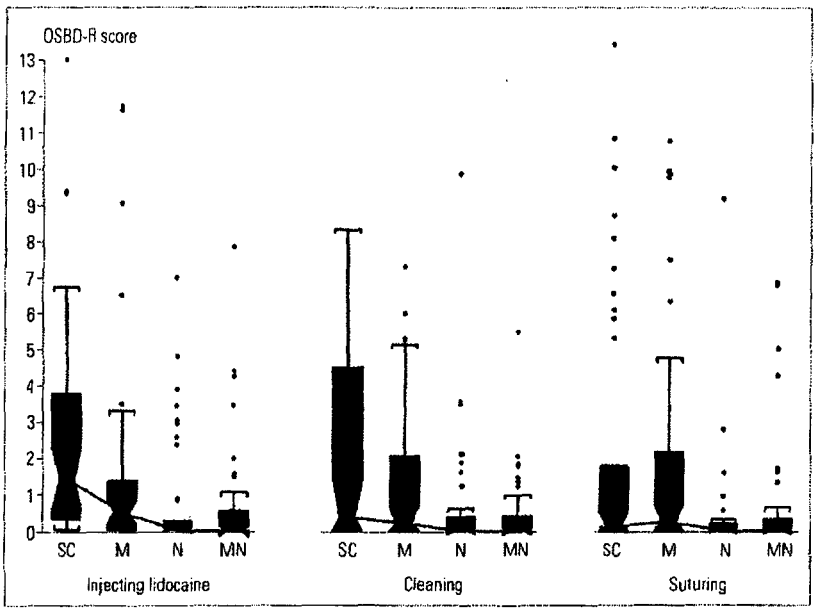
No cardiorespiratory adverse events including hypotension, hypertension, hypoperfusion, and hypoxia occurred in any subject at any time. No patient was

Table 2.
Analysis of variance tables.

	Least Square Means				*P* Value		
Period	**M**	**MN**	**N**	**SC**	**M**	**N**	**MN**
OSBD scores*							
Baseline	0.1	0.2	0.3	0.33	(.63)	.86	(.73)
Inject lidocaine	1.5	0.7	0.7	2.4	(.09)	.0001	(.0001)
Cleaning	1.2	0.4	0.6	2.0	(.04)	.0001	(.001)
Suturing	1.9	0.7	0.4	2.0	(.63)	.0001	(.01)
Recovery	0.1	0.6	0.3	0.3	(.86)	.48	(.71)
Suturer satisfaction†	7.5	8.0	8.2	6.6	(.41)	.02	(.22)
Recovery time (min)‡	30	28	21	20	(.01)	.90	(.63)

M, Midazolam; **MN**, midazolam and N_2O; **N**, N_2O; **SC**, standard care.
*Contrasts extracted from a repeated-measures ANOVA with tests of M, N, and their interaction (MN) done for each period. The pooled estimate of the within-cell SD was 1.58.
†From a simple 2-way ANOVA. The pooled within-cell SD for the Suturer Satisfaction VAS was 3.04.
‡The analysis of recovery time was done with a square root transformation because of a highly skewed distribution and then the least square means were back-transformed. The pooled within-cell SD (on the square root scale) was 2.38.

Figure 2.
OSBD-R intervals. SC, Standard care; M, midazolam; N, N_2O; MN, midazolam and N_2O.



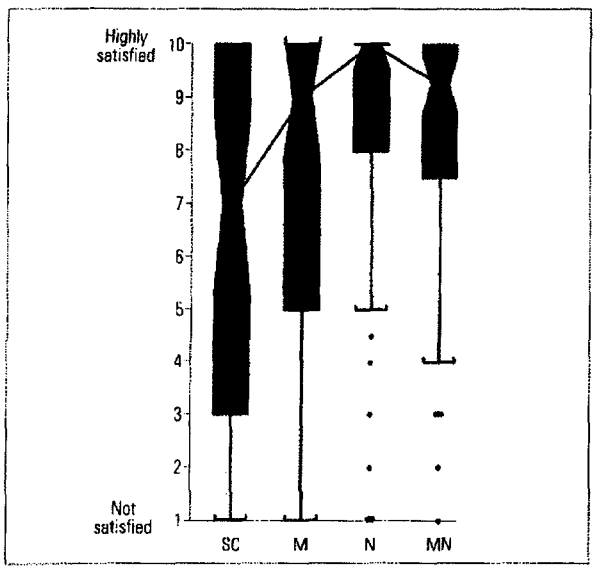
determined to be unresponsive, and the deepest level of consciousness observed in each group was as follows: standard care alone (A=50); standard care and oral midazolam (A=39, V=13); standard care and N_2O (A=14, V=34, P=3); standard care, midazolam, and N_2O (A=12, V=35, P=5).

Adverse effect questionnaires were completed in 176 (86%) of children. Parents of the 25 of 53 children who did not return for suture removal completed the questionnaire by mail or telephone. Children who received midazolam were more likely to have adverse events up to 24 hours after suturing, including ataxia, dizziness, difficulty walking, and crying more than usual (Table 3). Adverse events were not reported in any group at the time of suture removal.

Vomiting occurred in 6 children who received N_2O (standard care and N_2O 5; standard care, oral midazolam, and N_2O 1; Table 3). Three patients vomited during suturing and 3 after the last suture was placed but before oral intake. In the 3 children who vomited during suturing, the oropharynx was suctioned while the nasal mask was maintained; however, the N_2O administration was terminated and 100% oxygen was given for 1 to 3 minutes or until the end-tidal N_2O level was zero. The 3 patients who vomited during sedation were described as responsive to voice, and the 3 who vomited during recovery were alert. No clinically apparent aspiration occurred, and there were no reports of respiratory symptoms at 1 day and suture removal follow-up.

Two of the 3 patients in whom treatment failed were in the midazolam group. The other patient was randomly assigned to the standard care group. There was no difference in baseline OSBD-R scores for these patients compared with others. In addition, 2 patients in the midazolam group had inconsolable agitation consisting of loud crying, emotional lability, and resistance to comforting by parents during suturing, requiring recovery in the ED for 3 and 5 hours. Thirteen patients (5 standard care; 2 standard care and midazolam; 3 standard care and N_2O; 3 standard care, midazolam, and N_2O) were restrained at the discretion of the suturer with a papoose board. There was no difference in group assignment or baseline OSBD-R scores according to whether children were restrained.

Figure 3.
Suturer satisfaction. SC, Standard care; M, midazolam; N, N_2O; MN, midazolam and N_2O.



DISCUSSION

This study demonstrates that in our sample, continuous-flow 50% N_2O is more effective for relief of anxiety in young children during wound preparation and suturing, has fewer adverse effects, and shorter recovery times than oral midazolam. Although vomiting occurred more frequently in groups that received N_2O, there were no incidents of clinically apparent aspiration. In addition, suturer satisfaction with the sedation was highest when N_2O was used.

Few studies in children using N_2O for anxiety and pain relief during procedures have been undertaken. Procedures prospectively studied include suturing,[7,8] venipuncture,[14,29] fracture reduction,[13,17] and dental procedures.[30,31] During emergency suturing, Gamis et al[7] demonstrated safety and mild efficacy of 30% N_2O in children 8 years and older, and Burton et al[8] reported safety and efficacy of 50% N_2O in 17 children 2 to 7 years old. In 2 reports of children undergoing dental procedures, Litman et al[30,31] evaluated the ventilatory effects and levels of sedation achieved with the combination of oral midazolam (0.5 to 0.7 mg/kg) and 15% to 60% N_2O. In the first study of a small group of children 1 to 3 years old, there were no significant changes in end-tidal carbon dioxide tension with increasing concentrations of N_2O from 15% to 60% and a progression from conscious to deep sedation in 45% of children who received 30% to

60% N_2O.[30] In the second study, the authors demonstrated that the addition of 40% N_2O to 0.7 mg/kg oral midazolam in a small group of children 1 to 9 years old did not result in respiratory depression or upper airway obstruction, but did cause an increase in the level of sedation in some children beyond conscious sedation.[31] Vomiting has been reported in none to 6% of the aforementioned outpatient studies of N_2O and is similar to our incidence of 6%.[7,8,13,30,31]

Traditionally, N_2O has been self-administered in the outpatient setting by a device that delivers a fixed mixture of 50% N_2O and oxygen through a demand valve (eg, Nitronox). In our experience, children do not consistently achieve acceptable analgesia and sedation with this device. The demand valve requires an inspiratory effort of −3 to −5 cm H_2O to activate gas flow. This is difficult for young children who are crying, have weaker respirations than adults, or cannot follow instructions. In collaboration with the Departments of Anesthesiology, Dentistry, and Respiratory Therapy, we constructed and used in this study an inexpensive portable, continuous-flow system for delivery of N_2O and oxygen to young children.[23]

Other studies have compared children inhaling N_2O with a control group inhaling oxygen.[7,8] We believe that oxygen administration by nasal mask to an agitated young child likely increases the child's anxiety. This iatrogenically induced distress may increase the difference in distress between groups and does not represent a true control. Therefore, we chose as the control group our standard of care for suturing, which includes comforting activities, topical LET and, if needed, injected buffered lidocaine. Because we chose not to use oxygen as a control, we were unable to blind parents and sedators to the agent used.

Furthermore, most modalities of sedation involve a noxious stimulus associated with administration. In the case of N_2O, the facemask in some children may be perceived as noxious. Flavoring the mask and incorporating the mask into story-telling in young children were used to enhance acceptance of the nasal mask. Although the nasal mask alone may be noxious, OSBD-R scores for children who received N_2O and the accompanying nasal mask were lower than groups that did not receive N_2O.

Because this study was conducted in an ED staffed by nurses and physicians experienced in the care of critically ill and injured children and because only subjects 2 to 6 years old were studied using a continuous delivery system of N_2O, caution in generalization of these results to other clinical settings, equipment, and children of different ages is warranted.

Table 3.
Adverse effects.

Adverse Effects	Standard Care*	Midazolam*	N_2O*	Midazolam+ N_2O*	Midazolam Odds Ratio (95% CI)†	N_2O Odds Ratio (95% CI)†
Ataxia						
During ED visit‡	0	2	0	1	2.0 (0.7–6.2)	0.8 (0.3–2.0)
First 24 h§	0	12	1	14	6.0 (2.2–16.5)	1.1 (0.7–1.7)
Dizziness						
During ED visit	0	1	0	0	1.4 (0.4–4.9)	0.7 (0.2–2.5)
First 24 h	0	6	0	6	3.8 (1.4–10.6)	0.9 (0.5–1.5)
Difficulty walking first 24 h	0	10	0	8	4.7 (1.7–13.1)	0.7 (0.5–1.2)
Vomiting during ED visit	0	0	5	1	0.6 (0.3–1.3)	2.5 (0.9–7.5)
Crying more first 24 h	0	5	0	5	3.4 (1.2–9.6)	0.9 (0.5–1.6)
Hallucinations first 24 h	0	1	0	3	2.1 (0.7–6.4)	1.3 (0.5–3.1)
Sleeping more first 24 h	4	11	4	6	1.4 (0.9–2.2)	0.7 (0.5–1.1)
Headache						
During ED visit	0	0	1	0	0.7 (0.2–2.5)	1.4 (0.4–4.8)
First 24 h	3	1	4	4	0.8 (0.5–1.4)	1.3 (0.7–2.3)

*Frequency data.
†All interactions were insignificant, so a main-effect only/weighted least squares categorical model was computed, adding 0.5 to each cell because of the observed cells with a frequency of 0.
‡Two hundred four questionnaires completed during ED visit.
§One hundred fifty-six questionnaires completed at 24 h after ED visit.

Our results indicate that the addition of oral midazolam has no advantage over N_2O alone. However, in groups that did not receive N_2O, there seems to be an anxiety-reducing effect of midazolam during wound preparation, including the steps of lidocaine injecting and wound cleaning. The minor side effects of dizziness, ataxia, and irritability occurred only in children who received midazolam and were reported by some parents to persist for up to 24 hours after discharge. Furthermore, because the addition of midazolam to N_2O did not confer added benefit in reducing distress but increased adverse effects, the use of N_2O alone appears to be optimal.

We conclude that 50% N_2O, administered by a continuous-flow system, is more effective than midazolam and standard care for relief of anxiety during emergency suturing in young children. Furthermore, adverse effects occurred less frequently, recovery was shorter, and suturer satisfaction was greatest during suturing in groups that received N_2O.

REFERENCES

1. Alcock DS, Feldman W, Goodman JT, et al. Evaluation of child life intervention in emergency department suturing. *Pediatr Emerg Care.* 1985;1:111-115.

2. Schilling CG, Bank DE, Borchert BA, et al. Tetracaine, epinephrine (adrenaline), and cocaine (TAC) versus lidocaine, epinephrine, and tetracaine (LET) for anesthesia of lacerations in children. *Ann Emerg Med.* 1995;25:203-208.

3. Christoph RA, Buchanan L, Begalla K, et al. Pain reduction in local anesthetic administration through pH buffering. *Ann Emerg Med.* 1988;17:117-120.

4. McKay W, Morris R, Mushlin P. Sodium bicarbonate attenuates pain on skin infiltration with lidocaine, with or without epinephrine. *Anesth Analg.* 1987;66:572-574.

5. Hennes H, Wagner V, Banadio W. The effect of oral midazolam on anxiety of preschool children during laceration repair. *Ann Emerg Med.* 1990;19:1006-1009.

6. Fatovich DM, Jacobs IG. A randomized, controlled trial of oral midazolam and buffered lidocaine for suturing lacerations in children (the SLIC Trial). *Ann Emerg Med.* 1995;25:209-214.

7. Gamis AS, Knapp JF, Glenski JA. Nitrous oxide analgesia in a pediatric emergency department. *Ann Emerg Med.* 1989;18:177-181.

8. Burton JH, Auble TE, Fuchs SM. Effectiveness of 50% nitrous oxide/50% oxygen during laceration repair in children. *Acad Emerg Med.* 1998;5:112-117.

9. Schutzman SA, Liebelt E, Wisk M, et al. Comparison of oral transmucosal fentanyl citrate and intramuscular meperidine, promethazine, and chlorpromazine for conscious sedation of children undergoing laceration repair. *Ann Emerg Med.* 1996;28:385-390.

10. Oureshi FA, Mellis PT, McFadden MA. Efficacy of oral ketamine for providing sedation and analgesia to children requiring laceration repair. *Pediatr Emerg Care.* 1995;11:93-97.

11. Hoffman GA, Perloff WH. Efficacy of oral ketamine for providing sedation and analgesia to children requiring laceration repair. *Pediatr Emerg Care.* 1995;11:399.

12. Green SM, Rothrock SG, Lynch EL, et al. Intramuscular ketamine for pediatric sedation in the emergency department: safety profile in 1,022 cases. *Ann Emerg Med.* 1998;31:688-697.

13. Wattenmaker I, Kasser JR, McGravey A. Self-administered nitrous oxide for fracture reduction in children in an emergency room setting. *J Orthop Trauma.* 1990;4:35-38.

14. Vetter TR. A comparison of EMLA cream versus nitrous oxide for pediatric venous cannulation. *J Clin Anesth.* 1995;7:486-490.

15. Griffin GC, Campbell VD, Jones R. Nitrous oxide-oxygen sedation for minor surgery: experience in a pediatric setting. *JAMA.* 1981;245:2411-2413.

16. Stewart RD. Nitrous oxide sedation/analgesia in emergency medicine. *Ann Emerg Med.* 1985;14:139-148.

17. Hennrikus WL, Simpson RB, Klingelberger CE, et al. Self-administered nitrous oxide analgesia for pediatric fracture reductions. *J Pediatr Orthop.* 1994;14:538-542.

18. Dripps RD, Lamong A, Eckenhoff JE. The role of anesthesia in surgical mortality. *JAMA.* 1961;178:261-266.

19. Gabriel MJ, Barker DS. *Paediatric Acute Pain Management Handbook.* 4th ed. North Adelaide, South Australia: Women's and Children's Hospital; 1998.

20. Committee on Drugs, American Academy of Pediatrics. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures. *Pediatrics.* 1992;89:1110-1115.

21. Feld LH, Negus JB, White PF. Oral midazolam preanesthetic medication in pediatric outpatients. *Anesthesiology.* 1990;73:831-834.

22. Connors K, Terndrup TE. Nasal versus oral midazolam for sedation of anxious children undergoing laceration repair. *Ann Emerg Med.* 1994;24:1074-1079.

23. Luhmann JD, Kennedy RM, Jaffe DM, et al. Continuous flow delivery of nitrous oxide and oxygen: a safe and cost effective technique for inhalation and sedation of pediatric patients. *Pediatr Emerg Care.* 1999;15:388-392.

24. Dorsch J, Dorsch S. *Understanding Anesthesia Equipment.* 3rd ed. Baltimore, MD: Williams & Wilkins; 1994:167-169.

25. National Institute for Occupational Safety and Health (NIOSH). Nitrous oxide level recommendation: criteria for a recommended standard. Occupational exposure to waste anesthetic gases and vapors [NIOSH] publication No. 77-140]. Cincinnati, OH: Department of Health and Human Services; 1998.

26. Jay SM, Ozolins M, Elliott CH, et al. Assessment of children's distress during painful medical procedures. *Health Psychol.* 1983;2:133-147.

27. Jay SM, Elliot C. Behavioral observation scales for measuring children's distress: the effects of increased methodological rigor. *J Consult Clin Psychol.* 1984;53:1106-1107.

28. Marx CM, Stein J, Tyler MK, et al. Ketamine-midazolam versus meperidine-midazolam for painful procedures in pediatric oncology patients. *J Clin Oncol.* 1997;15:94-102.

29. Henderson JM, Spence DG, Komocar LM. Administration of nitrous oxide to pediatric patients provides analgesia for venous cannulation. *Anesthesiology.* 1990;72:269-271.

30. Litman RS, Berkowitz RJ, Ward DS. Levels of consciousness and ventilatory parameters in young children during sedation with oral midazolam and nitrous oxide. *Arch Pediatr Adolesc Med.* 1996;150:671-675.

31. Litman RS, Kottra JA, Berkowitz RJ, et al. Breathing patterns and levels of consciousness in children during administration of nitrous oxide after oral midazolam premedication. *J Oral Maxillofac Surg.* 1997;55:1372-1377.

Level of Sedation with Nitrous Oxide for Pediatric Medical Procedures

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BACKGROUND: Nitrous oxide (N_2O) delivered at a concentration <50% is accepted as a minimal sedation drug by both the American Society of Anesthesiologists and the American Academy of Pediatrics. The expected level of sedation at an N_2O concentration >50% is less clear.
METHODS: We conducted a retrospective chart review for all children receiving N_2O for procedural sedation at Children's Hospitals and Clinics of Minnesota. Patient age, maximal N_2O concentration, duration of N_2O administration, completion of procedure, and adverse events were recorded. Level of sedation was assessed on a 0 to 6 scale.
RESULTS: N_2O was administered on 1858 occasions to 1585 patients younger than 18 years. Most administrations (91.3%) were N_2O concentration >50%. Level of sedation scores were as follows: 6 (inadequate) = 1.3%; 5 (minimal) = 94.3%; and 4 (drowsy) = 4.3%; no patient reached a sedation score <4. Fifty-nine patients (3.3%) had adverse events of which 6 (0.3%) were atypical. There was no difference between N_2O ≤50% and N_2O >50% in the level of sedation or number of adverse events. More children ≤2 years (7.4%) achieved a sedation level of 4 than those older than 2 years (4%), but they experienced a similar rate of adverse events. There was no difference in the level of sedation by duration of N_2O administration. Inadequately sedated patients were younger than the remainder of the group. Most procedures (94.1%) were completed with the patient calm and still.
CONCLUSIONS: A significant number of children remain minimally sedated while receiving N_2O at concentrations >50% via nasal hood using a system designed to titrate N_2O concentration from 0% to 70%. Adverse event rates of patients receiving >50% N_2O in this manner are similar to rates reported in large studies of 50% N_2O administration. (Anesth Analg 2010;110:1399–405)

Although classified as an anesthetic gas, the potency of nitrous oxide (N_2O) is significantly less than other inhaled drugs frequently used to provide general anesthesia. The minimal alveolar concentration (that produces immobility in 50% of subjects exposed to a noxious stimulus) for N_2O is 104%, a level not achievable outside of a hyperbaric environment. N_2O delivered at a concentration <50% is accepted as a minimal sedation drug by the American Society of Anesthesiologists (ASA)[1] and at a concentration ≤50% by the American Academy of Pediatrics (AAP).[2] In concentrations >50%, however, the AAP cautions that "the likelihood for moderate or deep sedation increases."[2] According to the most recent guidelines, children intended to remain in a minimally sedated state require no more than observation and intermittent assessment of their level of sedation. Children intended to reach a level of moderate sedation require continuous monitoring of oxygen saturation and heart rate and intermittent recording of respiratory rate and arterial blood pressure.

Several studies, including one with >35,000 patients, have addressed the issue of safety of N_2O delivered at a fixed concentration of 50% N_2O:50% oxygen; however, these studies do not address the level of sedation achieved at this concentration.[3–6] Other studies have demonstrated safe delivery of N_2O in concentrations up to 70%.[7–9] One of these, in a pediatric emergency department setting, showed that "N_2O 70% provides similar sedation depth to N_2O 50% with no increase in adverse events."[9] The current investigation evaluated the level of sedation in children receiving N_2O for procedural sedation throughout our children's hospital system. We hypothesized that children administered N_2O at a concentration >50% would reach an equal level of sedation as those administered ≤50%.

METHODS

After approval by the IRB of Children's Hospitals and Clinics of Minnesota, a retrospective chart review was conducted for all children aged 18 years and younger receiving N_2O for procedural sedation from September 2006 through January 2008. Because the study involved only data collected routinely for patient care documentation, the need for specific written informed consent was waived.

N_2O Sedation Process

All children receiving N_2O sedation at Children's Hospitals and Clinics of Minnesota undergo a standardized presedation assessment to identify potential contraindications to sedation and/or N_2O. N_2O is administered by a registered nurse who has had institutional training in N_2O administration as described elsewhere.[10,11] N_2O sedation occurs in various departments throughout our hospital system, including the emergency department, radiology department, hematology/oncology clinic, special diagnostics unit, and short-stay areas. N_2O is administered via a continuous flow device (Porter Instrument Company, Hatfield, PA), which allows titration of N_2O from 0% to 70% with oxygen as the remaining gas. This standard "dental" N_2O flowmeter

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Table 1. Level of Sedation Score

6	Inadequate = anxious, agitated, or in pain
5	Minimal = spontaneous awake without stimulus
4	Drowsy = eyes open or closed, but easily arouses to consciousness with verbal stimulus
3	Moderate-deep = arouses to consciousness with moderate tactile or loud verbal stimulus
2	Deep = arouses slowly to consciousness with sustained painful stimulus
1	Deeper = arouses, but not to consciousness, with painful stimulus
0	Anesthesia = unresponsive to painful stimulus

includes a fail-safe device that terminates N_2O flow in the event of cessation of oxygen flow. A scavenging apparatus designed to eliminate exhaled N_2O is an integral part of the equipment and minimizes occupational exposure to N_2O. A standard dental nasal hood is used to administer the N_2O. The starting concentration and titration of N_2O are at the discretion of the sedation nurse. Although not protocolized, usual practice is to begin administration at 50% to 60% N_2O with titration to higher or lower concentration within 2 to 3 minutes based on patient response to the procedure. Sedation depth is recorded using the Children's Hospital of Wisconsin Sedation Scale (Table 1), which is a validated modification of the Ramsay scale.[12] N_2O concentration, patient oxygen saturation, and sedation level are documented in the medical record at 3- to 5-minute intervals or sooner if a change is made in N_2O concentration. Verbal distraction (e.g., storytelling and soothing discourse) is provided throughout the procedure. Our protocol dictates that all children receive 100% oxygen for 3 to 5 minutes after N_2O administration. Postprocedure documentation includes an electronic medical record prompt for description of the completeness of the procedure with limited options (completed, patient calm and still during procedure; completed, patient unable to stay still or calm; not completed, inadequate sedation; not completed, complications with sedation; not completed, problems not related to sedation; or other). This descriptive set corresponds to standardized study data collected by the Pediatric Sedation Research Consortium (PSRC) for analysis of multiinstitutional sedation practices.[13] Postprocedure documentation also includes adverse event choices corresponding to the PSRC study dataset and an area to enter additional information.

Children receiving N_2O as a single drug for procedural sedation are monitored with pulse oximetry and direct nursing observation until return to their baseline level of alertness. Patients receiving sedative medication in addition to N_2O receive more intensive monitoring (e.g., heart rate, respiratory rate, and arterial blood pressure every 5–10 minutes) per hospital policy for moderate sedation. Per hospital policy, all patients receiving N_2O as a single drug who reach a level of moderate sedation also require more frequent vital sign documentation.

Data Collection

The patient age and procedure performed at the time of N_2O administration were recorded. The total duration of N_2O administration and maximal concentration of N_2O delivered at any time during the sedation event were recorded. The lowest sedation score (corresponding to deepest level of sedation) reached at any time during the sedation event was noted. A description of completion of procedure and adverse event information was recorded.

Statistical Analysis

Descriptive statistics including median and range were used to describe the continuous variables such as age and duration of procedure. Frequency distribution was performed to describe categorical variables including the minimal level of sedation and the maximal N_2O concentration. Nonparametric Mann-Whitney test was used to compare age and procedure duration between N_2O low and high groups. χ^2 test was conducted to compare the level of sedation between groups ≤2 years and >2 years of age. $P < 0.05$ was considered to indicate a statistically significant difference. All statistical analyses were completed using SPSS 15.0 (SPSS, Chicago, IL).

RESULTS

A total of 2045 N_2O administrations were recorded in patients younger than 18 years during the study period. Level of sedation score data were missing for 187 administrations leaving 1858 sedation events available for analysis. These 1858 administrations were performed in 1585 patients because several patients received N_2O sedation on more than one occasion.

The median patient age was 5.2 years (range, 0.2–17.9 years). The median duration of administration was 6 minutes, with a range of 1 to 73 minutes. Characteristics including maximal N_2O concentration administered and procedures performed with N_2O sedation are shown in Table 2. Most administrations (91.3%) used a maximal N_2O concentration >50%.

Most patients were assessed at a sedation level of 5 (94.3%) or 6 (1.3%) with 4.3% reaching a sedation level of 4. No patient reached a sedation level <4. There was no difference in the number of patients reaching a sedation level of 4 between those receiving N_2O ≤50% (4 of 161 patients; 2.5%) and those receiving N_2O >50% (76 of 1697 patients; 4.5%) ($P = 0.234$). There was no difference in duration of N_2O administration between the groups reaching a level of sedation score of 4 and those remaining at level 5 or 6 (Table 3). Although there was no difference in median patient age between groups with a sedation score of 4 versus those at 5 or 6 (Table 3), when patients ≤2 years were compared with those >2 years, more of the younger patients (7.4%) achieved a sedation level of 4 than those older than 2 years (4%) ($P = 0.044$). Patients judged to be inadequately sedated (sedation level 6) were younger (median, 3.2 years; range, 0.8–16.8 years) than the remainder of the group (median, 5.2 years; range, 0.2–18.9 years) ($P = 0.017$).

Of the 80 patients reaching a sedation level of 4, 3 received a sedative or potentially sedating medication before N_2O sedation. One child received 0.5 mg/kg oral midazolam 24 minutes before N_2O administration. This child had a presedation history and physical examination per protocol for moderate sedation in anticipation of using the combination of midazolam and N_2O. Another patient received 0.3 mg/kg oral midazolam for a prior attempt at

Table 2. Characteristics of Nitrous Oxide (N_2O) Sedation Events

Maximum nitrous oxide concentration	n	%
30	16	0.9
40	14	0.8
50	131	7.1
60	511	27.5
65	240	13.0
70	946	50.9

	Overall n (% of total) (n = 1858)	Successfully completed n (% per procedure)	Unable to complete n (% per procedure)	Completion unknown n (% per procedure)
Procedures performed with nitrous oxide sedation				
Urinary catheterization (urologic imaging, urodynamics)	1095 (58.9)	1012 (92.4)	5 (0.5)	78 (7.1)
Botulinum toxin or other intramuscular injection	174 (9.4)	168 (96.6)	0	6 (3.4)
Vascular access or venipuncture	154 (8.3)	122 (79.2)	4 (2.6)	28 (18.2)
Computed tomography scan	100 (5.4)	91 (91.0)	1 (1.0)	8 (8.0)
Enteral tube placement (nasogastric tube) or replacement (gastrostomy/ gastrojejunal tube)	67 (3.6)	59 (88.1)	1 (1.5)	7 (10.4)
Minor surgical (e.g., laceration repair, joint injection, incision, and drainage of abscess)	39 (2.1)	37 (94.9)	0	2 (5.1)
Lumbar puncture	36 (1.9)	29 (80.5)	1 (2.8)	6 (16.7)
Other				
Electromyelography/nerve conduction	17 (0.9)	17 (100)	0	0
Gastrografin enema	8 (0.4)	8 (100)	0	0
Foreign body removal	7 (0.4)	7 (100)	0	0
Cast/splint placement	4 (0.2)	4 (100)	0	0
Other	10 (0.5)	9 (90.0)	0	1 (10.0)
Associated with other completed procedure (specific N_2O procedure information unavailable)	109 (5.9)	0	0	109 (100)
No information	38 (2.0)	13 (34.2)	2 (5.3)	23 (60.5)

Table 3. Level of Sedation Compared with Age and Duration of Procedure

	Sedation score = 4 (n = 80)	Sedation score = 5 or 6 (n = 1778[a])	P[b]
Age (y)			
Median	5.5	5.2	0.639
Range	0.7–16.6	0.2–17.9	
Duration (min)			
Median	7	6	0.062
Range	3–55	1–73	

[a] Seven patients missing duration data excluded from duration analysis.
[b] Mann-Whitney test.

nasogastric placement 90 minutes before N_2O administration. One child received acetaminophen-hydrocodone (0.09 mg/kg hydrocodone) 81 minutes before N_2O administration. The remainder of the 80 patients received either nonsedating medication (2 acetaminophen, 3 ondansetron, and 1 valproic acid) or no medication before the N_2O administration.

Adverse event data were available for 1762 sedation encounters (Table 4). Fifty-nine patients experienced ad-

Table 4. Complications with Nitrous Oxide (N_2O) Sedation

	≤50% N_2O		>50% N_2O	
	n	%	n	%
Complications				
No complications	152	98.1	1551	96.5
Vomiting	0	0	29	1.8
Nausea	1	0.6	6	0.4
Inadequate sedation	0	0	8	0.5
Agitation/delirium	0	0	2	0.1
Other	2	1.3	11	0.7
Description of other complications				
Apnea >15 s[a]	1			
Oxygen saturation 89%[a]			1	
Unresponsive episode with oxygen saturation 83%[a]			1	
Stridor[a]			1	
Seizure[a]			2	
Diaphoresis			1	
Burpy/hiccupy			1	
Gaggy	1		2	
Expectorated large amount of clear phlegm			1	
Screaming			1	

[a] Patients described in detail in text.

verse events, 3 of 155 patients (1.9%) in the ≤50% N_2O group and 56 of 1607 (3.5%) in the high-concentration group (P = 0.343). There was no difference in adverse events between patients ≤2 years and >2 years of age (P = 0.067).

Six patients experienced atypical adverse events. A 2-year-old girl with trisomy 21 hospitalized with pansinusitis, adenotonsillar hypertrophy, herpes stomatitis, and intermittent oxygen desaturation received 50% N_2O and then 100% oxygen for 3 minutes to facilitate peripheral venous cannulation. Her oxygen saturation remained at 100%. On return to room air, she was noted to have "apnea >15 seconds" with no associated color change or oxygen desaturation. She returned to her baseline state with no specific intervention. A 16-month-old boy was administered 65% to 70% N_2O and then 100% oxygen for 2 minutes to facilitate peripheral venous cannulation and urethral catheterization for radionuclide renogram. On return to room air, he developed oxygen desaturation to 89%. Additional supplemental oxygen was given and he returned to baseline status shortly thereafter. A 3-year-old boy hospitalized with acute encephalopathy was administered 60% to 70% N_2O, then 100% oxygen for 3 minutes for an unsuccessful attempt at lumbar puncture. On return to room air, the child "became unresponsive" with oxygen saturation decreasing to 83%. He recovered with stimulation and supplemental oxygen and returned to baseline status within 10 minutes. N_2O was then used for a subsequent successful lumbar puncture during which the patient was noted to "respond normally." No adverse events were noted during the second N_2O administration. A 2-month-old infant diagnosed in utero with a left neck mass was scheduled for computed tomographic (CT) scan of the head and neck when the mass, which had not been previously clinically apparent, became visible to caregivers. He received 70% N_2O followed by 100% oxygen during CT imaging with oxygen saturation remaining at 100% throughout. The presence of stridor was noted in the postprocedure assessment form. No airway intervention was required. The child was discharged shortly after the scan at baseline status. Two patients (aged 12 months and 17 months) developed generalized tonic-clonic seizure activity lasting 2 to 3 minutes, one during N_2O administration and one while receiving 100% oxygen after discontinuation of N_2O. Both patients developed oxygen desaturation of 78% to 79% during clinical seizure activity, promptly returning to 100% saturation with application of 100% oxygen by facemask. Neither patient required any specific airway intervention, although one received oral suctioning for a small amount of thin secretions. Both returned to baseline clinical status and were discharged to home later the same day.

Procedure completion information was available for 1590 sedation events. Most procedures (94.1%) were completed with the patient calm and still. For 5.0%, the procedure was completed with the patient unable to remain still or calm. Only 14 of 1590 events (0.9%) were unable to be completed because of either inadequate sedation or problems unrelated to sedation. All of the incomplete procedures used N_2O >50%. Procedure completion information was unavailable for 268 sedation events. Of these, 109 were coupled to an additional sedated procedure (e.g., deep sedation for magnetic resonance imaging) that was completed; however, because the completion descriptor could not be ascribed directly to the N_2O sedation, completion data from these events were excluded from analysis. Twenty-three events had no postsedation notation of completion or procedure performed. Breakdown of procedures by completion status is shown in Table 2.

Table 5. Patient Responsiveness at American Society of Anesthesiologists[1] and American Academy of Pediatrics[2] Recognized Levels of Sedation

Minimal	A drug-induced state during which patients respond normally to verbal commands, cognitive function, and coordination may be impaired
Moderate	A drug-induced depression of consciousness during which patients respond purposefully to verbal commands either alone or accompanied by light tactile stimulation
Deep	A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated verbal or painful stimulation
General anesthesia	A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation

DISCUSSION

In the interest of patient safety, the AAP originally published "Guidelines for the Elective Use of Conscious Sedation, Deep Sedation, and General Anesthesia in Pediatric Patients" in 1985 to aid practitioners in providing sedation to pediatric patients with appropriate assessment, monitoring, documentation, and equipment.[14] This document has been regularly updated, most recently in 2006.[2] While acknowledging that sedation occurs along an unbroken continuum from anxiolysis to general anesthesia, the process of breaking the continuum into definable levels (Table 5) allows for prescription of elements such as provider skill level, patient monitoring, and equipment that are appropriate to the potentially increased risks that accompany each deeper level of sedation.[1,2] However, because sedation occurs along a continuum, the distinction between each level may be difficult to discern. Placing the child who requires "light tactile stimulation" to "respond purposefully to verbal commands" into a moderate sedation category may be straightforward; however, deciding whether the child with eyes open responds "normally to verbal commands" versus "purposefully to verbal commands" or whether that child is in a "drug-induced state" in which "cognitive function and coordination may be impaired" versus a "drug-induced depression of consciousness" may be more problematic, allowing for some subjectivity in the categorization of the level of sedation between minimal and moderate.

This distinction, however, is more than just a matter of semantics. As stipulated in the ASA and AAP sedation guidelines, a child receiving a drug expected to result in

moderate sedation requires more intensive monitoring than a child receiving a drug expected to result in minimal sedation. In addition, presedation requirements may be more onerous for children receiving moderate sedation than for those receiving minimal sedation. At our institution, children scheduled for moderate sedation are required to undergo a separate presedation history and physical examination by their primary practitioner within 7 days of their scheduled procedure. Therefore, the expectation of level of sedation to be achieved by a given sedation medication has an effect not only on the institutional policies and procedures required for its use but also on the potential cost and time burden for patients, families, and the overall health care system.

In turn, these burdens may limit children's access to N_2O, a drug that has not only demonstrated to be useful for pediatric procedures by virtue of its analgesic and amnesic properties but has also been suggested to be a cost-effective alternative to other sedatives.[15–17] As our study shows, children receiving N_2O via a nasal mask, even in high concentrations, can remain in a minimally sedated state. The fact that a small percentage of patients achieve a deeper level of sedation than minimal highlights the ASA and AAP admonishment that "practitioners of sedation must have the skills to rescue the patient from a deeper level than that intended for the procedure."[2] Because of the pharmacokinetic properties of N_2O, patients who inadvertently reach a level of moderate sedation when minimal sedation is intended would be expected to return rapidly to a baseline level of alertness upon discontinuation of inhalation.

Although N_2O has been used for decades by dentists to provide sedation and anxiolysis for their patients, there are few data in the dental literature regarding the level of sedation with which to compare this study. In 1 prospective study of the psychomotor effect of N_2O, all 59 children, aged 4 to 13 years, were able to participate in a drawing activity while inhaling 50% N_2O.[18] In another study, all 25 children, aged 4 to 10 years, receiving N_2O titrated to achieve "relative analgesia" with a concentration 40% to 60% (mean 51%) were interactive enough to choose a color representing their level of pain.[19] The paucity of data regarding level of sedation, particularly at N_2O concentrations >50% and as a single drug sedative, likely reflects current dental practice. Although 89% of respondents to a survey of pediatric dentists reported the use of N_2O in their practice, only 1.8% reported using it at a concentration >50%.[20] In addition, only 29% of pediatric dentists reported using only N_2O for sedation[21]; the remainder used other sedative drugs in addition to N_2O. Dental practice also requires that N_2O be administered via a nasal mask while the mouth remains open for treatment. When delivered in this manner, the concentration of N_2O measured in the nasopharynx of cooperative volunteers was significantly lower than the flowmeter setting.[22] Although considerable interindividual differences were noted, inspired N_2O measured in the nasal mask averaged 31% lower than the flowmeter setting with a further decrease of 19% to the nasopharynx.[22]

We found no difference in the level of sedation or number of adverse events between children administered N_2O at a concentration >50% and those administered ≤50% in this study. In the medical literature, the most comparable study is that by Babl et al.,[9] who reported their experience with high-concentration N_2O in a pediatric emergency department. They found that 52 of 484 patients (10.7%) receiving 70% N_2O and 3 of 90 patients (3.3%) receiving 50% N_2O reached moderate or deep sedation, choosing to define moderate sedation as a sedation score of 3 and deep sedation as a score of ≤2. None of our patients reached a sedation score ≤3. Although Babl et al. excluded patients receiving additional sedative drugs for analysis, patients receiving analgesics, including opioids, were included but not quantified. In addition, the type of mask used for N_2O delivery in that study was not specified. For our study, a dental nasal mask, not a full facemask, was used for gas delivery. Although our patients are instructed to breathe through the nose while keeping the mouth closed, room air may be entrained, resulting in decreased inspired N_2O concentration. This may also account for the increased level of sedation in children ≤2 years in our study, whose mouths may be partially covered by our single-sized nasal mask. Our minimal sedation rate of 94.3% is consistent with the observation of Kanagasundaram et al.[7] that 93.3% of children were "awake" during administration of 50% to 70% N_2O in an emergency department setting. A future prospective evaluation of level of sedation using an independent observer would be useful in addressing differences in study findings. Similar to Babl et al., who relied on nurses and physicians participating in the procedural sedation to record the level of sedation for their report, we relied on the assessment and documentation of level of sedation by nurses responsible for N_2O administration. This nursing group is diverse, with staff working in the emergency department, radiology department, hematology/oncology clinic, special diagnostics unit, and short-stay areas of the institution. All of these nurses, however, receive training in institutional sedation policies and procedures, including use of the sedation scoring system, and are also responsible for monitoring and scoring children undergoing moderate and deep sedation for other procedures.

The overall adverse event rate of 3.3% (3.5% for the >50% group) seen in this study is less than the 8.3% reported by Babl et al.[9] in their report of high-concentration N_2O, but similar to rates found in larger studies of 50% N_2O administration.[3,4] Two of our patients, both of whom received high-concentration N_2O, developed unexplained oxygen desaturation. This rate of 11.4 per 10,000 is similar to the rate of 13.1 per 10,000 reported by Babl et al. As in that study, none of our patients required specific airway intervention other than administration of increased concentration of oxygen or had any clinical evidence of aspiration or laryngospasm. It is unclear whether some of the adverse events in this study were attributable to the administration of N_2O or to the underlying condition of the patient. For example, oxygen desaturation in the child with encephalopathy and an unresponsive episode may have been attributable to seizure or breath-holding rather than a specific response to N_2O.

We did observe an uncommon adverse event, with 2 patients developing seizures temporally associated with

N_2O administration. Although 1 case report in the literature clearly demonstrated the onset of electroencephalographic and clinical seizure activity with N_2O inhalation in an otherwise healthy 9-month-old infant,[23] the cause/effect relationship between N_2O administration and the clinical seizure activity demonstrated by the patients in this study remains speculative and is the subject of an ongoing review.

There are limitations of this study. Only the maximal concentration of N_2O administered was recorded. Our system allows rapid titration of N_2O concentration based on patient response, and titration to a lower concentration during the procedure may have occurred for some of the patients. Only the total time N_2O was administered, not the total time spent at the maximal concentration of N_2O, was used for analysis. In addition, procedures performed during the study period had various degrees of stimulation from noninvasive procedures (e.g., CT scans) to more painful procedures such as botulinum toxin A injections. It could be surmised that a child may reach a deeper level of sedation with less stimulation; however, no attempt was made to quantify the degree of stimulation or correlate with level of sedation for this study.

Conclusions regarding quality of sedation cannot be drawn from this study. Although the majority of procedures were noted as "completed, patient calm and still," the scale used is rather subjective. Although developed by the PSRC as a tool to ascertain whether sedation was not completed because of problems with the sedation itself or because of technical issues not related to the procedural sedation (equipment breakdown, etc.), this scale has not been validated. No information on mask acceptance was collected. One could speculate that poor mask tolerance may have played a role in the inadequately sedated group, whose median age was significantly younger than the whole.

No attempt was made to determine an optimal N_2O concentration for pediatric procedural sedation. Because the anesthetic and analgesic mechanisms of action occur by separate (although perhaps overlapping) pathways,[24] adequacy of analgesia and amnesia may not directly correlate with the level of sedation achieved. N_2O at 70% delivered by full facemask has been shown to be more effective than 50% for venipuncture.[25,26] Whether there is any added advantage to high-concentration N_2O compared with 50% for other procedures and with other delivery devices remains an area for future investigation.

Because a nasal mask was used to deliver N_2O for this study, conclusions cannot be generalized to the delivery of high concentration of N_2O via a full facemask system. Caution must also be observed if N_2O is administered in combination with other sedating medications because the combination increases the likelihood for moderate or deep sedation.[2] Even 30% N_2O may produce deep sedation when administered via a full facemask after premedication with oral midazolam, and a higher concentration (60%) administered after midazolam premedication may result in no response to painful stimulation.[27]

In conclusion, this study suggests that a significant number of children, particularly those older than 2 years, remain minimally sedated while receiving N_2O at concentrations >50% via nasal hood using a system designed to titrate N_2O concentration from 0% to 70%. There was no difference in the level of sedation or adverse events between children administered N_2O at a concentration >50% and those administered ≤50% when delivered in this fashion. The adverse event rate noted with N_2O >50% in this study is similar to rates reported in large studies of N_2O administered at 50% concentration.

REFERENCES

1. American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. Practice guidelines for sedation and analgesia by non-anesthesiologists. Anesthesiology 2002;96:1004–17
2. American Academy of Pediatrics, American Academy of Pediatric Dentistry, Cote CJ, Wilson S; Work group on Sedation. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures: an update. Pediatrics 2006;118:2587–602
3. Onody P, Gil P, Hennequin M. Safety of inhalation of a 50% nitrous oxide/oxygen premix: a prospective survey of 35 828 administrations. Drug Saf 2006;29:633–40
4. Gall O, Annequin D, Benoit G, Glabeke E, Vrancea F, Murat I. Adverse events of premixed nitrous oxide and oxygen for procedural sedation in children. Lancet 2001;358:1514–5
5. Annequin D, Carbajal R, Chauvin P, Gall O, Tourniaire B, Murat I. Fixed 50% nitrous oxide oxygen mixture for painful procedures: a French survey. Pediatrics 2000;105:e47
6. Kalach N, Barbier C, el Kohen R, Begon-Lours J, Nyombe-Nzungu P, Sonna M, Laurent A, Kremp O. [Tolerance of nitrous oxide-oxygen sedation for painful procedures in emergency pediatrics: report of 600 cases]. Arch Pediatr 2002;9:1213–5
7. Kanagasundaram SA, Lane LJ, Cavalletto BP, Keneally JP, Cooper MG. Efficacy and safety of nitrous oxide in alleviating pain and anxiety during painful procedures. Arch Dis Child 2001;84:492–5
8. Frampton A, Browne GJ, Lam LT, Cooper MG, Lane LG. Nurse administered relative analgesia using high concentration nitrous oxide to facilitate minor procedures in children in an emergency department. Emerg Med J 2003;20:410–3
9. Babl FE, Oakley E, Seaman C, Barnett P, Sharwood LN. High-concentration nitrous oxide for procedural sedation in children: adverse events and depth of sedation. Pediatrics 2008;121:e528–32
10. Zier JL, Drake GJ, McCormick PC, Clinch KM, Cornfield DN. Case-series of nurse-administered nitrous oxide for urinary catheterization in children. Anesth Analg 2007;104:876–9
11. Farrell MK, Drake GJ, Rucker D, Finkelstein M, Zier JL. Creation of a nurse-administered nitrous oxide sedation program for radiology and beyond. Pediatr Nurs 2008;34:29–35
12. Hoffman GM, Nowakowski R, Troshynski TJ, Berens RJ, Weisman SJ. Risk reduction in pediatric procedural sedation by application of an American Academy of Pediatrics/American Society of Anesthesiologists process model. Pediatrics 2002;109:236–43
13. Cravero JP, Beach ML, Blike GT, Gallagher SM, Hertzog JH; Pediatric Sedation Research Consortium. The incidence and nature of adverse events during pediatric sedation/anesthesia with propofol for procedures outside the operating room: a report from the Pediatric Sedation Research Consortium. Anesth Analg 2009;108:795–804
14. American Academy of Pediatrics, Committee on Drugs, and Section on Anesthesiology. Guidelines for the elective use of conscious sedation, deep sedation, and general anesthesia in pediatric patients. Pediatrics 1985;76:317–21
15. Burnweit C, Diana-Zerpa JA, Nahmad MH, Lankau CA, Weinberger M, Malvezzi L, Smith L, Shapiro T, Thayer K. Nitrous oxide analgesia for minor pediatric surgical procedures: an effective alternative to conscious sedation? J Pediatr Surg 2004;39:495–9

16. Luhmann JD, Kennedy RM, Jaffe DM, McAllister JD. Continuous-flow delivery of nitrous oxide and oxygen: a safe and cost-effective technique for inhalation analgesia and sedation of pediatric patients. Pediatr Emerg Care 1999;15:388–92
17. Keidan I, Zaslansky R, Weinberg M, Ben-Shlush A, Jacobson JM, Augarten A, Mor Y. Sedation during voiding cystourethrography: comparison of the efficacy and safety of using oral midazolam and continuous flow nitrous oxide. J Urol 2005; 174:1598–601
18. Houpt MI, Limb R, Livingston RL. Clinical effects of nitrous oxide conscious sedation in children. Pediatr Dent 2004;26: 29–36
19. Hammond NI, Full CA. Nitrous oxide analgesia and children's perception of pain. Pediatr Dent 1984;6:238–42
20. Wilson S. A survey of the American Academy of Pediatric Dentistry membership: nitrous oxide and sedation. Pediatr Dent 1996;18:287–93
21. Houpt M. Project USAP 2000—use of sedative agents by pediatric dentists: a 15-year follow-up survey. Pediatr Dent 2002;24:289–94
22. Klein U, Bucklin BA, Poulton TJ, Bozinov D. Nitrous oxide concentrations in the posterior nasopharynx during administration by nasal mask. Pediatr Dent 2004;26:410–6
23. Lannes M, Desparmet JF, Zifkin BG. Generalized seizures associated with nitrous oxide in an infant. Anesthesiology 1997;87:705–8
24. Sanders RD, Weimann J, Maze M. Biologic effects of nitrous oxide: a mechanistic and toxicologic review. Anesthesiology 2008;109:707–22
25. Henderson JM, Spence DG, Komocar LM, Bonn GE, Stenstrom RJ. Administration of nitrous oxide to pediatric patients provides analgesia for venous cannulation. Anesthesiology 1990;72:269–71
26. Furuya A, Masaki I, Suwa M, Nishi M, Horimoto Y, Sato H, Okuyama K, Ishiyama T, Matsukawa T. The effective time and concentration of nitrous oxide to reduce venipuncture pain in children. J Clin Anesth 2009;21:190–3
27. Litman RS, Berkowitz RJ, Ward DS. Levels of consciousness and ventilatory parameters in young children during sedation with oral midazolam and nitrous oxide. Arch Pediatr Adolesc Med 1996;150:671–5

Exhibit 3

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High-Concentration Nitrous Oxide for Procedural Sedation in Children: Adverse Events and Depth of Sedation

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ARTICLE

High-Concentration Nitrous Oxide for Procedural Sedation in Children: Adverse Events and Depth of Sedation

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ABSTRACT

OBJECTIVE. Nitrous oxide is an attractive agent for procedural sedation and analgesia in the emergency department; however, there are limited safety data for high-concentration continuous-flow nitrous oxide (50%–70%) and its use in young children. We set out to characterize the depth of sedation and incidence of adverse events associated with various concentrations of nitrous oxide used in a pediatric emergency department.

METHODS. This was a prospective observational study of nitrous oxide use for procedural sedation and analgesia in a tertiary children's hospital emergency department. Nitrous oxide concentration, adverse events, and sedation depth were recorded. Adverse events were categorized as mild or serious. Sedation depth was recorded on a sedation scale from 0 to 6.

RESULTS. A total of 762 patients who were aged 1 to 17 years received nitrous oxide during the 2-year study period. A total of 548 (72%) received nitrous oxide 70%, and 101 (13%) received nitrous oxide 50%. Moderate or deep sedation with scores of ≤2 occurred in 3% of patients who had received nitrous oxide 70% and no patients who had received nitrous oxide 50%. Mean sedation scores were 4.4 at nitrous oxide 70% and 4.6 at nitrous oxide 50%. Sixty-three (8.3%) patients sustained 70 mild and self-resolving adverse events, most of which were vomiting (5.7%); 2 (0.2%) patients had serious adverse events. There was no significant difference in adverse events rates between nitrous oxide 70% (8.4%) and nitrous oxide 50% (9.9%). There was no significant difference in the percentage of deep sedation when children who were ≤3 years of age (2.9%) were compared with older children (2.8%).

CONCLUSIONS. In this largest prospective emergency department series, high-concentration continuous-flow nitrous oxide (70%) was found to be a safe agent for procedural sedation and analgesia when embedded in a comprehensive sedation program. Nitrous oxide also seems safe in children aged 1 to 3 years.

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Key Words
nitrous oxide, procedural sedation and analgesia, adverse events, emergency department

Abbreviations
N_2O—nitrous oxide
ED—emergency department
PSA—procedural sedation and analgesia
O_2—oxygen
IQR—interquartile range
CI—confidence interval

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NITROUS OXIDE (N_2O) is an attractive agent for pediatric procedural sedation because it provides rapid onset and offset of sedation. Most research has used N_2O 50%, and there have been concerns regarding the variability of the sedation provided.[1,2] Furthermore, most studies of N_2O 50% have used a demand valve system, which is problematic for children who are younger than 5 years. It has been suggested that increasing the concentration of N_2O to 70%, by continuous-flow mechanisms with scavenging, may overcome these problems; however, concerns regarding deeper sedation and increasing complications, in view of the propensity of N_2O to cause vomiting in some children, have been raised.[1,2]

The primary objective of our study was to characterize the depth of sedation and incidence of adverse events associated with various concentrations of N_2O that are used in a pediatric emergency department (ED). Secondary objectives included identifying associations with sedation depth, adverse events, and age.

METHODS

Design and Setting

We conducted a prospective observational study in the ED of a large, urban children's hospital with an annual ED census of 60 000 patients. All children who were ≤18 years of age and presented to the ED from May 2004 to June 2006 and received N_2O for procedural sedation and analgesia (PSA) were eligible for enrollment. Patients who received other sedative agents, such as midazolam, were excluded. This study was approved by the hospital institutional review board.

PSA with any agent in the ED is performed using standardized presedation assessment, monitoring during the procedure, and postsedation discharge criteria as described previously.[3,4] As part of standard sedation practice, a sedation checklist, which becomes part of the medical chart, was used. For N_2O sedation, minimum departmental fasting times for solids and liquids was 2 hours. Monitoring during N_2O sedation included continuous oxygen (O_2) saturation, heart rate, and sedation depth, with recording every 5 minutes of O_2 saturation, heart rate, respiratory rate, and depth of sedation by nursing staff on the observation chart until the child had returned to the preprocedural state (within minutes). There was a dedicated trained senior nurse or physician to provide airway support and monitoring during the sedation in addition to the proceduralist. N_2O was administered by inhalation of a gas mixture with O_2. The administration was available in 2 forms, demand-valve-fixed N_2O 50%/O_2 50%, marketed as Entonox (BOC Gases, Sydney, NSW, Australia) and the continuous-flow system via the Quantiflex MDM (Matrx, Orchard Park, NY) machine, which delivers N_2O 0% to 70% and includes a scavenging system to decrease environmental contamination. The continuous-flow system was installed in the procedure rooms and used wall-mounted piped N_2O and O_2; the demand-valve system was portable and used only rarely and only outside the procedure rooms. Device and N_2O concentration used were at the discretion of the treating clinician.

The sedation checklist, which doubled as a case report form, was used to record data before, during, and after PSA with N_2O. This included age, risk assessment, fasting status, procedures undertaken, highest concentration of N_2O used, additional sedatives or opioids used, deepest level of sedation, and adverse events. The sedation checklist, including the recording of adverse events, was completed by the nurses and physicians who participated in the procedural sedation. All medical charts of patients who underwent sedation with N_2O were also reviewed retrospectively.

Data

To measure the level of sedation, a sedation scale that was developed and validated at the Children's Hospital of Wisconsin[5] was used. The scale has 7 levels of sedation ranging from 6 to 0 (6: anxious, agitated, or in pain; 5: spontaneously awake without stimulus [talking]; 4: drowsy, eyes open or closed, but easily arouses to consciousness with verbal stimulus; 3: arouses to consciousness with moderate tactile or loud verbal stimulus; 2: arouses slowly to consciousness with sustained painful stimulus; 1: arouses, but not to consciousness, with painful stimulus; 0: unresponsive to painful stimulus). Deepest level of sedation attained was recorded on the sedation checklist. Deep sedation was defined as sedation score of 0 to 2, and moderate sedation was defined as sedation score of 3.

Adverse events were defined a priori as serious or mild. Serious adverse events included O_2 desaturation <95%, apnea, stridor, airway misalignment requiring repositioning, laryngospasm, bronchospasm, cardiovascular instability, pulmonary aspiration, unplanned additional tests or hospital admission, endotracheal intubation, permanent neurologic injury, and death. Inadequate sedation was not regarded as an adverse event. O_2 administration, upper airway repositioning, and tactile stimulation were regarded as minor interventions. Escalation of respiratory or circulatory support beyond this was considered a major intervention.

Analysis

All data were entered into an Access software database (Microsoft, Redmond, WA). Median values are reported as median with interquartile range (IQR). We used χ^2 tests for dichotomous variables and t tests for parametric variables. For all tests, values of $P < .05$ were considered statistically significant. The effect of various levels of N_2O was analyzed by comparing N_2O 50% and N_2O 70%. Other concentrations were excluded from comparative analysis. Statistical calculations were performed on Stata 9.0 (Stata Corp, College Station, TX).

RESULTS

During the 2-year study period, we enrolled 762 patients who had received N_2O for PSA in the ED. Patient demographics are listed in Table 1. Seventy-two percent of patients received N_2O 70%. Nine percent received an adjunctive analgesic agent within 2 hours of the sedation. Most procedures were orthopedic (38%) and laceration repair (29%). Mean preprocedural fasting time for solids was 4.3 hours (IQR: 2.5–5.0 hours) and for liquids was 3.7 hours (IQR: 2–4.5 hours).

Sixty-three patients (8.3%; 95% confidence interval [CI]: 6.4%–10.4%) sustained 70 mild and self-resolving adverse events, mostly vomiting (5.7%), as shown in Table 2. Two (0.3%; 95% CI: 0.03%–0.9%) patients had serious adverse events; both had received N_2O 70%. An 11-year-old previously healthy boy underwent PSA with N_2O 70% to suture a toe laceration under lidocaine ring block. He was fasted (solids) for 5 hours. At the end of the procedure, the patient developed sustained stabbing central chest pain. His vital signs remained normal; an electrocardiogram and chest radiograph were also normal. He was administered an antacid (aluminum hydroxide, magnesium trisilicate, and magnesium hydroxide). His chest pain settled, and he was discharged from the hospital after a period of observation in the ED. A 12-year-old previously healthy boy sustained a displaced distal radius fracture. He received N_2O 70% for fracture

TABLE 1 Characteristics of ED Patients Who Received N_2O for PSA ($n = 762$)

Characteristic	Value
Age, y	
Mean (SD)	6.9 (4.0)
Median (range)	6.0 (1–17)
Male gender, *n* (%)	459 (60.0)
% N_2O, *n* (%)	
70	548 (71.9)
60	16 (2.0)
50	101 (13.2)
30–40	6 (0.8)
Missing[a]	91 (11.9)
Adjunctive agents, *n* (%)[b]	
N_2O alone	693 (90.0)
Codeine[c]	46 (6.0)
Morphine intravenous/intramuscular[d]	28 (3.7)
Procedures, *n* (%)	
Orthopaedic	293 (38.4)
Reduction fracture	167
LAMP[e]	45
Reduction dislocation	40
Application of plaster	41
Laceration repair	223 (29.2)
Facial	124
Nonfacial	99
Foreign body removal	71 (9.3)
Vascular access	37 (4.8)
Other	148 (19.4)
Abscess drainage	25
Urinary catheter	13
Wound debridement	13
Lumbar puncture	12
Other[f]	85

[a] LAMP indicates local anesthesia, manipulation, and plaster.
[b] Highest N_2O concentration not denoted.
[c] Within 2 hours before N_2O administration.
[d] Codeine alone or in combination with paracetamol.
[e] Five patients had received 2 agents (morphine plus codeine).
[f] Paraphimosis reduction, enema, arthrocentesis, dressing change, insertion of nasogastric or gastrostomy tubes, pelvic examination, examination under sedation, dental procedures, vaccination, and suprapubic aspiration.

reduction under intravenous regional anesthesia (Bier's block) with 35 mL of lidocaine 0.5%. He had received morphine sulfate 2.5 mg intravenously 1 hour before the procedure and was fasted (solids) for 4 hours. During the procedure, his sedation score was 4 (drowsy, eyes open or closed, but easily arouses to consciousness with verbal stimulus). During the procedure, while receiving N_2O 70%, his O_2 saturation was 100%. Immediately after the procedure and N_2O administration, his O_2 saturation dropped to 73% with visible cyanosis. His O_2 saturation returned to 100% on high-flow O_2 by mask. After 10 minutes, when the O_2 mask was removed, he again became cyanotic with O_2 saturation at ~70%. Two additional attempts again led to visible cyanosis on removal of O_2. Subsequent to this, he maintained his O_2 saturation at 95% to 99% on room air. Thereafter, he vomited once. At no point was he distressed, in pain, or short of breath, and his physical examination was normal with a clear chest. He was subsequently admitted for observation and discharged without additional complaints.

TABLE 2 Adverse Events of ED Patients Who Received N_2O for PSA

Parameter	Any Concentration of N_2O[b]		N_2O 50%[a]		N_2O 70%[a]	
	n	%[b]	*n*	%	*n*	%
Serious adverse events						
Chest pain	1	0.1	—	—	1	0.1
Desaturation[b]	1	0.1	—	—	1	0.1
Minor adverse events						
Vomiting	44	5.7	4	3.9	26	4.7
During sedation	19					
After sedation	19					
Unknown timing	6					
Agitation	10	1.3	—	—	10	1.8
Nausea	7	0.9	3	2.9	3	0.5
Light headed	3	0.4	1	0.9	1	0.2
Hyperventilation/carpopedal spasm	1	0.1	1	0.9	—	
Abdominal pain	1	0.1	1	0.9	—	
Pallor	1	0.1	—	—	1	0.2
Hallucinations	1	0.1	—	—	1	0.2
Hiccups	1	0.1	—	—	1	0.2

[a] Percentages based on total sedations ($n = 762$), N_2O 50% ($n = 101$), and N_2O 70% ($n = 548$).
[b] Unplanned hospital admission as a result of adverse events.

No patient experienced a clinically apparent pulmonary aspiration or laryngospasm or required advanced airway support. There was no significant difference ($P = .6$) in adverse event rates between N_2O 70% (8.4%; 95% CI: 6.2%–11.0%) and N_2O 50% (9.9%; 95% CI: 4.8%–17.4%).

Table 3 shows the deepest level of sedation recorded during sedation episodes with N_2O. Overall, 90.5% (95% CI: 88.0%–92.6%) of sedations for which deepest sedation score had been recorded ($n = 655$) were performed under mild sedation with sedation scores of ≥4 (drowsy, eyes open or closed, but easily arouses to consciousness with verbal stimulus). Overall, in 2.9% of sedation episodes, patients were deeply sedated with sedation scores of 0 to 2 (2: arouses slowly to consciousness with sustained painful stimulus; 1: arouses, but not to consciousness, with painful stimulus; 0: unresponsive to painful stimulus). Comparison of patients who received a N_2O /O_2 mix that contained a maximum of 50%

TABLE 3 Depth of Sedation in ED Patients Who Received N_2O for PSA ($n = 655$)

Depth of Sedation	Total (Any Concentration N_2O)		N_2O 50%		N_2O 70%	
	n	%	*n*	%	*n*	%
0	2	0.3	0	—	1	0.2
1	10	1.5	0	—	8	1.6
2	7	1.1	0	—	7	1.4
3	43	6.6	3	3.3	36	7.4
4	232	35.4	27	29.7	183	37.8
5	319	48.7	58	64.4	216	44.6
6	42	6.4	2	2.2	33	6.8
Total	655	100	90	100	484	100

Depth of sedation based on the Children's Hospital of Wisconsin sedation scale.[3] Deepest level of sedation not recorded for 107 patients.

(mean sedation score: 4.6; 95% CI: 4.5–4.8) as compared with a maximum of N_2O 70% (mean sedation score: 4.4; 95% CI: 4.3–4.5) showed significantly deeper sedation with N_2O 70% ($P = .002$). An analysis of sedation episodes with sedation scores 0 to 2 indicated that there were 3.3% (95% CI: 1.9%–5.3%) of episodes of deep sedation with N_2O 70% and 0% (95% CI: 0%–4.0%) with N_2O 50%. A similar analysis for sedation scores of 0 to 3 indicated 10.7% (95% CI: 8.1%–13.8%) of episodes of moderate to deep sedation with N_2O 70% and 3.3% (95% CI: 0.7%–9.4%) with N_2O 50%, a statistically significant difference ($P = .03$).

A total 190 children (24.9%; 95% CI: 21.9%–28.2%) who were ≤3 years had received N_2O of any concentration. Although this information was not collected, children who are younger than 4 years in general require administration of N_2O by assisted-mask application rather than patient controlled. When comparing mean sedation depth in children who were ≤3 years (mean sedation score: 4.5; 95% CI: 4.3–4.6) with children who were older than 3 years (mean sedation score: 4.5; 95% CI: 4.3–4.5) and for whom sedation depth was known, younger children were found to have similar sedation depths ($P = .7$). An analysis of sedation episodes with sedation scores 0 to 2 indicated that there was no significant difference ($P = .9$) in the percentage of deep sedation when children who were ≤3 years of age (2.9%; 95% CI: 0.9%–6.8%) were compared with older children (2.8%; 95% CI: 1.5%–4.7%).

DISCUSSION

In the past decade, N_2O has gained significant popularity for use in pediatric procedural sedation. A number of studies have tested it, often against other techniques, for laceration repair, fracture reduction, dental procedures, and vascular access.[6–11] Most of this literature is with the use of N_2O and O_2 mixtures in concentrations of up to 50% via demand valve or continuous flow. More recently, interest has been shown in higher concentrations of N_2O—up to 70%—given by continuous-flow mixers.[12] There remains concern about the use of these higher concentrations of N_2O with suggestions that deeper sedation is likely to result and that the incidence of complications is therefore likely to be higher.

This study describes experience with N_2O use in >700 patients in a single pediatric ED. The majority (72%) of children were sedated with N_2O 70%. The previous largest ED study of N_2O 70% was a report of N_2O use in 224 patients, 64 of whom received a maximum concentration of 70%.[12] The largest reported series of N_2O 70% was in 1018 children who underwent urethral catheterization in the radiology suite.[13] Neither of these studies reported sedation depth. We found that children who were sedated with N_2O 70% had overall deeper sedation ($P = .002$) and more had moderate or deep sedation ($P = .03$) than children who received N_2O 50%. Mean sedation depth with N_2O 70% was 0.2 sedation points lower than N_2O 50% (4.4 vs 4.6); however, even at the limits of the CIs, the difference would be only 0.5 sedation points (4.3 vs 4.8). This difference is unlikely to have any clinical significance.

Adverse events were infrequent and experienced by 8% of children, with only 2 patients, both having received N_2O 70%, experiencing serious adverse events. There were no airway problems encountered. The incidence and spectrum of adverse events is similar to that in other studies. There was no difference in the frequency or seriousness of adverse events between patients who were administered N_2O 70% or those who were administered N_2O 50%. Because of the variability of definitions used (eg, inclusion of mask intolerance), the incidence of adverse events reported here (8%) is difficult to compare with those in the other studies that used N_2O 70%, ranging from 27%[12] to 4%.[13]

The overall frequency of adverse events is higher than that cited by Cravero and Blike[14] in their review of 30 000 episodes of pediatric sedation/anesthesia outside the operating room. Their data did not include patients who were sedated with N_2O. The incidence of adverse events found in their study was 339.6 per 10 000, and our incidence was 944 per 10 000. The difference is made up entirely by the increased incidence of emesis in our population (595 per 10 000 compared with 47.2 per 10 000). The incidence of desaturation was only 13.1 per 10 000 in our population compared with 156.5 per 10 000. These data support existing studies that indicated that N_2O has a higher incidence of vomiting than many other procedural analgesic agents, but with current procedural sedation processes,[3,4] this did not translate into an increase in airway or breathing problems.

Reviews of N_2O and even proponents of its use have suggested that administration to children who are younger than 4 years should be performed with extreme caution. Luhmann et al[9] reported the use of continuous-flow N_2O (50%) in 2- to 6-year-olds for laceration repair, concluding it to be an effective procedural analgesic and sedative. Annequin et al[15] reported using premixed N_2O 50% in children for procedural sedation; 295 (24%) were younger than 6 years, and 46 (4%) were younger than 2 years. They noted more distress in the younger children but did not analyze depth of sedation or adverse events for these groups. Frampton et al[12] reported the use of N_2O (mostly using N_2O 50%–60%) in 224 children, 113 (50.4%) of whom were younger than 5 years. Their study did not analyze adverse events in age strata. Zier et al[13] described N_2O 70% use in 1018 children who were aged from 11 months (median age: 4.8 years) and underwent urethral catheterization, but, again, adverse events and sedation depth were not analyzed in age strata. Gall et al[16] reported the use of premixed N_2O 50% in 7511 cases of procedural sedation. They found age <1 year to be the main factor affecting the incidence of adverse events (2.3% vs 0.3% for children ≥1 year), with no difference in adverse events in other age strata. Our ED sedation guidelines recommend the use of N_2O only in children who are older than 1 year; almost one quarter of patients in this study were between 1 and 4 years of age. There was no difference in the mean sedation depth in those compared with older children (4.5 vs 4.5), and similar proportions in the groups of children who were younger than and older than 4 years experienced deep sedation (2.9% vs 2.8%; $P = .9$).

There are a number of limitations. Recording of adverse events depended on accurate recording of information on the sedation record or in the medical chart by staff who were involved in the procedural sedation. There were no independent observers, and staff might have felt pressured to underreport adverse events. It is possible that a number of mild transitory adverse events occurred in the ED without being recorded or occurred after discharge. Vomiting after N_2O use can occur after discharge[17]; however, on the basis of a review of the hospital-wide adverse events reporting system, we are confident that no major adverse events and specifically no admissions related to adverse events were missed during the study period. A number of procedures under N_2O during the study period were likely missed. Patients who were most likely to have been missed were those who presented with acute distress that required immediate N_2O use as an analgesic (eg, to apply a backslab in a displaced fracture, for dislocations). Analysis of sedation depth was limited to patients for whom deepest sedation depth had been recorded. The age distribution and diagnoses of patients without sedation scores were similar to the group who had sedation scores available for analysis. Assignment of sedation scores, although used for a number of years in the ED and taught to all ED medical and nursing staff in a standardized sedation education program,[3,4] is open to some interpretation, and the inter-rater reliability of staff-determined sedation depth was not assessed. We did not record which device was used to administer N_2O, continuous-flow or demand-valve administration; however, any concentration of N_2O other than N_2O 50% was available only via the variable-concentration continuous-flow system. We estimate that even N_2O 50% was administered only rarely via demand valve rather than continuous flow (in <5% of cases).

CONCLUSIONS

This is the largest reported ED study of sedation with N_2O 70%. It shows that N_2O 70% provides similar sedation depth to N_2O 50% with no increase in adverse events. N_2O seems safe for use in children who are 1 to 3 years of age. What remains to be shown is whether there is any advantage in using N_2O 70% (ie, an improved ability to complete a procedure without pain and distress).

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REFERENCES

1. Krauss B. Continuous-flow nitrous oxide: searching for the ideal procedural anxiolytic for toddlers. *Ann Emerg Med*. 2001; 37(1):61–62
2. Krauss B, Green SM. Procedural sedation and analgesia in children. *Lancet*. 2006;367(9512):766–780
3. Babl F, Priestley S, Krieser D, et al. Development and implementation of an education and credentialing programme to provide safe paediatric procedural sedation in emergency departments. *Emerg Med Australas*. 2006;18(5–6):489–497
4. Priestley S, Babl FE, Krieser D, et al. Evaluation of the impact of a paediatric procedural sedation credentialing programme on quality of care. *Emerg Med Australas*. 2006;18(5–6):498–504
5. Hoffman GM, Nowakowski R, Troshynski TJ, Berens RJ, Weisman SJ. Risk reduction in pediatric procedural sedation by application of an American Academy of Pediatrics/American Society of Anesthesiologists process model. *Pediatrics*. 2002; 109(2):236–243
6. Evans JK, Buckley SL, Alexander AH, Gilpin AT. Analgesia for the reduction of fractures in children: a comparison of nitrous oxide with intramuscular sedation. *J Pediatr Orthop*. 1995; 15(1):73–77
7. Gregory PR, Sullivan JA. Nitrous oxide compared with intravenous regional anesthesia in pediatric forearm fracture manipulation. *J Pediatr Orthop*. 1996;16(2):187–191
8. Hennrikus WL, Simpson RB, Klingelberger CE, Reis MT. Self-administered nitrous oxide analgesia for pediatric fracture reductions. *J Pediatr Orthop*. 1994;14(4):538–542
9. Luhmann JD, Kennedy RM, Porter FL, Miller JP, Jaffe DM. A randomized clinical trial of continuous-flow nitrous oxide and midazolam for sedation of young children during laceration repair. *Ann Emerg Med*. 2001;37(1):20–27
10. Luhmann JD, Schootman M, Luhmann SJ, Kennedy RM. A randomized comparison of nitrous oxide plus hematoma block versus ketamine plus midazolam for emergency department forearm fracture reduction in children. *Pediatrics*. 2006;118(4). Available at: www.pediatrics.org/cgi/content/full/118/4/e1078
11. Lyratzopoulos G, Blain KM. Inhalation sedation with nitrous oxide as an alternative to dental general anaesthesia for children. *J Public Health Med*. 2003;25(4):303–312
12. Frampton A, Browne GJ, Lam LT, Cooper MG, Lane LG. Nurse administered relative analgesia using high concentration nitrous oxide to facilitate minor procedures in children in an emergency department. *Emerg Med J*. 2003;20(5):410–413
13. Zier JL, Drake GJ, McCormick PC, Clinch KM, Cornfield DN. Case-series of nurse-administered nitrous oxide for urinary catheterisation in children. *Anesth Analg*. 2007;104(4): 876–879
14. Cravero JP, Blike GT. Pediatric anesthesia in the nonoperating room setting. *Curr Opin Anaesthesiol*. 2006;19(4):443–449
15. Annequin D, Carbajal R, Chauvin P, Gall O, Tourniaire B, Murat I. Fixed 50% nitrous oxide oxygen mixture for painful procedures: a French survey. *Pediatrics*. 2000;105(4). Available at: www.pediatrics.org/cgi/content/full/105/4/e47
16. Gall O, Annequin D, Benoit G, Glabeke E, Vrancea F, Murat I. Adverse events of premixed nitrous oxide and oxygen for procedural sedation in children. *Lancet*. 2001:1514–1515
17. Babl FE, Puspitadewi A, Barnett P, Oakley E, Spicer M. Preprocedural fasting state and adverse events in children receiving nitrous oxide for procedural sedation and analgesia. *Pediatr Emerg Care*. 2005;21(11):736–743

High-Concentration Nitrous Oxide for Procedural Sedation in Children: Adverse Events and Depth of Sedation

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Case-Series of Nurse-Administered Nitrous Oxide for Urinary Catheterization in Children

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BACKGROUND: Children undergoing urologic imaging studies requiring urethral catheterization experience considerable discomfort and psychological distress. Nitrous oxide sedation may mitigate these detriments but the requirement for physician administration has limited the applicability of this technique.
METHODS: Registered nurses underwent the nitrous oxide training requirements prescribed for state licensure of dentists and dental hygienists, with special emphasis on pediatric sedation principles. To evaluate the safety of nurse-administered nitrous oxide, we consecutively enrolled all children (ASA PS I–II) sedated for urethral catheterization for urologic imaging in an observational trial designed to identify sedation-related adverse events.
RESULTS: Nitrous oxide was administered on 1018 occasions. There were no major adverse events (apnea, oxygen saturation <92%). Minor adverse events (diaphoresis, nausea, vomiting) occurred in 4% of patients. Eight patients (1%) were described as over-sedated. In 11 (1%) patients, nitrous oxide provided insufficient sedation for completion of urologic imaging.
CONCLUSIONS: Nitrous oxide sedation can be provided by a nurse-administered program in pediatric radiology. Administration of nitrous oxide for pediatric procedures by adequately trained nursing staff with appropriate multidisciplinary oversight may increase children's access to this sedative/analgesic drug.
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Considerable and well-warranted attention has been focused recently on the issue of pediatric pain management (1,2) and procedural sedation (3). Pain and distress experienced by children during medical procedures increases distress and anxiety during subsequent procedures (4). Urethral catheterization, although not particularly traumatic from an adult perspective, can be especially troublesome and painful in children who lack the emotional or cognitive maturity to cooperate or to understand the reasons for the procedure (5,6). Urethral catheterization is required for urologic imaging with voiding cystourethrography (VCUG) and radionucleide cystography (RNC). As many children with urologic abnormalities will require testing at regular intervals, it is particularly important to use strategies that minimize distress and discomfort. Oral midazolam effectively mitigates the anxiety and distress associated with these procedures, but has a half-life which significantly exceeds the time required for imaging, and often results in unwanted behavioral side effects (7). Recent data suggest that nitrous oxide (N_2O) is as effective a sedative drug as oral midazolam for VCUG (8). Given the cost and workforce requirements of anesthesiologist or intensivist-administered N_2O sedation, Children's Hospitals and Clinics of Minnesota developed a nurse-administered N_2O program to facilitate procurement of VCUG and RNC studies. If both safe and effective, nurse-administered N_2O procedural sedation is likely to be less costly and more readily available than the traditional anesthesiologist-led procedure. The present study was undertaken to evaluate the safety and efficacy of the program by determining the incidence of adverse events and the ability to successfully complete the imaging using N_2O sedation administered by registered nurses.

METHODS

This study was approved by the IRB of Children's Hospitals and Clinics of MN. Given the observational study design, written informed consent was not required.

Nurse-administered N_2O Program

Registered nurses trained and experienced in monitoring deeply sedated pediatric patients underwent the training requirements prescribed for state licensure of dentists and dental hygienists for N_2O administration. Accreditation entailed attendance at an 8-h course designed to address the pharmacology, toxicity, and environmental safety of N_2O as well as the

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equipment used for its delivery. After successful completion of this course, the clinical competency of each qualified nurse was assessed during four additional hours of observation and mentored administration of N_2O. The program met the guidelines of the American Nurses' Association for registered nurses charged with the management of patients receiving IV medication for short-term diagnostic procedures (9).

N_2O Administration

A standard dental flowmeter and rubber goods were used for N_2O administration and scavenging. Inhaled N_2O was administered via a continuous flow device (Porter Instrument Company, Hatfield, PA) which allows titration of N_2O concentration from zero to a maximum of 70%, with oxygen as the remaining gas. Unlike the commercially available fixed 50:50 N_2O:O_2 mixture, there was no need for the patient to overcome a demand valve to maintain N_2O delivery. The equipment incorporates built-in safety features, including a non-rebreathing valve, emergency air intake valve, and fail-safe device that automatically terminates the flow of N_2O in the event of an interruption in oxygen flow. The equipment includes an apparatus for exhaled gas scavenging and evacuation. An adequate seal could be comfortably maintained using the nasal hood over the nose of the older child or over the nose and mouth of a toddler. Before clinical use, the equipment was assembled and tested for N_2O leakage by the hospital's biomedical department. Badge dosimetry monitoring was performed periodically to ensure compliance with National Institute of Occupational Safety and Health N_2O occupational exposure limit of less than 25 ppm time-weighted average.

N_2O Sedation for Urologic Imaging

All patients underwent a presedation assessment before sedation administration to identify potential contraindications to sedation (e.g., gastroesophageal reflux, craniofacial abnormalities) and inhaled N_2O (e.g., pneumothorax, bowel obstruction). A set of vital signs, including temperature, respiratory rate, heart rate, arterial blood pressure, and baseline pulse oximetry reading, were obtained during the presedation assessment. By hospital policy, all patients with ASA classification >II were ineligible to receive nurse-administered N_2O and did not participate in this study. During the initial 4 mo of the study, patients were kept fasting for a minimum of 4 h before sedation. On the basis of further literature review (10,11) and interim analysis of the study data, subsequent patients were instructed to restrict intake to at most a light meal for 4 h before the procedure. N_2O was administered at 70% N_2O/30% O_2 until completion of urethral catheterization. After catheterization, 100% oxygen was administered for 2–5 min. Throughout the N_2O administration, and until the child returned to the presedation level of alertness, the patient was monitored with continuous pulse oximetry and direct nursing observation. No additional arterial blood pressure recordings were obtained. VCUG or RNC was then performed as determined by radiology protocol. Venous access was not obtained in any child, either for the imaging study or, per policy, for N_2O sedation.

Table 1. Adverse Effects of Nitrous Oxide for Urologic Imaging in 1018 Children

	N	%
Apnea (>15 s)	0	0
O_2 saturation <92% (>1 s)	0	0
Diaphoresis	7	1
Nausea	9	1
Vomiting	21	2
Other (crying, pallor, agitation)	8	1
Total unique cases with any side effect	36	4

Data Collection

From September, 2004 through April, 2006, all children receiving N_2O sedation for urethral catheterization for VCUG or RNC in the radiology department of the St. Paul campus of Children's Hospitals and Clinics of MN were enrolled consecutively in the study. Data collection sheets were attached to each N_2O sedation order to ensure compliance with data collection for each patient. Data collected for this study included presence or absence of the side effects listed in the Table 1, duration of N_2O administration (<15, 15–30, >30 min), and whether the level of sedation was sufficient to allow successful completion of the procedure. Level of sedation was assessed as presence or absence of over-sedation, defined as sedation deeper than a drug-induced state during which patients respond normally to verbal commands.

RESULTS

N_2O was administered on 1018 occasions for urethral catheterization for either VCUG or RNC during the 20-mo study period. Review of departmental scheduling records revealed that there were 3398 VCUGs and RNCs scheduled during that time. One thousand ninety-three procedures were scheduled with sedation, representing data collection on a minimum of 93% of possible sedation encounters. The actual percentage may be higher, as last minute cancellations were not removed from the records. Patients ranged in age from 11 mo to 17 yr, with a mean age of 5.4 yr and median of 4.8 yr. Almost all (94%, n = 952) received N_2O for <15 min. Sixty-three patients (6%) received N_2O between 15 and 30 min and three patients (0.3%) received N_2O for longer than 30 min. No patient developed apnea (>15 s) or oxygen saturation below 92% (>1 s) at any time during N_2O administration or recovery. Thirty-six patients (4%) had minor adverse effects, including nausea, diaphoresis, and/or vomiting (Table 1). Eleven procedures (1%) were unsuccessful due to sedation failure.

Eight patients (1%) were described as over-sedated. Charts of all eight patients were reviewed. One patient was described as "snoring," with rapid response to discontinuation of N_2O and initiation of 100% oxygen. None required airway intervention.

DISCUSSION

Dentists have been administering N_2O alone or combined with other sedatives and analgesics since the 1800s (12). Eighty-five percent of pediatric dentists use N_2O for patient sedation (13). Although an article published in the Journal of the American Medical Association more than 20 yr ago described the use of N_2O for more than 3000 patients in a general pediatric office in UT, (14) the use of N_2O for pediatric procedural sedation in the United States likely remains sporadic. Use of N_2O outside of the operating room or dental clinic has been reported primarily in the pediatric emergency department for laceration repair (15,16) or fracture reduction (17,18).

N_2O administration by non-physician providers is routine. Either dentists or dental hygienists can deliver N_2O in much of the United States. Advanced practice nurses deliver N_2O to pediatric patients for minor surgical procedures in the United States (19). Registered nurses deliver N_2O in the emergency department and outpatient setting in Australia and England (20,21). The safety of N_2O administration to children by pre-hospital providers, including lay responders, has been documented (22).

A recent article (23) addressed the efficacy of a tiered approach to pediatric sedation including nurse-administered protocols. The authors stressed the importance of accurately matching the pharmacologic approach to appropriately trained personnel. The present report provides data that supports the notion that inhaled N_2O can be used by registered nurses for specific urologic procedures. While several articles have addressed the safety of N_2O sedation for a variety of pediatric procedures (24–31), the current study adds to this body of knowledge by reporting the largest series of patients sedated with N_2O using a nurse-administered protocol. In the present series, the use of N_2O to expedite the performance of urologic imaging studies in more than 1000 children did not result in a single major adverse event (apnea or arterial oxygen saturation <92%). Despite using N_2O at a concentration of 70%, the incidence of minor adverse effects of N_2O (nausea, vomiting, diaphoresis) in the present study was less than previously reported (20,24). The difference may derive from the relatively short duration of administration of N_2O required to expedite urethral catheterization.

Restriction of N_2O administration privileges to physicians or nurse anesthetists may not only considerably limit the use of N_2O as a sedative/analgesic drug due to workforce requirements, but also increase the cost of the procedure. An editorial (32) critical of N_2O use for laceration repair in a pediatric emergency department cited the labor-intensive need for a physician to administer the N_2O in addition to the physician performing the procedure and asked the question, "can the substantial logistical hurdle of a separate sedating physician be overcome through special nurse training in this technique?" The current study seems to answer that question in the affirmative.

The present study does not address the quality of sedation for urethral catheterization. Rather the study end-point was the successful completion of the imaging study. Similarly, the study does not address discomfort that may have been encountered during the remainder of the urologic imaging (bladder filling, voiding). Nevertheless, our experience mirrors the report of Keidan et al. (8) wherein N_2O provided a reduction in anxiety and distress associated with urologic imaging comparable to oral midazolam, but with a shorter recovery time.

N_2O administered at <50% concentration in oxygen with no other sedative or analgesic medications is recognized as minimal sedation (33). For this study, patients characterized as "over-sedated" correspond to a level of sedation deeper than minimal sedation, as outlined in the ASA Continuum of Depth of Sedation (33). Even though N_2O was administered at a concentration of 70%, more than 99% of the study patients remained at the level of minimal sedation, as judged by responsiveness to verbal stimulation. The fact that eight patients reached a level of moderate sedation nevertheless reinforces the importance of preparation to appropriately manage patients at the level of moderate sedation when N_2O is used at this concentration. Measurement of patient sedation level during N_2O administration using a validated sedation scale is important information for future study. Rates of dysphoria should also be measured in future studies with larger sample sizes to better estimate rates of adverse events.

In conclusion, the present data support the notion that N_2O sedation can be safely and effectively provided using a nurse-administered program in a hospital-based radiology department. Administration of N_2O for pediatric procedures by adequately trained nursing staff with appropriate multidisciplinary oversight may increase children's access to this sedative/analgesic drug.

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REFERENCES

1. Brislin RP, Rose JB. Pediatric acute pain management. Anesthesiol Clin North Am 2005;23:789–814.
2. Young KD. Pediatric procedural pain. Ann Emerg Med 2005;45:160–71.
3. Cravero JP, Bilke GT. Review of pediatric sedation. Anesth Analg 2004;99:1355–64.
4. Chen E, Zeltzer LK, Craske MG, Katz ER. Alteration of memory in the reduction of children's distress during repeated aversive medical procedures. J Consult Clin Psychol 1999;67:481–90.

5. Phillips D, Watson AR, Collier J. Distress and radiological investigations of the urinary tract in children. Eur J Pediatr 1996;155:684–7.
6. Stashinko EE, Goldberger J. Test or trauma? The voiding cystourethrogram experience of young children. Issues Compr Pediatr Nurs 1998;21:85–96.
7. Elder JS, Longenecker R. Premedication with oral midazolam for voiding cystourethrography in children: safety and efficacy. AJR 1995;164:1229–32.
8. Keidan I, Zaslansky R, Weinberg M, et al. Sedation during voiding cystourethrography: comparison of the efficacy and safety of using oral midazolam and continuous flow nitrous oxide. J Urol 2005;174:1598–601.
9. Odom-Forren J. The evolution of nurse-monitored sedation. J Perianesth Nurs 2005;20:385–98.
10. Babl FE, Puspitadewi A, Barnett P, et al. Preprocedural fasting state and adverse events in children receiving nitrous oxide for procedural sedation and analgesia. Pediatr Emerg Care 2005;21: 736–43.
11. American Academy of Pediatric Dentistry. Guideline on appropriate use of nitrous oxide for pediatric dental patients. Pediatr Dent 2005;27:107–9.
12. Yagiela JA. Office-based anesthesia in dentistry. Dent Clin North Am 1999;43:201–15.
13. Dock M, Creedon RL. Pharmacologic management of patient behavior. In: McDonald RE, Avery DR, Dean JA, eds. Dentistry for the child and adolescent. St. Louis: Mosby, 2004:285–311.
14. Griffin GC, Campbell VD, Jones R. Nitrous oxide-oxygen sedation for minor surgery. Experience in a pediatric setting. JAMA 1981;245:2411–3.
15. Luhmann JD, Kennedy RM, Porter FL, et al. A randomized clinical trial of continuous-flow nitrous oxide and midazolam for sedation of young children during laceration repair. Ann Emerg Med 2001;37:20–7.
16. Gamis AS, Knapp JF, Glenski JA. Nitrous oxide analgesia in a pediatric emergency department. Ann Emerg Med 1990;19:843–4.
17. Gregory PR, Sullivan JA. Nitrous oxide compared with intravenous regional anesthesia in pediatric forearm fracture manipulation. J Pediatr Orthop 1996;12:187–91.
18. Hennrikus WL, Shin AY, Klingelberger CE. Self-administered nitrous oxide and a hematoma block for analgesia in the outpatient reduction of fractures in children. J Bone Joint Surg Am 1995;77:335–9.
19. Burnweit C, Diana-Zerpa JA, Nahmad MH, et al. Nitrous oxide analgesia for minor pediatric surgical procedures: an effective alternative to conscious sedation? J Pediatr Surg 2004;39:495–9.
20. Frampton A, Browne GJ, Lam LT, et al. Nurse administered relative analgesia using high concentration nitrous oxide to facilitate minor procedures in children in an emergency department. Emerg Med J 2003;20:410–3.
21. Cleary AG, Ramanan AV, Baildam E, et al. Nitrous oxide analgesia during intra-articular injection for juvenile idiopathic arthritis. Arch Dis Child 2002;86:416–8.
22. Faddy SC, Garlick SR. A systematic review of the safety of analgesia with 50% nitrous oxide: can lay responders use analgesic gases in the prehospital setting? Emerg Med J 2005;22:901–8.
23. Dalal PG, Murray D, Cox T, et al. Sedation and anesthesia protocols used for magnetic resonance imaging studies in infants: provider and pharmacologic considerations. Anesth Analg 2006;103:863–8.
24. Kanagasundaram SA, Lane LJ, Cavalletto BP, et al. Efficacy and safety of nitrous oxide in alleviating pain and anxiety during painful procedures. Arch Dis Child 2001;84:492–5.
25. Annequin D, Carbajal R, Chauvin P, et al. Fixed 50% nitrous oxide oxygen mixture for painful procedures: a French survey. Pediatrics 2000;105:e47.
26. Michaud L, Gottrand F, Ganga-Zandzou PS, et al. Nitrous oxide sedation in pediatric patients undergoing gastrointestinal endoscopy. J Pediatr Gastroenterol Nutr 1999;28:310–4.
27. Bar-Meir E, Zaslansky R, Regev E, et al. Nitrous oxide administered by the plastic surgeon for repair of facial lacerations in children in the emergency room. Plast Reconstr Surg 2006;117: 1571–5.
28. Fishman G, Botzer E, Marouani N, DeRowe A. Nitrous oxide–oxygen inhalation for outpatient otologic examination and minor procedures performed on the uncooperative child. Int J Pediatr Otorhinolaryngol 2005;69:501–4.
29. Ekbom K, Jakobsson J, Marcus C. Nitrous oxide is a safe and effective way to facilitate procedures in paediatric outpatient departments. Arch Dis Child 2005;90:1073–6.
30. Faroux B, Onody P, Gall O, et al. The efficacy of premixed nitrous oxide and oxygen for fiberoptic bronchoscopy in pediatric patients. Chest 2004;125:315–21.
31. Gall O, Annequin D, Benoit G, et al. Adverse events of premixed nitrous oxide and oxygen for procedural sedation in children. Lancet 2001;358:1514–5.
32. Krauss B. Continuous-flow nitrous oxide: searching for the ideal procedural anxiolytic for toddlers. Ann Emerg Med 2001;37:61–2.
33. American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. Practice guidelines for sedation and analgesia by non-anesthesiologists. Anesthesiology 2002;96:1004–17.

Exhibit 5

ORIGINAL ARTICLE

Nitrous oxide inhalation is a safe and effective way to facilitate procedures in paediatric outpatient departments

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See end of article for authors' affiliations

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Aims: To evaluate the efficacy and safety of nitrous oxide treatment given to children presenting procedural problems in a paediatric outpatient department.

Methods: The study comprised 70 children 6–18 years old. Two different groups were studied. (1) Children presenting with problems in establishing venous cannulation (VC) (n = 50). The patients were randomised to conventional treatment (CO); cutaneous application of EMLA or nitrous oxide treatment (NO); N_2O and EMLA. (2) Anxious children/children undergoing painful procedures who repeatedly come to the clinic (n = 20). These children underwent two procedures with CO/NO, the order of priority being randomised. Altogether the study included 90 procedures. Main outcome measures were procedure time, number of attempts required to establish VC, pain, and evaluation.

Results: All procedures were performed with NO while four VC (8%) were not possible to perform with CO. The number of attempts required to establish VC was lower when using NO (median 2, range 2–9), compared with CO (median 4, range 2–9). The estimated pain was lower with NO. The total mean time required was similar for NO and CO when the time required for the NO procedure was included. One complication, tinnitus, was observed; it disappeared within 3 minutes.

Conclusion: The pretreatment with nitrous oxide is a time effective and safe method for use at paediatric outpatient departments to reduce pain, facilitate venous cannulation, and thereby reduce the number of costly cancellations of planned procedures.

Pain, anxiety, and difficulties related to venipunctures (VP), venous cannulations (VC), and other procedures are recurrent problems in paediatric outpatient departments, resulting in trauma for the children and sometimes delayed and cancelled procedures.[1 2]

Although the use of anaesthetic creams such as EMLA has significantly reduced the problems associated with VP, VC, painful injections, and implants,[3] the pain alleviation obtained with EMLA is sometimes insufficient and a conflict easily arises between the need for speed, efficiency, and adequate pain reduction.

In obese patients, VC/VP is regularly associated with technical problems. The number of severely obese children is increasing dramatically in the western world and the need for examinations and treatments will increase in order to prevent and treat potential obesity complications. In obese children, the veins are hidden deep in the subcutaneous adipose tissue, which makes it impossible to visualise the veins and also very difficult to feel them.

Consequently, there is a demand for more efficient methods for patients in whom technical difficulties in effectuating VC or VP can be expected, for children who are treated on a regular basis with painful injections and implants, and finally, for generally anxious children.

Treatment with nitrous oxide (NO) is a well established method for pain alleviation[4–7] and has been used with good results, in particular in children who fear the dentist.[8 9] According to an extensive retrospective French survey, the method works very well in minor surgery.[5]

NO has both pain reduction and sedation effects,[10 11] which may be useful when the VP is performed; it may also simplify the VC in cases where it is technically difficult to establish.[12–15]

NO inhalation in paediatric outpatient care has not yet been evaluated; the aim of this study was to evaluate the advantages, disadvantages, and safety of NO in a paediatric outpatient setting.

METHODS

Patients

The study was approved by the Ethical Committee at Huddinge University Hospital and the written informed consent of all parents and children was obtained.

The study comprised 70 children aged 6–18 years. The inclusion criteria included: ASA status I, American Society for Anesthesia classification of health (http://www.asahq.org), a classification as a normal healthy child with no disturbance,[16] ability to breathe by means of a mask, and the ability to interpret a visual analogue scale (VAS).

Age, diagnosis, and sex are presented in table 1.

Two different groups of children were studied:

- Children with well known difficulties in effectuating VC (DVC). All of these children had previously experienced difficulties in connection with VP/VC and it was necessary to make several attempts at different sites before being able to take a sample or establish intravenous access (n = 50). The children came for a double VC as preparation for an intravenous glucose tolerance test. The patients were randomised to conventional treatment (CO) or nitrous oxide treatment (NO) by envelope technique. A specialist nurse in anaesthesia effectuated 30 of the VCs using a 22 G catheter (15 CO/15 NO) and a general nurse established 20 VCs using a 22 G catheter (10 CO/10 NO).
- Anxious children and children undergoing painful procedures (ACP) who come repeatedly to the clinic for these procedures (n = 20). The children were subjected to two procedures, one with CO and one with NO. The order was randomised. All procedures were performed by the same nurse.

Abbreviations: ACP, anxious children and children undergoing painful procedures; CO, conventional treatment; DVC, difficulties in effectuating venous cannulation; NO, nitrous oxide; VAS, visual analogue scale; VC, venous cannulation; VP, venipuncture

Table 1 Clinical diagnosis and characteristics of the patients

	DVC Children with difficulties in effectuating venous cannulation (n = 50)	ACP Anxious children/children undergoing painful procedures (n = 20)
Age	13 (6–18)	11 (6–17)
Boys/girls	27/23	4/16
Diagnosis	49 OB/1 SS	8 OB/8 PP/2 SS/1 DI/1 AL
Procedure	50 VC	8 I/11 VP/1V

Results are presented as median (range).
Diagnosis: OB, obesity; PP, puberty praecox; SS, short statue; DI, diabetic AL, allergy.
Procedure: VP, venipuncture; VC, venous cannulation; V, vaccination; I, injection/implant: procren (n = 3), decapeptyl (n = 3), suprefact(n = 2).

The equipment included an anaesthetic block (Dräger RCD DS3) with separate rotameters for oxygen/nitrous oxide/air connected to a Bains circuit (partial rebreathing system), a regulator, a fail safe system which shuts off the N_2O if there is an oxygen pressure decrease, and a pulse oximeter (Date-Ohmeda TUFF SAT).

Children who fulfilled the inclusion criteria were consecutively asked if they wanted to participate in the study. Four children did not choose to participate (3 DVC/1 ACP).

These patients received conventional treatment (EMLA cream). In one case, the procedure was cancelled.

Procedures

All children had cutaneous application of anaesthetic EMLA cream one hour before the procedure. NO included N_2O and EMLA cream. The children in the DVC group were not given any solid food or liquid after midnight because of the glucose tolerance test. In order to diminish the risk of nausea/vomiting,[17 18] the children in the ACP group were not given any solid food within 4 hours and no liquid within 2 hours before the treatment.

A nurse specialised in paediatric anaesthesia performed all the nitrous oxide treatments. The nitrous oxide concentration was increased in gradual stages to facilitate the cooperation and participation of the child, starting with 2 l N_2O/6 l O_2 (8 l/min fresh gas flow) for 2 minutes, thereafter increasing to 3 l N_2O for 2 minutes, and 4 l N_2O for 1 minute: the procedure was then performed. Altogether the time required for introduction and emergency of N_2O was 8 minutes. The time required to achieve an adequate level of sedation/analgesia was 5 minutes; after the procedure there was an additional 3 minutes for nitrous oxide washout, with the child breathing 100% oxygen. The children held the mask themselves; if necessary, they were assisted by a parent.

Parameters

The following variables were assessed and recorded: *the number of attempts* that were required for double VC was measured as well as *the time required for the procedure* with and without the NO procedure. *Pain* was evaluated by means of a VAS ranging from 1 to 10,[19], 5 minutes after performing the procedure or 5 minutes after accomplishing treatment with NO. *The children's and parents' evaluation of the procedure* were evaluated on a five point global rating scale: 1, poor; 2, fair; 3, good; 4, very good; 5, excellent.[19] The children performed the evaluation before the parents and the parents were present when the children made their assessment; *the nurses' assessment of the treatment* was made using a three point scale: 1, procedure without complications; 2, the procedure was performed with difficulties since the child was protesting and found it difficult to remain lying down; 3, the procedure could not be performed. The children in DVC were followed up 4 hours after NO treatment and children in ACP at the next visit to the clinic. The children who tested both CO and NO were asked which method they would prefer next time.

Heart rate and oxygen saturation were followed throughout the procedures by means of pulse oximetry. Side effects were recorded.

Statistics

All results are presented as median and range. In the first part the groups were compared by means of the Mann-Whitney test. For comparisons of paired data the Wilcoxon test was used in the second part of the study. All statistical analyses were performed using SPSS for Windows software.

RESULTS

Table 2 summarises the results for children with previous difficulties with venous cannulation.

In the CO group, four VC procedures (8%) were not accomplished, three because of too many unsuccessfully attempts and in one case because only one attempt was allowed by the frightened adolescent. The procedures were interrupted when the child refused to cooperate. The time required for these four procedures was 21–85 minutes. Nine procedures (18%) were accomplished with difficulty. In 84% of the cases more than two attempts were required to establish double VC. The pain was rated as high. Children and parents considered the procedure trying. The time of the procedure varied considerably (range 7–95 minutes).

All procedures were accomplished in the NO group. The number of attempts required to establish double VC was significantly lower. In 40% of the cases, more than two attempts were required to effectuate double VC. The pain was rated as low in this group. Children and parents considered the treatment to be tolerable. There was no significant difference in time required for VC between CO and NO. If the time for induction and completion of NO was excluded, the time required was significantly lower. Whether a specialist nurse or general nurse performed the VC did not affect the results. No complications were detected during the treatment or at follow up after NO treatment.

Table 3 summarises the results of anxious children/children undergoing painful procedures.

With CO, one procedure (5%) could not be performed; on nine occasions (45%), it could only be performed with difficulty. The pain was estimated as high in each case according to VAS. The comments of children and parents indicated that they considered the procedure difficult. The time for the procedure varied (range 4–95 minutes).

All procedures with NO were performed without problems. The experience of pain was rated lower in all cases. The

Table 2 Children with difficulties in effectuating venous cannulation, DVC (n = 50) with CO (conventional treatment) or NO (nitrous oxide treatment

	DVC/CO	DVC/NO	p†
No. of attempts	4 (2–9)	2 (2–6)	0.001
Pain, VAS	5 (2–10)	2 (1–4)	<0.001
Time required*, min	21 (7–95)	18 (5–57)	0.005
Satisfaction score, parents 1–5	3 (1–4)	5 (3–5)	<0.001
Satisfaction score, children 1–5	2 (1–4)	5 (4–5)	<0.001
Nurse's assessment 1–3	2 (1–3)	1 (1)	<0.001

Results are presented as median (range). In the satisfaction score, 5 is most satisfactory, in nurse's assessment, 1 is best (see Methods).
*In the time required for cannulation, the time for induction and completion of NO is not included (see Methods).
†Mann-Whitney test.

Table 3 Anxious children/children undergoing painful procedures, ACP(n=20) with CO (conventional treatment), and NO (nitrous oxide treatment)

	ACP/CO	ACP/NO	Difference CO v NO	p†
Pain, VAS	5 (1–10)	1 (1–6)	3 (0 to 9)	<0.001
Time required*, min	9 (4–95)	5 (1–18)	4.5 (−1 to 88)	<0.01
Satisfaction score, parents 1–5	3 (1–4)	4 (3–5)	−1 (−4 to −1)	<0.001
Satisfaction score, child 1–5	2 (1–3)	5 (4–5)	−3 (−4 to −1)	<0.001
Nurse's assessment 1–3	1.5 (1–3)	1 (1)	0 (0 to 2)	<0.005

Data are presented as median (range). In the satisfaction score, 5 is most satisfactory, in nurse's assessment, 1 is best (see Material and Methods).
*In the time required for the procedure is the time for induction and completion of NO not included (see Material and Methods).
†Wilcoxon signed rank test.

comments of children and parents indicated that they considered the treatment to be tolerable. The time required for the procedure was significantly lower with NO if the time for induction and completion was excluded. Ten minutes after the procedure, all children were able to walk by themselves.

The number of side effects with NO was low. One complication was documented during the NO treatment, tinnitus, and it disappeared within 3 minutes after the completion of NO. There were no other side effects reported by the children when they came back for the next treatment.

Ninety per cent of the children who tried both treatments preferred NO. There was a weak correlation ($r = 0.21$) between age and the number of attempts for VC in the DVC (CO) group. No other correlations were found between pain, age, and time required.

DISCUSSION

In a considerable number of children treated at outpatient departments, as shown both in this study and in previous ones,[2 26] anaesthetic cream does not induce sufficient analgesia. Among the 45 children in this study who underwent procedures with anaesthetic cream, 60% found it painful, defined as VAS >5.[19] This might lead to a vicious circle of anxious children becoming even more afraid, and implants, injections, and venous cannulations becoming technically more difficult to perform. Scheduled procedures cannot be completed when the venous cannulation fails and has to be postponed, and this is often regarded as a failure by the children, their parents, and the nursing staff. Furthermore, it is uneconomical for both the parents, who are losing a day's income, and for the medical services when an examination is postponed.

Consequently, there is a demand for effective means of anxiety and pain reduction for a selected group of children at outpatient departments. The results show that treatment with nitrous oxide augments the quality of care by facilitating venipuncture/venous cannulation without prolonging the effective time and making it possible to complete all procedures and examinations. The number of attempts needed to establish venous cannulation was also significantly lower with nitrous oxide. It made no difference whether a specialist or general nurse performed the venous cannulation. Thus, our results indicate that the need for a better pain reduction and to facilitate procedures for this group of patients can not be fulfilled solely by improving the technical skills of the nurse.

With CO we found a weak correlation between the age of the child and the number of attempts at venous cannulation, which means the number of attempts does not decrease when the children get older. This also indicates that procedural problems exist in all age groups, and most probably also in adults.

The ideal procedural method for pain relief is non-invasive and effective, with a rapid onset, reversal, and brief duration and with minimal side effects. Midazolam is an alternative method[20–24] or a complement to EMLA for anxious children, but it has no analgesic effect, a slow onset, and a long duration of action; it can also be difficult to administer orally or rectally. More efficient analgesic alternatives, like morphine or pethidine, require monitoring and personnel resources which are not available in paediatric outpatient clinics.

Administration of nitrous oxide is simple and painless, has a rapid onset and short duration, and its effects are analgesic, anxiolytic, and sedative with minimal side effects.[17 18] It is well known that nitrous oxide has a weak emetic effect[17] but no side effects like nausea/vomiting were documented in this study. This can be explained by the fact that obese children, who were performing glucose tolerance tests, were not given any solid food or liquid from midnight before the day of treatment and the other children were not given any food for four hours, and no liquid for two hours, before the treatment. However, there was no association between preprocedural fasting state and adverse events in a recent article; 50% of children having procedural sedation in the emergency department were not fasted.[25]

The NO concentration was increased in gradual stages. We believe that this facilitated the cooperation and participation of the children who held the mask themselves; loss of response to verbal command were not seen in any case, which made over sedation with NO almost impossible. The children should be old enough to cooperate by holding the mask, which makes the lowest age limit around 5–6 years old. Avoiding the smaller children decreases dramatically the risk for unforeseen negative effects.[18] In this study, only ASA 1[16] patients were included and only one minor complication was recorded, thereby confirming that nitrous oxide treatment is a safe method.[10 11 18] Because of the good results, we see no reason why ASA 2[16] patients could not be included when nitrous oxide is administered in this safe manner.

The treatment with nitrous oxide is easy to perform; the equipment required is an anaesthetic block, a suction unit, a scavenging system, and a pulse oximeter. The whole procedure, administration of NO and venous cannulation, when the maximum nitrous oxide concentration does not exceeded 50% and no other concomitant drugs are given apart from EMLA, can easily be performed by a single specially trained nurse if local regulations so permit. In the present study a registered specialised nurse in paediatric anaesthesia gave the sedation.

In conclusion, the described method, with nurse controlled self administered nitrous oxide has all the necessary properties to facilitate procedures and augment the quality of paediatric care for children, parents, and the nursing staff when needed.

What is already known on this topic

- Nitrous oxide is an anaesthetic gas commonly used in general anaesthesia
- In sub-anaesthetic concentrations, nitrous oxide has analgesic properties with rapid onset and offset of action that promotes its use in ambulatory setting

What this study adds

- This study has shown that at a paediatric outpatient clinic, nitrous oxide inhalation is a time effective and safe method to facilitate venous cannulation, reduce pain, and thereby reduce the number of costly cancellations of planned procedures

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REFERENCES

1 **Bristin RP,** Stayer SA, Schwartz RE, *et al.* Analgesia for venepuncture in a paediatric surgery centre. *J Paediatr Child Health* 1995;**31**:542–4.
2 **Jylli L,** Olsson GL. Procedural pain in a paediatric surgical emergency unit. *Acta Paediatr* 1995;**84**:1403–8.
3 **Kennedy RM,** Luhmann JD. Pharmacological management of pain and anxiety during emergency procedures in children. *Paediatr Drugs* 2001;**3**:337–54.
4 **Krauss B.** Continuous-flow nitrous oxide: searching for the ideal procedural anxiolytic for toddlers. *Ann Emerg Med* 2001;**37**:61–2.
5 **Annequin D,** Carbajal R, Chauvin P, *et al.* Fixed 50% nitrous oxide oxygen mixture for painful procedures: a French survey. *Pediatrics* 2000;**105**:e47.
6 **Cleary AG,** Ramanan AV, Baildam E, *et al.* Nitrous oxide analgesia during intra-articular injection for juvenile idiopathic arthritis. *Arch Dis Child* 2002;**86**:416–18.
7 **Burton JH,** Auble TE, Fuchs SM. Effectiveness of 50% nitrous oxide/50% oxygen during laceration repair in children. *Acad Emerg Med* 1998;**5**:112–17.
8 **Hallonsten AL,** Koch G, Schroder U. Nitrous oxide sedation in dental care. *Common Dent Oral Epidemiol* 1983;**11**:347–55.
9 **Roberts GJ.** Inhalation sedation (relative analgesia) with oxygen/nitrous oxide gas mixtures. *Dent Update* 1990;**17**:139–42.
10 **Kanagasundaram SA,** Lane LJ, Covaletto BP, *et al.* Efficacy and safety of nitrous oxide in alleviating pain and anxiety during painful procedures. *Arch Dis Child* 2001;**84**:492–5.
11 **Luhmann JD,** Kennedy RM, Jolfe DM, *et al.* Continuous-flow delivery of nitrous oxide and oxygen: a safe and cost-effective technique for inhalation analgesia and sedation of pediatric patients. *Pediatric Emerg Care* 1999;**15**:388–92.
12 **Henderson JM,** Spence DG, Komocar LM, *et al.* Administration of nitrous oxide to provide analgesia for venous cannulation. *Anesthesiology* 1990;**72**:269–71.
13 **Vetter TR.** A comparison of EMLA cream versus nitrous oxide for pediatric venous cannulation. *J Clin Anesth* 1995;**7**:486–90.
14 **Paut O,** Calmejane C, Delorme J, *et al.* Emla versus nitrous oxide for venous cannulation in children. *Anesth Analg* 2001;**93**:590–3.
15 **Hee HI,** Goy RW, NG AS. Effective reduction of anxiety and pain during venous cannulation in children: a comparison of analgesic efficacy conferred by nitrous oxide, EMLA and combination. *Paediatr Anaesth* 2003;**13**:210–16.
16 **Atkinson RS,** Rushmon GB, Alfred Lee. A synopsis of anesthesia. *Preanaesthetic Assessment* 1987;**109**:388–9.
17 **Houck WR,** Ripa LW. Vomiting frequency in children administered nitrous oxide/oxide in analgesic doses. *I Dent Child* 1971;**38**:404–7.
18 **Gall O,** Annequin D, Benoit G, *et al.* Adverse events of premixed nitrous oxide and oxygen for procedural sedation in children. *Lancet* 2001;**358**:1514–15.
19 **Hosey MT,** Blinkhorn AS. An evaluation of four methods of assessing the behaviour of anxious child dental patients. *International Journal of Paediatric Dentistry* 1995;**5**:87–95.
20 **Hulland S,** Freilich M, Sondor G. Nitrous oxide-oxygen or midazolam for paediatric outpatient sedation. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2002;**93**:643–6.
21 **Luhman JD,** Kenedy RM, Porter FL, *et al.* A randomised clinical trial of continuous-flow nitrous oxide and midazolam for sedation of young children during laceration repair. *Ann Emerg Med* 2001;**37**:20–7.
22 **Otley CC,** Nguen TH. Conscious sedation of pediatric patients with combination oral benzodiazepines and inhaled nitrous oxide. *Dermatolog Surg* 2000;**26**:1041–4.
23 **Bryan RAE.** The success of inhalation sedation for comprehensive dental care within the Community Dental Service. *International Journal of Paediatric Dentistry* 2002;**12**:410–14.
24 **Wilson KE,** Welbury RR, Girdler NM. A randomised, controlled, crossover trial of oral midazolam and nitrous oxide for paediatric dental sedation. *Anaesthesia* 2002;**57**:860–7.
25 **Agrawal D,** Manzi SF, Gupta R, *et al.* Preprocedural fasting state and adverse events in children undergoing procedural sedation and analgesia in a pediatric emergency department. *Ann Emerg Med* 2003;**42**:636–46.

Exhibit 6

ORIGINAL ARTICLE

Nurse administered relative analgesia using high concentration nitrous oxide to facilitate minor procedures in children in an emergency department

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Aims: To describe the experience of using high concentration nitrous oxide (N_2O) relative analgesia administered by nursing staff in children undergoing minor procedures in the emergency department (ED) and to demonstrate its safety.

Method: Data were collected over a 12 month period for all procedures in the ED performed under nurse administered N_2O sedation. All children greater than 12 months of age requiring a minor procedure who had no contraindication to the use of N_2O were considered for sedation by this method. The primary outcome measure was the incidence of a major complication namely respiratory distress or hypoxia during the procedure. Secondary outcome measures were minor complications and the maximum concentration of N_2O used.

Results: Data were collected for a total of 224 episodes of nurse administered N_2O sedation over a 12 month period. In 73.2% of children no complications were recorded. One major complication was recorded (respiratory distress) and the most common minor complication was mask intolerance in 17%. The mean maximum concentration of N_2O used was 60.2%.

Conclusions: N_2O is a safe analgesic in children over the age of 1 year undergoing painful or stressful procedures in the ED. It may safely be administered in concentrations of up to 70% by nursing staff after appropriate training.

Many ill and injured children attending emergency departments (EDs) require sedation and analgesia for brief procedures that are painful or anxiety provoking but that do not justify a general anaesthetic.[1] In our ED these procedures include cannulation, wound repair, minor fracture manipulation, lumbar puncture, bone marrow aspiration, and removal of foreign bodies from ears and noses. Choosing a safe and efficacious sedative agent for these procedures that is suitable for use in the ED is a daily consideration for emergency physicians.

Procedural sedation has been defined by the American College of Emergency Physicians as "a technique of administering sedatives or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate unpleasant procedures while maintaining cardiorespiratory function . . ."[2] Relative analgesia refers to this state of analgesia and sedation.

Nitrous oxide (N_2O) has a number of advantages that make its use preferable to other agents for relative analgesia in the ED. It provides analgesia within three minutes of inhalation and this analgesic effect disappears less than four minutes after cessation.[3] The physical properties of N_2O account for its efficacy as a short acting agent. Because it is not metabolised, N_2O is almost completely eliminated by the lungs in an unchanged state. It does not bind to any carrier proteins during transport and therefore avoids the difficulties of drug interactions.[4]

Previous studies have demonstrated that N_2O may safely be used, when administered by doctors, at concentrations of up to 50% in children for a wide variety of procedures.[3 5–10] Our hospital has developed a programme to train nurses in the administration of N_2O in concentrations of up to 70%. Hospital policy allows the administration of N_2O to children by staff who have undergone the appropriate training and accreditation and who have applied to and have been approved by the director of clinical services. The accreditation process consists of attendance at an introductory lecture on the technique and successful completion of a nitrous accreditation package, followed by a demonstration of practical ability in using the technique. This includes three observed N_2O administrations under the guidance of an educator or clinical nurse specialist. To maintain an acceptable level of skill, annual attendance at a review lecture on the technique and re-accreditation is required if staff are not administering N_2O on a regular basis (that is, two per month). This programme was initially implemented on the wards and after its success[11] has been developed to permit relative analgesia using this technique in the ED.

The aim of this paper is to report our experience using nurse administered N_2O and to demonstrate its safety when used to facilitate minor procedures undertaken in the ED.

METHODS

Setting

This prospective descriptive study was conducted over 12 months from 1 July 2001 to 30 June 2002 on all consecutive patients receiving nurse administered N_2O relative analgesia presenting to the ED of the Children's Hospital at Westmead. The Children's Hospital is the tertiary paediatric centre for the western area of Sydney (feeding population of 2 million) and the western region of NSW as well as parts of the South Pacific and the paediatric burns' referral centre for NSW. The ED during the time this study was undertaken had a patient census of around 45 000 presentations.

Population

Any child over 12 months of age requiring relative analgesia for a minor procedure in the ED was eligible for consideration for inclusion in the trial. Children were excluded from the study if they had a longstanding disease, acute respiratory infection, upper airway obstruction, asthma, previous anaesthetic reactions, recent middle ear surgery, penetrating eye

Table 1 Study procedures (n=224)

Procedure undertaken	Number (%)*
Wound examination and closure (tissue glue/steri-strip/suturing)	81 (36.2)
Investigative procedure (intravenous cannulation, venepuncture, lumbar puncture, bone marrow aspirate)	74 (33.0)
Application of dressings (wounds and burns)	19 (8.5)
Orthopaedic (manipulation of fractures and dislocations)	18 (8.0)
Miscellaneous (removal of foreign body, urinary catheterisation and change of gastrostomy tube)	32 (14.3)
Total	224 (100)

*Column percentage.

injury, or undrained pneumothorax. In addition ED nurses may not administer N_2O to children who have received intravenous opioids or sedatives although nurses on the pain team may do so.

Procedural protocol

(A full protocol of the procedure is available from the authors). Before the administration of the N_2O the patient was assessed by a medical officer to ensure that the administration of N_2O was appropriate and the patient was kept fasted for two hours before the procedure.

Equipment

The apparatus used to administer N_2O at a variable concentration consisted of the Quantiflex Mark II relative analgesia machine (Cyprane, Keighley, Yorkshire, UK) a Lack circuit, minimum volume antiviral, antibacterial filter (for children >10 kg), appropriate facemask, scavenger equipment, oximeter, and suction. The relative analgesia machine is a constant flow device that has a failsafe delivery of minimum 30% oxygen at all times.

Procedure for the administration of N_2O

The ED has piped N_2O in all patient clinical areas and at each procedural and resuscitation bed. The patient started breathing the gas using either the facemask or mouthpiece. Administration was started at least three minutes before any painful procedure was attempted. The N_2O/oxygen mixture was then titrated and the nitrous flow adjusted by 1 litre/min at the discretion of the administrator to a maximum of a 70% mixture of N_2O. At the end of the procedure, or at any time when the mask was removed for more than 30 seconds, the patient breathed 100% oxygen for three minutes or until the procedure was resumed.

Patient monitoring

The administrator of the N_2O relative analgesia monitored the patient, and maintained constant appropriate communication with the patient at all times. They observed and recorded the patient's state of consciousness, respiration, and airway patency. Pulse oximetry was used in all cases and any episode of desaturation (oxygen saturation <90%) was recorded and 100% oxygen administered.

Study outcome measures

All outcomes were defined a priori and applicable data collected. The primary outcome measure used in this study was the occurrence of a major adverse event. This occurred when a patient developed during or within one hour after the procedure respiratory distress (defined as tachypnoea with nasal flaring and chest retractions) or hypoxia (defined as desaturation as measured by pulse oximetry <90%). Secondary outcomes were; (a) minor adverse events—vomiting (defined as one single vomit during the procedure or an episode of vomiting in the immediate recovery period), mask intolerance (the inability or unwillingness of the child to tolerate the mask for the duration of the procedure), convulsion (loss of consciousness associated with myoclonic movements), or dysphoria (unpleasant dreams) and (b) the maximum concentration of N_2O administered during the procedure.

Data collection

Data were prospectively collected over a 12 month period. As well as data relating to the outcome measures, we also recorded basic demographic data, the use of adjuncts such as local anaesthetics and other analgesics, the types of procedure performed, and the duration of each procedure. Data were routinely recorded on a pain management data collection form by the nurse administering the N_2O. This form was developed by the hospitals pain management committee.

Statistical analysis

Descriptive analyses were applied to the data with frequencies and percentages presented for major outcome variables.

RESULTS

Study population and procedures

Data for 224 episodes of N_2O use were collected over the period of the study. A total of 138 (61.6%) of the children were male. A total of 113 children (50.5%) were under 5 years of age, 74 (33.0%) were aged between 5 years and 10 years, and 37 (16.5%) were aged 10 years and above. A parent or other carer was present throughout the duration of the procedure in 219 (97.8%) of cases and 50 children (21.9%) had received N_2O previously.

Table 1 shows the procedures performed during the study. The length of procedures undertaken under N_2O relative analgesia ranged from 1 minute to 60 minutes with the mean duration being 13.7 minutes (95% CI 12.3 to 15.1 min) and a median duration of 10 minutes.

Outcome measures

Table 2 summarises primary and secondary outcome measures. Only one major adverse event was recorded, this was

Table 2 Study outcomes (n=224)

Outcome measure	Frequency (%)
Adverse events	
None	164 (73.2)
Major	
Respiratory distress	1 (0.4)
Hypoxia	0
Minor	
Vomiting	19 (8.5)
Mask intolerance	38 (17.0)
Dysphoria	2 (0.9)
Maximum concentration of nitrous oxide (N_2O as %)	
50%	67 (29.9)
60%	88 (39.2)
70%	69 (30.8)
	mean 60.2%
	(95% CI 59.1 to 61.2)
	median 60%

respiratory distress in an 18 month old child with a history of a recent bronchiolitis illness. He experienced a short period of tachypnoea during the procedure; however this was not associated with a fall in oxygen saturation and rapidly resolved after the withdrawal of the N_2O without the need for any intervention or treatment other than the administration of oxygen. A total of 164 children (73.2%) recorded no complications. Two procedures were abandoned however because of minor adverse events. These were a 7 year old girl undergoing a lumbar puncture who was unable to remain still for the procedure (she eventually underwent the procedure under a general anaesthetic) and a child who vomited while undergoing suturing.

Of the 224 children 214 (95.5%) required no other sedation. Where additional sedation was given this was midazolam in 9 (4.0%) cases and trimeprazine in 1 (0.4%) case. Similarly 215 (96.0%) children required no other oral analgesia. Where this was given the most common adjunct was paracetamol in seven (3.1%) of the cases and codeine in two (0.9%). Local anaesthesia was infiltrated in 76 (33.3%) cases.

Distraction techniques were used in 86.6% of children. These were used either by the nursing staff or the parents and were age appropriate to the child.

DISCUSSION

We have shown that relative analgesia with high concentrations of N_2O (up to 70% with oxygen) can be safely administered to children over the age of 12 months by appropriately trained nursing staff. We report only one significant (and transient) complication and despite a small number of minor complications, notably mask intolerance, all but 2 of the 224 procedures were successfully completed using this method of relative analgesia in our ED.

Our major adverse event rate (0.4%) is similar to that described in previous studies and comparable to adverse events recorded for other agents.[12 13] Previously a 5%–15% rate of minor side effects, notably vomiting has been reported.[5 12 14 15] We recorded 19 cases of vomiting (8.3%) of which 18 were after the withdrawal of N_2O administration. Despite the concern that emesis may place patients at risk if they are unable to protect their airways, in the absence of other sedatives clinical trials have demonstrated that the protective airway reflexes are intact.[16 17] We also encountered a surprisingly high number of cases of difficulty with mask acceptance, 39 cases (17.1%). Of note however is that no procedures were abandoned because of difficulty with mask acceptance and in most cases it was noted that this was an initial problem that resolved quickly with distraction techniques. We believe that this number recorded reflects a "normal" response to a facemask in young children that can easily be overcome with appropriate distraction and not a true complication of the procedure.

At a time when EDs are facing an increasing workload, the role of ED nurses is evolving[18] with nurse practitioners becoming an integral part of the ED team. Recommendations from France after experience with more than 7500 children have concluded that concentrations of N_2O up to 50% may be safely administered, by nursing staff after training, to children greater than 4 years of age. However, they also noted that as the incidence of side effects does not appear to be greater in the 1–4 year age group this age limit may be lowered to 1 year.[19] Our study shows that with appropriate training nurses can safely deliver relative analgesia to paediatric patients undergoing minor procedures.

Much of the previous work on the use of N_2O to provide relative analgesia has concentrated on its use in the outpatient or ward based setting.[8 11 19 20] Within our own hospital, the pain team have already demonstrated the effectiveness of nurse administered N_2O at high concentrations during painful procedures that are carried out on the wards.[11] Despite the less controlled environment in the ED, our complication rate was almost identical to the ward based studies. Where ED use has previously been studied, the N_2O has been administered in lower concentrations (ranging from 30% to 50% N_2O), to older children (ages >2) by physicians.[5–7 9] This approach has the obvious disadvantage that two doctors are required to be present to carry out the procedure—not often a realistic prospect in most EDs.

In contrast with some previous studies,[7 8] we have also been able to demonstrate a success with younger children. The reasons for this may include: the use of higher concentrations of N_2O (up to 70%), the use of distraction techniques such as singing and storytelling used both by the nurses administering the nitrous and the parents present, and the use of a system that does not require the child to produce large negative inspiratory pressures. Our experience compares with a similar undertaking by Vic *et al* in France.[20]

The main limitation of our study was the lack of a validated method of measuring the pain experienced by these children. Although we collected some data on this using a linear scale, this had not been previously validated and it was felt that the information did not add to the overall content of the paper. Future studies would be helpful to address this issue. We also had no data comparing the safety of nurse administered N_2O as compared with other medical staff within our own department although we felt that this was not an important shortcoming.

Our study adds weight to the argument that N_2O is a safe agent when used for relative analgesia in children over the age of 12 months undergoing minor procedures in the ED. We have also demonstrated that after appropriate training it may be delivered by nursing staff and that this does not appear to have an effect on the adverse event rate. It has the added advantage over other sedative agents that recovery is rapid and therefore early discharge may be facilitated. We have also demonstrated that higher doses may be given successfully in the ED. That one fifth of children in the study had had N_2O for previous procedures suggests that it is acceptable to parents as a sedative agent although data on this were not formally collected.

In conclusion, relative analgesia using high concentrations of N_2O administered by appropriately trained nursing staff is a safe agent for the sedation of children undergoing minor painful or anxiety producing procedures in the ED.

Authors' affiliations

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REFERENCES

1 **Evered L**, Klassen TP, Hartling L, *et al*. Options for procedural sedation in paediatric patients requiring painful or anxiety provoking procedures outside the operating room. *Cochrane Library*. Oxford: Update Software, 2001.
2 **American College of Emergency Physicians**. Clinical policy for procedural sedation and analgesia in the emergency department. *Ann Emerg Med* 1998;31:663–77.
3 **Carbajal R**. Analgesia using a (50/50) mixture of nitrous oxide/oxygen in children. *Arch Pediatr* 1999;6:578–85.
4 **Griffin G**, Campbell V, Jones R. Nitrous oxide-oxygen sedation for minor surgery—experience in a paediatric setting. *JAMA* 1983;245:2411–13.
5 **Gamis A**, Knapp J, Glenski J, *et al*. Nitrous oxide in a paediatric emergency department. *Ann Emerg Med* 1989;18:177–81.
6 **Luhmann J**, Kennedy R, Porter F, *et al*. A randomised clinical trial of continuous flow nitrous oxide and midazolam for sedation of young children during laceration repair. *Ann Emerg Med* 2001;37:20–7.
7 **Hennrikus W**, Simpson R, Klingelberger C, *et al*. Self-administered nitrous oxide for paediatric fracture reductions. *J Pediatr Orthop* 1994;14:538–42.
8 **Cleary A**, Ramanan A, Baildam E. Nitrous oxide analgesia during intra-articular injection for juvenile idiopathic arthritis. *Arch Dis Child* 2002;86:416–18.
9 **Wattenmaker I**, Kasser J, McGravey A. Self-administered nitrous oxide for fracture reduction in children in an emergency room setting. *J Orthop Trauma* 1990;4:35–8.

10 **Pietrement C**, Salomon F, Monceaux C, *et al*. Analgésie par le protoxide d'azote pour le réalisation de la biopsie rénale percutanée chez l'enfant. *Arch Pediatr* 2001;**8**:145–9.
11 **Kanagasundaram S**, Lane L, Cavalletto B, *et al*. Efficacy and safety of nitrous oxide in alleviating pain and anxiety during painful procedures. *Arch Dis Child* 2001;**84**:492–5.
12 **Gall O**, Annequin A, Benoit G, *et al*. Adverse events of pre-mixed nitrous oxide and oxygen for procedural sedation in children. *Lancet* 2001; **358**:1514–15.
13 **Pena B**, Krauss B. Adverse events of procedural sedation and analgesia in a paediatric emergency Department. *Ann Emerg Med* 1999;**34**:483–91.
14 **Duncan G**, Moore P. Nitrous oxide and the dental patient. A review of adverse reactions. *J Am Dent Assoc* 1984;**108**:213–19.
15 **Muir J**, Warner M, Offord K, *et al*. Role of nitrous oxide and other factors in post operative nausea and vomiting. *Anesthesiology* 1987;**66**:513–18.
16 **Roberts G**, Wagnall B. Efficacy of the laryngeal reflex during oxygen-nitrous oxide sedation. *Br J Anaesth* 1982;**54**:1277–81.
17 **Clayton-Jones P**. The laryngeal-closure reflex and nitrous oxide-oxygen analgesia. *Anesthesiology* 1976;**45**:569–70.
18 **Sakr M**, Angus J, Perrin J, *et al*. Care of minor injuries by emergency nurse practitioners or junior doctors: a randomised controlled trial. *Lancet* 1999;**354**:1321–6.
19 **Hulland S**, Freilich M, Sandor G. Nitrous oxide-oxygen or oral midazolam for paediatric outpatient sedation. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2002;**93**:643–6.
20 **Vic P**, Laguelte D, Blondin G, *et al*. Utilisation du mélange équimolaire oxygène-protoxyde d'azote un service de pédiatrie générale. *Arch Pediatr* 1999;**6**:844–8.

Exhibit 7

TRACKING TOOL

Purpose: To monitor effectiveness of Nitrous Oxide for various procedures on variety of patients.

PATIENT FIN #	AGE	DIAGNOSIS	PROCEDURE	LENGTH OF INDUCTION	LENGTH OF PROCEDURE	LENGTH OF RECOVERY	PERCENT OF NITROUS USED	ADVERSE REACTIONS	PERTINENT MEDICAL HISTORY

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Nitrous Oxide Psychosedation

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Dr. Ulrich Foerster

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Works Cited

Babl, Franz E., et al. "High-Concentration Nitrous Oxide for Procedural Sedation in Children: Adverse Events and Depth of Sedation." *Pediatrics* 121.3 (2008): 528-32. Print.

Clark, Morris S., and Ann L. Brunick. *Handbook of Nitrous Oxide and Oxygen Sedation.* Third ed. St. Louis: Mosby Elsevier, 2008. Print.

Ekbom, K., J. Jakobsson, and C. Marcus. "Nitrous Oxide Inhalation is a Safe and Effective way to Facilitate Procedures in Paediatric Outpatient Departments." *Archdischild.com.* bmj.com,, 25 Jan. 2005. Web. 3 June 2013.

Frampton, A., et al. "Nurse Administered Relative Analgesia using High Concentration Nitrous Oxide to Facilitate Minor Procedures in Children in an Emergency Department." *Emerg Med J* 20 (2003): 410-13. Print.

Luhmann, Jan D., et al. "A Randomized Clinical Trial of Continuous-Flow Nitrous Oxide and Midazolam for Sedation of Young Children During Laceration Repair." *Annals of Emergency Medicine* 37.1 (2001): 20-27. Print.

Zier, Judith L., et al. "Case-Series of Nurse-Administered Nitrous Oxide for Urinary Catheterization in Children." *Anesthesia & Analgesia* 104.4 (2007): 876-79. Print.

Zier, Judith L., Rod Tarrago, and Meixia Liu. "Level of Sedation with Nitrous Oxide for Pediatric Medical Procedures." *Anesthesia & Analgesia* 110.5 (2010): 1399-405. Print.

Nitrous Oxide Proposal for St. Joseph's Children's Hospital

When **CHILDREN** come into the hospital they are fearful of the "little" poke, a "small" test that just takes a second, or just the "unknown" that lurks around each corner.

How can **WE** make the fear disappear?

The hospital has a lot of medications and test, needles and tubes; and the process to administer these "little" things **IS** as traumatic as the procedure itself. What if we could do something to make this less painful and more pleasant for **ALL** involved?

At St. Joseph's Children's Hospital- we have a **chance** to make Nitrous Oxide **THE** answer!

Prepared by: Leslie Mellin, RN; Wendy Leonard, RN; Amy Dittmer, ARNP;

Policies and Procedures
for NO

Protocol for Nitrous Oxide/Oxygen Administration

DRAFT

Date: _____ Time: _____ Weight: _____kg

Allergies: _____

- A pre-sedation assessment will be performed by a Nitrous Oxide credentialed provider to include ASA status and to be evaluated for the presence of contraindications to use of nitrous oxide

  ***Contraindications:** Any condition where air may be trapped in the body including: Pneumothorax, intestinal obstruction, middle ear occlusion (e.g., tympanoplasty), severe bullous emphysema (e.g., use with caution in cystic fibrosis), maxillofacial injuries, post intraocular surgery (injected gas may last up to 10 weeks),penetrating injury to the globe, craniotomy (within 3wks), Increased intracranial, pressure, pregnancy, vitamin B12 deficiency, impaired level of consciousness, and history of bleomycin administration.*

- Verify NPO status (solids and non-clear liquids-6hrs; clear liquids-2hrs)
- Obtain informed consent
- Consult Child Life
- Obtain pre-sedation VS and maintain monitoring continuously with documentation every 5 minutes throughout procedure to include oxygen saturation, HR, and LOC.
- Nitrous Oxide may only be administered by staff trained in the use of nitrous oxide/oxygen sedation using fail safe equipment.
- Equipment fail safe must be checked prior to patient administration.
- Credentialed provider to initiate administration of nitrous oxide
- Credentialed RN to titrate as necessary to maintain minimal to moderate sedation, not to exceed 70% nitrous oxide/30% oxygen throughout the procedure.
- Scavenging equipment to be operative during nitrous oxide administration.
- Administer 100% oxygen for 2-5minutes post nitrous oxide administration.
- Continue to monitor for a minimum of 15 minutes post procedure.
- Discharge/transfer once minimal discharge criteria met.

_____

Provider Signature

POLICIES AND PROCEDURES
St. Joseph's Children's Hospital

TITLE: Nitrous oxide administration for the pediatric patient		
ISSUED FOR: ☐ St. Joseph's Hospital ☐ South Florida Baptist Hospital ☒ St. Joseph's Children's Hospital		POLICY NUMBER: PAGE: 1 of
Original Issue Date:	**Revision Date:**	**Review Date:**
Sponsored By: Director of Pediatric Patient Care Services,, Pain task force team, Director of anesthesia, Pharmacy, Kids Medication Utilization Safety Team	**Approved by:** **Approved by:**	

PURPOSE:

1. To provide safe and appropriate care for the pediatric patient receiving nitrous oxide to facilitate performance of therapeutic or diagnostic procedures.

2. To protect the health and safety of all employees who may be occupationally exposed to nitrous oxide.

DEFINITIONS:

Nitrous oxide inhalation analgesia – The administration by inhalation of a combination of nitrous oxide and oxygen producing an altered level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command.

Minimal sedation (anxiolysis) – A medically controlled medication induced state where the patient is able to respond normally to verbal commands. Cognitive functioning and coordination may be affected. Protective reflexes, ventilator and cardiovascular status are not affected.

Moderate sedation/analgesia – A medically controlled medication induced state of depressed consciousness that 1)allows airway protective reflexes to be maintained, 2) retains the patient's ability to maintain a patent airway independently and continuously, and 3) permits appropriate response by the patient to physical stimulation or verbal command. Despite appropriate dosages of sedatives/analgesics for conscious sedation, patients are at risk for respiratory depression, apnea, and loss of protective reflexes. Cardiovascular function is usually maintained.

Deep sedation/analgesia – A medically controlled medication induced state of depressed consciousness or unconsciousness from which the patient is not easily aroused buy responds purposefully following repeated or painful stimulation. It may be accompanied by a partial or complete loss of airway protective reflexes and includes the inability to maintain a patent airway independently. Cardiovascular function is usually maintained.

Titration - A method of administering a medication in incremental amounts until a desired endpoint is reached. If done properly the patient does not receive more medication than is necessary.

Allied Health Practitioner (AHP) – As defined by this organization, for the purpose of this policy, is any individual under the direct supervision of a physician, permitted by law, license, and organization to provide services and care within the scope of the individual's license and consistent with the individually granted medical staff services clinical privileges (i.e. CRNA, ARNP, PA).

POLICY:

An order is required by a physician or allied health practitioner for the administration of nitrous oxide. All patients receiving nitrous oxide will be cared for by a credentialed nurse, physician, or allied health practitioner. Administration will be documented in the patient's medication medical record. Sedation, with or without analgesia Policy and Procedure will be followed, in conjunction with this policy, when administering nitrous oxide.

Title: Nitrous oxide administration for the pediatric patient

If a patient progresses from minimal or moderate sedation to deep sedation, the physician will be required to assume care of the patient as indicated for deep sedation.

Contraindications: Any condition where air may be trapped in the body including: Pneumothorax, intestinal obstruction, middle ear occlusion, severe bullous emphysema, maxillofacial injuries, post intraocular surgery (injected gas may last up to 10 weeks), penetrating injury to the globe, craniotomy (within 3 weeks). Other contraindications include increased intracranial pressure, pregnancy, vitamin B12 deficiency, impaired level of consciousness, and history of bleomycin administration. Caution in patients with cystic fibrosis.

PRIVILEGING OF PHYSICIANS, ALLIED HEALTH PRACTITIONERS, AND NURSES:

A. Physician and Allied Health Practitioners responsible for the administration of nitrous oxide must be appropriately trained and privileged through Medical Staff Services. Competency requirements include: an approved course on the administration of nitrous oxide (if lack of post graduate residency training in anesthesiology), BLS, ACLS, PALS, maintain sedation competence.

B. Nurses administering nitrous oxide must complete an approved course on the administration of Nitrous Oxide, BLS, ACLS, PALS, maintain sedation competency, and complete a minimum of 4 hours of continuing education relating to sedation (each biennium)

LOCATION OF NITROUS OXIDE ADMINISTRATION

Sites for the administration of nitrous oxide and recovery must have immediate access to emergency equipment and access to additional help. Emergency equipment includes: defibrillator, ECG monitor, suction device, oxygen, airways, ambu, emergency medications, and intubation equipment. Examples of sites where nitrous oxide administration will occur include (but are not limited to):

1. Day Hospital
2. Emergency department
3. Critical care units

PROCEDURE:

A. Prior to the administration of nitrous oxide

1. A pre-sedation nitrous assessment will be performed by the AHP to include airway assessment, ASA class, prior sedation/anesthesia experience, vital signs and NPO status
2. A physician is responsible for reviewing the pre-sedation, pre-anesthesia assessment and determining or concurring with the plan that the patient is an appropriate candidate for Nitrous Oxide. Plan, risks, benefits, limitations and alternative to nitrous oxide should be discussed with the patient and/or legal guardian and informed consent documented in the medical record.
3. A physician or AHP will document a relevant history and physical in the medical record prior to the procedure. A history and physical performed by an AHP must be co-signed by a physician.
4. A pregnancy test will be performed on all menstruating females within seven (7) days of nitrous oxide administration.
5. The physician credentialed in nitrous oxide administration is responsible for the treatment of any complications that may occur as a result of the administration.
6. The nursing staff will verify that the following guidelines have been met:
   a. Informed consent
   b. NPO status (Solids and non-clear liquids – 6 hours; clear liquids – 2 hours)
7. Correct identification including name and date of birth will be verified prior to the start of administration
8. Verification of allergies and medication history
9. Pre-procedure nursing assessment includes vital signs (BP, pulse, respirations), oxygen saturation, pain score and level of consciousness.
10. Pre-procedure education will be provided by the RN, child life specialist and physician according to the plan of care.

B. During the procedure

1. Nitrous oxide administration and techniques
   a. Failsafe equipment must be checked prior to administration
   b. Start nitrous oxide administration at a low percentage (20-30%) and titrate as necessary to maintain minimal to moderate sedation. Do not exceed 70% nitrous oxide/30% oxygen
   c. Scavenging equipment must be operative during nitrous oxide administration
   d. 100% oxygen should be given for 2-5 minutes post nitrous oxide administration

2. Monitoring and assessment
   a. Emergency equipment must be at the bedside including: appropriate size ambu bag, weight based code sheet, suction, patient monitor, and emergency call system.
   b. Patients receiving nitrous oxide must be monitored continuously and include documentation of oxygen saturation, heart rate, and level of consciousness/sedation response every five (5) minutes.
   c. The nurse must be prepared to monitor blood pressure, cardiac rhythm, and CO2 if necessary.

C. Post procedure

1. Patients who received minimal to moderate sedation will have a post procedure assessment every 5 minutes for a minimum of 15 minutes which includes vital signs, pain score and level of consciousness until vital signs are stable and within pre-procedure range and level of consciousness returns to baseline
2. Patients who received deep sedation will have an assessment every 5 minutes for a minimum of 15 minutes, which includes vital signs, oxygen saturation, pain score, cardiac rhythm, and level of consciousness. After the first 15 minutes if stable then progress to assessments every 15 minutes of vital signs, pain score, and level of consciousness for a minimum of 30 minutes post procedure, and until vital signs are stable and within pre-procedure range and return to baseline level of consciousness.
3. All patients receiving nitrous oxide will have a recovery score evaluated on admission, at 15 minutes, at 30 minutes (if present), and upon transfer/discharge.

D. Discharge/Transfer criteria

1. Discharge may be done by the physician or AHP in person, by phone, or by approved discharge criteria.
2. Patients not meeting criteria need physician approval to discharge/transfer
3. Minimal discharge criteria:
   a. Temperature >97 degrees
   b. Stable vital signs for 15 minutes prior to discharge
   c. Oxygen saturation 95% or above or return to pre-procedure level
   d. Pain score 4 or less or acceptable to the patient
   e. Nausea and vomiting addressed and treated
   f. Level of consciousness comparable to pre-procedure state
4. Discharge instructions provided
5. A designated team member will attempt to call outpatients within 24 hours of discharge to query for any questions or concerns

E. Documentation

1. Patient assessment and interventions during the procedure must be documented as per Clinical Standard 'Sedation, with or without analgesia, care of the patient receiving'
2. Documentation in the medical record should be done using the sedation record or other approved format

POLICIES AND PROCEDURES
Surgical Services

TITLE: Safety, Anesthesia Gas Scavenging		
ISSUED FOR: ☒ St. Joseph's Hospitals ☐ St. Joseph's Diagnostic Centers ☒ St. Joseph's Women's Hospital		POLICY NUMBER: VII. E PAGE: 1 of 1
Original Issue Date: April 1990	Revision Date: 2/92, 3/96, 6/02, 5/05, 5/08, 5/11	Review Date:
Sponsored By: Clinical Engineering and Surgical Services Title of Originator:	Approved by: Director Surgical Services Director of Women's Health SJW Director Heart Institute Chief of Anesthesia Regional Manager BayCare Clinical Engineering	

PURPOSE:
To provide a safe surgical experience for patient and staff.

POLICY:
Guidelines for anesthetic gas scavenging and monitoring.

PROCEDURE:

1. All exhaled gases during general anesthesia will be disposed through the vacuum line in the operating room and vented to outside the hospital.
2. All patients having general endotracheal anesthesia will have the approved scavenging system utilizing a vacuum line.
3. Waste anesthesia gas testing is performed every six months. Levels less than 25ppm of nitrous oxide will be deemed acceptable. All results will be documented and filed for future reference. Records are kept in clinical engineering.
4. Levels of nitrous oxide higher than 25 parts per million (ppm) will be reported to the Director of Surgical Services for corrective action.
5. Levels of halogenated inhaled agents should be less than 0.5ppm when used in combination with nitrous oxide or a ceiling limit of 2 ppm time weighted average (TWA) when used alone.
6. Reference BayCare Waste Anesthetic Gas Testing and Repair Policy CES-50 as needed.

Nitrous Oxide Rapid Cycle Test Patients

2012

1. Botox Injections – 85
2. Echocardiograms – 55
3. Voiding Cystourethrogram (VCUG) – 21
4. Long Term Monitoring (LTM) Hook-up – 30
5. Difficult IV Starts
6. Electroencephalogram (EEG) – 46
7. Peripherally Inserted Centeral Catheters (PICC) – 38
8. Dressing Changes – 14
9. ABR – 23
10. Incision and Drainage (I & D) - 23

Florida on Rulings
and Care for NO

Florida Board of Health

March 20

2013

These compilations and excerpts were obtained from the FL Board of Health in regards to the Nursing care and Dental standards related to Nitrous Oxide.

Please refer to hearings and proposals for expanded review.

64B5-14.001 Definitions. ANESTHESIA

(6) Nitrous-oxide inhalation analgesia – The administration by inhalation of a combination of nitrous-oxide and oxygen producing an altered level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command.

64B5-14.002 Prohibitions.

(4) Nitrous-oxide inhalation analgesia. No dentists licensed in this State shall administer nitrous-oxide inhalation analgesia in the practice of dentistry until they have complied with the provisions of this rule chapter.

(6) The only agents that can be used for inhalation analgesia pursuant to Rule 64B5-14.003, F.A.C., below are nitrous-oxide and oxygen.

64B5-14.003 Training, Education, Certification, and Requirements for Issuance of Permits.

(4) Nitrous-Oxide Inhalation Analgesia.

(a) A dentist may employ or use nitrous-oxide inhalation analgesia on an outpatient basis for dental patients provided such dentist:

1. Has completed no less than a two-day course of training as described in the American Dental Association's "Guidelines for Teaching and Comprehensive Control of Pain and Anxiety in Dentistry" or its equivalent; or

3. Has adequate equipment with fail-safe features and a 25% minimum oxygen flow.

(b) A dentist utilizing nitrous-oxide inhalation analgesia and such dentist's assistant/dental hygienist personnel shall be certified in an American Heart Association or American Red Cross or equivalent Agency sponsored cardiopulmonary resuscitation course at the basic life support level to include one man CPR, two man CPR, infant resuscitation and obstructed airway with a periodic update not to exceed two years. Starting with the licensure biennium commencing on March of 2000, a dentist and all assistant/dental hygienist personnel shall also be trained in the use of either an Automated External Defibrillator or a defibrillator and electrocardiograph as part of their cardiopulmonary resuscitation course at the basic life support level. In addition to CPR certification, a dentist utilizing pediatric conscious sedation must be currently trained in ACLS (Advanced Cardiac Life Support), ATLS (Advanced Trauma Life Support), or PALS (Pediatric Advanced Life Support).

(d) Nitrous oxide may be used in combination with a single dose enteral sedative or a single dose narcotic analgesic to achieve a minimally depressed level of consciousness so long as the manufacturer's maximum recommended dosage of the enteral agent is not exceeded. Nitrous oxide may not be used in combination with more than one (1) enteral agent, or by dosing a single enteral agent in excess of the manufacturer's maximum recommended dosage unless the administering dentist holds a conscious sedation permit issued in accordance with subsection 64B5-14.003(2), F.A.C., or a pediatric conscious sedation permit issued in accordance with Rule 64B5-14.010, F.A.C.

64B5-14.004 Additional Requirements.

(2) Dental Assistants, Dental Hygienists – Dental assistants and dental hygienists may monitor nitrous-oxide inhalation analgesia under the direct supervision of a dentist who is permitted by rule to use general anesthesia, conscious sedation, pediatric conscious sedation, or nitrous-oxide inhalation analgesia, while rendering dental services allowed by Chapter 466, F.S., and under the following conditions:

(a) Satisfactory completion of no less than a two-day course of training as described in the American Dental Association's "Guidelines for Teaching and Comprehensive Control of Pain and Anxiety in Dentistry" or its equivalent; and

(b) Maintenance of competency in cardiopulmonary resuscitation evidenced by certification in an American

Heart Association or American Red Cross or equivalent Agency sponsored cardiopulmonary resuscitation course at the basic life support level to include one man CPR, two man CPR, infant resuscitation and obstructed airway, with a periodic update not to exceed two years.

(3) After the dentist has induced a patient and established the maintenance level, the assistant or hygienist may monitor the administration of the nitrous-oxide oxygen making only adjustments during this administration and turning it off at the completion of the dental procedure.

Notice of Change/Withdrawal

DEPARTMENT OF HEALTH
Board of Nursing
RULE NO.: RULE TITLE:
64B9-8.005: Unprofessional Conduct

NOTICE OF PUBLIC HEARING

(b) A registered nurse may administer prescribed pharmacologic agents to mechanically ventilated and non-mechanically ventilated patients for the purpose of moderate sedation in anticipation of anxiety and or discomfort during a time-limited surgical, diagnostic or therapeutic procedure. The registered nurse must continuously monitor the patient throughout the procedure and have no other responsibilities that would require leaving the patient unattended or would compromise continuous monitoring during the procedure. The registered nurse must document the non-mechanically ventilated patient's level of consciousness at least every five minutes during the procedure. In the event a deeper level of sedation (such as deep sedation or general anesthesia) unintentionally results from the administration of prescribed pharmacologic agents to the non-mechanically ventilated patient, the registered nurse must immediately notify the duly authorized practitioner and document the actions taken until the patient's level of sedation returned to moderate sedation with the assistance of the duly authorized practitioner. Pharmacologic agents that may be administered by a registered nurse pursuant to this subsection shall not include medications that intended to result in loss of consciousness such as propofol, penthothal, etomidate, or any medication which the manufacturer's package insert states should be administered only by individuals trained in the administration of general anesthesia. When a duly authorized practitioner is actively managing a patient's sedation, a registered nurse may monitor the patient under moderate sedation.

1. Prior to any administration or monitoring of any pharmacologic agents, successfully demonstrate competence which reflects the extent of privileges requested, including a criteria-based competency evaluation. The evaluative criteria for the competency demonstration will cover knowledge and psychomotor skills in physical assessment and monitoring of sedated patients, principles of pharmacodynamics and pharmacokinetics (onset, duration, distribution, metabolism, elimination, intended and adverse effects, interactions, dosages and contraindications) of the pharmacologic agents being administered or monitored, basic and difficult airway management, mechanical ventilation, and cardiopulmonary resuscitation. The registered nurse must also be certified in advanced cardiac life support that is appropriate for the patient's age;

2. Complete a patient assessment and ensure that the practice setting requires that the duly authorized practitioner prescribing the pharmacologic agent has evaluated the patient based on established criteria;

3. Ensure that the practice setting requires that the prescribing practitioner, or in a hospital licensed under Chapter 395, Florida Statutes, a practitioner who has demonstrated competence in emergency airway management is physically present throughout the procedure and immediately available during the recovery period unless the patient is mechanically ventilated;

4. Ensure that the practice setting has in place a quality assurance and performance improvement process that measures patient, process and structural outcome indicators; and

5. Evaluate the patient for discharge readiness based on specific discharge criteria and ensure that the practice setting requires that the physician approves of the patient discharge.

(e) In order to administer or monitor any pharmacologic agents to achieve moderate sedation in accordance with subsection (b) above, a registered nurse must:

1. Ensure that the practice setting requires that the prescribing practitioner, or in a hospital licensed under Chapter 395, Florida Statutes, a practitioner who has demonstrated competence in emergency airway management is physically present throughout the procedure and immediately available during the recovery period unless the patient is mechanically ventilated;

2. Ensure that written policies and procedures for managing patients who receive moderate sedation are reviewed periodically and are readily available within the practice setting;

3 Ensure that the practice setting has in place a quality assurance and performance improvement process that measures patient, process and structural outcome indicators; and

4. Evaluate the patient for discharge readiness based on specific discharge criteria and ensure that the practice setting requires that the physician approves of the patient discharge.

(f) Administration or monitoring of the administration of medication to achieve moderate or deep sedation is beyond the scope of practice of licensed practical nurses, except as described in paragraph (c) above.

Equipment and Supplies Quotes

Parker Hannifin Corporation
Porter Instrument Division
205 Township Line Road
Hatfield, PA 19440

Office 215 723 4000
Fax 215 723 5106

E-STAND PACKAGE QUOTATION

Leslie Mellin RN, BSN St. Joseph's Children's Hospital	**PHONE: 813-554-8511** **FAX:** **E-MAIL: leslie.mellin@baycare.org**
SHIP TO: **TBD**	**DATE: 2-11-13** **PAGE 1 OF 1** **PREPARED BY: MIKE CIVITELLO – 215-723-4000 X8224** **michael.civitello@parker.com** **ESTIMATED SHIP DATE: 5 BUSINESS DAYS FROM DATE OF ORDER** **F.O.B. Hatfield, PA**
PRICES FIRM FOR: 90 Days **TERMS: N30/CC**	

ITEM	QTY	DESCRIPTION	RETAIL PRICE	MEDICAL PRICE	TOTAL
		MXR E STAND PACKAGE			
3445-2AV	1	PORTER MXR E STAND PACKAGE	$6032	$3921	**$3921**
		(Includes: flowmeter, 4 cylinder E-stand,and Automatic Vacuum Switch)			
B-5129-000	1	FLOWMETER BREATHING CIRCUIT HOOK	$77	$62	**$62**
HANDLE-1	1	E-STAND POST HANDLE	$125	$102	**$102**
8015	1	OXYGEN HOSE - DISS TO CHEMETRON QC 5 FT*	$206	$165	**$165**
5602-CT	1	VACUUM CHEMETRON QUICK CONNECT*	$112	$90	**$90**
		SHIPPING AND HANDLING (PER PACKAGE)		$75	**$75**
		DISPOSABLE FULL FACEMASK BREATHING CIRCUITS			
SACA120	2	Small Adult Full Facemask Breathing Circuit (10)		$285	**$570**
PDCA130	2	Pediatric Full Facemask Breathing Circuit (10)		$285	**$570**
YMCA140	2	Youth Medium Full Facemask Breathing Circuit (10)		$285	**$570**
		Full Facemask Shipping and Handling (Multiply Total QTY by $20)		**$20**	**$120**
		TOTAL			**$6245**

NOTES: *Custom length hoses available for additional cost. Quick connect can be specified by digital image of outlets.

SIGNED:

Mike Civitello

SEDATION

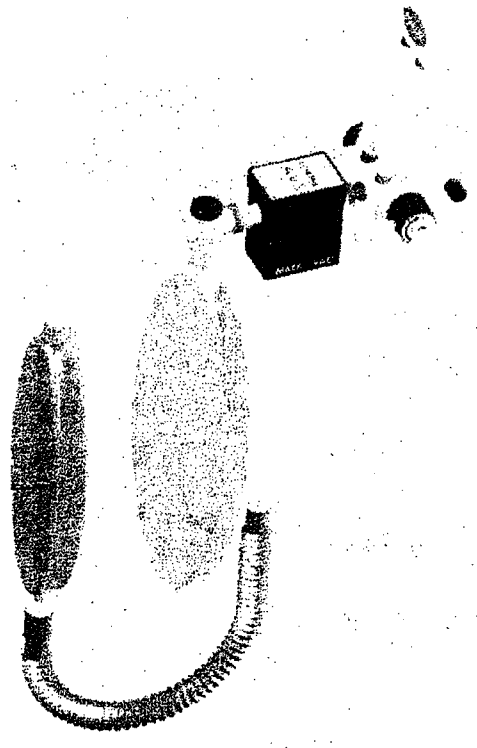
SYSTEMS

Introducing the SEDATION™ MASK and BREATHING CIRCUIT

The new SEDATION™ MASK and BREATHING CIRCUIT, invented by a Board Certified Anesthesiologist, and engineered by SEDATION SYSTEMS LLC, provides a total solution for using nitrous oxide in a hospital environment to sedate patients of all ages -- safely, effectively and inexpensively.

The SEDATION MASK designed expressly for sedated patients -- unlike standard general anesthesia masks -- fits under the patient's chin anchoring the Mask while forming an excellent comfortable seal on the patient's face. It is the only full-face Mask with this unique patented design now being used to administer nitrous in a hospital setting.

The SEDATION BREATHING CIRCUIT easily connects the SEDATION Mask to a standard nitrous/oxygen Flowmeter through a co-axial main limb, a one-way valve and an exhalation bag. Breathing and exhalation is restrictionless and maintained in a continuous circular unidirectional flow path. The combination facilitates scavenging of all of exhaled air from the room, eliminates re-breathing and allows safe delivery of nitrous at any selected concentration up to 70% in an easy to use, comfortable, and relatively inexpensive disposable system.



Schematic of SEDATION™ Mask and Circuit shown connected to a Porter MXR Flowmeter

The SEDATION™ Mask and Breathing Circuit is easily connected to a portable or wall-mounted nitrous/oxygen Flowmeter. The Circuit is compatible with standard commercially distributed Flowmeters.

The SEDATION Mask and Breathing Circuit enables patients to inhale and exhale any selected nitrous/oxygen mixture with minimal resistance through a self-contained system. When the Mask is properly sealed on the patient's face, all exhaled air is scavenged from the room through the Flowmeter vacuum connection.

The proprietary SEDATION Mask engages underneath the patient's chin and seals on the face over the nose and mouth. The Mask's resilient sealing cushion is extremely comfortable, and its unique chin-engagement feature maintains the Mask stabilized to help avoid leakage of nitrous.

The SEDATION Mask and Breathing Circuit is so easy to use, nitrous sedation is facilitated with a minimum of training and instruction. Personnel and patient satisfaction are maximized, patient throughput is increased and in-Hospital costs are reduced.

The new SEDATION™ MASK AND BREATHING CIRCUIT
Specifications and Ordering Information:

The Series "120" – Small Adult

Unilimb-style corrugated breathing circuit main limb 60" (152 cm), Latex-free 2 Liter bag, corrugated single-lumen exhalation limb 12" (30.48 cm), smooth PVC vacuum connector hose 10" (25.40 cm) and SMALL ADULT size **SEDATION**™ Mask packaged together in a single poly bag. Fits teenagers and most adults.

Catalog No. CA0120. Minimum Case size: 10 units. Price: $285./cse plus shipping and handling FOB Stow, Ohio.

The Series "130" – Pediatric

Unilimb-style corrugated breathing circuit main limb 60" (152 cm), Latex-free 2 Liter bag, corrugated single-lumen exhalation limb 12" (30.48 cm), smooth PVC vacuum connector hose 10" (25.40 cm) and PEDIATRIC size **SEDATION**™ Mask packaged together in a single poly bag. Fits infants and toddlers.

Catalog No. CA0130. Minimum Case size: 10 units. Price: $285./cse plus shipping and handling FOB Stow, Ohio.

The Series "140" – YOUTH Medium

Unilimb-style corrugated breathing circuit main limb 60" (152 cm), Latex-free 2 Liter bag, corrugated single-lumen exhalation limb 12"(30.48 cm), smooth PVC vacuum connector hose 10" (25.40 cm) and YOUTH Medium size **SEDATION**™ Mask packaged together in a single poly bag. For all the "in between" sizes.

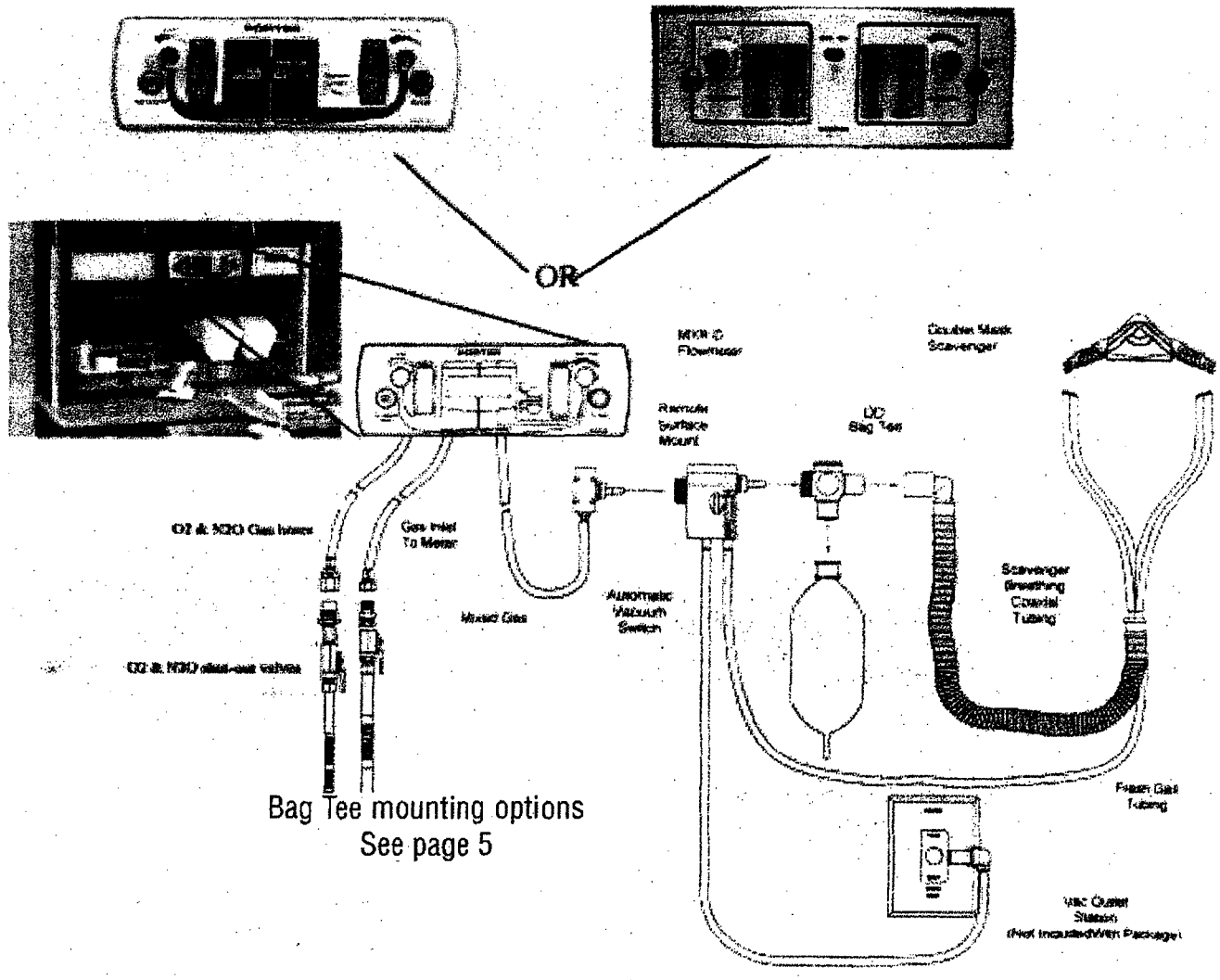
Catalog No. CA0140. Minimum Case size: 10 units. Price: $285./cse plus shipping and handling FOB Stow, Ohio.

To order, call toll-free:
1-888-282-1223
or

email: info@sedationsystems.com

SEDATION SYSTEMS
Clearwater, Florida 33759

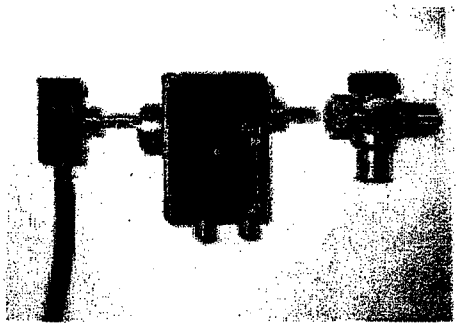
Flushmount Flowmeter Packages w/standard equipment



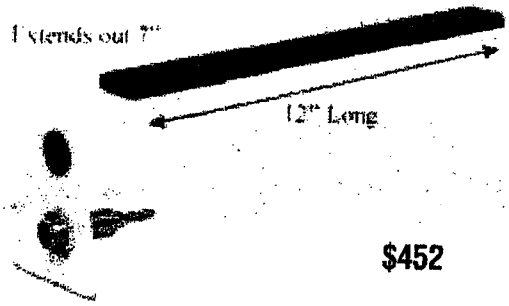
Bag Tee mounting options
See page 5

Bag Tee Mounting Options for Flushmount Flowmeters

A-1679 included with meter packages

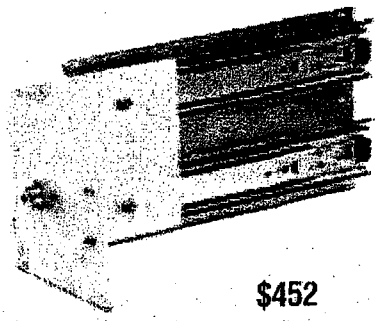


2037-1 under cabinet mount



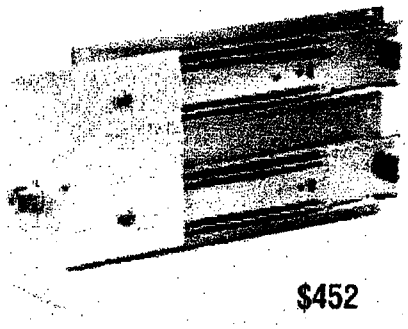
$452

2036-2 Left or Right side Slide mount with rubbergoods hook mounting option 5" wide



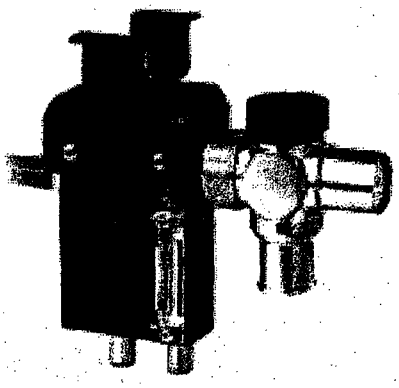
$452

2036-4 Left or Right side Slide mount 3 1/2" wide for narrow installs



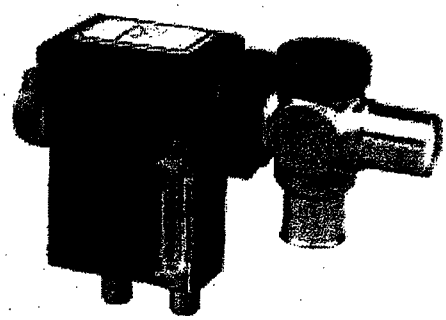
$452

AVS-50008 Special 180 Swivel Under cabinet or chair mount

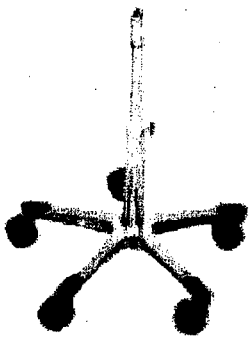


$564

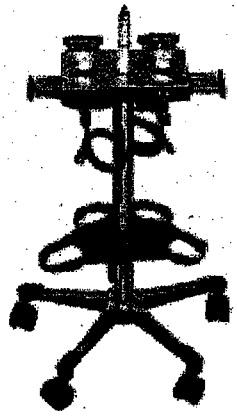
P1407QD w/Quick Disconnect Option (T-Only)



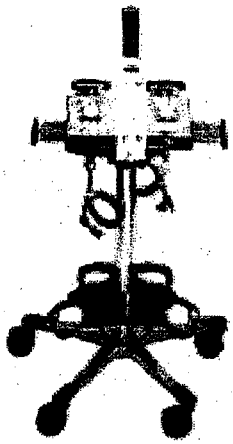
$294 (T-OPTION ONLY)



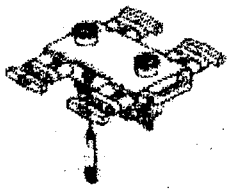
2040	**Compact Mobile Stand** (Top of Meter Telescopes from 24" to 36")	$464
2042	**Tall Mobile Stand** (Top of Meter Telescopes from 43" to 50")	$475



2045-3	**Tall Mobile Stand** for 2 "E" Tanks of 02 and 2 "E" Tanks of N20 (Top of meter telescopes from 43" to 50") *Gas Supply Tubing included*	$2,642



2045-Short-3	**Under Cabinet Stand** for 2 "E" Tanks of 02 and 2 "E" Tanks fo N20 (Top of meter telescopes from 31" to 41") *Gas Supply Tubing included*	$2,765



C-1667-000	**E-Block Assembly** for 5 leg base	$2,206

C-1658-000	**Tank Restraints** for 5 leg base	$99

RE: Nitrous Oxide

Ayers, Daniel
Sent: Monday, February 25, 2013 9:53 AM
To: Mellin, Leslie
Cc: Morley, Susan; Dubra, Outar

Hello Leslie,

Sorry I haven't gotten back to you. Outar Dubra our Equipment tech or Susan Morley our Department Administrative Assistant will order the gas for your department and deliver it. We would need to set up an account for your department. Attached is a form that needs to be completed that allows us to charge the gas back to your department. Please print out the form, complete the highlighted areas, sign under manager and fax to BISC 813-901-6300. You need to let him know when you need a tank ordered by. When you order on Thursday by 12 noon, order comes on Monday and Tuesday by noon comes in on Thursday. He can be reached at 80-1323

I think you had asked about the specifics of how it needs to be stored. We do not use this gas, so you may need to get in touch with Anesthesia department as to the specifics of Nitrous Oxide storage... I would imagine this would need to be closely monitored and locked up due to its anesthetic properties and possibility of misuse. As for the tanks themselves, they need to be in carriers or chained to the wall, just like oxygen tanks, never free standing. Only 12 total tanks (empty and full) of any gas should be stored in one area. (depending on the size, I am assuming E size). You can call us when you receive the gas to inspect storage situation.

How would this be administered? It is my understanding it is used in a closed system with some sort of scavenger (reabsorber). Just curious.

Let me know how I can help

Dan Ayers, BS, RRT-NPS, CPFT
Manager
Respiratory Care Services
(813)870-4954

From: Mellin, Leslie
Sent: Monday, February 25, 2013 8:54 AM
To: Ayers, Daniel
Subject: Nitrous Oxide

From: Mellin, Leslie
Sent: Friday, February 15, 2013 4:31 PM
To: Ayers, Daniel
Subject: RE: Nitrous Oxide

Dan,

I am a nurse in the Pediatric Day Hospital, and we are initiating a Nitrous Oxide program in our future. You have had previous correspondence with my educator, Cindy Hyde. You informed us that Airgas provides nitrous for the OR. I am looking to find out the current availability of portable nitrous and any restrictions on storage in the Day Hospital. Is it also possible to get a price on how much each tank would be? Thanks, for your help as we attempt to get this new program started!

Thank you,
Leslie

Leslie Mellin RN, BSN
Day Hospital
813-554-8511 option 1
Leslie.mellin@baycare.org

St Joseph's Children's Hospital
3001 W. Dr. M. L. King Jr. Blvd
Tampa, FL 33607

From: Ayers, Daniel
Sent: Tuesday, November 20, 2012 10:30 AM
To: Hyde, Cynthia
Cc: Mellin, Leslie
Subject: Re:

Our gas delivery company is Airgas. Only the OR's use this. We do not currently do this, but love to get involved. Forward any info you may have. Thanks

Sent from Dan's phone

On Nov 20, 2012, at 10:17 AM, "Hyde, Cynthia" <Cynthia.Hyde@baycare.org> wrote:

> Hello Dan! I am the educator over our Pediatric Day Hospital. We are looking into the logistics of using Nitrous Oxide in the Day Hospital in the near future. We are in the early stages of our investigations and processes and would like to inquire which vendor Baycare uses for the gas and delivery system? I contacted SDS and they forwarded your name. Once again, we are only at the beginning stages of this process, and want to gather all our pieces of information for further process approvals. Any assistance or direction in this matter would be greatly appreciated! Please feel free to contact me if you have any questions or concerns.
> Thank you again! Have a wonderful week ☺!
>
> Sincerely,
>
> Cindy Hyde, BSN, RN
> Education Specialist
> St. Joseph's Children's Hospital
> Day Hospital, Surgical Services
> Vascular Access Team, Non-Invasive Lab
> Cynthia.Hyde@baycare.org
> 813-554-8559 office
> 813-332-0769 pager
> 813-554-8596 fax

LAWSON ACCESS AND RQC ACCESS REQUEST FORM

Complete all information and fax to 813-901-6300 or email to MM.systemSupport@BayCare.org

Employee #: 55876	Name: Susan Morley		Date Requested: 2/25/2013
Home Dept: 35050	Job Title: Dept. Secretary	Email (Required): Morley.susan@baycare.org	Phone: 813-870-4900

Type of Request:
☐ New login ☐ Remove Access
☒ Change/Addn'l Access

Training Completed (Requirement):
☐ Instructor Lead ☐ Computer-Based (CBT)

Will User be Involved in Testing? ☐ Yes ☐ No
If Yes, Select from list
☐ Train ☐ Test (cv=crp)
☐ DEV (cv=TEST)

What is your role?
☐ VP/COO/CFO
☐ Director/Manager
☒ TM/Non-Management

Check all that Apply:
☒ Create requisitions
☐ Approve Requisitions
☐ Create eBuilder Requisitions
☐ Mobile hand held

Location: ☐ BayCare ☐ HomeCare ☐ JKV ☐ MPM ☐ SAH ☐ SFB ☒ SJH ☐ SJN ☐ PrimaryCare ☐ Other

Security Role – MM only:

Lawson Company ex. 1105	AU/Cost Center 12520	Description Cardiac Admiss & Recovery	Notes

Statement of Team Member Responsibility: My acceptance of this password to access the Lawson/BOB System is my acknowledgement that I will not disclose it to anyone nor use it to perform unauthorized functions.
Team Member Signature: Susan Morley

Manager's Name (Printed):

Manager's Signature:

MM Authorization Signature:

LAWSON ACCESS AND RQC ACCESS REQUEST FORM

Complete all information and fax to 813-901-6300 or email to MM.systemSupport@BayCare.org

Employee #: 55771	Name: Outar Dubra		Date Requested: 2/25/2013
Home Dept: 35050	Job Title: Equipment Tech	Email (Required): Outar.Dubra@baycare.org	Phone: 813-357-1323

Type of Request:
☐ New login ☐ Remove Access
☒ Change/Addn'l Access

Training Completed (Requirement):
☐ Instructor Lead ☐ Computer-Based (CBT)

Will User be Involved in Testing? ☐ Yes ☐ No
If Yes, Select from list
☐ Train ☐ Test (cv=crp)
☐ DEV (cv=TEST)

What is your role?
☐ VP/COO/CFO
☐ Director/Manager
☒ TM/Non-Management

Check all that Apply:
☒ Create requisitions
☐ Approve Requisitions
☐ Create eBuilder Requisitions
☐ Mobile hand held

Location: ☐ BayCare ☐ HomeCare ☐ JKV ☐ MPM ☐ SAH ☐ SFB ☒ SJH ☐ SJN ☐ PrimaryCare ☐ Other

Security Role – MM only:

Lawson Company ex. 1105	AU/Cost Center 12520	Description Cardiac Admiss & Recovery	Notes

Statement of Team Member Responsibility: My acceptance of this password to access the Lawson/BOB System is my acknowledgement that I will not disclose it to anyone nor use it to perform unauthorized functions.
Team Member Signature: Outar Dubra

Manager's Name (Printed):

Manager's Signature:

MM Authorization Signature:

RE: Contact for vendor credentialing

Kimery, Allison
Sent: Friday, March 01, 2013 10:06 AM
To: michael.civitello@parker.com
Cc: Mellin, Leslie

Hi Mike,

Your vendor number with BayCare is 44666.

Let me know if I can be of further assistance.

Thank you,

Allison Kimery
AP Vendor Master Analyst
BayCare Health System
16255 Bay Vista Dr
Clearwater, FL 33760-3127
727-519-1710
Allison.Kimery@baycare.org

-----Original Message-----
From: michael.civitello@parker.com [mailto:michael.civitello@parker.com]
Sent: Thursday, February 28, 2013 11:38 AM
To: Kimery, Allison
Subject: RE: Contact for vendor credentialing

Hi Allison -

I'm traveling today. I think I did a quote for Leslie which she may have. Otherwise I'll have to send later today. Standard terms are N30. Will the quote suffice for what you need? We can't generate an invoice until an order ships.

Mike Civitello, Product Sales Manager
Porter Instrument Division
Parker Hannifin Corporation
245 Township Line Rd
Hatfield, PA 19440 USA
direct 215-723-4000 x8224
fax 215-723-5106
michael.civitello@parker.com
www.porterinstrument.com

-----"Kimery, Allison" <Allison.Kimery@baycare.org> wrote: -----

==========
To: "'michael.civitello@parker.com'" <michael.civitello@parker.com>
From: "Kimery, Allison" <Allison.Kimery@baycare.org>
Date: "02-28-2013 "11:30AM"
Subject: RE: Contact for vendor credentialing
==========
Hi Mike,

Can you please also provide your payment terms? We need a contract or agreement or

invoice.

Thank you,

Allison Kimery
AP Vendor Master Analyst
BayCare Health System
16255 Bay Vista Dr
Clearwater, FL 33760-3127
727-519-1710
Allison.Kimery@baycare.org<mailto:David.Purcell@baycare.org>

[cid:image002.png@01CDE4D5.1372F3C0]

From: michael.civitello@parker.com [mailto:michael.civitello@parker.com]
Sent: Tuesday, February 26, 2013 4:00 PM
To: Kimery, Allison
Subject: RE: Contact for vendor credentialing

Allison -

I apologize for the delayed response - I was out most of last week. Attached please find your Setup/Maintenance form, and our W-9. Our Duns # is: 00-417-5550. Let me know if you need any additional information that I can help you with.

Mike Civitello, Product Sales Manager
Porter Instrument Division
Parker Hannifin Corporation
245 Township Line Rd
Hatfield, PA 19440 USA
direct 215-723-4000 x8224
fax 215-723-5106
michael.civitello@parker.com
www.porterinstrument.com

From: "Kimery, Allison" <Allison.Kimery@baycare.org>
To: "'michael.civitello@parker.com'" <michael.civitello@parker.com>
Date: 02/18/2013 04:26 PM
Subject: RE: Contact for vendor credentialing

Hi Michael,

Please find attached our new vendor packet. Once I have the information listed I can begin the process of setting you up as a BayCare vendor.

I've also attached our credit information/W9 and tax exempt certificate.

Let me know if I can be of further assistance.

Thank you,

Allison Kimery
AP Vendor Master Analyst
BayCare Health System
16255 Bay Vista Dr
Clearwater, FL 33760-3127
727-519-1710
Allison.Kimery@baycare.org<mailto:David.Purcell@baycare.org>

[cid:image002.png@01CDE4D5.1372F3C0]

From: michael.civitello@parker.com [mailto:michael.civitello@parker.com]
Sent: Monday, February 18, 2013 3:29 PM
To: Kimery, Allison
Subject: Fw: Contact for vendor credentialing

Hello Allison -

Leslie Mellin provided me with your email. She is in the process of getting the approvals to implement a new program to use some of our equipment. Whenever you are ready - we can start the process to get you whatever information you need to set us up as a Vendor. We will also need a couple of things from you as well (credit info and W9/tax exempt cert).

Sincerely,

Mike Civitello, Product Sales Manager
Porter Instrument Division
Parker Hannifin Corporation
245 Township Line Rd
Hatfield, PA 19440 USA
direct 215-723-4000 x8224
fax 215-723-5106
michael.civitello@parker.com
www.porterinstrument.com
----- Forwarded by Michael Civitello/PNC/ING/PARKER on 02/18/2013 03:30 PM -----

From: "Mellin, Leslie" <Leslie.Mellin@baycare.org>
To: "michael.civitello@parker.com" <michael.civitello@parker.com>
Date: 02/15/2013 04:08 PM
Subject: Contact for vendor credentialing

Michael,

Allison Kimery is a contact that should be able to walk you through the process to get credentialed as a Vendor in our facility. Thanks for your continued support in our endeavor to start a Nitrous program. Please let me know if you need further information.

Leslie

Leslie Mellin RN, BSN
Day Hospital

NO Certification
Course Require

College *of* Dentistry
UNIVERSITY *of* FLORIDA
(http://dental.ufl.edu)

Nitrous Oxide Psychosedation: Certification Course

This course is also approved for certification and training for dental auxiliaries in Florida, as per Florida Board of Dentistry Rule Assistants And Dental Hygienists may monitor nitrous-oxide inhalation analgesia under the direct supervision of a permitted de conditions: 1) Satisfactory completion of no less than a two-day course of training as described in the American Dental Associa and Comprehensive Control of Pain and Anxiety in Dentistry" or its equivalent, and 2) Maintenance of competency in cardiopul approved in Georgia).

Course Description

Nitrous oxide-oxygen sedation properly administered to the conscious child or adult provides an important adjunctive aid to the mar patient. This course is designed to prepare the general dentist and auxiliary to use nitrous oxide psychosedation confidently in the c clinical instruction will give the participant a step-by-step procedural approach for the control of anxiety in the conscious patient. The guidelines for an approved office inhalation analgesia course as required by both Florida and Georgia Boards of Dentistry. To m delines, twelve hours of this course will consist of a review of the instructional material, in a home-study format, which will be ma course; therefore, advanced registration is required. A preand post-test will be given for certification. Registration fee includes one c Oxide and Oxygen Sedation" by Morris Clark and Ann Burnick.

Course Objectives

At the completion of this course the participant should:

1. Know the history and characteristics of Nitrous Oxide Sedation
2. Know the basic respiratory physiology, including the uptake and distribution of gases
3. Know the states of anesthesia and phases of State I Anesthesia
4. Know the pharmacology, and physiology of Nitrous Oxide
5. Know the indications, contraindications, and complications of inhalation analgesia
6. Know the characteristics of the Nitrous Oxide/Oxygen delivery system
7. Know a clinical protocol for the use of Nitrous Oxide/Oxygen Sedation

Due to concern for your health and welfare, pregnant women cannot participate in the clinical portion of this course, and certification.

Faculty

Franci Stavropoulos, D.D.S., Associate Professor, Department of Oral & Maxillofacial Surgery and Diagnostic Services.

Continuing Education Units

20 contact hours. Participation

25 participants

Registration Fees

Breakfast on Saturday is included.
Friday: 1:00 p.m. – 5:00 p.m.
Saturday: 8:30 a.m. – 12:30 p.m.

Participant	Regular Fee	Early Bird Fee (Expires 1 month before course date)
Dentists	$679	$649
Auxiliaries	$479	$449

Dates	Location	Course #	
January 25-26, 2013 (Fri-Sat)	Gainesville, FL	140011.01	Register Online (http://xms.dce.ufl.edu/reg/groups/cde/sectic
April 19-20, 2013 (Fri-Sat)	Seminole, FL	140011.02	Register Online (http://xms.dce.ufl.edu/reg/groups/cde/sectic
July 19-20, 2013 (Fri-Sat)	Seminole, FL	140011.03	Register Online (http://xms.dce.ufl.edu/reg/groups/cde/sectic
October 25-26, 2013 (Fri-Sat)	Seminole, FL	140011.04	Register Online (http://xms.dce.ufl.edu/reg/groups/cde/sectic

Continuing Education at UFCD wishes to express its appreciation to Porter Instruments for unrestricted educational grants, which h sible.

ADA CERP® Continuing Education Recognition Program

The University of Florida is an ADA CERP Recognized Provider and a member of the Association for Cc

Bill Online (https://billpointe.com/billpointe/cubfogram.do?id=1A26-B76C-C9BC-FBF)

Questions & Answers (http://dental.ufl.edu/patient-care/patient-information/questions-answers/)

(http://dental.ufl.edu/admissions/d

(http://dental.ufl.edu/alumni-giving/news-events/)

Photo Galleries (http://dental.ufl.edu/about/news-communications/photo-galleries/)

governance/committees/)