The Freedom to Birth—The Use of Cytotec to Induce Labor: A Non-Evidence-Based Intervention

Madeline Oden, Doula Certificate

ABSTRACT

The off-label use of Cytotec (misoprostol) to induce labor has increased over the past few decades. The increase in medical interventions in childbirth, many of which are not based on scientific evidence, and the rise in maternal and infant morbidity and in maternal and infant mortality cannot continue to go unrecognized. This column serves as a teaching tool for childbirth educators and provides an example of two unnecessary, potentially avoidable deaths that occurred during a birth with questionable medical interventions.

The Journal of Perinatal Education, *18*(2), 48–51, doi: 10.1624/105812409X426332
Keywords: Cytotec, misoprostol, standard of care, labor and birth, evidence-based practices, avoiding adverse events

As childbirth educators, doulas, midwives, nurses, and obstetricians and gynecologists (OB/GYNs), we all need to be aware of the evidence-based interventions that are used in childbirth. The American College of Obstetricians and Gynecologists (ACOG) makes recommendations for care that have become the standard of care for labor and birth, and that sometimes deviate from the recommendations supported by published research. The routine practices of episiotomies, induction, and denying food to the mother during labor without true medical indication have all been shown to be unnecessary interventions and can contribute to a spiraling effect of adverse events up to and including deaths of the mothers and/or infants. The off-label use of Cytotec (misoprostol) to induce labor and soften the cervix is an excellent example of an unnecessary intervention that is not supported by research (Enkin et al., 2000) (see Table) yet is rapidly becoming the standard of care, despite the evidence demonstrating the catastrophic events that can occur when it is used.

The off-label use of Cytotec (misoprostol) to induce labor and soften the cervix is an excellent example of an unnecessary intervention that is not supported by research.

A FIGHT FOR LIFE: A MOTHER'S STORY

In December 2001, my 32-year-old daughter, Tatia Oden French, entered a well-known hospital in Oakland, California, to have her first child. She was in perfect health. The baby was in perfect health. The pregnancy was ''unremarkable.'' Tatia was almost 2 weeks past the due date, and the doctor wanted to induce her. After much stalling on Tatia's part, she reluctantly agreed to submit to induction. The

TABLE 1
What the American College of Obstetricians and Gynecologists and the Cochrane Collaboration Say About the Use of Cytotec for Induction

American College of Obstetricians and Gynecologists (ACOG) Committee Opinion	Cochrane Collaboration Opinion
Given the current evidence, intravaginal misoprostol tablets appear to be effective in inducing labor in pregnant women who have unfavorable cervices. The use of higher doses (50mcg every 6 hours) may be appropriate in some situations, although increasing the dose appears to be associated most closely with uterine tachysystole and possibly with uterine hyperstimulation and meconium staining of amniotic fluid. Further prospective trials are required to define an optimal dosing regimen for misoprostol. (ACOG, 2006, p. 102)	*As for vaginal misoprostol, insufficient data have been produced to evaluate the safety of this approach. Thus, though misoprostol shows promise as a highly effective, inexpensive, and convenient agent for labor induction, it cannot be recommended for routine use at this stage. It is also not registered for such use in many countries.* (Enkin et al., 2000, p. 394)

agent used was Cytotec (misoprostol). None of the medical staff told us anything about Cytotec. When I asked what Cytotec was, I was told it is ''the standard of care... we use it all the time.'' Tatia said it was ''not approved by the FDA [U.S. Food and Drug Administration] for use in labor.'' Nothing else was said about the potential side effects, the dangers to the mom and child, or the alternatives. However, phrases such as ''You don't want to go home with a dead baby, do you?'' were said. The pressure was on. Tatia conceded. She told me to go home and that she would call me, believing it would be a long night. We told each other we loved each other and, having not decided on which specialty she would focus on in medical school, she smiled and said, ''Maybe I'll be an OB/GYN.''

Ten hours after Tatia was induced with Cytotec, both she and her baby girl, Zorah, were dead. When I asked Tatia's doctor what happened, she just said, ''It was a very rare adverse effect of Cytotec, but it does happen.'' Still not comprehending what had just happened, I heard myself ask the doctor, ''Could you at least tell me that you will not use that drug again?'' Surprised, she looked at me and said, ''No, I cannot promise that.'' Finally, my two sons, Tatia's dad, Tatia's husband, and I were allowed into the operating room where Tatia and Zorah were lying perfectly still. We gathered and said a prayer around both of them. When I left the hospital, it was raining and gray and cold. I heard myself say out loud, ''That drug is going to go away.''

Several months after Tatia and Zorah's deaths, I started the process of forming a nonprofit organization dedicated to saving the lives of expectant mothers and their infants. On March 3, 2003, The Tatia Oden French Memorial Foundation received its official U.S. nonprofit status. The foundation's mission is to empower women around the issues of childbirth and pregnancy. In my role as the foundation's Executive Chairperson, I give presentations to high schools, churches, midwives, doula organizations, and many others.

Also, at least once a year since 2004, representatives from The Tatia Oden French Memorial Foundation have met with agents of the FDA to discuss the foundation's online petition regarding Cytotec inductions (Oden, n.d.). The petition was submitted to the FDA on November 22, 2004, and has been filed with the FDA and remains open in the agency's Division of Dockets Management. To date, over 2,100 online signatures and 1,000 hard-copy signatures have been gathered. The result, so far, has been that the FDA (2005) now has an alert posted on its Web site that speaks to the possible adverse events when Cytotec is used to induce labor.

CONTROVERSY OVER THE USE OF CYTOTEC TO INDUCE LABOR

In August 2000, the original manufacturer of Cytotec, G.D. Searle & Co. (Searle), sent a letter to over 200,000 OB/GYNs in the country stating the possible side effects of Cytotec when given to pregnant women, such as hyperstimulation of the uterus, uterine rupture, fetal bradycardia, amniotic fluid embolism, death of the mother, and death of the child. Subsequently, ACOG wrote a rebuttal to the FDA regarding Searle's letter, claiming not enough evidence and scientific studies warrant eliminating misoprostol's use to induce labor. Searle, however, found enough evidence in its trials of misoprostol for the treatment of ulcers to issue the letter. Searle also stated that the company did not intend to study

For more information about The Tatia Oden French Memorial Foundation, log on to the organization's Web site (http://www.tatia.org/).

To view The Tatia Oden French Memorial Foundation's online petition and to read comments from those who suffered from Cytotec inductions and from loved ones who witnessed deaths of mothers and babies due to Cytotec induction, log on to http://www.petitiononline.com/cytotec/. Also, to view the FDA's alert regarding the risks of using Cytotec in birth and labor, log on to http://www.fda.gov/Cder/drug/infopage/misoprostol/default.htm

To view Searle's August 2000 letter warning about the possible side effects of Cytotec when given to pregnant women and to read ACOG's subsequent response, log on to www.fda.gov/ohrms/dockets/dailys/00/Nov00/111500/cp0001.pdf

or support the use of Cytotec for induction of labor or cervical ripening.

Why is Cytotec routinely used in labor and birth when its own manufacturer does not recommend its use? Cytotec is indicated for reducing the risk of gastric ulcers induced by nonsteroidal anti-inflammatory drugs, including aspirin, in patients at high risk of complications from gastric ulcers (Searle, n.d.). Searle also claims, ''Cytotec may cause abortion (sometimes incomplete), premature labor, or birth defects if given to pregnant women'' (p. 6). Without adequate testing of Cytotec, physicians and midwives were able to use the drug for labor induction under a loophole in the drug regulatory system. Cytotec produces uterine contractions as a side effect and, after it was approved by the FDA for a specific medical indication and placed on the market, there were no restrictions preventing physicians or midwives from using Cytotec for any reason, for any patient, or at any dosage. Such usage is referred to as ''off-label'' use of a drug (Wagner, 2003).

For more information about Ina May Gaskin's Safe Motherhood Quilt Project, log on to www.rememberthemothers.net

Maternal and infant deaths from Cytotec inductions continue to occur. Cytotec is used off-label; therefore, no accurate statistics are kept on adverse events when it is used to induce labor. Pregnant women are still being given Cytotec, and some come through unscathed. However, many women and babies are permanently harmed.

THE ADVERSE EFFECTS OF CYTOTEC

At the Motherbaby International Film Festival in Traverse City, Michigan, in October 2008, Steve Buonaugurio's film, *Pregnant in America*, was shown. During the question-and-answer session, the emcee asked audience members to stand if they were given Cytotec to induce their labor and had suffered hyperstimulation of the uterus. About six women stood up. Then, the emcee asked women to stand if they thought their babies had suffered any neurological issues due to the Cytotec induction. About 20 more women stood. Next, the emcee asked those to stand who knew of women who were given Cytotec to induce labor and had died. Six more women stood. This continued for about 5 more minutes, with the emcee naming side effects caused by Cytotec inductions and women continuing to stand. In the end, there were over 30 women standing in an audience of approximately 150 people (20%).

In her role as a commissioner on the Alameda County Public Health (ACPH) Commission in California and as Chairperson of the ACPH Maternal, Child Health subcommittee, author Madeline Oden has played a significant part in developing helpful resources for expectant parents. Visit the following link at the ACPH Web site to view and download pamphlets that provide information about interventions and drugs used in labor and birth, as well as about informed consent: http://www.acphd.org/user/services/AtoZ_PrgDtls.asp?PrgId=98

After Cytotec is inserted in the vagina, it dissolves instantly. There is no turning back. There is nothing that can be given to reduce the severe tetanic (very violent and painful) contractions wearing on the mother's uterus and depriving the baby of oxygen far longer than can be tolerated. These and many other side effects do not need to continue to occur. Alternative interventions are available to induce labor and can be turned down or off (Pitocin) or withdrawn (Cervidil, Prepidil).

Why do health-care professionals continue to use Cytotec, knowing of the potentially devastating adverse effects? Cytotec is inexpensive. The cost is 25 cents per pill. The pill is scored in quarters, which poses another problem, because the pill was not meant to be scored. A quarter (25mcg) could be given to one person, and a different quarter from the same pill could be given to another person, and each could react differently because the chemical composition might be different in each quarter. The pill can be stored in both hot and cold conditions and has a very long shelf life. It works very quickly. In contrast, without Cytotec induction, most births occur within 12 hours.

The cost in terms of human life and the resulting permanent damage that Cytotec can do cannot be measured, although the number of deaths represented on the Safe Motherhood Quilt Project, coordinated by Ina May Gaskin (2008), continues to rise. As long as this non-evidence-based practice continues, babies may suffer permanent brain damage. Mothers might never have children again because tetanic contractions caused their uterus to rupture, requiring a hysterectomy to save their lives. Mothers who suffer amniotic fluid embolism may live through it, but with near-death experiences. Families will endure the lifelong agony of waiting with joy-filled hearts for the birth of a new life only to ache endlessly because that day ended the life of the mother and/or the baby. These costs, along with the tragic outcomes of mothers who took diethylstibestrol (DES) or thalidomide while pregnant, are much too high; these practices must be stopped. As with the history of DES and thalidomide, only a public outcry will stop the use of Cytotec to induce labor.

IMPLICATIONS FOR CHILDBIRTH EDUCATORS AND HEALTH-CARE PROVIDERS

What are the implications for childbirth educators, doulas, midwives, nurses, and physicians? It is our responsibility to look at the evidence rather than the recommendations of a trade organization whose mission is to protect its members. Every

day, we see many birth interventions done for convenience while decreasing the safety of mothers and babies. Interventions, such as Cytotec inductions, are not always researched for a specific use to assess the risks and benefits. Our clients trust us to base what we say and how we advise them on research and evidence. We should encourage mothers to move around during labor, consume food for energy, and let the birth process take its natural course (while observing carefully how the mothers and babies are progressing) without interfering. We should inform our clients, *before* they go into labor, of all the known side effects of interventions used in labor and birth for both the mother and baby. We should encourage them to do more research on their own, giving them the necessary resources, and to discuss fully with their provider what they will and will not agree to during labor. They should be aware that they have the right to refuse any treatment or drug.

Compared to a medicated birth, when babies come into the world naturally, they are more alert, bond immediately, nurse quicker, have fewer respiratory problems, and know instinctively they have arrived into a welcoming space. As mothers, childbirth educators, midwives, doulas, labor and delivery nurses, and obstetricians, we must start now to actively support our freedom to birth based on the scientific evidence, which overwhelmingly lets birth progress on its own, in its own time and its own way (unmedicated, moving around, and surrounded by loved ones and the new life that is coming into this world). By doing so, we will not only change how birth is accomplished in the United States but, more importantly, we will bring forth new generations who come here in the natural way they were meant to arrive, honoring the process, the baby, and the mom, and saving many, many lives.

Compared to a medicated birth, when babies come into the world naturally, they are more alert, bond immediately, nurse quicker, have fewer respiratory problems, and know instinctively they have arrived into a welcoming space.

REFERENCES

American College of Obstetricians and Gynecologists. (2006). *2006 Compendium of selected publications.* Washington, DC: Author.

Enkin, M., Keirse, M. J. N. C., Neilson, J., Crowther, C., Duley, L., Hodnett, E., et al. (2000). *A guide to effective care in pregnancy and childbirth* (3rd ed.). Oxford, U.K.: Oxford University Press. Retrieved February 19, 2009, from http://www.childbirthconnection.org/article.asp?ClickedLink=194&ck=10218&area=2

Gaskin, I. M. (2008). Maternal death in the United States: A problem solved or a problem ignored? *The Journal of Perinatal Education*, *17*(2), 9–13.

G.D. Searle & Co. (n.d.) *Cytotec® (misoprostol).* Retrieved February 14, 2009, from www.fda.gov/Cder/foi/label/2002/19268slr037.pdf

Oden, M. (n.d.) *Cytotec (misoprostol) for labor induction consumer awareness.* Retrieved February 20, 2009, from http://www.petitiononline.com/cytotec/

U.S. Food and Drug Administration. (2005, May). *Misoprostol (marketed as Cytotec) information: FDA alert – Risks of use in labor and delivery.* Retrieved February 14, 2009, from http://www.fda.gov/Cder/drug/infopage/misoprostol/default.htm

Wagner, M. (2003). Cytotec induction and off-label use. *Midwifery Today*, *67*, 31–33. Retrieved February 14, 2009, from http://www.midwiferytoday.com/articles/cytotec.asp

---

MADELINE ODEN *is currently the Executive Chairperson of The Tatia Oden French Memorial Foundation, the Chairperson of the Maternal, Child Health subcommittee of the Alameda County Public Health (ACPH) Commission in California, and a commissioner on the ACPH Commission. She has been a certified practicing doula for 3 years.*