CE 1.5 ANCC Contact Hours

A Nurse-Directed Model FOR NITROUS OXIDE USE During Labor

Abstract

Background: Nitrous oxide has a long history of use and has been well documented in the literature as a safe, effective, and inexpensive option for pain management in labor in other countries, but it is underused in the United States.

Local Problem: Pain relief options for laboring women in rural community hospitals with a small perinatal service are limited due to lack of availability of in-house anesthesia coverage.

Method: This quality improvement project involved development and implementation of a nurse-driven, self-administered, demand-flow nitrous oxide program as an option for pain relief for laboring women in a rural community hospital.

Intervention: Women's Services registered nurses developed the project using an interdisciplinary team approach based on an extensive literature review and consultation with experts across the country. The hospital is part of a large healthcare system; approval was sought and obtained by the system as part of the project. Cost analysis and patient satisfaction data were evaluated. Outcomes were monitored.

Results: Approximately one half of the patients who have given birth at the hospital since initiation of the project have used nitrous oxide during labor. The majority of women who participated in a survey after birth found it helpful during mild-to-moderate labor pain. No adverse effects have noted in either the mother or the baby following nitrous oxide use.

Clinical Implications: Initiation and management of nitrous oxide by registered nurses is a safe and cost-effective option for labor pain. It may be especially beneficial in hospitals that do not have 24/7 in-house anesthesia coverage.

Key words: Birth; Intrapartum nursing care; Labor; Laboring mothers; Nitrous oxide; Pain relief; Quality Improvement.

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Since the 2011 publication of *The Future of Nursing: Leading Change, Advancing Health* report by the Institute of Medicine (IOM) in concert with the Robert Wood Johnson Foundation, registered nurses (RNs) have expanded their practice based on the four key messages cited in the report. One of those key messages is that "nurses should practice to the full extent of their education and training" (IOM, 2011, p. S3). Nurses in the Women's Services Unit at the hospital where this project was implemented believed that they could develop and direct self-administration of a demand-flow 50% mixture of nitrous oxide/oxygen (NO/O) to women in labor who wished to use it once an order from a physician or nurse midwife was obtained.

Local Problem

Our facility is a 137-bed small community hospital in rural Texas where both physicians and nurse midwives attend births. The perinatal service averages less than 200 births per year. Until this project, use of NO/O for patients in labor was not feasible as a physician-driven option due to the paucity of anesthesia providers available to cover after hours use. Our anesthesia providers, obstetrical providers, and hospital administrators were supportive of developing an RN-driven and managed model for demand-flow, self-administration of NO/O. Once a written or verbal order is received from a physician or nurse midwife (CNM), nurses prepare, implement, and manage NO/O administration to the laboring woman without physician oversight.

Risk, Benefits, and Safety of Nitrous Oxide/Oxygen

Self-administration of NO/O is accomplished via a handheld mask connected to the NO/O machine. The patient must place the mask over the nose and mouth with sufficient force to create a seal and inhale with enough force to initiate the gas release, in other words the machine functions on a demand-flow system. If the patient becomes too drowsy while inhaling NO/O, she cannot seal the mask or inhale with enough force to trigger gas release. She receives no further NO/O until her drowsiness passes and she can once again seal the mask and inhale with enough force to trigger the gas. Nurses monitoring the laboring patient explain the process to family and friends who are present. These support persons are instructed that only the patient should place the mask over her face and that they should not help the patient by placing the mask over her face if she is too drowsy to do it herself.

The 50% mixture of NO/O has some benefits over other forms of analgesia. It does not cause diffusion hypoxia (an abrupt, short-lasting decrease in alveolar oxygen when room air is inhaled following high-dose nitrous oxide anesthesia), interfere with oxytocin function, have an impact on spontaneous vaginal birth rate, increase risk for complications, have an impact on Apgar scores, impair ability to breastfeed, depress neonate respiration rate, or require intensive monitoring. It can also be safely used with other forms of analgesia. It does cross the placenta, but is eliminated quickly once the newborn starts to breathe. Side effects and adverse reactions to NO/O appear to be dose-dependent. The most frequently seen side effects with self-administered NO/O are: nausea, vomiting, dizziness, and dysphoria. Inability to tolerate any of these side effects should result in discontinuation (Stewart & Collins, 2012).

There are contraindications to using NO/O. It inactivates vitamin B-12 so it should not be used in people with B-12 deficiency, such as those who are malnourished, are alcoholics, or suffer from anorexia nervosa. Other contraindications include pulmonary hypertension, increased intracranial pressure, hemodynamic instability, impaired oxygenation, increased intraocular pressure, drug or alcohol impairment, or the patient's inability to hold the mask to the face. Absolute contraindications include patients with a potential space that the gas could fill, like

Nitrous oxide is safe and effective when used during labor.

those with pneumothorax, bowel obstruction, and recent intraocular or middle ear surgery (Stewart & Collins, 2012). Few of these contraindications are seen in laboring women. Information from the attending healthcare provider and the initial comprehensive nursing assessment are used to determine if any of these issues apply to the patients who wish to use NO/O.

Literature Review

A comprehensive literature review was undertaken in Academic Search Complete, Medline, and CINAHL databases using the search terms of nitrous oxide, laboring patients, and 50% nitrous oxide/oxygen. Twenty-two articles were identified and reviewed. Although the mechanism of action is not completely understood, nitrous oxide is believed to stimulate release of endorphins and other pain modulators producing an anxiolytic effect. Onset of action is rapid (30 seconds), as is the elimination of the drug following discontinuation (within a few breaths) (Agency for Healthcare Research and Quality [AHRQ], 2012; Collins, 2015; Collins, Starr, Bishop, & Baysinger, 2012; Rooks, 2011; Stewart & Collins, 2012). Self-administration equipment was introduced in 1934 in England. Up to 75% of laboring women use NO/O in the United Kingdom, Canada, Finland, Sweden, Australia, and New Zealand (AHRQ). In the United States, devices delivering a 50% mixture of NO/O are approved by the Food and Drug Administration for use during labor (United States Food and Drug Administration, 2012).

Rigorous research studies testing use of a 50%NO/50%O mixture during labor to support that it is 100% safe are lacking and are sorely needed (Likis et al., 2014). No contradictory findings for use at a 50% mixture of NO/O concentration were found in any of the literature reviewed (Klomp et al., 2012; Pamaiahgari, 2014; Xue, 2013a; Xue, 2013b). Use of NO/O has been found to have no significant effects on either maternal or fetal outcomes (AHRQ, 2012; Rooks, 2011). The American College of Nurse-Midwives (ACNM) (2010) has a position statement supporting NO/O as an option for laboring women. The American College of Obstetricians and Gynecologists (2017) discusses the advantages of using NO/O in its recent practice bulletin on obstetric analgesia and anesthesia.

Women report nitrous oxide is helpful in relieving mild-to-moderate labor pain.

Intended Improvement

The goal of the project was to develop an RN-directed process for self-administered, demand-flow NO/O for laboring women in Women's Services at our hospital. Until recently, patient self-administration of NO/O use in the United States has been almost nonexistent because no vendor supplied the equipment to deliver it. Table 1 lists parameters to assure safety for the system purchased by the hospital. Since then, use of patient self-administration of NO/O has grown, but many hospitals and birthing centers in the United States still do not offer it as an option for obstetrical patients. Collins (2015) recommended broader use of NO/O because its anxiolytic properties mediate fear and anxiety in early-stage labor.

Planning for the Intervention

Scope of Practice Determination

Much like fentanyl, NO has been classed as an anesthetic. When fentanyl patches were developed for analgesia, the classification was broadened and the scope of practice for nurses expanded to deliver this form of analgesia. Efficacy of use during labor as analgesia has broadened the classification of NO as an analgesic, allowing RNs to deliver a self-administered, demand-flow NO/O. To be certain the state board of nursing (BON) would support this RN-driven model, the Women's Services nurses used the BON's six-step decision-making model for nurses to use to determine if a skill is within their scope of practice. Following review, they concluded that they could legally provide self-administered, demand-flow NO/O to patients in labor once they received education on the use of NO/O and the equipment to deliver it.

Data Gathering

A review of national evidence-based practice guidelines or standards found nothing prohibiting RNs from initiating patient self-administration of NO/O once it is ordered by a provider. Institutions using NO/O were contacted by the medical director of anesthesia and the Women's Services nursing leaders and asked why the intervention was ordered and initiated by the anesthesia department. The three main reasons given for the practice were 1) traditionally medical gases have been administered by anesthesia providers, 2) it's the way it's always been done, and 3) billing codes exist to support charging for the service when it is coded as an anesthetic, not an analgesic.

An extensive search was conducted by contacting nurse leaders in obstetrics in hospitals that use NO/O via personal contact at state and national meetings, and email messages or phone calls prior to beginning policy and procedure development. Protocols for RN-directed patient self-administration of demand-flow NO/O were requested. We were unable to locate any through our search. A task force with a collaborative interdisciplinary team was formed and began development of a nurse-driven model for patient self-administration of demand-flow NO/O.

Policy and Procedure Development

The Women's Services nurses drafted a policy and procedure and presented it to the task force. Mechanism of action, side effects and adverse reactions, contraindications, and benefits of using NO/O were evaluated. A draft of the policy and procedure was subsequently presented to the interdisciplinary team, which included nurses, obstetricians, pediatricians, family physicians, CNMs, anesthesiologists, and certified registered nurse anesthetists (CRNAs) practicing in Women's Services. The team edited and refined the draft and approved the finished product. Tables 2 and 3 contain the policy and the procedure (Supplemental Digital Content 1, http://links.lww.com/MCN/A37). The task force then discussed the policy and procedure with hospital administrators, risk managers, and the employee health nurse, receiving support for implementation.

System Approval for the Project

A Failure Mode Effects Analysis was conducted. No issues with implementation of NO/O were identified. The evidence-based policy and procedure were vetted by the system legal department and approved. The policy and procedure were then submitted to and approved by system-level department-specific committees: the quality and safety committee and the pharmacy and therapeutics committee. The Women's Services nurses developed and presented a business case for a clinical documentation build in the electronic health record to support ease of documentation and data collection to system leadership. Approval was obtained to add the information to the electronic health record.

Implementation at the Hospital

Following system-level approval, the hospital's medical executive committee reviewed the policy and procedure and approved it. During a routine, planned hospital risk assessment survey, the hospital's insurer was asked to review the NO/O policy and procedure and render an opinion about implementation. The hospital's insurer approved implementation of the nurse-directed policy and procedure for self-administration of demand-flow NO/O to laboring patients. The quality and safety department determined that use of NO/O was covered under the hospital consent form signed upon admission, so no additional consent form was needed.

The vendor from which we purchased the equipment provided an educator to conduct an initial educational program covering operation of the self-administration equipment for the Women's Services nurses and other members of the interdisciplinary team. Education was provided several times over a 1-week period so that all involved staff and providers could attend. Equipment super users were identified among the Women's Services nursing staff. They were trained to provide NO/O education to new nurses as needed. Use of the NO/O system was added as a required area of competence in the annual competence validation program. The procedure in Table 3 (Supplemental Digital Content 1, http://links.lww.com/MCN/A37) contains information required during the annual competence program.

Table 1.
Parameters to Assure Safety of the Nitrous Oxide/Oxygen Systems

A preset mixture of 50% nitrous oxide and 50% oxygen that cannot be changed
An oxygen-driven pressure control that shuts off nitrous oxide if the oxygen supply is depleted
Three different visual pressure gauges to confirm the appropriate supply of nitrous oxide and oxygen
If tidal volume drops to below 200 cubic centimeters, the delivered oxygen will automatically increase to 65% or greater
A patient-activated, hand-held supply valve that activates only during inspiration
The unit delivers 100% oxygen to the patient if the nitrous oxide is depleted
There is a built-in scavenging interface for removal of exhaled nitrous oxide

Discussion and Interpretation

Patient Evaluation

Since self-administration of NO/O became an option for analgesia in May of 2011, more than half (466 of 866 from September 2014 to September 2016) patients who gave birth at our hospital used it exclusively or in concert with other analgesics for pain control during labor. Intravenous narcotic use decreased since use of NO/O began, having a positive impact on rates of respiratory depression in our neonates. Nineteen nulliparous and multiparous patients were given a paper-and-pencil survey containing two 10-point numeric pain scales and asked to rate their pain level before and after using NO/O. Results showed an average 3-point reduction in labor pain with NO/O. The patients were then asked to give us their opinions about using NO/O. When labor pain was mild to moderate during the first or second stage of labor, patients believed it relieved pain by relaxing them and causing them not to focus on the pain. Patients in the third stage of labor did not find NO/O useful for pain relief.

Staff Safety

The literature reflected some issues when higher levels of NO/O are used. Fertility hazards associated with higher

Clinical Implications of Implementing a Nitrous Oxide/Oxygen Program

Others interested in implementing a nurse-driven, self-administered, demand-flow NO/O program should:
Confirm with their state board of nursing that it is within nurses' scope of practice.
Identify mentors from other facilities that use the system to help them develop the process.
Obtain broad buy-in from stakeholders before developing the process.
Expect that once implemented, the popularity of NO/O will grow and other departments will wish to borrow the NO/O equipment.
Continue to formally collect data about the patient experience with NO/O so the body of knowledge about the use of NO/O can grow.

concentrations of NO/O than 50% were seen in rats (National Institute for Occupational Safety and Health [NIOSH], 1994). Rats exposed to very high doses of NO/O over a long period of time had more malformed babies (NIOSH). In clinical practice, dental assistants working in dental offices using NO/O without scavenging equipment showed a 59% decrease in conception probability during fertile periods when compared with the unexposed assistants (NIOSH). No recent studies on the effects of NO/O on fertility in nurses have been published in from any country using it. A 2011 literature review concluded NO/O was safe for mothers, babies, and caregivers when a scavenging system was employed (Rooks, 2011). Occupational hazard risk increased as the dose of NO/O and length of exposure increased. Lack of a scavenging system or a poorly ventilated room was thought to also increase risk to nurses (ACNM, 2010). All FDA-approved systems currently in use are a 50% NO/O mixture and have a built-in scavenging system, which is considered the primary mechanism and the preferred method to prevent employee exposure. Scavenging systems trap NO/O waste gases in a receptacle so that the gases can be disposed of at a later time in a safer environment (Occupational Safety and Health Administration, 2000).

In the United States, the maximum 8-hour, time-weighted, average NO/O exposure rate is 25 parts per million (ACNM, 2010). To determine Women's Services nurses' exposure rates, nurses working with patients using NO/O wear an NO/O dosimeter. Readings have consistently shown that exposure rates are less than 1 part per million, significantly less than the maximum exposure rate.

Cost-Benefit Analysis

The initial expenditure for the NO/O demand-flow system was approximately $5,000. Cost of the NO/O gas is less than $1.00 per patient. Each delivery system apparatus (mask and tubing) costs about $10.00. A total of 466 patients have used NO/O exclusively or in conjunction with other pain management technics since implementation for a total delivery system apparatus cost of $4,660. Cost for the NO/O gas totaled approximately $466. Nurse education time was 1 hour and cost $680 (20 nurses at $34/hour). Total expenditures since beginning NO/O have been $10,806.

Since Women's Health Services began using NO/O in September of 2012, there have been 866 births (as of September 2016). Of those, 251 used NO/O only during labor and birth. According to Hogan, Seifert, Moore, and Simonson (2010), the average charge for anesthesia by an anesthesiologist per procedure is $1,087.15. We learned CRNAs charge slightly lower, but there is an anesthesiology supervisory fee added making the cost higher than physician only charges. In an anesthesiologist-driven model, the total cost for the 251 patients who used only NO/O during labor and birth would have been $272,874.65 or $1,087.15 per patient. No additional charges are passed on the patients using NO/O in the nurse-driven model.

Conclusions

Approximately 54% of the women who gave birth at our hospital since initiating this project used NO/O for a pain relief option for some or all of their labor pain management. There have been no complications or adverse effects noted for laboring women or their babies. Nitrous oxide/Oxygen has also been used for its anxiolytic properties during intravenous catheter insertion, indwelling urinary catheter insertions, perineum repairs, incisional care postpartum, and for mothers who have a fetal demise.

Other hospitals within our health system have plans to adopt use of NO/O. Several inquiries from across the nation about an RN-directed, self-administration of demand-flow NO/O by patients have resulted in the policy and procedure being shared. In institutions without 24/7 in-house obstetrical anesthesia coverage, availability of an RN-directed procedure allows laboring women an alternative option for pain control. The major benefit the Women's Services team has seen when using NO/O is that it often can replace intravenous narcotics for pain control. Babies born following NO/O do not show the sedation and potential respiratory issues seen after intravenous narcotics have been used during labor. ✣

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