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Nitrous oxide in labor : approval, implementation, and quality consideration

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DNP Project

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I. Introduction: The Clinical Problem

A: Description of the clinical, health system, organizational, or policy problem

Nitrous Oxide for Labor Analgesia

For many women labor causes severe pain (comparable to a complex regional pain syndrome or the amputation of a finger), yet each woman's experience of labor pain is highly individual in its intensity, nature of the sensations, and her ability to cope (Lowe, 2002). Some women experience a higher degree of physical pain without suffering, while others suffer greatly from pain that caregivers may perceive as modest (Rooks, 2012). In the United States, women desiring relief from pain associated with labor, have relatively few options available – especially pharmacological. Non-pharmacological pain-relieving options such as continuous labor support, water immersion, and sterile water papules have been demonstrated to be helpful (Kozhimannil et al., 2014), but are not always available to women in labor, and for some women, do not provide adequate pain relief.

The two most common and regularly available pharmacological methods of pain relief in labor are epidural or spinal neuraxial analgesia and parenteral opioids. Epidural analgesia is a highly effective analgesic for most women, but not without risks. Epidurals can cause acute hypotensive events, increase the duration of the second stage of labor by 15 to 30 minutes, increase the rate of instrument-assisted vaginal deliveries, and elicit a need for oxytocin administration (Hawkins, 2010). For some women, epidural analgesia may not be a viable option due to preexisting hematologic disorders, spinal injury or malformation, localized infection at the injection site of the proposed epidural, or allergy to local anesthetics. Many women also want to avoid interventions that accompany epidurals, including IV placement, bladder catheterization, continuous external fetal monitoring, and confinement to the bed (Stewart & Collins, 2012).

Systemic opioids such as meperidine, morphine, and fentanyl are widely used by laboring women in the United States, but they also carry certain risks and side effects for some. Side effects include respiratory depression, sedation, nausea/vomiting, dizziness, altered mental status, euphoria, decreased gastric mobility, decreased gastric emptying, and urinary retention (Anderson, 2011). No high-quality randomized controlled trials have demonstrated this, but observational studies suggest neonatal respiratory depression, decreased neonatal alertness, inhibition of suckling, lower neurobehavioral scores, and a delay in effective feeding with use of opioids in labor (Bricker & Lavender, 2002).

Inhaled nitrous oxide (N_2O) is commonly used as a labor analgesic in many Western countries, but it is infrequently used in the United States – mostly due to limitations in availability. It is used by 60% of laboring women in the United Kingdom, 50% of laboring women in Australia, and nearly 50% by laboring women in Finland and Canada (Baysinger, 2014). N_2O works as a weak anesthetic at high doses and an analgesic and anxiolytic at low doses (Dundee & Moore, 1960). It is one of the only patient-administered analgesics used in labor, and can be used for analgesia during the first, second, and third stage of labor, as well as during post-delivery procedures such as laceration repair, manual removal of the placenta, and uterine curettage (Stewart & Collins, 2012). N_2O crosses the placenta yet it appears to have no effect on fetal heart rate or on the suckling behavior of neonates (Littleford, 2005). Existing studies – though limited in volume and quality – have found no effect on neonatal Apgar scores or NICU admission rates (Leong, Sivanesaratnam, Oh, & Chan, 2000).

In her editorial, *Nitrous oxide for pain in labor – why not the U.S.?*, Judith Rooks (2007) eloquently writes, “Labor pain is a subjective, multidimensional, and highly individualized response that occurs in the context of a particular woman’s physiology and psychology. Her

own and her family's beliefs, expectations, and values, as well as the environment in which she labors are all involved, and, in turn, her response to pain is affected by the beliefs, expectations, and values of her health care providers…With such variation in women's experiences of, and attitudes toward, labor pain, providing a single highly effective but expensive and intrusive analgesic, such as an epidural, is simply not enough (p. 3)." Women deserve to have a variety of safe options for managing pain in labor, and to deny women a method that is used safely and effectively in several developed countries with better birth outcomes than the U.S. seems discordant. A growing number of hospitals are offering nitrous oxide to patients in labor in the U.S., but the number is still small. The list includes University of California at San Francisco Medical Center, Vanderbilt University Medical Center, and Dartmouth-Hitchcock Medical Center. Expanding this option at other institutions will further enhance the ability of midwives and other OB providers to facilitate more positive, empowering, and satisfying birth experiences for the patients who deliver in their hospitals.

Population Affected By the Problem

Any woman who desires nitrous oxide for relief of pain in labor and is unable to access it at the hospital or birth center at which she is delivering is affected by the lack of access. Many women requesting "gas and air" in labor come from countries where it is commonly offered, or have heard positive stories from friends or family members who have used it in labor at select hospitals in the United States. For women who are not candidates for epidural analgesia (i.e., labor is progressing too quickly or a patient with HELLP syndrome develops severe thrombocytopenia), or desire a low-interventive birth, there are relatively few options to offer. Pharmacological methods of pain relief are limited to parenteral opioids and epidural analgesia.

Epidemiology

As mentioned above, few hospitals in the U.S. currently offer nitrous oxide as an option for analgesia in labor. The introduction of an FDA-approved apparatus for administration of nitrous oxide such as Nitronox® and Pronox® has allowed an increasing number of hospitals to offer it to patients, but they are still relatively few and far between. Rooks (2007) cites the following explanations for its limited use in the United States: nitrous oxide is unglamorous, not highly potent, presents a concern for potential environmental contamination and may be associated with occupational hazard (though not an issue when properly scavenged and disposed of).

Purpose of the Project

The purpose of my DNP project is to investigate existing institutions in the United States that currently offer nitrous oxide to patients, or are in the process of adopting its use for patients in the near future to understand patients' patterns of use, patient satisfaction, barriers and facilitators to adoption and implementation and common quality measures.

B. Review of the literature

A literature review was conducted using Medline, PubMed, and Google Scholar online search databases for relevant journal articles on nitrous oxide use in labor. Keywords included: nitrous oxide, labor analgesia, labor pain, pharmacological pain relief, and labor anesthesia. Specific articles were also identified and searched for using several authors' reference lists.

Pain in Labor:

Clear understanding of the complex, interrelated influences on the painful experience of labor is limited by the quality and quantity of the available research (Lowe, 2002). This topic is

subjective and difficult to measure and compare among women. Randomization of women to a placebo group is not ethical, and for most studies of labor analgesia, it is difficult to hide assignment of pregnant women or investigators to the treatment group assigned, which can introduce potential bias (Rosen, 2002). When a woman suffers with pain in labor, she releases catecholamines, which reduce the effectiveness of contractions, and can lead to dystocia, maternal exhaustion, and fetal distress (Rooks, 2012). Severe pain in labor is not life threatening in healthy pregnant women, but it can have neuropsychological consequences (Hiltunen, Raudaskoski, Ebeling, & Moilanen, 2004).

In their stance on pain in labor, The American College of Obstetricians and Gynecologists and the American Society of Anesthesiologists state, “There is no other circumstance where it is considered acceptable for an individual to experience untreated severe pain, amenable to safe intervention, while under a physician’s care. In the absence of a medical contraindication, maternal request is a sufficient medical indication for pain relief during labor” (ACOG, 2004). The American College of Nurse-Midwives states: “Experience of labor pain differs among women, and the response to pain is highly individual. Women should have access to a variety of approaches to promote comfort and reduce pain throughout labor, but women in the United States have fewer options than those in many other advanced countries” (ACNM, 2011). These three respected organizations are in consensus that if a woman desires relief from painful labor, she should be offered options that are effective yet safe for her and her baby.

The negative effects of labor pain described above can be reduced by care from midwives and other health-care professionals who provide emotional support, which can enhance the woman’s sense of self-control, and help her avoid feelings of panic, anger, being overwhelmed, or giving up (Creedy, Shochet & Horsfall, 2012). Pain can be managed in labor with non-

pharmacological methods (i.e. continuous one-to-one support, immersion in water, acupuncture, and sterile water injections) that emphasize coping with labor and pain, and drug-based methods that reduce or potentially obliterate the pain sensation (Rooks, 2012).

Current Pharmacological Options for Pain Management in Labor:

In most Labor and Delivery units in the United States, epidural analgesia continues to be the preferred analgesic method for women in labor, and is considered by most to be effective and well tolerated (Althaus & Wax, 2005). In certain clinical situations, regional analgesia is unavailable, is contraindicated, or declined by the laboring women (Tveit, Seiler, Halvorsen, & Rosland, 2012). Systemic opioids are another methods of analgesia widely used for labor analgesia in the U.S., yet patterns of use in labor remain less clear (Evron & Ezri, 2007). Parenteral opioids used in labor have been reported to include meperidine, morphine, fentanyl, butorphanol, and nalbuphine, although no recent surveys have been published to verify this (Anderson, 2011). It not entirely understood whether the main effect of opioids is analgesic or sedative. The sedation that accompanies opioids may mask a weak analgesic effect by producing a generalized quieting effect while eliciting an apathetic or suppressed affective response to labor pain. Attempts to improve the analgesic effect with increasing doses results in increased sedation and side effects, and more newborns requiring naloxone therapy. Even with these added effects, higher doses have not been found to produce better labor analgesia (Anderson, 2011). Several side effects are associated with intrapartum use of opioids: respiratory depression, sedation, nausea/vomiting, dizziness, altered mental status, euphoria, decreased gastric mobility, decreased gastric emptying, and urinary retention (Anderson, 2011).

Nitrous Oxide in Labor:

The American Society of Anesthesiologists defines use of 50/50 N_2O/O_2 as analgesia (Baysinger, 2014) N_2O's efficacy, safety, and risks are all related to dose, which is correlated to the concentration and duration of exposure (Rooks, 2011). The N_2O concentration inhaled in labor is a sub-anesthetic concentration that allows the mother to remain awake and maintain her protective laryngeal reflexes (Klomp et al., 2012). It helps many women relax, gives them a sense of control, and reduces their perception of pain even though they still may be aware that the pain is present (Rooks, 2011). It can be used for analgesia during the first, second, and third stage of labor, as well as during post-delivery procedures such as laceration repair, manual removal of the placenta, and uterine curettage (Bishop, 2007). Like most pharmacological methods of pain relief, the effects can vary from woman to woman. Some women do not like how N_2O makes them feel – i.e., nauseated or dizzy – and some want a stronger analgesic. N_2O is effective enough for many women, and can fill a currently unmet need for labor analgesia (Rook, 2011).

Most of the studies on effectiveness of nitrous oxide for pain management are of poor or fair quality at best. In one study, 2482 women completed a questionnaire 2 months after labor and birth that included assessment of their pain management methods as very effective, some effect, or no effect. The proportion of very effective responses for primiparas and multiparas respectively was 84% and 72% for epidural analgesia, 38% and 49% for nitrous oxide, 41% for both groups for meperidine, 29% and 35% for bath or shower, and 10% and 23% for acupuncture (Waldenström & Irestedt, 2006). Waldenström's (1999) cross-sectional study surveying 1111 women on satisfaction with their birth experience at 2 months postpartum, found that of 362 women who had nitrous oxide, 57% reported a positive or very positive birth experience compared with 49% of women who had meperidine and 34% of women who had epidural analgesia.

The precise mechanism of action for nitrous oxide analgesia remains unclear, but it is believed that N_2O affects the brain, which modulates pain stimuli via the descending spinal cord nerve pathways (Rosen, 2002). Maze and Fuginaga (2000) hypothesized that N_2O induces release of endogenous opioid peptides in the periaqueductal gray area of the midbrain. This release then stimulates descending noradrenergic neuronal pathways, which modulate pain processing by norepinephrine-acting alpha-2 adrenoceptors in the dorsal horn of the spinal cord. N_2O may also trigger dopamine release in the CNS, and block N-methyl-D-aspartate receptors, which in turn elicits a euphoric effect in the body (de Lima, Hatch & Torsney, 2000). The analgesic action of N_2O is dependent on the inhibition of supraspinal and activation of spinal $GABA_A$ receptors (Sanders et al., 2008). In labor, nitrous oxide increases release of prolactin and decreases release of cortisol (Gillman & Katzeff, 1989).

Nitrous oxide is the only inhalation analgesic agent adopted for widespread use in the world. Other possibilities for inhaled analgesia in labor (though not widely available) include isoflurane, sevoflurane, trichloroethylene in air, methoxyflurane, and cyclopropane (Klomp et al., 2012). The reasons for the nearly exclusive use of N_2O among inhaled analgesics in labor are not entirely clear, but it is mostly likely related to "the ease of administration of nitrous oxide, its lack of flammability, absence of pungent odor, minimal potential for toxicity, minimal depression of the cardiovascular system, lack of effect on uterine contractility, and the fact that it does not trigger malignant hyperthermia" (Rosen, 2002, p. 110).

N_2O is administered by inhalation, typically mixed with oxygen. In the U.K. and elsewhere, 50% O_2 and 50% N_2O are delivered premixed in a single cylinder (Entonox®). A combination of N_2O and O_2 can also be delivered at a fixed concentration (50/50) from two separate cylinders (tanks) or hospital pipeline supply with a small regulator apparatus

(Nitronox®) or a device that allows N_2O adjustment within a narrow range (Midogas) (Rosen, 2002). Entonox® has never been approved by the FDA for use in the U.S, bur Nitronox®, LifeGas®, and CAREstream® are all FDA-approved delivery apparatuses currently in use in this country (Collins et al., 2012).

Outside of the US midwives typically manage administration, but in the US it is a variety of providers that administer N20. Midwives typically oversee the administration of N_2O, instructing patients how to self-administer the gas through a facemask or mouthpiece that has a demand valve connected. Previously, anesthesiologists were the only practitioners who could set up the equipment and teach a woman how to use N_2O, but now midwives can provide the same instructions after being adequately trained (Bishop, 2007). The demand valve opens only when the user applies negative pressure by inspiring through a mouthpiece or well-sealed mask (Rosen, 2002). Laboring women control the dose of N_2O/ O_2 by how much they inhale and how long they use it. Inhaling N_2O either continuously (during and between contractions) or intermittently (timing use with each contraction) can have a big impact on dose and effect on the individual (Rooks, 2011).

N_2O has a rapid onset of 30 to 50 seconds, which correlates with the volume and rate of inhalation. The patient's inhalation ideally coincides with uterine contractions for maximum analgesic effect. Anecdotal reports have noted that the laboring woman experiences the greatest relief when she begins inhalation approximately 30 seconds prior to the start of her contraction (Collins et al., 2012). Rosen (2002) posits that this can be difficult, because it "requires careful attention to contraction timing and intervals to allow onset of administration of nitrous oxide in anticipation of the onset of the next contraction rather than at the onset of contraction pain, which is difficult for many parturient women to do" (Rosen, 2002, p.111). Careful timing of

inhalation allows for peak serum levels of N_2O to coincide with the peak of the uterine contraction. As rapidly as N_2O takes effect in the body, it is also eliminated rapidly as well. Nitrous oxide enters and is eliminated from the body through the lungs. Less than 1% of the gas is metabolized (none of it stored) and 99% is exhaled unchanged (Rooks, 2011).

As mentioned above, concerns about the safety of nitrous oxide were raised over 50 years ago. There has been question whether exposure to the gas at anesthetic levels is harmful to the hepatic, neurologic, myocardial, and immune systems in the body, and more recently, nitrous oxide-induced neurotoxicity has been implicated in the development of long-lasting cognitive defects when administered to either infants or older adults (Cully et al., 2007). One of N_2O's known effects in the body is its inhibition of methionine synthase (Sanders et al., 2008). N_2O oxidizes the cobalt I (CO^{+}) form of cobalamin (vitamin B12) to CO^{3+} in the body, which prevents the necessary reaction of methionine synthase + cobalamin to convert homocysteine to methionine. Methionine plus folate play an important role in the sequence of methyl group formations that are involved with DNA, RNA, myelin, and catecholamine synthesis (Rooks, 2011; Sanders et al., 2008). This chemical sequence is critical to cell function, and decreasing its activity with extended exposure to N_2O may result in genetic and protein irregularities or megaloblastic anemia (a hepatologic complication) (Reynolds, 2005). Individuals with diseases that reduce cobalamin function (i.e. pernicious anemia) are at higher risk with exposure to N_2O, and are not advised to use it in labor. Extremely high doses of N_2O over time reduce cobalamin function enough to cause bone marrow depression, macrocytic anemia, and neuropsychiatric disorders (Rooks, 2011).

Immunologically, N_2O has been associated with decreased proliferation of peripheral blood mononuclear cells and changes to neutrophil chemotaxis (Sanders et al, 2008). Chronic

hyperhomocysteinemia is an independent risk factor for premature peripheral, cerebral, and coronary vascular disease; and use of N_2O anesthesia during surgery is known to increase the incidence of postoperative hyperhomocysteinemia and subclinical myocardia ischemia (Rooks, 2011). There is some concern that N_2O can cause neuro-apoptosis, but when neonatal rat brains were exposed to N_2O concentrations less than or equal to 75% (higher than any dose used in labor), no apoptosis occurred (Sanders et al. 2008). The FDA has recommended primate studies to understand the cognitive and neurobehavioral effects of exposing pregnant women to prolonged anesthesia better (Rooks, 2011).

Nitrous oxide can affect several hormones that are critical during labor and birth (i.e. endorphins, prolactin, cortisol, and epinephrine/norepinephrine) but does not influence the release or effectiveness of endogenous oxytocin, and has no effect on uterine contractions or labor progress (Rosen, 2002). It is very rare for the 50/50 concentration of N_2O/O_2 to cause loss of consciousness for the parturient because she has to hold the mask up to her face and self-administer the gas (Rosen, 2003). If she becomes sedated, she is unable to hold the mask or mouth tube and breath in the gas appropriately, and the residual N_2O leaves her lungs rapidly. As previously mentioned, the most common side effects of N_2O in labor are nausea and vomiting (due to pressure changes in the middle ear cause by diffusion of N_2O), and changes in consciousness (i.e. dizziness, sedation, light-headedness) (Rooks, 2011; Rosen, 2002). Paech (1991) found that 13% women reported nausea and vomiting after use of nitrous oxide. Concern over O_2 desaturation with use of N_2O sparked Rosen (2002) to analyze the best studies available, and he found that episodes of O_2 desaturation of closely monitored women using only N_2O/O_2 are infrequent, transient, not extreme, and more common when 75%/25% N_2O/O_2 is used.

The dose of N_2O used in current labor analgesia (significantly lower than the dose for anesthesia) has minimal toxicity, and causes minimal depression of the cardiovascular system (Rosen, 2002). N_2O crosses the placenta—resulting in an 80% fetal hematologic concentration compared with the mother's within 15 minutes—yet it appears to have no effect on fetal heart rate or on the suckling behavior of neonates (Littleford, 2005). In Su et al.'s (2002) study involving 1300 Chinese women, comparing intermittent inhalation of 50% N_2O/O_2 to just 50% O_2 without N_2O, researchers found no significant difference between the two groups in the incidence of meconium-stained fluid, Apgar score, or blood-gas analysis of fetal umbilical cord blood whether the mother had used it for 5 minutes or 5 hours. Leong, Sivanesaratnam, Oh, & Chan's (2000) prospective study of 123 women comparing the combined use of nitrous oxide and intramuscular meperidine with epidural anesthesia, found no statistically significant difference in Apgar scores or special care nursery admission rates between the 2 groups, and no newborn had an Apgar score lower than 7 at 5 minutes. In Likis et al.'s (2014) systematic review of nitrous oxide for management of labor pain, the authors found no good or fair quality studies that reported increased incidence of "fetal resuscitation, asphyxia, depressed neonates, sleepy neonates, prolonged time to sustained respiration, treatment for apnea, or neurobehavioral status" when mothers used nitrous oxide in labor (p.160).

Though nitrous oxide exposure during labor does not seem to influence suckling behavior in neonates, there are no existing data on effects of N_2O on breastfeeding. Klomp et al. (2012) propose further randomized controlled trials that are adequately powered to study the following three outcomes with N_2O use: 1) sense of control in labor and 2) satisfaction with childbirth and 3) breastfeeding experience of women.

One of the reasons for the existing scarcity of use of N_2O for pain relief in labor in the U.S. is the perceived occupational risk for the health professionals involved (Chessor, Verhoeven, Hon & Teschke, 2005). Nitrous oxide is currently used in many types of medical practices outside Labor and Delivery (Anesthesia, Pain Medicine, Emergency Medicine, and Dentistry) and has long been a concern to nurses, dental workers, and veterinarians (Lawson et al., 2012). When N_2O is not regulated or scavenged, it can be detrimental to the health of the professional exposed on a chronic basis (Sanders et al., 2008). Though Lawson et al.'s study (2012) did not show an association with spontaneous abortion in pregnant healthcare providers, a meta-analysis of studies that were conducted in the absence of a scavenging system reported increased risk for spontaneous abortion (Boivin, 1997). Dose is clearly the critical determinant of risk from environmental exposure. Recognition of risks associated with occupational exposure has led to the introduction of occupational exposure limits (OELs), which are expressed as an 8-hour time-weighted average. An OEL represents the concentration of a toxic agent that which above is not safe for a worker to be exposed to (Howard, 2005). The concept of OELs dates back to 1886 in Germany, when the country aimed to set a standard for assessing and managing risk posed by the new industrial workplace (Howard, 2005). Since then use of OELs has become widespread throughout the developed world.

The National Institute for Occupational Safety and Health (NIOSH) has suggested the OEL in the U.S. to be 25 parts per million (ppm), which is congruent with recommendations in The Netherlands and Ontario, Canada. This level is far lower than the 1,000-2,000 ppm often measured in medical settings before the use of scavenging (Mehta, Burton & Simms, 1978). OELs in the U.K., Italy, Sweden, Norway, Denmark, and Alberta allow 100 ppm (Sanders et al., 2008). Newton, Fitz-Henry, & Bogod (1999) evaluated 8-hour time weighted average nitrous

oxide exposure (in ppm) for 15 midwives at a newly built hospital in the UK with a ventilation system that involved 6-10 air changes per hour, and found that none of the midwives were exposed to levels of nitrous oxide greater than 100 ppm. Six of the 15 midwives were exposed to levels of nitrous oxide >25 ppm, the U.S. limit, an improvement from the older hospitals that used Entonox without ventilation.

The use of scavenging is required to capture exhaled air through a negative pressure device and remove it completely from the environment (Sanders et al., 2008). Proper N_2O scavenging requires the laboring woman to exhale back in the mouth-tube or facemask for several breaths after she stops inhaling the N_2O. Without scavenging of the exhaled nitrous oxide, health care workers may be exposed to levels of N_2O above the occupational exposure limit. Staff exposure can be effectively measured through the use of a commercially available dosimetry badge. This badge has been utilized at UCSF and VUMC to monitor ambient levels of N_2O, and consistently, their dosimetry data are well below the current NIOSH limit (Collins et al., 2012).

At the recommended OEL, there appears to be no conclusive evidence for reproductive, genetic, hematologic, or neurologic occupational toxicity from nitrous oxide exposure (Sanders et al., 2008). In Likis et al.'s (2014) systematic review of the literature on use of nitrous oxide for management of pain in labor, they found 59 distinct studies reported in 58 publications that met their criteria for the review, however only 2 were of good quality, 11 fair, and 46 poor. The majority of studies are observational research. Likis et al. write, "Deficiencies in the strength of evidence most often related to a preponderance of study designs with a high risk of bias, inconsistent findings across studies and inconsistencies among outcomes that would be expected to show corresponding benefit, use of intermediate outcomes, and studies with poor precision"

(p.164). There are studies that compare nitrous oxide to other inhaled anesthetic gases that are no longer used to manage labor pain, studies that use pain scores to evaluate pain relief from nitrous oxide when really it is meant to produce dissociation from pain, and studies that attempt to measure maternal satisfaction but have no uniform measure, making it impossible to synthesize findings (Likis et al., 2014). Like so much of obstetrics, there is great need for higher quality, prospective randomized controlled trials to study the safety and efficacy of this therapy.

Nitrous oxide is not a potent analgesic, but studies suggest that it has a beneficial effect for many women in labor. In the Cochrane review, Klomp et al. (2012) found that women reported less pain intensity for intermittent N_2O 50% when compared to no analgesia during the first stage of labor, and less intense pain for intermittent N_2O 50% when compared to O_2 50% in the first stage of labor. Nitrous oxide is easy to administer, and despite reports of brief periods of unconsciousness (particularly with 75% nitrous oxide), it appears to be very safe for laboring women and their babies when given at the level of 50% (Rosen, 2002). Short-term and low concentrations of N_2O in labor are most likely harmless, but high concentrations for prolonged periods may de deleterious to a woman's health (Collins et al., 2012). Nitrous oxide has been used for 150 years for analgesia and when used at the appropriate dose and duration, it has proven safe and efficacious (Sanders et al., 2008). Sanders et al. (2008) argue, "Exclusion from clinical practice is not warranted with the current level of evidence. Nitrous oxide currently has a niche role as an inhalational analgesic and sedative" (p.719).

Nitrous oxide is inexpensive, easy to administer, has a rapid onset of action and rapid rate of metabolism in the body, and from the available data, it is known to be comparatively benign (Rosen, 2002). It can be administered during first and second stage of labor without affecting uterine contractility, as well as in third stage and beyond for procedures such as manual removal,

and laceration repair. Women who do not like nitrous oxide or find it inadequate for pain management can easily discontinue its use and switch to another method for pain management, unlike the prolonged effects of epidural analgesia and systemic opioids that diminish gradually over a much longer time period (Likis et al., 2014). Nitrous oxide preserves mobility and does not require additional monitoring and potential anesthesia- related interventions (i.e., bladder catheterization).

It is the responsibility of the midwife or other provider to assess whether the option of inhaled analgesia is a safe one – just like he/she would with any pharmacological pain-relieving agent in labor. Safe practices for N_2O/O_2 labor analgesia should require that 1) the N_2O is administered with O_2, and the N_2O concentration does not exceed 50%; 2) it is self-administered, and the laboring woman holds the mask or mouthpiece without any assistance; and 3) the N_2O/O_2 delivery equipment uses a demand valve to stop the supply when the woman is not inhaling and uses scavenging equipment to capture the exhaled N_2O. These measures ensure that a woman using N_2O/O_2 cannot overdose or become hypoxic, and they protect healthcare workers from contaminated air (Sanders et al., 2008; Rosen, 2002).

Summary of Project Purpose

Increased access to N_2O services in hospitals and birth centers has long been advocated by the midwifery profession (Rooks, 2007). A position statement on nitrous oxide for labor analgesia issued by the ACNM in 2009 endorses the availability of N_2O to all laboring women, and recommends that all CNMs be trained "to administer and oversee safe use of N_2O analgesia during labor" (ACNM, 2009). UCSF has offered N_2O for over 30 years, and just recently, other hospitals such as Vanderbilt University Medical Center (VUMC) and Dartmouth-Hitchbock Medical Center started offering nitrous oxide to their laboring patients. To implement its use at

VUMC, the hospital took a multi-disciplinary team of medical professionals to exchange ideas, acknowledge and evaluate concerns, review evidence, and ultimately move forward with the development of new guidelines and policies (Collins et al., 2012).

There is equal hope that academic health centers in the U. S. will incorporate the safe administering of nitrous oxide to parturient women into their practice. So far, it has largely been academic hospitals opting to start offering inhaled analgesia, but as awareness grows and demand from patients builds, more private hospitals may decide to adopt it is well. Adding administration of nitrous oxide to the midwifery practice guidelines at institutions like OHSU will further enhance the ability of midwives and other OB providers to facilitate more positive, empowering, and satisfying birth experiences for the patients who deliver in their hospitals. It is a cost-effective and safe option for women that is well within the scope of practice for nurse-midwives, and an option for women who want to remain alert, mobile, and conscious during their labor. Expanding cost-effective, low-risk analgesic options for women is a definite step in the right direction for health care delivery in this country.

Potential Barriers to Nitrous Use in the U.S.

Nitrous oxide is routinely used by laboring women in developed countries that are similar to the United States in terms of socioeconomic and medical standards, yet surpass the United States in maternal and infant health outcomes, and spend fewer healthcare dollars each year. These countries such as the UK, Canada, and Finland regularly offer epidural analgesia and parenteral opioids for analgesia in labor as the U.S. does, but they also offer inhaled analgesia, which may be the preferred choice for a woman desiring a low-interventive birth or with a medical contraindication for other pharmacological methods of pain relief. There are a handful of institutions in the U.S. that are now recognizing the safety and efficacy of nitrous oxide in labor

and beginning to implement it, however this process has been relatively slow moving. To date, there are over 100 hospitals and over 50 birth centers in the US offering nitrous oxide. Rooks (2007) cites the following reasons for its limited use: "Obstetric use of nitrous oxide in America is similar to that of any older, inexpensive, …unglamorous, safe and reasonably effective but not highly potent drug" (p. 4). She also notes that some obstetricians and hospitals are afraid to use it because of the possible risk of environmental contamination and occupational hazard despite effective methods of scavenging. The cost of buying equipment and installing scavenging capabilities on L&D units, only recently having an FDA-approved device for administration, and lack of public demand describe some of the current barriers to implementation on L&D units.

Project Proposal

In order to mobilize a movement of change in an environment that may be resistant, inflexible, or wary of a shift in culture, it seems important – if not essential – to gather data from institutions that currently offer inhaled analgesia, to try to understand its use better. Through interviews with staff at various hospitals around the country, the author set out to explore barriers and facilitators to implementation and utilization of nitrous oxide in labor, perceived efficacy of nitrous as a method of labor analgesia, methods of data collection, and perceived cost-effectiveness. To achieve this understanding, the author set out to visit hospitals that currently offer nitrous oxide for labor analgesia, or are in the process of implementing it, and interview staff (i.e., nurses, nurse-midwives, obstetricians, anesthesiologists) regarding their implementation process, current utilization, and any barriers to use of nitrous oxide in labor at their respective institutions. As nitrous oxide grows in popularity, and more and more hospitals are looking to implement this alternate form of analgesia on their Labor and Delivery units, the

author anticipates there will be a need for more information to guide and streamline the process for individuals also looking to implement it.

II. Approach to the Conduct of the Project

Setting

Interviews took place in settings where nitrous oxide has either been offered for several decades, has been newly implemented, or is still in the process of implementation. Interviews were conducted face-to-face at the institution or on the phone, depending on interviewer's travel budget and availability of staff to meet.

Participants

Interviews and site visits took place at five hospitals in the United States. Interviews consisted of open-ended questions with hospital staff from the Labor and Delivery units that explored utilization of nitrous oxide as a method of pain relief in labor and in the postpartum period, barriers and facilitators to implementation of nitrous oxide, rate of patient use and satisfaction with use, quality measures, and process of staff training. Site visits also included the opportunity to observe nitrous oxide delivery equipment within labor rooms on various Labor and Delivery units. Anticipated challenges or barriers to accessing data from hospital sites prior to starting the project included limited time to spend at each site and limitations in the staff schedules to accommodate appropriate interview time.

Clinical sites that were visited represented several of the prominent hospitals in the U.S. now offering nitrous oxide. There are relatively few hospitals offering nitrous oxide to laboring women compared to other developed countries such as the United Kingdom, Australia, Finland,

and Canada. Hospital sites that the author visited included a combination of institutions that have either been offering nitrous oxide to parturient women for several decades, or have newly adopted on the Labor and Delivery units. This variety represents the continuum of successful implementation of nitrous oxide for use in labor and in the postpartum period. They are also representative of a variety of geographical locations in the United States. 1-3 providers and/or other hospital staff were interviewed from each site. Contacts were made through use of existing connections at each clinical site in addition to contacting staff through online directories at each clinical site.

III. Implementation and/or Outcome Evaluation

At each hospital site, select staff including an OB provider (physician or nurse-midwife), anesthesiologist, and nurse manager were contacted and introduced to the topic of this project. Participation in the project was entirely voluntary, and participants' identities as well as the institution with which they are affiliated remain anonymous. Interviews were recorded using a digital recording device, and stored on the author's personal computer for the duration of the project until the results were compiled and analyzed. No identifiers were attached to the digital recordings to protect participants' privacy. Participants were informally consented to participate in the study with the attached document introducing and outlining the purpose and scope of the project. The following description of the project was sent to prospective participants:

* * *

Description of Doctor of Nursing Practice Project:

This project aims to explore the barriers and facilitators to implementation of nitrous oxide for analgesia in in labor. Five hospitals in the US have been selected for

participation in the study, which represent the continuum of hospitals offering nitrous oxide for labor analgesia: from those who have offered it for several decades to those who are currently in the stages of implementation. Information will be gathered from interviews with OB providers, nurses, and hospital administrators, and compiled anonymously to understand better how an institution implements this option of pain relief in labor. Data will be summarized in a document that outlines findings, and serves as a resource for other institutions wanting to implement nitrous for use as labor analgesia.

* * *

Interview transcripts including participant responses to standardized questions and any expounded responses unique to a particular clinical site were gathered and are summarized in the findings section of the final paper. Interview findings could inform the creation of a staff-training document in addition to a patient education document for dissemination to patients during prenatal visits or upon admission to the hospital prior to delivery. In addition to the information gathering from select medical centers offering nitrous oxide to parturient women this next year, the author participated in a committee to introduce nitrous oxide analgesia to OHSU as well. Speaking to institutions who have either recently implemented its use or are in the process of offering it soon informed the work of the committee to move the effort forward at OHSU and ultimately expand the options for low-interventive, pain-relieving options to women in labor.

IV. Implementation of Project

OHSU Institutional Review Board approval was granted prior to initiating contact with any potential study participants. As initially planned in the proposal, interviews were conducted at 5 hospitals across the United States that currently offer nitrous oxide to their patients in labor,

or are in the process of implementing a nitrous oxide program. The researcher made site visits to 4 of the 5 hospitals, and conducted the remaining interviews by phone due to scheduling and travel constraints. There were nine interviews in total, ranging from 25-60 minutes in length. The 5 hospitals represented a mix of community and tertiary-level academic hospitals that were all in urban settings. Study participants included one or more anesthesiologists, nurse managers, nurse educators, and nurse-midwives. A minimum of one and maximum of three staff members were interviewed at each site, depending on the number of people involved with the implementation process and availability of staff to participate in the project. Interviews consisted of seven pre-set, open-ended questions, with opportunities for the interviewees to respond to the questions with as little or as much detail as they wanted to share. Interviews were recorded, transcribed, and then analyzed for common themes regarding the use of nitrous oxide in labor; also analyzed and the barriers and facilitators to implementation of nitrous oxide for use on a Labor and Delivery unit.

V. Project Findings/Outcomes

There were two overarching themes that emerged from interviewing participants: efficacy of nitrous oxide as a method of analgesia in labor, and systems-level issues related to the implementation of nitrous oxide. Individuals described the ways in which nitrous oxide is an effective method of labor analgesia for women that deserves a place on Labor & Delivery Units in the United States. They also spoke about a variety of systems-level issues that either facilitated the implementation process or served as a barrier.

Nitrous Oxide as an Effective Method of Labor Analgesia

Under the theme of nitrous oxide as an effective method of labor analgesia, several sub-themes were identified. These included options, control, dissociation/anxiolysis, safety, and other uses. Summaries of these sub-themes and examples are provided:

Options: Rather than describing nitrous oxide as a replacement to existing options for pain management in labor, participants described nitrous oxide as simply another option of pain management that meets a currently unmet need or "fills gaps left by other choices." Participants saw particular benefit for: 1) individuals who "don't want epidural analgesia but want some pharmacological relief"; 2) for those who want some analgesia in the early stages of labor prior to getting an epidural; or 3) for those who cannot receive the standard options for pain relief—i.e., epidural analgesia or IV opioids—due to a physical condition that prevents it such as scoliosis, or a history of opioid addiction that might reduce the effectiveness or safety of that modality. One individual likened pain relief in labor to a menu: "What is good for one woman is maybe not the thing for the next one. But it should be available whenever is safe." Another participant—an anesthesiologist—concluded her interview with this statement: "I have full respect for people that 'It's your choice.' There are no gold medals either way. And you do your plan based on what is best for you [the patient]. And nitrous can be just another option to manage your pain that is non-invasive and that can give you some pain relief."

Control: The sense of control that a woman maintains with the self-administration of nitrous oxide was another common sub-theme that emerged. The majority of participants explained that unlike other modalities of pain management, laboring women can use nitrous when they feel they need it. They don't *have* to use it. Comparing nitrous oxide to another modality of pain management in labor such as IV opioids, one nurse educator explained a key difference: "With [stadol] you feel out of it even when you are not having a contraction. You don't control it

yourself. So for patients who choose nitrous, I think that is a benefit. They are self-administering it. There is some patient satisfaction with that: the fact that while you have a mask on it is giving you that effect, but when you take it off, you feel like a normal person again as opposed to the loopy-ness you might feel with IV narcotics." A nurse-midwife states, "It's self-administered and I think that for women—and patients in general—that self-administration makes people feel more in control, which automatically makes them feel a little safer and a little more confident about their pain relief." The majority of participants perceived sense of control and self-administration as a significant reason for high patient satisfaction with this pain modality.

Dissociation/Anxiolysis: Participants remarked on nitrous' unique ability to distract women from pain associated with labor and childbirth and/or alter her perception of pain. Unlike epidural analgesia, which is designed to significantly reduce pain associated with labor, nitrous oxide has some mild pain-relieving qualities, but for the most part, as one nurse manager said, "It just makes you not care as much. [The pain] might still be the same, but patients don't care as much. They are handling it." Another nurse manager at the same institution expanded on the relaxation aspect of nitrous oxide: "It does have a little bit of pain-[relieving] properties in it, but it takes their minds off of focusing solely on the pain. They are focusing on something a little bit different. There's a little relaxation added in there, too." This from an anesthesiologist: "The studies show that a majority of [laboring women] are not going to change pain scores. But when you ask them if this is effective and this is manageable, it *is* because there is that dissociative and anxiolytic property of nitrous that tends to kind of calm you down. You know you are in pain, but you just don't care as much." One of the nurse participants who used nitrous oxide in her own labor said, "I did end up getting an epidural. It wasn't like the nitrous took the pain away, but it took [me] away from the pain."

Safety: There was overwhelming consensus among participants that nitrous oxide for use in labor and in the postpartum period is considered safe. One main reason cited was that it is cleared very quickly by the lungs so it doesn't build up in the mom or the baby. "It is so safe…it's a gas that you breathe off basically as soon as you are done breathing it." One participant, discussing the transition from provider initiated set-up and consent of nitrous oxide in labor to a nurse-led process, stated that the transition was very easy "because it is so safe…it's a gas that you breathe off basically as soon as you are done breathing it in. Even when Anesthesia was setting it up, it was still managed by Nursing. So Anesthesia turned the machine on, but a nurse was the one at the bedside—not the anesthesiologist. So, really, it makes more sense for the bedside nurse who is watching the patient *use* the machine actually know the proper settings and the proper way to use that since [the nurses] are the ones present. But if you look at other countries, like homebirths in the U.K., midwives there have 50/50 nitrous oxide tanks in their car, and they use it in the home setting because it is so safe."

Other uses: Several participants noted that in addition to its analgesic use during all three stages of labor, there are additional uses for nitrous while a woman is laboring. These other uses are particularly beneficial in some cases, and fill some of the gaps in pharmacological pain management that other methods leave out. One nurse-midwife stated, "It's kind of multi-purpose. We have seen it used for IV starts. We use it through the epidural placement, for manual removal of the placenta…We've even done some bedside procedures under conscious sedation." At another hospital, an anesthesiologist said they "supply nitrous not just for labor, but for external cephalic versions, for postpartum laceration repair, [and] for bedside sweeps."

Systems Issues Related to Implementation of Nitrous Oxide

Under the theme of systems issues related to implementation of nitrous oxide, several sub-themes were identified as well. These sub-themes champions, stakeholders, ownership, billing, education, and quality improvement. Summaries of these sub-themes and examples are provided:

Champions: All five hospitals required a champion (or two) to facilitate the implementation of nitrous oxide on their Labor and Delivery units. The champion saw the process through from its inception to its rollout on the unit, often having to address and overcome barriers along the way. When describing what is required of this champion, one nurse-midwife described him/her as "Someone whose passion it is, because you are going to hit roadblocks and you need to not give up….You have to have someone with that kind of personality who won't take no for an answer." Another, this time a nurse, described the champion as being "someone like me who is driven with the breadth to really develop it and facilitate it…I have taken it through the whole process – the convoluted process here at [X] Hospital. I think that's the one thing that has been instrumental in seeing it to completion, although it's taken us 2 years." When remarking on the work of the nitrous champions at her hospital, another participant said, "They wouldn't take no for an answer, to be honest with you. They had the research. We are an evidence-based facility, but you know how that is. It is easy to say that, but a lot of times we go back to our old habits or our old ways, or our old fears. And so they just kept presenting it, and pushing it until it was done." At another hospital, the head of OB Anesthesia approached one of the nurse-midwives and asked if they were willing to work on getting "nitrous up and going." The nurse-midwife paired with another anesthesiologist and together saw the implementation efforts to completion. They faced fewer barriers there than other institutions because "everyone was on board and open-minded to get things up and going. It was pretty easy."

Stakeholders: Participants noted the importance of identifying all of the stakeholders early on in the implementation process, and getting buy-in from them prior to moving the process forward. Stakeholders include many departments: Anesthesia, Obstetrics, Maternal-Fetal Medicine, Family Medicine, Pediatrics, Neonatology, Midwifery, Nursing, Facilities, and Risk Management. Getting buy-in from stakeholders was achieved differently among the five institutions. At one hospital, the champions "presented a proposal to each team/department for approval of nitrous oxide" and addressed concerns as they arose. The proposal consisted of a survey "asking people before [they] implemented what their interest, support, and concerns were for doing this…It went out to everybody who would be involved, and 98% of the people who responded were very supportive with it." At another hospital, the champion "personally took the policy to all [members] of the committee that needed to approve it." And at yet another hospital, the champions asked "the leadership" to come together in person for a meeting to discuss the implementation process: "Everybody had to be at the table and decide on it from the beginning…Just sort of making sure everybody was on board." The amount of resistance raised by the stakeholders during this process varied by institution, but there was consensus among the nine participants being interviewed that once concerns were addressed from stakeholders early on in the implementation process, barriers to change were reduced. This interviewee summarized the benefit from showing respect to all stakeholders very well: "I recommend talking to everybody first. Get your key people from Nursing Management, Nursing, Risk Management, Pediatrics, Maternal-Fetal Medicine, Obstetrics, Midwifery. [Get] all of those people in one room and talk about what their concerns are. Because if you can address their concerns, people are [ultimately] going to be fine with it." Anesthesia was notably not mentioned in this person's

comment, but it was also one of the institutions where Anesthesia was co-leading the implementation process, and ultimately came to own nitrous oxide once it was implemented. Anesthesia was identified by several participants as the key stakeholder and the one most frequently expressing the most resistance. One nurse manager said, "The Chief of Anesthesia at the time did tell me that some of his colleagues at the time had said 'Don't do it.' They just weren't sure how it was going to impact them. They saw no benefit to themselves. I don't mean that in an overly negative way, but everybody looks at things as how is this going to impact *me*, and they didn't see [the change] as positive." At another hospital, another nurse manager said, "…Our anesthesiologist decided [the department] did not want to be a part of it." At yet another institution, this from a nurse-midwife: "Going back to the implementation process, the biggest hurdle was getting Anesthesia to listen because it was a midwifery-led effort. That was probably the first hurdle – getting someone from Anesthesia to buy in to it."

Ownership: The theme of ownership came up in most interviews. The stakeholder that took ownership of nitrous oxide at each hospital was not necessarily the champion, and this was due to several reasons, including billing and concerns for the safety and liability with other providers or nurses' consenting patients for its use. At several institutions, Anesthesia owns nitrous oxide on Labor and Delivery. The Anesthesia Department "implements it, sets it up, and educates the patient…it's an Anesthesia-initiated service." This scenario is well accepted at some hospitals, but at others, they have pushed for OB providers and/or nurses to oversee its use for increasing patient access since Anesthesia is often off the floor or tied up in the OR. At one hospital, the nitrous champion, a nurse-midwife, pushed for bedside providers—i.e., obstetricians, nurse-midwives, etc.—to be able to initiate nitrous, or even "bedside nurses," but received pushback. Speaking to this: "That was quite a leap to go from three places using it in the country to 'Let's

let the bedside nurses start it.' That was too big a leap for people here, so my suggestion was to let Anesthesia, OBs, and midwives initiate it, and then a year down the road when we see that it is very easy and the nurses are familiar with it, then we move toward the nurses' initiating. (Incidentally, Anesthesia currently "owns" nitrous at this hospital.) At another hospital, nitrous recently transitioned from sole Anesthesia ownership, to nurse-midwife ownership, to now a nurse-led process. There was more ambivalence from Anesthesia about ownership there, which may have actually led, in this case, to an easier transition: "At this institution, nobody wanted to own it. Pharmacy didn't want to own it because it's a gas, RT didn't want to own it because it is being used as pain management…so [nurses] sort of moved forward with it. We asked permission from everybody and nobody said it was a problem. So we just trained all nurses on the proper use…We went from anesthesiologists to midwives to eventually nurses setting it up." At two other hospitals, however, the champions (both nurse managers) initially asked the Anesthesia Department to take ownership of nitrous, and were disappointed when it declined. They are getting ready to start the rollout of nitrous programs in a few months, and nurses will be overseeing its use and consenting/educating patients. At one of those hospitals: "Part of the agreement with anesthesia [approving nitrous implementation] was that they are basically washing their hands of the whole thing….I don't mean that if the patient had a problem they wouldn't respond, but they can't bill for the service so they are not going to set it up. That is one thing [name of co-champion] and I felt very disappointed about." At the other hospital, "Anesthesia decided they did not want to be a part of it…an 11th hours denial of any part of their involvement was a little bit disconcerting, given that the policy explicitly stated that Anesthesia will provide informed consent…They absolutely did not want to be involved in that way. Especially when they found out there was no charge for it, quite frankly speaking."

Billing: Billing was discussed numerous times as participants described both specific barriers and facilitators to implementation of nitrous oxide as analgesia for labor. Currently, no specific CPT code exists for nitrous oxide use in labor. As a result, obstetrical providers who order nitrous oxide for labor analgesia cannot bill patients for the cost of gas and set-up, and many hospitals end up "eating" the cost of gas and equipment. Speaking to this issue, a participant said, "Another potential issue [for implementation] was the lack of being a billable service. At least as far as I have been able to ascertain." Some hospitals justify its use on Labor and Delivery despite the inability to recoup cost because "it's very handy and useful and fills those niches like someone without anesthesia in need of a repair." Nitrous indirectly pays for itself when its availability specifically attracts pregnant women, when "one patient comes [to their hospital] because of nitrous and not something else." One participant mentioned hearing of several hospitals' deciding *against* implementing nitrous because the unit owning the service cannot bill for it. Some hospitals are working around the CPT code issue by Anesthesia's billing for nitrous under a more broad "labor analgesia for vaginal delivery" code. As one of the nurse-midwives states, "The only way to bill for it in a hospital institution is through Anesthesia. When Anesthesia bills, they bill the same that they bill for an epidural...For us, we had to find a way to make the money back to pay for the machines. And so we decided to roll it out through Anesthesia." Another nurse-midwife said, "Anesthesia sets it up at our place and they bill for it. We are working on developing a CPT code, so then everyone will have to use [it]. Then we can't all be creative about how [we are billing] which will be good! It will be better for women, because in a lot of places this is a barrier starting [to offer nitrous oxide] because they say, 'Oh well we can't bill for it.'" There were varying opinions about cost-effectiveness depending on the billing practices at each hospital. At the hospital that charges the same amount for nitrous as

epidurals, the interviewee said, "You would think it would be [cost-effective] but it's not. The reason why is because the only way to bill for it in a hospital institution is through anesthesia. So when anesthesia bills, they bill the same that they bill for an epidural. Now, there are institutions that are eating the cost like [names other hospital offering nitrous oxide]. They do, but for us, we had to find a way to make the money back to pay for the machines. And so we decided to role it out through anesthesia." At a hospital where they are not billing for nitrous use, the interviewee said, "I think that, relative to expenses in the hospitals, [nitrous] is not expensive and that your payback is patient satisfaction. It is useful for the things that nothing else is useful for—goodwill and advertising, at least for a while."

Education: Clear and effective education was another common facilitating theme discussed during all stages of implementation: inception, rollout, and training necessary for new staff and residents orienting to the unit. Since nitrous oxide for labor analgesia is less familiar to most OB providers and nurses than the standard analgesic agents such as epidural and opioids, participants remarked on the importance of providing accurate, evidence-based information to staff prior to going forward with the implementation process. One anesthesiologist at a hospital that has implemented the use of nitrous oxide said, "[The co-champion] and I gave grand rounds to the Anesthesiology department, Obstetrics department, Pediatrics, NICU, Family Medicine. Everybody got a full grand rounds presentation on this where we pretty extensively addressed the data with Apgar scores and cord gases and NICU admission and hemodynamics of mom regarding nitrous administration in labor, so people had a fair share of information about that." This same doctor also spoke of the importance of setting clear expectations about its use to staff as well as patients. In other words, bedside nurses needed to understand that nitrous oxide for use in labor is mild analgesic at best, and is really used for its dissociative and anxioloytic properties:

"One of the big things that I have seen [in the effective rollout of nitrous oxide] that has been helpful has been nursing education. [For nurses] to let patients know what the real expectations are ….Our patients needed to understand that this wasn't an option for complete pain relief. But this was an option for *some* pain relief.

Educating staff on the use of nitrous oxide for labor analgesia varied by institution. At some hospitals, nurses were given an in-service training by one of the equipment representatives and at others they were required to complete a PowerPoint training module with a quiz at the end. Many hospitals elected super users to help train other staff and troubleshoot when problems with the equipment arose. One of the challenges with educating staff has been the consistent turn-over of obstetrical and anesthesiology residents. Most new residents coming on the unit have not worked with nitrous before for labor and analgesia, and participants remarked that some will either assume that patients need more monitoring and restrictions on their movement, or they will share their opinion about nitrous' efficacy – sometimes with a negative slant – to the patient when they are reviewing options for pain management upon admission to the hospital, which can dissuade the patient from opting to use it.

Quality Improvement: When asking participants what (if any) data they were collecting for quality improvement purposes, there were a variety of responses. Many remarked that there were plans to collect data regarding patient satisfaction and neonatal outcomes in the future, but were not looking at very much beyond utilization rates and effect on pain scores currently. A nurse-midwife working at an institution that has been offering nitrous for several decades remarked, "We have not [collected data]. It's funny. I think this is a product of taking it for granted. No one thinks of it particularly, but the nurses do their same kind of pain scale questions that they are obligated to do." There was one hospital that implemented nitrous oxide within the last year that

is currently querying more than utilization rates and satisfaction scores described above. They are currently looking at "quantitative satisfaction, percentage of use, all of the side effects including dizziness, nausea, emesis, treatment for any of those, discontinuation because of any side effects or just continuation to another modality." Evaluation of these data will inform the leaders of the nitrous program and identify whether this is, in fact, a safe and effective tool for labor analgesia at their hospital, and a service to be continued.

VI. Practice-Related Implications/Recommendations:

Among this project's goals was to identify barriers and facilitators to implementation of nitrous oxide for labor analgesia with the aim of informing and streamlining the process for hospitals wanting to expand pain management options in labor. Through in-person and over-the-phone interviews with nine clinical staff from five hospitals across the country, the author gained insight into the complex, and often understandably personal and political, aspects of implementing this emerging (or, in some cases, re-emerging) form of labor analgesia in the United States.

When asked about specific barriers to implementation, not surprisingly, the participants' responses tended to be more site-specific than universal. For example, resistance from a key stakeholder was frequent, although which stakeholder might vary from institution to institution. At several hospitals the Anesthesia Department expressed resistance to the idea of implementing another modality of pain management; at others, it was the Anesthesia Department that actually championed the effort to bring it to their hospital. At one of the hospitals that implemented

nitrous oxide nearly four years ago, one of the most significant barriers they faced was in acquiring the equipment to deliver gas to women in labor. For hospitals going through the process more recently, this was less of an issue.

The barriers that were more commonly shared were related to all-too-common delays and setbacks in any organizational change effort (Kotter, 1996); some staff reluctance despite recent growth in popularity and consumer demand for more pain-relieving options in labor; and reimbursement and billing issues. The barriers to initiating an effort to change or expand pain-relieving options for women, it turns out, were not all that unique to Labor and Delivery Units. In Kotter's (1996) book, *Leading Change,* he describes some of the challenges and setbacks when organizations attempt to change. He writes, " To some degree, the downside of change is inevitable. Whenever communities are forced to adjust to shifting conditions, pain is ever present" (p.4). Eisold (2010), a psychoanalyst and organizational consultant, writes, "Whether the company is a Fortune 100 colossus or a modest not-for-profit, a family business or a professional organization, the problem is that people fear change, resist it, fight it and often end up sabotaging what they might even consciously agree are a good means to move things forward."

Factors that facilitated the process of implementation were more commonly shared among the five hospitals studied. They included the presence of a champion; offering, early in the implementation process, comprehensive education to staff and stakeholders less familiar with nitrous oxide use in labor; attaining buy-in from stakeholders; and having a department willing to take ownership of nitrous and oversee its use by patients. In *Leading Change,* Kotter (1996) discusses the elements necessary in leading a successful change movement within an organization in his book. Many of these elements are similar to the facilitators participants

identified in the effort to implement nitrous oxide on their Labor and Delivery Units. They include the presence of a strong leader who has the support of a "guiding coalition" to and momentum to the change effort, educating other staff about the issue and engendering a sense of urgency to motivate others to support the effort, and "communicating the change vision" effectively to everyone involved. Evidence supporting the safety of the fixed 50/50 concentration of nitrous that is self-administered; and the fact that the use of nitrous oxide possesses some unique qualities such as self-administration and anxiolysis that make it a desirable choice, were key in the persuasion of disparate disciplines involved in the care of laboring women. Many of the sub-themes related to efficacy that emerged from the interviews reinforced and reiterated findings in the nitrous oxide literature from Rosen (2002), Collins et al. (2012), and Likis (2014).

It was surprising how little data about efficacy and outcomes are currently being collected for quality assessment and quality improvement purposes. Several institutions mentioned plans to collect more data in a yet-to-be IRB-approved study, but it was still concerning to find that little data collection research was being done to reinforce the at-times good, but largely fair (and sometimes poor) quality of much of the research on nitrous oxide use in labor. The introduction of a new pain-relieving modality seems like a critical opportunity for documenting practice improvement at most of the institutions that were interviewed.

It seems clear from these interviews and from the literature that women are asking for more pharmacological options for pain management, and nitrous oxide seems to be filling that gap. Nitrous oxide is not specifically intended to replace existing methods of analgesia such as epidural or IV opioids, but rather, to add another option for women who desire some pharmacological pain relief but not complete obliteration of pain. Or, even for those who desire stronger agents but do not have time to receive them because they are progressing too quickly in

labor, or Anesthesia is unavailable to place the epidural. Each institution required a champion who believed in this as an option for women, and was willing to "roll with" resistance and be persistent and maintain their vision throughout the implementation process. Many participants who were also champions in their hospital's implementation process expressed gratitude for the guidance they had received from champions at other hospitals that had already gone through the process. For others, however, who blazed the trail at their hospital more independently, they said wished they could have had a checklist or guide on how to implement nitrous oxide on their Labor and Delivery unit. Even when everyone at their hospital was on board and few barriers remained, the steps going forward in terms of actual implementation weren't necessarily straightforward or easy. Some of these challenges included what equipment to purchase and how to install it in a room that was not designed to have nitrous oxide, figuring out which care provider would consent patients for nitrous, and writing new protocols for its use on Labor and Delivery.

This project was constrained by both time and money. Ideally, the author would have interviewed a broader range of clinicians including an obstetrician and another anesthesiologist at more institutions to provide a richer base from which to draw findings/themes. The Doctor of Nursing Practice program allows students only one year in which to complete the project, and given the common delay in IRB approval, there was even less time to collect data than anticipated. The author did not receive outside funding for this project, and limitations on funds dictated the amount of travel the author could take as well.

VII. Summary: The author hopes that those who are looking to implement nitrous oxide for labor analgesia at their institution will be informed by the findings of this paper. While each

institution has its own culture and politics, many of the themes about implementation raised in this paper are in fact shared, or at least instructive. Being able to anticipate some of the barriers and facilitators that other institutions faced in their implementation process may prevent similar setbacks—and in turn, accelerate the process. Women are increasingly asking for more options for pharmacological pain management in labor, and specifically for nitrous oxide. Implementation of nitrous oxide on Labor and Delivery units in this country can provide laboring women who seek analgesia as a safe, effective, and low-interventionist option. As one of the participants said, " I think it is so nice that we have [nitrous] because everybody's birth plan and expectations are going to be different. Why not give women the option—you don't have to do anything, or you can step your way up to what you want to do."

Table 1: Interview Questions:

1)	Where is your institution in the process of implementation of nitrous oxide for use in labor?
2)	What are some of the benefits you have seen with utilization of nitrous oxide use in labor?
3)	What (if any) barriers existed to the implementation of nitrous oxide in your hospital's Labor and Delivery Department? Are there barriers that remain?
4)	What facilitated the implementation of nitrous oxide for labor analgesia at your institution?
5)	What data (if any) do you collect for quality assessment purposes (i.e., utilization rates, patient satisfaction)?
6)	How successful has nitrous been at: a) Offering effective analgesia to patients in labor, patient satisfaction? b) Ease of set up and patient teaching for staff, ease of documentation, satisfaction with who is in charge? c) Being a cost-effective method of labor analgesia?
7)	Do you have policies and procedure for set-up, billing, and documentation of use (i,e, dose, who administers, how long utilized, etc.)

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