

# OXYTOCIN SAFETY

#### LEGAL IMPLICATIONS FOR PERINATAL NURSES

A culture of safety regarding the administration of oxytocin can decrease the risk of patient harm, adverse birth outcomes and potential litigation. Patient injury from drug therapy is the single most common type of adverse event that occurs in the inpatient setting, resulting in cost increases to the patient, health care providers and institutions (Simpson & Knox, 2009). Safeguards around the administration of oxytocin should be a priority for policy and administration guidelines for physicians and nursing professionals at facilities that use it. Although oxytocin is used frequently in hospitals around the world, it is important to recognize and appreciate the dangers inherent in the use of oxytocin as it is associated with preventable adverse birth outcomes and litigation.

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## CASE STUDY

The following is a case study of a true scenario that resulted in an adverse fetal outcome, which took place in a hospital outside of North Carolina. When reading this case, it might be easy to think, "This would never happen to me" or "I would never do that," when identifying errors in practice. But a word of caution: No one who has found themselves in a deposition or courtroom ever thought they would be there. This case was shared by an obstetrical nurse consultant who granted permission for its use in this article with anonymity. There has been no alteration to the documentation by nurses and physicians or to the outcome results. The name of the patient along with her Gravida/Para were changed to maintain anonymity. Box 1 lists instances in this case where adverse outcomes could have been prevented.

"Brenda" is a G2P1 at 38.5 weeks gestation whose previous delivery was an uncomplicated vaginal delivery. Brenda presented to her routine prenatal office visit at 1:00 p.m. with a complaint of decreased fetal movement over the last 8 hours. A nonstress test in the office demonstrated a baseline fetal heart rate of 135, no decelerations, no 15x15 accelerations in 30 minutes and moderate variability. The physician sent Brenda to the hospital for further monitoring and ultrasound biophysical profile (BPP) and amniotic fluid indexing

#### Bottom Line

• Nurses who administer oxytocin while caring for laboring women need to be well informed of safety issues.

- With regard to legal implications, clear and complete documentation of care is crucial.
- An organizational culture of safety regarding the administration of oxytocin can decrease the risk of patient harm, adverse birth outcomes and potential litigation.

(AFI). Continued monitoring showed a baseline fetal heart rate of 135, absence of accelerations and decelerations, and moderate variability. AFI was documented at 6.2 and BPP 6/8, with no score for fetal movement. Cervical examination was 2 cm/80%/-3 station. The decision was made to induce labor with oxytocin.

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**3:00 p.m.**—After all admission procedures were complete, the nurse started the oxytocin at 6 mU/min per physician orders. Oxytocin order written by physician reads "start oxytocin and increase until good labor pattern established." After 30 minutes of oxytocin administration, fetal monitoring demonstrated no change in fetal heart rate tracings since oxytocin started, occasional 40 second contractions documented as mild.

**3:20 p.m.**—Fetal heart rate 145, 15x15 accelerations present with moderate variability. Contractions every 1.5 minutes lasting 60 to 100 seconds, toco baseline at 50. Oxytocin increased to 12 mU/min.

3:32 p.m.—MD in room, AROM, clear fluid.

**3:55 p.m.**—FHR 140, reactive, contractions every 2 minutes, lasting 100 seconds, adjusted toco baseline. Oxytocin increased to 18 mU/min.

**4:20 p.m.**—FHR 140, minimal to moderate variability, "unable to determine contraction pattern" is documented by nurse. Oxytocin increased to 24 mU/min. Toco adjusted.

**4:38 p.m.**—FHR 145, minimal variability, RN documents "unable to determine contractions," oxytocin increased to 30 mU/min.

**4:40 p.m.**—FHR 135, minimal variability, no accelerations, contractions documented as every 1.5 minutes lasting 100 seconds.

**5:00 p.m.**—FHR 140, minimal to moderate variability, contractions every 1 to 1.5 minutes. Lasting 40 to 80 seconds.

**5:30 p.m.**—FHR 145, no accelerations, contractions every 1 to 1.5 minutes, lasting 50 to 80 seconds. Oxytocin increased to 32 mU/min.

**6:00 p.m.**—Patient requests pain medicine. SVE 5/90/-1. MD notified of patient request for pain medication, vaginal exam. Verbal order taken by nurse from MD states order for pain medicine and to continue to increase oxytocin.

**6:10 p.m.**—FHR 150, minimal variability, variables, oxytocin increased to 34 mU/min, contraction frequency documented. Demerol 75 mg with Phenergan 12.5 mg IM given.

**6:34 p.m.**—FHR 155, minimal variability, variables, contractions every 1 to 1.5 minutes. Oxytocin increased to 40 mU/min.

**6:49 p.m.**—FHR 155, minimal variability, variables, no documentation of contraction pattern documented at this entry. Oxytocin increased to 42 mU/min.

7:10 p.m.—SVE 7 cm documented.

7:20 p.m.—FHR 155, minimal variability, variables

documented as late. IV bolus, oxygen and position change to left lateral documented.

7:30 p.m.—MD called to review tracing.

**7:35 p.m.**—MD in room, SVE 8 cm, IFSE applied. FHR 160, minimal to absent variability, variables documented as late, contractions every 1 to 1.5 minutes, lasting 60 to 80 seconds. Order from MD to continue oxytocin at current rate.

**7:45 p.m.**—MD remains at bedside. FHR 170, minimal to absent variability, no decelerations noted. SVE 9 cm by MD and attempted to push past cervix. FHR then drops to 90s. Stat c-section is called, oxytocin is turned off.

7:50 p.m.—Patient to operating room.

**8:10 p.m.**—Delivery of infant with Apgar scores of 0, 0, 5, cord Ph 6.89 with mixed acidosis. Neonate admitted to NICU with seizure activity in first hour of life.

**Outcome**—This child has severe long-term neurologic deficits.

# ABOUT OXYTOCIN

Oxytocin is a synthetic octapeptide used as a potent utero-tonic agent in obstetric practice to stimulate contractions in the smooth muscle of the uterus. It's administered to mimic the responses of endogenous oxytocin, which is produced by the hypothalamus and secreted from the

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posterior pituitary. Administration of oxytocin is used for the purpose of inducing labor, augmenting ineffective labor and to induce contractions after birth to reduce uterine bleeding. The most common reversible complication of oxytocin administration is uterine tachysystole (Moleti, 2009). Tachysystole is defined as more than five uterine contractions occurring within any 10-minute time period. This results in an absence of uterine rest between contractions, thereby causing decreased oxygen levels to the fetus. Tachysystole is an undesirable side effect of the use of oxytocin and when left unaddressed can create conditions that may lead to poor birth outcomes such as non-reassuring fetal heart rate tracings, fetal distress and fetal hypoxia (Jonsson, Norden-Lindeberg, Ostlund, & Hansson, 2008).

In 2007, oxytocin was added to the Institute for Safe Medication Practices (ISMP) high alert list of medications that have

#### BOX 1

#### INSTANCES IN CASE WHERE ADVERSE OUTCOMES COULD HAVE BEEN PREVENTED

- **1**. *Incomplete description and documentation of contraction pattern despite evidence of tachysystole.* There were examples in the documentation where there was no documentation of frequency of contractions.
- 2. Failure to properly administer oxytocin.

The nurse failed to decrease or discontinue the oxytocin infusion when tachysystole and/or evidence of fetal intolerance of labor was present. Despite documenting loss of variability, changing fetal heart rate baseline and contraction frequency qualifying as tachysystole, the oxytocin was continually increased and documentations of interventions to address the non-reassuring fetal heart rate tracing was noted only once during the case review by attorneys.

3. Communication failure between nurse and obstetric provider.

There was a failure to communicate changes in fetal heart rate pattern. There was no documentation that the nurse's report to the physician included communication of an increasingly non-reassuring state. Writing an order to increase oxytocin until a "labor pattern is adequate" is not an effective way to communicate the desired response to oxytocin administration. To prevent this in the future, the use of an SBAR report facilitates communication between a nurse and physician or midwife.

4. Failure to document intrauterine resuscitation interventions, such as IV bolus and repositioning, and failure to communicate to physician the nature of fetal heart rate tracing.Although the nurse stated in deposition that she did perform interventions, the failure to document them sealed the fate of the verdict in favor of the plaintiff.



Due to the significant risk in the administration of oxytocin, perinatal nurses as well as physicians and midwives can benefit from understanding the legal ramifications associated with oxytocin management

a heightened risk of harm that may require special safeguards to reduce risk of error (Clark, Simpson, Knox, & Garite, 2009). There are only 11 medications on this list. Failure to follow established policy and procedures and manufacturer recommendations regarding the administration of this medication has been the basis of much litigation in the United States and around the world (Greenwald & Mondor, 2003).

#### LABOR INDUCTION

Rates of elective labor induction have risen from 9.5 percent in 1990 to 22 percent in 2005 (Moleti, 2009). The resulting effect is that oxytocin continues to be a frequently used induction agent despite its potential for harm. All labor inductions have the potential for minor and life-threatening complications for both mother and fetus, including an increased risk of surgical cesarean delivery, hemorrhage, infection, uterine rupture and neonatal respiratory distress due to transient tachypnea of the newborn and iatrogenic prematurity (Simpson & Thorman, 2005).

The Institute for Healthcare Improvement (IHI) initiated a no elective induction before 39 weeks gestation initiative, which

is having an impact on elective delivery numbers and ultimately the use of oxytocin. The IHI developed the concept of "bundles" to help nurses, physicians, midwives and other health care providers in a multitude of specialties more reliably deliver the best possible care for patients undergoing particular treatments with inherent risks. The bundles provide a structured way of improving the processes of care and patient outcomes through evidence-based practices (IHI, 2010). The IHI bundles represent a group of best practices that show documented and proven success in improving patient outcomes while supporting a culture of patient safety in the obstetrical arena.

#### SAFETY CONCERNS

Due to the significant risk in the administration of oxytocin, perinatal nurses as well as physicians and midwives can benefit from understanding the legal ramifications associated with oxytocin management. Recent studies show that oxytocin use is often associated with uterine tachysystole and neonatal morbidity. In a study by Simpson and James (2008), tachysystole was found to be associated with negative effects on fetal oxygenation status with concomitant increase in negative effects with more significant tachysystole findings. In studies comparing variations in dosing protocols (low, high, pulsatile), research showed no difference in the percentage of successful labor induction (Arias, 2000). Some researchers suggest that the use of protocols and dosing regimens provide the lowest total dose of oxytocin with a resulting decrease in side effects and adverse outcomes (Moleti, 2009).

In 2008, Jonsson et al. studied the association between oxytocin administration, uterine tachysystole and fetal acidemia.

### IMPLICATIONS FOR NURSES

It's important that obstetric nurses understand not only their scope of practice and responsibilities but also the legal framework that surrounds litigation. As nurses, we can no longer claim that we were just "following orders." Documentation of nursing care should reflect a clear assessment and documentation of interventions related to that assessment. Failure to assess, intervene or communicate information effectively the way a reasonable and prudent clinician would do in the same circumstances is considered malpractice or professional neg-

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During a 10-year period, 28,486 deliveries were evaluated for acidemia at time of delivery. The chart review revealed that in cases where more than six contractions in a 10-minute period were recorded, 75 percent of the patients had oxytocin administered during the last 2 hours of labor despite non-reassuring fetal heart rate tracings. In 2009, the same researchers found that metabolic acidosis and related neonatal morbidity could potentially have been prevented in 40 percent to 50 percent of cases reviewed and is often associated with suboptimal intrapartum care. Suboptimal care was described in the study as continued oxytocin administration despite non-reassuring fetal heart rate tracings. The rate of suboptimal care found in this study with regard to oxytocin use and fetal surveillance illustrates a gap between safe practice guidelines and actual clinical practice (Jonsson, Norden-Lindeberg, Ostlund, & Hansson, 2009). ligence. Clinicians are held to national standards of care and practice within "same or similar circumstances" and "reasonably expected" parameters (Tucker, Miller, & Miller, 2009). It's for these reasons that perinatal nurses practice within their scope of practice and within the expected standards of their professional organizations. Box 2 defines the components of a malpractice claim that are used as basis of litigation against medical professionals, and Box 3 lists areas of practice that are commonly identified in malpractice claims as contributing to an adverse birth outcome.

The goal of fetal heart rate monitoring is to prevent fetal injury that might result from disrupted fetal oxygenation during or before labor (Tucker, Miller, & Miller, 2009, p. 1). It's imperative that nurses utilize the valuable information given from the tracings to provide the best care possible in an attempt

OF A MALPRACTICE CLAIM
DEFINITION
Standard of care that is owed to a patient
Failure to meet standard of care set forth by professional organizations and governing bodies
Actual harm or injury that occurs to the woman, fetus or neonate as a result of breach of duty
Relationship between breach of duty and the harm or injury caused to the patient
Failure to act in the required manner, causing harm to an individual
An unintentional act performed by a person to an individual

#### BOX 3

#### COMMONLY CITED ERRORS IN PERINATAL CARE

- Inaccurate interpretation of fetal heart rate tracings
- Lack of appropriate and timely responses to non-reassuring fetal heart rate tracings
- Delay in decision to perform and initiate cesarean delivery (Note: While performing the cesarean is not a nursing action, failure to facilitate transport can delay the initiation of the delivery and contribute to adverse neonatal outcomes)
- Lack of appropriate neonatal resuscitation skills
- Failure to discontinue oxytocin or other induction agents in the presence of non-reassuring fetal heart rate tracings
- Failure to reduce administration rates of oxytocin or other induction agents in the presence of non-reassuring fetal heart rate tracings
- Application of fundal pressure even with physician or midwife order
- Lack of communication between nurses and physicians or midwives
- Incomplete and/or inaccurate documentation



to prevent adverse birth outcomes. The nurse in the case study failed to decrease or discontinue the oxytocin infusion despite evidence of tachysystole fetal intolerance of labor. Failure to follow established policy and procedures and manufacturer recommendations regarding the administration of oxytocin has been the basis of much negligence litigation in the United States and around the world. Legal victories citing negligence occur frequently and are usually the result of poor judgment on the part of both nurses and physicians/midwives through failure to implement the chain of command, human error and failure to act on non-reassuring fetal heart rate tracings. Greater than 50 percent of all legal settlements involved perinatal cases, with 40 percent to 50 percent of these cases related to management of oxytocin (Jonsson, Norden-Lindeberg, & Hanson, 2007).

Nurses must minimize the risk of patient harm by being well-educated regarding oxytocin risks as well as being proactive with interventions when there is evidence of tachysystole or fetal intolerance of labor. Key issues for perinatal nurses who want to avoid litigation include sound and current education in the interpretation of fetal heart rate tracings, adoption of welldesigned policies for the administration of oxytocin, ability and willingness to use the chain of command, comprehensive documentation and an awareness of the fact that making the patient's well-being the focus of every nursing action is the perinatal nurse's best defense (Greenwald & Mondor, 2003). The reasons there are high malpractice lawsuit payouts include evidence of permanent brain damage, costs of lifelong medical care and emotional suffering of the "loss" of the perfect child and the lost dreams that are associated with adverse birth outcomes. The image of a brain damaged child is a powerful courtroom tool that is used to sway juries into high dollar settlements.

## PREVENTING ADVERSE BIRTH OUTCOMES

Education for health care professionals of all disciplines including nurses, physicians and midwives, on the safe administration of oxytocin is invaluable. Orientation of new nurses along with competency-based annual education of all staff is a key element to ensuring patient safety. It's not enough to talk about oxytocin administration safety; an organizational culture of safety is necessary for proper support of safety measures. Perinatal nurses need to be confident in their ability to correctly interpret fetal monitor tracings as well as have an accurate and concise relay of information to convey fetal tracing interpretation with physicians or midwives. In conjunction with evidence-based policies and procedures, documentation is a key component of safe nursing care. It's not enough to document a phone call; inclusion of interventions and their responses is a key element to documentation.

Chain of command is an area of uncertainty in many institutions. Fear of retaliation and lack of support can prevent nurses from implementing the chain of command when they feel inappropriate orders are implemented or a provider fails



to respond to nurse requests for interventions, including their presence at the bedside. This lack of action fails to keep the patient's safety and best interest at the forefront of the plan of care. It's important that organizations have a clear chain of command along and educate staff regarding proper implementation of that chain of command.

# CONCLUSION

Any health care professional involved in patient care that includes oxytocin administration needs to be well aware of the safety implications. A collaborative approach to safe administration of oxytocin, which is based on scientific evidence along with guidelines from professional associations such as the American College of Obstetricians and Gynecologists (ACOG) and the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN), should be of paramount importance to perinatal nurses, physicians, midwives and hospitals. **NWH** 

http://nwhTalk.awhonn.org

# REFERENCES

Arias, F. (2000). Pharmacology of oxytocin and prostaglandins. *Clinical Obstetrics and Gynecology, 43,* 455–468. It's not enough to talk about oxytocin administration safety; an organizational culture of safety is necessary for proper support of safety measures

- Clark, S., Simpson, K., Knox, E., & Garite, T. (2009). Oxytocin: New perspectives on an old drug. *American Journal of Obstetrics and Gynecology*, *35*, 1–6.
- Greenwald, L., & Mondor, M. (2003). Malpractice and the perinatal nurse. *Journal of Perinatal and Neonatal Nursing*, 17(2), 101–109.
- Institute for Healthcare Improvement. (2010). *Bundle definition*. Retrieved from http://www.ihi.org/IHI/Topics/CriticalCare/ IntensiveCare/ImprovementStories/WhatIsaBundle
- Jonsson, M., Norden-Lindeberg, S., & Hanson, U. (2007). Analysis of malpractice claims with a focus on oxytocin use in labour. *Acta Obstetricia et Gynecologica*, *86*, 315–319.
- Jonsson, M., Norden-Lindeberg, S., Ostlund, I., & Hansson, U. (2008). Acidemia at birth related to obstetric characteristics and to oxytocin use during the last two hours of labor. *Acta Obstetricia et Gynecologicia*, *87*(7), 745–750.
- Jonsson, M., Norden-Lindeberg, S., Ostlund, I., & Hansson, U. (2009). Metabolic acidosis and suboptimal care: Illustration of the gap between knowledge and clinical practice. *Online International Journal of Obstetrics and Gynaecology*, *116*(11), 1453–1460. doi:10.1111/j.1471-0528.2009.02269.x
- Moleti, C. (2009). Trends and controversies in labor induction. *MCN The American Journal of Maternal Child Nursing*, 34(1), 40–47.
- Simpson, K., & James, D. (2008). Effects of oxytocin-induced uterine hyperstimulation during labor on fetal oxygen status and fetal heart rate patterns. *American Journal of Obstetrics and Gynecology*, 199(1), e1–e5.
- Simpson, K., & Knox, G. (2009). Oxytocin as a high alert medication: Implications for perinatal patient safety. *MCN The American Journal of Maternal Child Nursing*, 34(1), 8–15.
- Simpson, K., & Thorman, K. (2005). Obstetric conveniences: Elective induction of labor, cesarean birth on demand, and other potentially unnecessary interventions. *Journal of Perinatal and Neonatal Nursing*, 19, 134–144.
- Tucker, S., Miller, L., & Miller, D. (2009). Patient safety, risk management, and documentation. In C. Jackson & L. Gower (Eds.), *Fetal monitoring: A multidisciplinary approach* (pp. 210–241). St. Louis: Mosby-Elsevier.