the LiNC

The Link between Health Care and the Legal Profession

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Contents

Introduction:
The incidental discovery that an inexpensive medication being used to treat gastric disease was effective in cervical ripening and labor induction changed the clinical practices of many obstetricians. Over the past decade Cytotec® has become the preferred agent for induction in many labor units across America, as the convenience of induction becomes an increasingly popular choice. Cytotec's success, however, has been clouded by its adverse effects that have resulted in fetal and maternal mortality and morbidity from its unpredictable uterine hyperstimulation. The theme of misoprostol, i.e., Cytotec®, carries through this newsletter as two nurse midwives (Cydney Menihan and Linda Turcic), a hospital risk manager (Jane Collins), and a plaintiff's attorney (Mark Bower), each provide information for the LNC from their very different perspectives on the use of this drug. The opinions within these submissions covering this very contentious subject are those of the authors and do not reflect a position taken by the Pittsburgh Chaper AALNC. This newsletter concludes with a primer on Tort Law by Alan Meisel, who is a Professor of Law and Ethics. Enjoy!

Nursine S. Jackson, MSN, RN

Misoprostol (Cytotec®): *an overview*

Excerpted by Cydney Afriat Menihan, CNM, MSN, RDMS from the AWHONN publication: **Cervical Ripening and Induction and Augmentation of Labor**, 2nd Edition, *by Kathleen Rice Simpson, PhD, RNC, FAAN. Cydney is a Nurse midwife, author and educator from Narragansett, RI.*

Misoprostol (brand available in America - Cytotec®) is a synthetic prostaglandin E_1 analogue that has FDA approval for the prevention of peptic ulcers. Because of its prostaglandin effects, it has found an off-label use for cervical ripening in preparation for the induction of labor. This use in obstetrics has generated controversy in the United States due to a lack of consensus among experts as to whether there is enough evidence to support its safe use in pregnancy.

When used for cervical ripening, an initial dose of 25 mcg in tablet form is placed in the posterior vaginal fornix.(American College of Gynecology, Committee Opinion # 228, 1999). Higher doses have also been used. However, hyperstimulation and nonreassuring fetal heart rate (FHR) tracings have been associated even with the 25 mcg dose, and the rate of hyperstimulation and nonreassuring FHR patterns is significantly higher with misoprostol when compared to oxytocin (Hofmeyr, Gulmezoglu & Alfirevic, 1999). The longer the interval between doses, the less the incidence of hyperstimulation.

Continued on page 9

A Message from our President

Dear Colleagues:

As I review my thirteen years as a member of the Pittsburgh Chapter of AALNC, I can only feel gratitude for the benefits I have realized. Having served as your President twice, Secretary for at least two (2) terms, and several terms as a Board Member, I have been provided many professional opportunities, as well as the enjoyment of the development of wonderful collegial relationships. Becoming involved in the chapter will only serve you well.

The newsletter, *LiNC,* and our website, www.PittsburghChapterAALNC.org, reflect the professional stature of our membership. Our chapter supports your educational growth. Most of our meetings include a speaker. Our Business Directory assists our members in growing their consulting practice. Our local nursing community is provided educational support annually through our Fall Conference.

Our chapter members are supportive of one another in times of joy and in times of sorrow. We are a special group! Pat yourself on the shoulder. You deserve it.

Please mark your calendars and bring a nursing friend to our fall conference on October 23, 2004 at Mercy Hospital of Pittsburgh. We have a Business meeting in November and our annual holiday get-together is planned for December.

Your President,

Linda M. Fowler, Dr.P.H., R.N., N.H.A.

OUR UPCOMING OCTOBER EDUCATIONAL CONFERENCE

The Pittsburgh Chapter of AALNC is proud to present "**Practical Pathways to a Legal Nurse Consulting Career"** on October 23, 2004 at The Mercy Hospital of Pittsburgh, Sister Ferdinand Clark Auditorium.

GUEST SPEAKER:
Our keynote speaker, Barbara Levin, President of the national organization of AALNC will discuss "The Future of Legal Nurse Consulting."

CONTENT:
This conference is packed with down-to-earth suggestions for starting your own legal nurse consultant practice, and strategies to enhance the existing practices of seasoned LNCs. Mini clinics will be led by LNCs who work in various settings. The diversity of this exciting nursing specialty will be explored. Attendees will learn about the LNCC certification.

NETWORKING LUNCHEON:
A luncheon will afford the opportunity to network with LNCs who work in law firms, independently, on behalf of the Plaintiff, or for the defense.

For further information or to register, contact Kathy at (412)939-4326 or at kesrehab@aol.com.

Clinical Point: the ACOG Perspective On Cytotec®

by Linda K. Turcic, MS, RN, CNM, CRNP, CLNC
Linda Turcic is the Clinical Nurse Specialist of the St. Clair Family Birth Center

A meta analysis of 12 trials including 2,613 participants found that misoprostol (Cytotec®) improved cervical ripening compared to placebo and was associated with a 40 % reduction in the use of oxytocin. In addition, misoprostol was more effective for induction of labor than prepidil or cervidil. However, uterine hyperstimulation with fetal heart rate changes and meconium stained amniotic fluid were more common with misoprostol use.

Misoprostol was more effective for labor induction than oxytocin, but did not result in a significant reduction in the Cesarian Section rate compared to other prostoglandins or oxytocin.

The optimal dose and timing of intravaginally applied misoprostol are unknown. Since the safety of higher doses (50 mcg.) could not be adequately evaluated, lower doses such as 25 mcg. should be used, with redosing intervals of 3 to 6 hours. Oxytocin (Pitocin®) may be initiated, if necessary, four hours after the final misoprostol dose.

Misoprostol should NOT be used in term pregnancies in women with a prior cesarean birth or other prior major uterine surgeries (e.g., extensive myomectomies and hysterotomies), because of the increased risk for uterine rupture.

Orally administered misoprostol for cervical ripening and labor induction is being explored. Most trials have used an oral dose of 50 mcg. every 4 hours. This regimen appears less effective than vaginal administration with either 25 mcg. or 50 mcg. However, there was less uterine hyperstimulation with the oral route.

American College of Gynecology (ACOG) has endorsed the use of misoprostol as a safe and effective cervical ripening and/or labor induction agent when utilized as described above.

Continued on Page 9

INDUCTION OF LABOR

According to ACOG Practice Bulletin #10 (1999), induction of labor should be undertaken when the benefits to either the mother or fetus outweigh the risks of continuing the pregnancy. There are several generally accepted medical and obstetrical indications for induction of labor:

- hypertensive disorders of pregnancy (preeclampsia, eclampsia, and others)
- maternal diabetes
- premature (pre-labor) rupture of membranes
- intrauterine growth restriction
- chorioamnionitis
- post-term pregnancy
- fetal demise

Contraindications include:

- prior classical (vertical) uterine incision
- active genital herpes lesions,
- placenta or vasa previa
- umbilical cord prolapse
- some fetal malpresentations (transverse lie)

Conditions in which caution should be exercised:

- multiple gestation
- previous low transverse C Section
- breech presentations
- certain maternal cardiac conditions
- abnormal fetal heart rate patterns not requiring immediate delivery

INFORMED CONSENT AS IT RELATES TO THE USE OF MISOPROSTOL (CYTOTEC ®) FOR CERVICAL RIPENING AND INDUCTION OF LABOR:

A Risk Manager's Perspective

by Jane Collins, RN, BSN, JD

Jane is the Director of Risk Management at St. Clair Hospital in Pittsburgh, PA.

Background

Labor induction in the presence of an unfavorable cervix is often prolonged, tedious, and may lead to induction failure. A protracted induction may also incur other antepartum complications, such as chorioamnionitis, uterine hypertonus, or water intoxication when oxytocics are used *[Wing, D.A. et al. (1995). A comparison of misoprostol and prostaglandin E2 gel for preinduction cervical ripening and labor induction. Am J Obstet Gynecol, 172(6). pp. 1804-10]*.

Prostaglandins have been shown to be effective agents for cervical ripening and labor induction. Prostaglandins have the advantage over oxytocin both of acting locally to enhance cervical ripening and of increasing myometrial contractility, either primarily or secondarily by inducing endogenous oxytocin release *[Chuck, J. (1995, November 4) . Labor induction with intravaginal misoprostol versus intracervical prostaglandin E2 gel (Prepidil gel): Randomized comparison. Am J Obstet Gneycol.,173 (4). PP 1137-1142.]*

Since the early 90's, several investigations described the use of an alternative prostaglandin (prostaglandin E1, of which misoprostol or Cytotec® is used in the U.S.) for cervical ripening and labor induction. Although Cytotec is not FDA approved for cervical ripening and labor induction, vaginal administration of Cytotec, outside of its approved indication, has been used for this purpose. It has also been used for treatment of serious postpartum hemorrhage in the presence of uterine atony. Cytotec is inexpensive and easy to administer, because it is placed in the vagina, not the cervix. *[Wing, ibid]*.

Prostoglandins have been known to cause uterine hyperstimulation, which may progress to uterine tetany with marked impairment of uteroplacental blood flow, uterine rupture, or amniotic fluid embolism. Pelvic pain, retained placenta, severe vaginal bleeding, shock, fetal bradycardia, and fetal and maternal death have also been reported. However, studies have demonstrated that Cytotec is associated with a comparatively higher incidence of uterine tachysystole or hyperstimulation and meconium-stained amniotic fluid. *[Buser, D. et al. (1997, April). A randomized comparison between misoprostol and dinoprostone for*

Continued on page 5

Collins - Risk Mgr: Continued from page 5

cervical ripening and labor induction in patients with unfavorable cervices. Obstetrics & Gynecology, 189 (4). pp. 581-585.]

Studies suggest that the benefit of misoprostol over dinoprostone (distributed in the US under the trade names Prepidil®, Cervidil®, Prostin E2® and is FDA approved for use in induction) is that it is more effective in achieving vaginal deliveries within 24 hours and reduces the need for, and total amount of, oxytocin augmentation. Later studies, using 25 micrograms as opposed to 50 micrograms, demonstrated a decreased incidence of uterine tachysystole/hyperstimulation and meconium passage, but still higher than that for patients who received Prepidil. *[Wing, D.A. et al. Misoprostol:an effective agent for cervical ripening and labor induction. Am J Obstet Gynecol, 172 (60). pp 1811 - 1816.]*

The Medical Director for Searle, the manufacturer of Cytotec, issued a "Dear Doctor" letter in August of 2000, when it became aware that Cytotec was being used off label for induction of labor. The purported purpose of the letter was to remind health care providers that Cytotec is not approved for the induction of labor and that it is contraindicated in pregnant women. In addition to the reported adverse events referenced above, the "Dear Doctor" letter included the following cautionary note: the effect of Cytotec, when used for induction of labor or cervical ripening, on the later growth and development of the child has not been established. The letter also stated, "Searle promotes the use of Cytotec only for its approved indication." Clearly, the manufacturer is attempting to insulate itself from liability.

In a rebuttal letter, addressed to the Food and Drug Administration, the ACOG Committee on Obstetric Practice reaffirmed its position that misoprostol, *when used appropriately*, is a safe and effective agent for cervical ripening and labor induction. The basis for their conclusion appears to be that "the vast majority of adverse maternal and fetal outcomes associated with misoprostol therapy resulted from the use of doses greater than 25 micrograms, dosing intervals more frequent that 3-6 hours, addition of oxytocin less than 4 hours after the last misoprostol dose or use of the drug in women with prior cesarean delivery or major uterine surgery." *(available on the ACOG website @ www.ACOG.com)*

Subsequently, the Food and Drug Administration revised the Cytotec label in several ways. First, it revised the contraindication section by clarifying that Cytotec should not be taken by pregnant women *to reduce the risk of ulcers induced by NSAIDs* [italics added]. Second, it added a labor and delivery section where the adverse effects and associated risk factors are described. Clearly, the FDA is acknowledging the recognized off label use of Cytotec for labor induction and cervical ripening. *[www.fda.gov/medwatch/SAFETY/2003/0AUG_PI/Cytotec_PI.pdf.]*

Common Law Basis for Informed Consent

- Right to refuse medical treatment is a fundamental concept of personal autonomy.
- Doctrine of informed consent is grounded upon the tenet that the physician is precluded from administering to, or operating upon, mentally competent adult patient in non-emergency situation absent that patient's consent.
- Persons who assist primary treating physician, including nurses, do not have the duty to obtain informed consent from patient.
- As a matter of law, hospitals cannot be held vicariously liable for failure of its physician to obtain the patient's informed consent.
- Tort of failure to obtain informed consent sounds in battery, not negligence.
- A claim of a lack of informed consent sounds in the intentional tort of battery, because an operation performed without

Continued on page 6

the patient's consent is deemed to be the equivalent to a technical assault.

- Doctrine of informed consent is limited to those cases involving surgical or operative procedures.
- Doctrine of informed consent should be limited in its applicability to only those cases involving surgical or operative medical procedures and should not be expanded to include cases involving solely the administration of therapeutic drugs.
- A physician need not inform patients of the Food and Drug Administration (FDA) classification of a medical device in order to obtain informed consent.
- Injection of steroid into heel of patient who had pain in her heel was not surgical or operative procedure, and thus, doctrine of informed consent was inapplicable; procedure involved only injection of medication, which did not rise to the same level of bodily invasion as surgery.
- A physician's failure to obtain a patient's informed consent prior to administering therapeutic drugs (Procan-SR) may not be the basis of a medical malpractice action.
- Vascular surgeon, in using TPA to treat patient's blood clots, was not required to obtain patient's informed consent; TPA therapy, which involved injection of a drug, was not surgical or operative.
- Natural delivery process does not require that the patient give specific informed consent for procedure; rather, general consent is appropriate.
- Plaintiff's claim that defendants failed to obtain plaintiff mother's informed consent to a vaginal birth after cesarean procedure failed because informed consent is not necessary for non-surgical procedures.

Based upon the above case law, there appears to be no legal basis for concluding that informed consent is required for prescribing medications, including misoprostol for cervical ripening and/or induction of labor.

Statutory Basis for Informed Consent

The Pennsylvania legislature most recently codified the law of informed consent in the Medical Care Availability and Reduction of Error (Mcare) Act, Act of March 20, 2002, P.L. 154, No. 13. Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient prior to conducting the following procedures:

(1) Performing surgery, including the related administration of anesthesia.
(2) Administering radiation or chemotherapy.
(3) Administering a blood transfusion.
(4) Inserting a surgical device or appliance.
(5) Administering an experimental medication, using an experimental device or ***using an approved medication*** or device ***in an experimental manner***. [Emphasis added.]

One could argue that off- label use, in and of itself, constitutes using an approved medication in an experimental manner. However, there are plenty of examples where medications are used off label and their use does not amount to experimentation. For example, beta-blockers are used off label for congestive heart failure and myocardial infarction, multiple drugs are used off label to treat AIDS and agents approved for cancer treatment are used off label for osteoarthritis.

A physician has a legal right to prescribe medications for indications not approved in the product labeling. Protection for the physician who prescribes medications in an off-label fashion exists in a 1962 congressional amendment to the Food, Drug, and Cosmetic Act of 1938. This amendment indicates that the FDA has no control over the manner in which a physician may use an approved drug and that, once marketed, a product may be used in different treatment regimens or for medical disorders that are not included in the original labeling. *[Beck, J.M. et al. FDA, off-label use, and informed consent: debunking myths and misconceptions. Food and Drug Law Journal, 53, p. 71.]* Furthermore, such prescribing habits are not considered experimental if based on sound scientific evidence, including evidence of widespread use. *[Wing, D.A. Labor induction with misoprostol. Am J Obstet Gynecol, 181, (2), pp. 339-345.]*

Continued on page 7

On the other hand, the legislature clearly distinguished between administering experimental medication and administering approved medication in an experimental manner. It could be argued that "experimental medication" refers to drugs that are not yet approved by the FDA; drugs that are administered in clinical trials during the process of FDA approval. What does it mean, then, to use an approved medication in an experimental manner. Interpreted narrowly, it would seem to suggest a clinical trial or research protocol involving a drug already approved by the FDA. Interpreted broadly, it could apply to off label use of FDA approved drugs.

Justification for obtaining informed consent prior to administering Cytotec for cervical ripening and induction of labor

Even if the law does not require it, there are many good reasons to obtain informed consent prior to administering misoprostol for cervical ripening and induction of labor.

The Conditions of Participation (COPs) for health care facilities receiving Medicare and/or Medicaid dollars state, in a pertinent part, that:
The patient has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment.

According to the American Medical Association's Code of Medical Ethics, the patient has the right to receive information from physicians and to discuss the benefits, risks, and costs of appropriate treatment alternatives. The patient has the right to make decisions regarding the health care that is recommended by his or her physician. Accordingly, patients may accept or refuse any recommended medical treatment.

Lastly, informed consent is a valuable risk management tool for physicians. By helping a patient understand his or her illness, medical condition and treatment, and developing reasonable and realistic expectations about the outcome of that treatment, physicians can reduce the chances that the patient will become disappointed and angry. This, in turn, may reduce the chance of a lawsuit.

What information should be shared with the patient as part of the informed consent process?

It is important to note that informed consent is a process. It is a sharing of information between a physician and his or her patient; the result of which is a knowing and voluntary decision made by the patient to undergo or forego, a certain treatment.

It is not necessary for the physician to disclose to the patient all known risks of a given procedure. Rather, Pennsylvania law requires that the patient be advised of those material facts, risks, complications and alternatives that a reasonable person in the patient's situation would consider significant in deciding whether to undergo the procedure.

According to the Mcare Act, consent is informed if the patient has been given a description of the procedure, the risks and alternatives that a reasonably prudent patient would require to make an informed decision. A physician is liable for failure to obtain informed consent only if the patient proves that receiving such information would have been a substantial factor in the patient's decision whether to undergo the procedure.

According to the American Medical Association, physicians should share the following information with patients:

1. Diagnosis, if known;
2. The nature and purpose of a proposed treatment or procedure;
3. The risks and benefits of a proposed treatment or procedure;
4. Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);
5. The risks and benefits of the alternative treatment or procedure; and

Continued on page 8

6. The risks and benefits of not receiving or undergoing a treatment or procedure.

Generally speaking, non-medical information is not included in the informed consent process. Arguably, FDA regulatory status is non-medical information and conveys nothing about the risks or benefits of the treatment. There is a limit to the amount of information physicians can be expected to explain to patients, and there is a limit to what patients can absorb, particularly in what are often trying and emotional circumstances. Some go so far as to argue that regulatory status is irrelevant and is potentially misleading information. Clearly though, the risks associated with induction generally, and the use of misoprostol, including uterine hyperstimulation and its effects, should be explained to the patient.

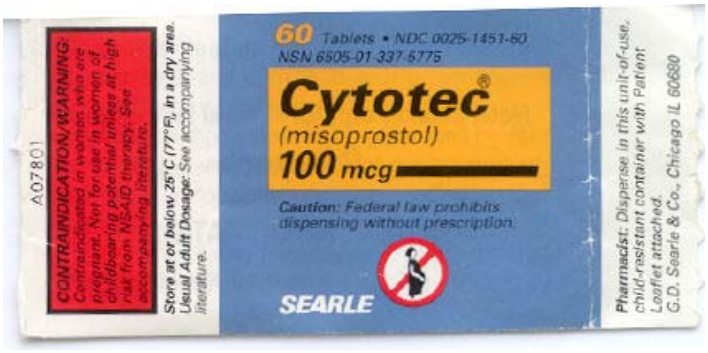
The documentation of this process is often on a consent form; however, this is not necessarily the case. In Pennsylvania, a physician is not required to have the informed consent in writing; however it is easier to prevail in a lack of informed consent case, when you can show documentation to a jury regarding informed consent. In addition to the consent form, a contemporaneously handwritten progress note will provide additional evidence that the consent process took place. If possible, it is advisable to have another health care professional and family member present during the consent process and to have a patient's signature witnessed.

Risk reduction techniques when using misoprostol for cervical ripening and induction of labor

- Obtain informed consent in writing, using lay terms when possible.
- Inform the patient of the need for induction and the risks versus the benefits.
- Explain the choice of medications available to induce labor and bring about cervical ripening, and the relative risks and benefits associated with each.
- Establish written guidelines for monitoring and treating the side effects of misoprostol, most notably, uterine hyperstimulation.
- Monitor outcomes and perform peer review or quality assurance on adverse outcomes.
- Monitor adherence to the established guidelines.
- Evaluate non-compliance with guidelines to ensure deviation is based on sound clinical judgment.
- Dispense misoprostol in unit dose instead of floor stock, and dispense it in the dosage to be administered (25 mcg or one-fourth of a 100 mcg tablet).
- Follow ACOG guidelines for administration: initial doses not to exceed 25 mcg, dosing intervals no more frequent than 3-6 hours, not administering oxytocin less than 4 hours after the last dose of misoprostol, not using the drug in women with prior cesarean section or major uterine surgery or grand multiparity.
- Develop pre-printed orders, approved by the medical staff, in order to avoid errors associated with illegible handwriting.
- Educate nursing staff regarding misoprostol, including recommended doses, side effects, etc . . .
- Consider requiring certification in fetal heart rate monitoring for nurses caring for patients at high risk for obstetric related complications.
- Develop a culture of learning and cooperation in which nurses feel comfortable questioning physician orders or the physician's plan of care.
- Educate patients and involve them in their care, including the medication administration process.

References Continued on Page 9

CLINICAL POINTS: by Turcic - Continued from Page 3



BENEFITS:

- A 100 mcg. tablet is approximately $0.36 (cervidil costs about $175.00 per insert)
- Misoprostol is also easily stored at room temperature
- It is rapidly absorbed by both the oral and vaginal routes
- It causes few systemic side effects.

RISKS:

-Adverse effects of hyperstimulation with evidence of fetal distress are more common;

-Once absorbed, Cytotec cannot be taken out, turned off or turned down.

OVERVIEW ON THE USE OF CYTOTEC by Menihan

-Continued from Page 1

Recommendations for use include the following:

1) Redosing is acceptable if cervical condition remains unfavorable,
2) Uterine activity is minimal,
3) FHR is reassuring, ***and***
4) It has been a minimum of 3 hours since the last dose.

Redosing is withheld if:

1) There are 2 or more contractions in 10 minutes,
2) Adequate cervical ripening has been achieved,
3) The patient enters active labor, ***or***
4) The FHR is nonreassuring.

Collins - Risk Mgr, Continued from Page 8

Additional References Used

1# In re Duran, 769 A.2d 497.
2# Sagala v. Tavares, 533 A.2d 165, 367 Pa.Super. 573.
3# Davis v. Hoffman, 972 F.Supp. 308
4# Valles v. Albert Einstein Medical Center, 805 A.2d 1232, 569 Pa. 542.
7# Corrigan v. Methodist Hosp., 869 F.Supp. 1208.
8# Valles v. Albert Einstein Medical Center, 805 A.2d 1232, 569 Pa. 542.
9# Jones v. Philadelphi College of Osteopathic Medicine, 813 F.Supp. 1125.
10# Boyer v. Smith, 497 A.2d 646, 345 Pa.Super. 66.
11# Southard v. Temple University Hosp., 781 A.2d 101, 566 Pa. 335.
12 #Morgan v. MacPhail, 704 A.2d 617, 550 Pa. 202.
13# Bykens v. Hsu, 13 D&C 4th 356.
14# Stalsitz v. Allentown Hosp., 814 A.2d 766.
15# Sinclair by Sinclair v. Block, 633 A.2d 1137, 534 Pa. 563, reargument denied.
16# Kremp v. Yavorek, 57 D&C 4th 225.

CYTOTEC

AND

(LACK OF) INFORMED CONSENT:

A Plaintiff's Attorney's Perspective

by Mark R. Bower, Esq.

Mark R. Bower is a Plaintiff's Attorney from New York City with a special interest and expertise in obstetrical issues. He has lectured and published extensively in this area of law. Mr. Bower is a frequent guest commentator on Court TV, a member of the Million Dollar Advocates Forum, is Board-Certified in Medical Professional Liability by the American Board of Professional Liability Attorneys, and is an Associate of the American College of Legal Medicine.

His firm is proud to be a participant in the Trial Lawyers Care Program, providing free legal assistance to victims of the September 11th World Trade Center disaster.

To learn more about this author's publications, his legal work, and his experience with Cytotec, please visit his websites:

www.BowerLawPC.com
and
www.CytotecCase.com

There are approximately 200,000 Cytotec-induced deliveries each year in the U.S.A. Some of those deliveries are blighted by uterine hypertonicity, tetanic contractions, fetal stress/distress, uterine ruptures, fetal demise, emergency cesarean sections, emergency hysterectomies, maternal deaths, and other obstetrical catastrophes. But how many?

No one knows. As of 2000, the FDA had only 49 reports of cases of uterine ruptures and 10 reports of infant deaths due to Cytotec, but internet websites, such as: http://health.groups.yahoo.com/group/Meghanswish/ and http://health.groups.yahoo.com/group/Auterinerupturesupportgroup/ describe many hundreds, perhaps thousands, more. About 2.5% of all induced deliveries are accompanied by uterine ruptures, so that it is fair to estimate that there are approximately 5,000 uterine ruptures associated with Cytotec annually. Clearly, the problem is massively under-reported in the medical community for reasons described later in this article.

The obstetrical community generally loves Cytotec, as it allows doctors (and patients) to time deliveries both to suit medical needs, and physicians' and patients' convenience. Hospitals love Cytotec because it is easy to use, inexpensive to purchase. In addition since the 100 mcg. tablet is typically quartered by the hospital pharmacy for administration in 25 mg. doses, it is subject to a huge mark-up. Managed care companies love Cytotec because it is cost-saving (ranging $0.36 to $1.20 per dose before markups, as contrasted to Cervidil or Prepadil, chemically-similar prostaglandin vaginal inserts that costs over $175 per dose).

The FDA has never approved Cytotec for cervical ripening or induction of labor, and has little reason to monitor its complications for unapproved uses. Certainly, malpractice insurers are not desirous of documenting Cytotec disasters. And Searle, the manufacturer, being fully aware of Cytotec's many dangers, expressly *prohibits* its use in pregnant women

Continued on page 11

Bower - Plaintiff's Attorney: Continued from Page 10

in Cytotec's package and in the P.D.R. Searle has cleverly distanced itself from the use of Cytotec for its most common use, insulating itself from legal liability, while happily selling the drug to hospitals and obstetricians with a wink and a nod, knowing full well that its product will be used on a massive scale in a contraindicated way. The logo below, from the actual Cytotec packaging, is a picture that is worth a thousand words:

Given Searle's stated prohibition against the use of Cytotec in pregnancy, it must be realized that the common nomenclature, "off-label," is inaccurate. "Off-label" implies the benign use of a drug for something other than an approved purpose. When Cytotec is used in labor, this is *directly violative* to the manufacturer's *explicit prohibition*. This is ***contrary to the label***. "Off label" is a grossly misleading understatement.

To assess the rate of complications due to Cytotec, one must first recognize when a complication is due to Cytotec. We have been involved in several cases where mothers have suffered obstetrical catastrophes in Cytotec deliveries, but the relationship between the Cytotec and the problems have never been documented in the delivery records, ever.[1] There are two obvious explanations for the lack of documentation: (1) The doctors and nurses are unaware of the connection; or (2) they are afraid to concede the connection because it might expose them to legal liability for the use of this dangerous drug.

Because the medical community does not recognize or document Cytotec catastrophies, no data base exists that accurately records the incidence of Cytotec-related problems. The absence of good data makes obtaining a proper informed consent for the use of Cytotec particularly troublesome. ACOG inferentially recognizes some of Cytotec's dangers, but you have to read between the lines: "[Searle's] 'letter [to] the FDA correctly points out the potentially serious, but relatively rare risks of misoprostol when employed for cervical ripening and labor induction. . . [T]hese studies do suggest misoprostol [Cytotec ®] is associated with a higher incidence of uterine hyperstimulation and meconium-stained amniotic fluid. . ." But ACOG goes on to defend the contrary-to-label use of Cytotec under some circumstances.

On paper, ACOG is highly sensitive to informed consent issues. Its website, www.acog.edu, has a lengthy, in-depth section dedicated to informed consent, and particularly, ethical issues of informed consent in obstetrics. ACOG correctly notes that informed consent is an expression of the patient as a person, respecting the patient's moral right to bodily integrity and self-determination, protecting the patient against unwanted medical treatment and making possible the patient's active involvement in their own medical planning and care. It points out that informed consent is "a process rather than [merely] a signature on a form."[2]

The key word in "informed consent" is *informed*. Securing a patient's signature on a consent form does not demonstrate *informed* consent, and simply captioning the document with a heading such as "Informed Consent" does not eliminate a shortfall. While the specifics of informed consent rules vary somewhat from state to state, as a general principle, to obtain a proper informed consent requires that before obtaining a patient's permission for an operation or invasive diagnostic procedure or the use of medication, a doctor has the duty to provide appropriate information concerning what the doctor proposes to do, the alternatives to that operation, procedure or medication and the reasonably foreseeable risks of such operation, procedure or medication. This information must be conveyed to the patient *in a way that is meaningful to the patient*, in words understandable to the patient, taking into consideration the patient's education, sophistication, and abilities to comprehend, so that after being properly apprised, the patient can make their own educated decision as to what treatment they accept and what

Continued on page 12

they refuse.[3] A decision made out of ignorance cannot possibly be an *informed* consent (or refusal).

It is this author's opinion that in practice, it is impossible for a woman to give a true informed consent for the use of Cytotec to induce labor. To get a true informed consent, a practitioner would have to inform the mother that the Cytotec manufacturer writes on the package insert that Cytotec should not be used to induce labor, and it is absolutely contra-indicated for any use in a pregnant woman. [If the patient were given a prescription for Cytotec to fill at a pharmacy, rather than having someone administer it in a hospital setting, she would get the package insert and could read this for herself.] Searle, Cytotec's manufacturer, says: "CYTOTEC (MISOPROSTOL) ADMINISTRATION TO WOMEN WHO ARE PREGNANT CAN CAUSE ABORTION, PREMATURE BIRTH, OR BIRTH DEFECTS. UTERINE RUPTURE HAS BEEN REPORTED WHEN CYTOTEC WAS ADMINISTERED IN PREGNANT WOMEN TO INDUCE LABOR OR TO INDUCE ABORTION BEYOND THE EIGHTH WEEK OF PREGNANCY. . . . A major adverse effect of the obstetrical use of Cytotec is hyperstimulation of the uterus, which may progress to uterine tetany with marked impairment of uteroplacental blood flow, uterine rupture (requiring surgical repair, hysterectomy, and/or salpingo-oophorectomy), or amniotic fluid embolism, pelvic pain, retained placenta, severe bleeding, shock, fetal bradycardia, and even fetal and maternal death have been reported. In fact, Searle considers its product to be so dangerous that it sent a "Dear Doctor" letter to every physician in the country warning them not to give Cytotec to their pregnant patients. (Searle did this to insulate itself from liability. If a woman has problems due to Cytotec, you can't go back to the manufacturer and sue them. The manufacturer said 'Don't do it!')"

If a doctor actually gave a patient this information - which is right there on the paper that is in every package of Cytotec - no informed woman would EVER consent to taking this drug except out of abject desperation. Therefore, the only reason women can

Bower - Plaintiff's Attorney: Continued from Page 11

be given Cytotec is that doctors routinely WITHHOLD this information. Then, when a disaster occurs, the doctors express shock and amazement, and claim they had no idea this could happen, or deny the causal relationship. But the warning that it can happen is published and printed with each bottle of Cytotec.

Thus, this author's logical conclusion is that any woman and her child, whose childbirth resulted in a Cytotec disaster, have a good case of malpractice for lack of informed consent.

Endnotes

[1]In our experience, the delivery personnel confronted with Cytotec catastrophes invariably deny causal connection, contending that the temporal relationship between hypertonicity, uterine rupture, and Cytotec is coincidental. In one case, they went so far as to re-define hypertonicity, so that given their unconventional and self-serving definition, there was no hypertonicity despite the self-evident patterns on the fetal monitor strips.

While shocking at first, on further thought, these people had no choice but to deny the causal connection. When offering the mother Cytotec, they never told her "this drug might cause your uterus to rupture". Since the mother was never told of this major risk, the delivery people had no choice but to deny that the risk was realized.

[2] http://www.acog.org/from_home/publications/ethics/ethics009.pdf

LITIGATION INVOLVING CYTOTEC IN THE NEWS

from the Ft. Worth Star Telegram:

A Texas Ob/Gyn was placed on five years' probation and was required to attend 25 hours of classes for high-risk obstetrics training and 25 hours of continuing education classes. He was also ordered to pay $50,000 penalty.

The action was based on allegations that this physician failed to properly monitor a baby during the last stages of delivery, improperly used Cytotec to induce labor when there were indications that its use might be harmful, and failed to timely perform a C-section, all of which resulted in an emergency hysterectomy for the mother and brain damage to the child. He reportedly used excessive amounts of Cytotec to induce labor after failing to inform the patient that the drug had not been approved by the Food and Drug Administration for use in labor and delivery. Another charge was that he failed to inform the patient that Cytotec, the brand name for Misoprostol, could increase the chance of uterine rupture when the patient has previous pregnancies. The patient had three prior pregnancies, according to board documents.

INTERNET RESOURCES: SELECT LINKS FROM THE WEBSITE, WWW.CYTOTECCASE.COM

- **Association of Nurse Advocates for Childbirth Solutions: http://anacs.org/html/index.php**

Founded by a registered nurse dedicated to excellence in the care of mothers, this site has been honored by Nurses~4~ Nurses and received the Golden Nursing Excellence Award! ANACS covers a diverse set of issues including birthing options, informed consent of mothers, breastfeeding, using doulas, circumcision, nursing practice and parenting issues, as well as ongoing updates in the status of the Cytotec controversy..

- **DrugIntel: http://www.drugintel.com/drugs/cytotec.htm**

DrugIntel furnishes scientific and medical information about potentially major side effects of drugs to professionals and the public. The information is provided to healthcare professionals and also focuses on debate in the litigation arena, in the public interest. Consumers are aided to find best pharmaceutical information to use in consultation with the best medical expertise concerning drug effects. The President of DrugIntel.com is a specialist in all aspects of drug research and development.

- **Midwife Archives: http://www.gentlebirth.org/archives/cytotec.html**

The Midwife Archives is a collection of information about all aspects of pregnancy, birth and well-woman care from a midwifery perspective.

- **Misoprostol (Cytotec) for Labor Induction: A Cautionary Tale** and **Cytotec Induction and Off-Label Use by Marsden Wagner, MD, MS: http://www.midwiferytoday.com/articles/cytotecwagner.asp**

Marsden Wagner, MD, is a neonatologist and perinatal epidemiologist. He was responsible for maternal and child health in the European Regional Office of the World Health Organization for 14 years. Now living in Washington, D.C., he travels the world talking about appropriate uses of technology in birth and utilizing midwives for the best outcome.

- **Induced and Seduced: The Dangers of Cytotec, *Issue 107, July/August 2001,* By Ina May Gaskin: http://www.mothering.com/11-0-0/html/11-2-0/11-2-cytotec107.shtml**

A review of an adverse outcome due to the use of Cytotec for cervical ripening and a summary of other related Cytotec issues in Mothering magazine, Issue #118

- **Virginia Birthing Freedom: http://www.vbfree.org/cytotec/why.html**

This site is an interesting collection of data and excerpts of data relating to labor induction. For example, an excerpt from the Journal of the American Medical Society:: " Elective induction of labor is associated with a significantly increased risk of cesarean delivery in nulliparous women. Avoiding labor induction in settings of unproved benefit may aid efforts to reduce the primary cesarean delivery rate." *from: JAMA,. Obtsterics and Gynecology. Vol. 94, pp. 600-607, Oct. 1999* .

- **Cytotec and Drugs in Labor: http://www.midwiferytoday.com/cytotec/**

Learn about the effects of drugs used during labor and other interventions.

What is a "Tort," Anyway?

by Alan Meisel

Alan Meisel is Professor of Law and the Dickie, McCamey & Chilcote Professor of Bioethics at the University of Pittsburgh.

If you are interested in learning more about the law of torts—or other areas of law—consider enrolling in the Master of Studies in Law (MSL) Program at the University of Pittsburgh. For more information on the 20 different concentrations in this program—including health law—go to www.law.pitt.edu/msl or write to msl@law.pitt.edu.

There is much in the news about "tort reform." This is especially true for health care professionals. But many people probably do not know what a tort—and the law of torts—is.

The law of torts has been a part of American law since colonial times. It is derived from the English law of torts which has beginnings going back in one form or another over 800 years. Tort law is almost predominately judge-made law. Tort law has been, and continues to be made, whenever one person sues another charging that he has been harmed by that other person's conduct. Only rarely has the legislature stepped in to pass "laws"—what are technically known as statutes or legislation—to change tort law.

A tort is a harm caused to a person or property by the actions of another. Torts are civil offenses (as opposed to criminal offenses). In a civil offense, the party who causes the harm is liable to the injured party for the damages he or she has caused. Some torts are intentional (such as battery and assault), and others occur accidentally and are referred to as negligence.

One *intentional* tort that a nurse might be faced with is battery. In order for there to be a battery, a person must perform an act with the intent to cause harmful or offensive contact to another. For example, if a nurse administers a drug to a patient that the nurse knows will be harmful to the patient and the drug does indeed harm the patient, a battery has been committed. The nurse administered the drug (the "act') that the nurse knew would be harmful ("intent") and because of this ("cause") the patient is harmed ("consequences").

In some circumstances, a nurse is allowed to treat a patient without being subject to liability for battery because of two legal defenses: consent and privilege. If there is consent or if there is a privilege, the person causing the harm is excused from liability for what would otherwise be a tort.

Consent may be express or implied. Express consent is usually verbal, and it may be written or oral. The nurse may ask if he or she can give the patient a particular treatment and the patient says "Yes" or responds in some other verbal, affirmative manner. Consent is implied when the manner in which a patient behaves lets the nurse know that the patient agrees to the treatment. For example, if a nurse tells a patient that he needs to give the patient a vaccination and the patient lifts the sleeve of his shirt and puts out his arm, the patient's actions imply that consent is being given. The patient agreed to the vaccination in every way except by verbally saying "Yes."

In order to give consent, one must have the capacity to do so. Children are ordinarily not considered to have the capacity to consent. People in seriously debilitated conditions, such as those

Continued on page 15

who are unconscious or mentally handicapped, often do not have the capacity to consent either. And consent may be withdrawn as long as it is still feasible to do so.

A privilege has the same effect as consent. A nurse is legally privileged to treat a patient without the patient's consent if it is in the patient's or the public's interest to be treated and the failure to do so could cause substantial harm to the public and sometimes to the patient. However, this must be balanced against the patient's very strong right to refuse treatment, and therefore the scope of privilege to treat without consent is very narrow. One example is an emergency in which the patient is unable to consent. Also, in a public health emergency, a patient might be able to be treated without consent. An example would be if there is an outbreak of a certain illness and the only way to prevent a very harmful spread of it was to vaccinate a patient against his will. The nurse would probably be protected from liability for battery in this situation as well.

Negligence is the other tort relevant to the nurse-patient relationship. The elements of the tort of negligence are duty, breach, causation and damages. That is, if one owes another a duty, breaches that duty, and the breach of the duty causes damages, one is liable for negligence. Everyone owes a duty to use ""reasonable care to conduct their affairs so as to avoid harming other people or their property. "Reasonable care" is the same level of care that other nurses under similar circumstances would use. A breach of duty would occur if the nurse failed to use reasonable care. If, as a result the patient were harmed, the nurse would be subject to liability.

For example, if the standard treatment for the illness is Treatment A but the nurse administers Treatment B and the patient is harmed because of it, the nurse could be found to have been negligent. There is no requirement of intent to harm in negligence. The nurse might have administered the improper remedy by accident, or because he or she did not know what the proper remedy was. Either way, the nurse was still negligent if his or her conduct departed from the standard that a reasonable nurse would follow in such a situation.

An important defense to negligence is comparative or contributory negligence. Sometimes, when a person is negligent and that negligence causes another person harm, the injured party may also be partially responsible for the harm. For example, suppose that a nurse decides that she is going to attempt a procedure that she has never done before and doesn't really know how to perform. She tells the patient not to move so that the patient won't get hurt, but the patient tries to get up and is indeed hurt. If the patient was hurt due to *both* the nurse's negligence (attempting a procedure he didn't know how to administer) and the patient's own negligence (trying to get up when she was told by the nurse not to), then it could be a case where the patient could be found to have negligently contributed to her own harm.

Until the last quarter of the last century, most states refused to impose liability if the patient were negligent too. Today, however, in most states the fault between the parties is divided up in proportion to their degree of negligence. Thus, if the nurse were found to be 60% at fault, because he attempted a procedure he knew he couldn't perform, and the patient was 40% negligent because she moved even though the nurse told her not to, the patient would be able to recover that portion (60%) of her damages caused by the nurse's negligence, but not any of the damages caused by her own negligence.

Principles of tort law pervade almost every aspect of both daily life and professional life. A knowledge of basic principles of tort law can be useful in avoiding liability, in understanding one's professional responsibilities, and it acting in conformity with them. Law is so extensive today that, as in the health professions, lawyers increasingly tend to be specialists. Tort law is only one small corner of the law. Nonetheless, it—along with criminal law, property law, and contracts—is such a fundamental part of law that all lawyers are required to study it and know its basic principles.

End

Pittsburgh Chapter
AALNC
PO Box 97104
Pittsburgh, PA 15229-0104

Phone:
412.939.3426

Fax:
412.939.3427

E-mail:
kesrehab@aol.com

Website:
http://
www.PittsburghChapterAALNC.org

about
THE LiNC

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Nursine S. Jackson, MSN, RN
E-mail: *Nursine@JacksonLaw.net*

ABOUT OUT CHAPTER

Monthly Meeting Information

The Pittsburgh Chapter meets the second Wednesday of every month (except during the summer). The Law Offices of Dickie McCamie have graciously hosted our monthly meetings, however please confirm the meeting location each month on the Calendar of Events page of our website to verify the meeting location has not been changed due to a special event. Non-members are welcome to educational presentations. If you have questions about upcoming events, contact Costantini Rehab: 412.939.3426, or visit our Website: *http://www.PittsburghChapterAALNC.org*.

Educational Programming

If you have a topic that you would like to have presented at a meeting, recommendations for a speaker, a new site, or other ideas for enhancing our monthly meetings, please speak with our Programming Chairperson, Patty Costantini.

Membership Inquiries

Information about joining this organization is available through our Membership Chairperson, Patty Costantini at Costantini Rehab. Call 412.939.3426; FAX 412.939.3427, or e-mail: kesrehab@aol.com.

Speaker's Bureau Inquiries

Do you need a speaker for an upcoming meeting? The Speakers Bureau is a free service to Medical-Legal Community. The Pittsburgh Chapter of AALNC provides experienced LNC's who are prepared to speak on a variety of nursing, healthcare and legal topics.

Pittsburgh Chapter Business Directory

Are you seeking a nurse expert, or an LNC to consult with or to develop a case for you? You may find an LNC within our chapter who has the specific expertise you need, and who is interested in providing consultative services . Peruse our Business Directory on our Webpage. A Pittsburgh Chapter LNC may very well have the skills you need.

The Pittsburgh Chapter does not, in any way guarantee the work of the members who are listed in this directory .