The Journal of
Legal Nurse Consulting

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▲ DUI/DWI: Hospital Lab Testing (CNE Program Article)
▲ “Daylight Obstetrics”
▲ The Disclosure of Unanticipated Medical Outcomes
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The Journal of Legal Nurse Consulting

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The purpose of The Journal is to promote legal nurse consulting within the medical-legal community; to provide both novice and experienced legal nurse consultants (LNCs) with a quality professional publication; and to teach and inform LNCs about clinical practice, current legal issues, and professional development.

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This article has been selected for inclusion in the 2009 JLNC Nursing Contact Hour Program. Participants of the program will be able to earn CNE credits for completion of an online post-test on this article. Please see the conclusion of the article for more detailed instructions.

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As the practice of “daylight obstetrics” increases in the United States, women are often subjected to unapproved medications to induce labor. This trend in American culture, to attempt to control what nature has worked out perfectly, can have some inconvenient and sometimes devastating effects. The LNC reviewing medical records in obstetrical cases must consider the care given to the obstetric patient and make connections regarding bad outcomes related to medications and procedures. The LNC should evaluate how informed the patient was in her decisions to induce her labor, and be sure that she received information regarding appropriate alternatives.

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Communication is the foundation of every aspect of health care. Dangerous situations are created when physicians, nurses, pharmacists, and support staff do not communicate clearly with one another. Good communication skills are essential to help preserve the physician-patient relationship when things do not go as expected. This article discusses a physician-owned liability insurance company’s approach to creating a disclosure program, highlighting the challenges created by disclosure and the role of the LNC as potentially the first person to explain to a patient what actually happened after the review of the medical records.

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Dear Readers:

We have just passed the time of year where television is dominated by themes of celebrations, family gatherings, and seasonal music. This medium can make us laugh, inspire our spirituality, or trigger fond memories. Fortunately, the forum is also used to imprint messages of social responsibility. To me, the most powerful and compelling of these are the those that innocently begin with warm and joyous family moments such as a handsome teenage boy opening a birthday present from his grandparents or the audible laughter as a toddler takes their deliberate first steps toward the camera. I brace myself as the inevitable white letters flash onto the black background: a simple date, location, and the words "Killed by a drunk driver." I am at once emotionally shaken by the tremendous loss and forever touched by the families who, even through their unimaginable pain, share these memories and insight into their profound heartbreak to somehow, somewhere prevent future tragedies. To these families, I say thank you. The effort of your message finds its mark. I respectfully remind our readers to responsibly and safely enjoy all celebrations now and throughout the year.

Driving under the influence is the topic of this issue’s lead article. Undeniably, our legal system provides occasional cracks into which justice falls. Legal technicalities may provide escape from valid charges or false accusations may imprison the truly innocent. With the celebrity status of forensic science, Joe Citron illuminates the process of testing of BAC, which requires the utmost attention to detail and the proper equipment. Initiating our CEU offering, the author offers an instructive article that not only informs but provides the opportunity for the reader to test their understanding.

In emergent situations and where clinically indicated, the obstetrician familiar with the intrapartum progression of the laboring women may need to intervene. However, this issue’s submission by Tammey Dickerson makes the observation that, at a time when women is often at her most vulnerable, the decision to medically control an otherwise naturally progressing course of labor may be capriciously made.

Elizabeth Bridgeman offers a comprehensive look at one insurance company’s founding movement to incorporate apology laws into their risk management program. With a background in defense, Ms. Bridgeman brings a unique perspective as co-founder of the program.

From a case study perspective, Bill Sheehan, Corey Sperweik, and Kathleen Ashton have provided an informative piece on celiac disease. This Working World column takes an extensive look at a frequently misdiagnosed condition.

Our Questions & Answers column by the Kentucky Chapter addresses and answers many of the questions the new LNC will have with regard to the process of billing, tracking and collecting fees.

The Clinical Maxim is a new column designed to focus on a specific disease or diagnosis and the factors important to the LNC’s review. The Journal is interested in your submissions for this area and topic suggestions for what you, as the reader, would like to see addressed in this column. As always, I welcome suggestions from the readership for future topics for all Journal features.

Best regards,

Kara DiCecco, MSN RN LNCC

Kara DiCecco, MSN RN LNCC
Editor, The Journal of Legal Nurse Consulting
DUI/DWI: Hospital Laboratory Testing Lacks Forensic Reliability

Joseph Citron

There are several scenarios where a hospital laboratory will be involved in determining alcohol concentration. It will be shown, however, that the hospital-determined alcohol concentration lacks the forensic reliability needed for courtroom settings. This article serves as a primer for the legal nurse consultant working with cases involving alleged driving under the influence or driving while impaired. Among other topics, collection of blood specimens, the chain of custody, storage, and blood alcohol concentration analysis are the critical concerns that are covered. This article has been selected for inclusion in the 2009 JLNC Nursing Contact Hour Program. Participants of the program will be able to earn CNE credits for completion of an online post-test on this article. Please see the conclusion of the article for more detailed instructions.

Cases of driving under the influence (DUI) or driving while impaired (DWI) can involve hospital laboratories. The usual circumstance occurs when an accident results and drawing a blood alcohol test is part of the emergency department protocol. Another possible involvement of the hospital lab is when an arrestee requests an independent blood test of his blood alcohol concentration (BAC) after submitting to the state-administered breath test or the arresting officer requests a blood test instead of the breath test. Such lab results, however, lack forensic reliability and therefore are not acceptable as legal evidence (Garriott, 1996).

Civil litigation attorneys are very interested in accurately identifying a party with an alcohol level at the time of incident. The value of settlements and verdicts are greatly enhanced by which other forms of BAC determinations are compared in the final measurement, or the chemical measurement can be of the total of alcohol concentration that could include extraneous contaminants (Jain, 1971; Solon, 1972).

Erich Widmark, a Sweden-based physiologist, established a formula to determine blood alcohol levels when certain factors are known. These factors include gender, weight, amount of alcohol, drinking pattern, and drinking timeframe. This eponymous formula is still the benchmark by which other forms of BAC determinations are compared (Widmark, 1981).

A 1992 Texas case, Mata v. State of Texas, challenged retrograde determination of BAC by requiring testifying experts to possess sufficient information about the factors of the case, including gender, weight, drinking pattern, and timeframe. The expert must have the ability to apply the science of the retrograde extrapolation and an understanding of the difficulties associated with the process such as delayed alcohol absorption caused by the presence of food in the stomach and the competition for liver metabolism sites by drugs (Mehta, 1996). There is a 20% margin of error associated with the Widmark formula when used in retrograde extrapolations (Widmark, 1981).

In legal settings, BAC is expressed as grams of alcohol in deciliters of whole blood. Many hospital lab machines do not use these denominations, so there is a need to shift decimal points to conform with the legal formulation (Harding, 2008). For example, a BAC of .08% means that there is .08 grams of alcohol in a deciliter of whole blood; a hospital lab might report this as .80 gm/ml (grams/milliliter).

The United States and Western European communities of toxicologists agreed to maintain the metric units in regard to alcohol concentrations and not use the International System of Units (SI) that were adopted in 1986 by the Journal of the American Medical Association (Lundberg, 1988). As a result, metric units are currently used universally. Blood alcohol concentrations are typically reported to the second decimal point, and the remaining numbers are dropped. This is called truncation. For example, determinations of .081% and .087% are both reported as .08% (Gullberg 1991).

**Collection**

Venipuncture, the act of drawing blood from someone’s veins, for a BAC specimen must be performed without any extraneous alcohol exposure from the skin prep. If isopropyl alcohol is used to clean the skin prior to venipuncture, it is possible to contaminate the vacutainer tube because of the vacuum within the blood tube. Alcohol on the skin may be pulled into the tube. It is recommended to use a non-alcohol skin cleanser for site preparation such as povidine iodine or zepharin. Depending on the technique used to measure alcohol concentration, contamination can be discovered and excluded in the final measurement, or the chemical measurement can be of the total of alcohol concentration that could include extraneous contaminants (Jain, 1971; Solon, 1972).

Depending on the hospital lab equipment, there are several, albeit very different, tubes for the blood collection. A whole blood specimen is collected in grey top tubes containing...
specimen is contaminated with isopropyl alcohol from the skin disinfectant, the ADH will react with the isopropyl and yield an alcohol concentration reading higher than that of the ethanol content alone.

EIA testing really measures the amount of NADH, one of the enzymes used in oxidizing the alcohol to acetaldehyde. NADH, the reduced form of NAD, is measured directly by a colorimetric device at 340 nm. This colorimetric device is part of the hospital laboratory machine. This is a purple hue, with the intensity of the color indicating the concentration of the NADH produced. NADH production is directly related to the amount of alcohol oxidized to acetaldehyde (Cobras, 2003).

Most laboratories have automated machines using a spectrophotometer calibrated to 340nm. The 340nm wavelength is used to measure various blood chemistries such as electrolytes, glucose, BUN, etc. The processes are automated and rapid. A BAC can be measured within 20 minutes of the specimen arriving at the lab (Young, 2006). The EIA measurement process is, however, considered an indirect alcohol concentration determination because the amount of alcohol is not really measured. Instead, the alcohol concentration is determined by the known relationship of how much NAD is needed to oxidize a known amount of alcohol (Solon, 1972).

A variant to this measurement system is an indirect colorimetric system in which a dye is coupled to one of the enzymes and the amount of dye is measured indicating the amount of enzyme used. This adds an additional layer to this indirect measurement of alcohol concentration so that the alcohol concentration measurement is two stages away from the actual chemical being measured. Additional errors can occur with additional steps such as just described (Nine, 1995). For one, color contaminants to the serum can cause false readings. Hemolysis of the blood specimen adds color to the normally clear serum. Thus, hemolyzed specimens may cause false high readings of the EIA colorimetric determinations. This occurs for any of the testing resultants, whether trying to measure alcohol, electrolytes, or other components (Cobras, 2003). Best practices would indicate that any result tested be redrawn before basing any treatment decisions or legal consequences on the result.

As reported by Nine (1995), false positives can occur in the presence of lactated ringer’s IV solution because lactate is metabolized in the presence of NAD. This process produces NADH that is not related to any alcohol present or not present in the serum specimen. In emergency department settings, this is a common source of mistaken BAC levels. To avoid hemodiluted specimens, no blood specimens should be drawn from the same arm that has an IV line and certainly not above this is a common source of mistaken BAC levels. To avoid hemodiluted specimens, no blood specimens should be drawn from the same arm that has an IV line and certainly not above the IV site. Certain antibiotics can also give false positive or falsely elevated BAC measurements (Mehta, 1996). Each lab machine handbook has a list of the medications affecting the chemistry of the measuring process.

The EIA method has significant limitations. It cannot differentiate the quantities of ethanol (drinking alcohol) and isopropyl alcohol (Garriott, 1983). Additionally, EIA is a less

Transit and Storage

Specimens should be delivered to the lab directly after they are collected. The lab personnel receiving the specimen is a link in the chain of custody. While in transit, the specimens should be refrigerated as close to 4 degrees centigrade as possible. Hospital and state laboratories maintain policy procedures that require storage of specimens at 4 degrees centigrade for a certain time before discarding the specimens (Jones, 1999). Forensic specimens should be kept by the state laboratory for preservation of evidence.

If specimen testing is not done immediately upon blood draw, the specimen should be secured in a locked refrigerator. The ideal temperature range should preclude any chemical reactions from occurring within the specimen and prevent freezing, and 4 degrees centigrade is considered appropriate to address these two concerns (Jones, 1990).

Testing

Enzymatic Immunoassays

Most hospitals use a variation of enzymatic assay testing (known as enzymatic immunoassays, or EIAs) of serum. This technique lacks the specificity to measure only ethanol (drinking alcohol). EIA is the most common chemical process for BAC measurement, a serum preparation is mixed with the enzymes alcohol dehydrogenase and nicotinamide adenine dinucleotide (NAD). First described by Bonnichsen and Theorell in 1951, it remains the basis for hospital laboratory blood alcohol level determinations today.

Figure 1. Enzymatic Assay Testing.

| ALCOHOL DEHYDERGENASE        |
| NAD + == NADH + H +         |
| ALCOHOL ACETALDEHYDE        |
| NAD-NICOTINAMIDE ADENINE    |
| DINUCLEOTIDE                |

Alcohol dehydrogenase (ADH) is the primary enzyme in this reaction. It is not selective for ethanol and therefore will react with any alcohol present in the specimen. When a specimen is contaminated with isopropyl alcohol from the
desired method because it utilizes no individual internal quality controls. These deficits are countered by the ready availability of the machinery in every hospital lab and the rapidity of the measuring process.

Gas Chromatography

Gas chromatography (GC) is another technique used for determination of BAC. GC can measure each alcohol separately, and the results are graphed as individual quantities. The GC process involves using a vapor of the heated whole blood’s volatile content (alcohols) that is gas-propelled through a column packed with chemicals and resins. Each alcohol molecule travels through the column at a different rate of speed. This enables separation of the different blood volatiles for identification and quantification. Additionally, propanol, an internal control substance, is added to each sample and measured at the end of the column run. This is an internal quality control feature that is not available in the EIA method (Jain, 1971).

GC measurements are considered the gold standard for BAC determinations. The specificity of the technique for measuring ethanol and the internal quality control in each test are the prime reasons for this recognition (Solon and Baird, 1972). The process is, however, slower and more labor-intensive than that seen with EIA testing. Most hospitals do not possess a GC machine. The specimen has to be sent to a reference lab for GC analysis. The results are usually available within 24 to 48 hours after collection.

Serum vs. Whole Blood

Serum is the liquid portion of the blood without the cells and clotting factors. Alcohol concentrations will be higher in serum than in whole blood because there is less volume in the serum specimen. Alcohol does not move into the intracellular areas and is not part of the clotting factors. The alcohol in the blood stays with the serum as the volume of the cells and clotting proteins are removed (Young, 2006).

Unfortunately, there is no formula to convert serum alcohol concentration into the whole blood concentration level (Charlebois, 1996). The difference between whole blood BAC and serum BAC ranges from 9-32%, with the serum BAC level higher. There is no agreement among alcohol physiologists for a conversion factor or formula to convert serum to whole blood BAC levels. The conversion factor varies between 1.13 and 1.18, as noted in papers by Dotzauer, et al (1972) and Payne, et al (1968).

Forensic BAC

There are several reasons that BACs determined via the EIA method should be disqualified as possessing forensic value. The legal definition of intoxication per se is a BAC of .08%, based upon a whole blood measurement. Whether the reason for testing blood alcohol is for a commercial driver’s license (CDL), a per se level of .08%, or an under-age drinker, the laws are written in terms of alcohol concentration in whole blood (Georgia, 2006). The absence of a reliable conversion factor from serum to whole blood precludes the serum level as a forensic value.

All EIA process manufacturers have caveats in their handbooks that attempt to exclude the EIA-determined serum BAC value from being a forensic value. Some of the handbooks describe the EIA method as semi-quantitative and in need of clinical correlation. The intent is to have the physician interpret the numerical result in the context of the clinical findings (Cobras, 2003). As an illustration, a semi-comatose person with a low BAC needs further work-up to determine other factors, such as injuries or drugs, that account for the low level of consciousness. Similarly, a reported EIA-determined BAC of .60%, usually considered fatal, needs to be given little credibility when the patient is awake, oriented x3, and responsive to questions.

Roche Diagnostics, a manufacturer of blood analysis machines, states in the preamble of the operator’s manual, 2003 version for their Cobras Integra models 400, 700 and 800, that the readings from this machine are not intended for forensic purposes.

EIA test results for BAC should not be used anywhere outside of the clinical setting. The values are out of context when not used in the presence of the patient symptomatology or when not used by the physician in determining treatment or diagnostics.

GC is a whole blood measuring test. This complies with the legal requirement for the type of specimen tested. As the gold standard in more than 35 years of use, the GC test is used by every state and federal crime lab in this country for measuring BACs (Garriott, 1996). The process was first reported in 1971 by Jain. The inclusion of an internal standard in each test sample, in conjunction with duplicated testing for each sample, amplifies the high level of esteem for this testing method. The GC measurement can, therefore, be recognized as a valid BAC determination. When done correctly, GC is valid forensically and valid as an accurate process (Garriott, 1996).

Summary

Enzymatic immunoassays are preliminary tests and should be considered presumptive. Confirmatory gas chromatography testing is required. Determining an accurate blood alcohol concentration requires adherence to correct procedures – from the technique for venipuncture, chain of custody, transport, and storage to the laboratory. When all procedures and protocols are properly followed, the BAC value should be accurate and forensically valuable.

References
Joseph Citron, a Mayo Clinic-trained physician, has practiced medicine in Atlanta, Georgia for more than 25 years. In 1989, Citron started and was an active participant in American Clinical Laboratory, a medical reference laboratory. In 1997, he graduated from the Georgia State University College of Law and is a member of the Georgia Bar Association. Citron has written several chapters for DUI/DWI law books and lectured at many legal symposia on topics related to medicine. He currently consults on medical-related legal issues and is of counsel to the Barnes Law Group. He can be reached at joeccitron@aol.com.

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“Daylight obstetrics” is the increasing practice in the United States to deliver obstetrical care during daylight or bankers’ hours. Elective induction of labor and cesarean-on-demand are becoming more commonplace, often becoming the “norm” in obstetric health care. Labor and Delivery nurses will exclaim with awe, “My patient had a spontaneous labor and delivery today (last night)! What a nice experience.” This does not necessarily mean that the patient went without pain meds or did not have to push for a while. It means that there was no hurry to “get the baby out” by augmenting or inducing a patient in early or prodromal labor so birth will occur before the obstetricians’ bedtime, office hours, or surgical schedule.

When left to their own devices, such spontaneous deliveries occur with much fewer complications. Babies usually have the best judgment regarding when they should be born. Jackie Tillett, a practicing nurse midwife from Wisconsin, counsels her patients that “…birth is not convenient, infants are not convenient, and indeed parenting is not convenient” (Tillett, 2007, p. 3). Unfortunately, as society becomes more technological and the medical model is applied to low-risk pregnancy and birth, more patients and obstetricians will opt for the “ease” and “convenience” of scheduled labor and birth – not always without consequence. Women are often subjected to unapproved medications to induce labor, which can lead to devastating effects.

Induction

Induction of labor is the stimulus of labor before the uterus begins this process spontaneously. Induction can be medically necessary for several reasons including, but not limited to, pregnancy greater than 42 weeks gestation, A1 or A2 diabetes, and pregnancy induced hypertension (PIH), when the uterine environment is no longer conducive to fetal survival. It is necessary to weigh the risks and benefits of allowing the pregnancy to continue vs. a timely delivery that may increase the risks of cesarean section and a premature infant requiring extended care in a neonatal special care unit or even lifetime care.

Elective induction of labor can be defined as “induction of labor without any obvious recorded medical or obstetric reason” (Rayburn, 2007, p. 671). Induction of labor in America is climbing at an alarming rate, with up to 53% of inductions being elective (Simpson and Atterbury, 2003). While some reasons for elective induction are geographical, social, and psychological, the greatest percentage of elective induction are done for patient and/or physician convenience, more often in community hospitals than in large educational facilities (Rayburn, 2007).

Induction of labor for convenience (the so-called “daylight obstetrics”) often leads to some very inconvenient circumstances and can have long-term effects on the woman, the infant, and health care economics. Women seek and/or are encouraged to be electively induced but are often unhappy and disappointed with the result for themselves or their infant. This brings into play litigation, adding even further stress to the health care and insurance systems.

Maternal outcomes related to elective induction include an increased risk of long labor, more pain, uterine hyperstimulation, and fever and infection due to prolonged rupture of membranes. Women can experience cervical, vaginal, and perineal lacerations, which can impinge on future sexual intercourse for her and her partner. There is also increased risk for hysterectomy in the event of uterine rupture and placental abruption if maternal bleeding can not be stopped. Pulmonary or amniotic fluid emboli have been known to occur, especially with uterine rupture and postpartum hemorrhage. Any of these events can potentially lead to posttraumatic stress disorder due to the urgency and frightening chain of events, not only for the mother but for the father as well. Maternal death can also occur and is devastating to all involved (Cunningham, et al., 2000; Simpson and Atterbury, 2003; Simpson and Thorman, 2005; Wagner, 2004; Wing, 2007).

There are also several risks to the fetus/newborn. Some infants develop respiratory distress syndrome because their lungs are not mature at the time of induction. There is
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increased “risk of iatrogenic fetal prematurity and potential admission to the neonatal intensive care unit if estimations of gestational age are inaccurate” (Simpson and Atterbury, 2003, p. 770). The American College of Obstetrics and Gynecology (ACOG) (1999) states that fetal lung maturity needs to be established before elective induction is implemented. Inductions most often include internal fetal and uterine monitoring, which allows bacteria access to the uterus and the fetus. Elective induction also increases the infant’s risk of hypoxic ischemic encephalopathy and cerebral palsy due to uterine hyperstimulation, which leads to a decrease in the oxygenation of placenta and fetus (Wagner, 2004). Premature birth and the need for forceps or vacuum delivery or cesarean section often occur, resulting in a traumatized infant requiring short- or long-term specialized care and, therefore, more financial resources.

In order to begin an induction, an artificial stimulus needs to be applied to start contractions, usually by chemical means. There is often a need for intravenous medication, forced bed rest, continuous fetal monitoring, increased pain, and increased need for analgesia and anesthesia. Wing states, “Elective induction of nulliparous women appears to double their risk of operative delivery” (2007, p. 2). If a woman is unable to deliver vaginally and has a cesarean section, she will most likely be subjected to cesarean sections for any subsequent births.

**Induction Medication**

Misoprostol (Cytotec), a prostaglandin E1, is used off-label to induce labor. Developed to decrease production of stomach acid to minimize the risk of ulcers for patients taking high-potency anti-inflammatory medications, Misoprostol also causes significant uterine contractions. In the obstetric patient, it has been used since the late 1980s for a myriad of treatments and complications. In early pregnancy, it can be used for abortion and is found in emergency birth control as part of the RU486, known as the morning after pill. It is also used for second trimester abortions, legally and illegally, elective abortions, or abortions due to fetal deformity. Finally, it is used for post-delivery to control hemorrhage due to uterine atony.

Misoprostol sounds like a wonder drug. Why is it used for gastrointestinal issues when it has so many obstetric uses? Unfortunately, this medication comes with many known safety risks, such as uterine hyperstimulation, which can lead to fetal distress, placental abruption, and uterine rupture, to name a few potential complications. Other medications can be used for each of these situations that are approved by the Food and Drug Administration (FDA) and have been tested and used safely in obstetrics for years.

In 1999, ACOG made a statement in Committee Opinion #228 regarding the use of Misoprostol for the induction of labor. ACOG stated that Misoprostol had been found more stable (not needing refrigeration or mixing), less expensive, and effective for induction of labor. ACOG goes on to state that, although the FDA had approved it for gastrointestinal use, it was not approved for obstetric uses. Searle, the company that manufactures the drug, would not be pursuing approval for this indication. In 2000, Searle sent a letter, written by Dr. Michael Cullen, to thousands of obstetric/gynecologic (OB/GYN) practitioners in the United States. Dr. Cullen advised them that Misoprostol was not tested for use in obstetrics and was known to have significant risks to both mother and fetus:

“Serious adverse events reported following the off-label use of Cytotec in pregnant women include maternal and fetal death, uterine hyperstimulation, rupture or perforation requiring uterine surgical repair, hysterection or salpingo-oophorectomy; amniotic fluid embolism, severe vaginal bleeding, retained placenta, shock, fetal bradycardia, and pelvic pain” (para. 4).

Cullen (2000) also cautions in the letter “...the effect of Cytotec (Misoprostol) on the later growth, development, and functional maturation of the child when Cytotec is used for induction of labor has not yet been established” (para. 5). ACOG rebutted this letter with a petition to the FDA, asking for the labeling on Misoprostol to be changed in order to include obstetric uses. ACOG disputed every one of these requests, and the FDA continues to allow Misoprostol to be used in obstetric care, despite maternal and fetal death being a significant complication. Not only does the FDA continue to sanction this use; it has also bent to ACOG’s pleas and allowed a change in the labeling to include a section for induction of labor.

Misoprostol has never had appropriate testing for use in induction. The trials that have been done are too small and were done on term healthy pregnancies. The studies were not done on pregnancies where the placenta is compromised by high blood pressure, diabetes, renal disorder, or prematurity. There have been no long-term studies on the effects of the fetus into childhood or adolescence.

Misoprostol can be given orally or intravaginally. There are various studies regarding the efficacy of each method, but there have been no firm conclusions. Once it is in place, there is no removing it. Misoprostol is not controllable, and it is difficult to predict how it will affect each patient. Some patients start to contract almost immediately, others not for several hours. For those needing subsequent doses, there is a cumulative effect. Wilson (2000) cautions; “The appropriate dosage, route, and timing of misoprostol administration within safety limits have yet to be determined” (p. 576).

Although Misoprostol is inexpensive, easy to store, easy to administer, and can be a rather effective induction agent, it can cause violent and traumatic birth. The labor caused by Misoprostol is often extremely painful and can be very rapid. There have been no qualitative studies addressing how women who are induced with Misoprostol regard the event. Along with all of the risks mentioned in Searle’s letter, it has been known to cause abruption of the placenta, fetal distress,
severe maternal cervical and vaginal lacerations, and potential post-traumatic stress syndrome to the mother and/or father due to the violent birth and complications (Wagner, 2004). Obstetricians tend to define safety as “...the absence of adverse outcome” (Lyndon, 2008, p. 16), often considering anything short of death to the mother or infant a good outcome.

Implications of Induction

A change is needed in practice regarding elective inductions. Women, children, and our health care dollars are at stake. ACOG encourages all physicians to use evidence-based practice, meaning that all clinical care should be based on relevant and well-developed studies. ACOG is, however, a political body and, as with many political institutions, speaks from both sides of its mouth. ACOG Practice Bulletin #10 states that “the benefits of labor induction must be weighed against the potential maternal or fetal risks associated with this procedure” (1999, p. 562). Despite this statement, ACOG also states that “psychosocial reasons” are adequate reasons for induction. Wagner (2004) states that many prestigious medical journals have questioned standards of practice encouraged by associations like ACOG. Although ACOG states its commitment to women’s health through its goal of the health and protection of women through evidence-based care, ACOG ignores the best scientific evidence available through scientific bodies such as the Cochrane Firm and the pharmaceutical companies that manufacture the medications used for induction.

Changes in clinical practice are not easy when ACOG does not take a firm negative stance regarding a procedure that is proven to increase risks to mother and child and ultimately costs more in health care dollars. Insurance companies have a vested interest in this practice – not only those paying for the care, but those that will need to pay the cost of litigation should the patient be unhappy with the outcome of her induction. Insurance companies have dominion over many treatments and procedures used in health care practice today. Since elective inductions have been shown, with scientific evidence, to cost more money (Santana, Mayer, and Flake, 2006), it is surprising that the medical insurance companies have allowed this trend to continue and increase. If the health insurance companies were to refuse to pay for any cesarean section that was required due to failed elective induction or for the care of a patient whose labor was induced without a documented medical reason, it is certain that these inductions for convenience would cease. If malpractice liability insurance companies refused to pay litigation costs for those who are electively induced and have a poor outcome, physicians would rapidly stop recommending this option.

This country is seeing a significant rise in the number of elective inductions for patient and/or physician convenience, which is putting a burden on our health care facilities, nursing staff, health care economics, legal system, and sometimes quality of life for mother and/or infant. While there will always be reasons to induce labor, it should be decided with the utmost care in regards to the mother and infant. The patient needs to know all the risks and benefits involved in the process, even the risks that are not so pleasant. Simpson and Thorman (2005) give the following opinion regarding elective induction and safe care:

“If safe care for mothers and infants is the collective goal, then obstetrical interventions should provide clear benefits for the mothers and infants as a primary consideration. Mothers should be fully informed of potential risks, benefits, and alternative approaches by their primary health care providers and given the option to choose what is best for them on the basis of available evidence and individual clinical situations” (p. 134).

Case Studies

The following cases are clinical experiences. These are examples of clinical outcomes that could have been much worse and even fatal to the mother and infant. There are hundreds of cases out there, both clinical and legal, regarding induction and especially induction with Misoprostol.

Case 1

Mrs. B is a 38-year-old gravida 7 para 3. Her obstetric history includes dilatation and curettage for two missed abortions and a spontaneous miscarriage. At 39 weeks of pregnancy, Mrs. B was diagnosed with mild preeclampsia and was admitted for induction of labor at 09:00 on Monday morning. Following admission, the first dose of Misoprostol 25mcg was placed vaginally. Mrs. B was monitored for 2 hours and was off the fetal monitor to ambulate for 1 hour. Mrs. B had a total of three doses of Misoprostol and had minimal cervical change by 20:00 that evening and was started on Pitocin. The Pitocin was increased by two milliunits every 15 minutes until she reached 20 milliunits, and the pitocin was left at that rate. At 04:00 on Tuesday morning, Mrs. B spontaneously ruptured membranes. On cervical exam, she was four centimeters dilated. Mrs. B’s contractions did not trace well on the monitor, and on palpation it was difficult to assess the strength and frequency of the contractions. At 07:00, she requested an epidural and hydration was initiated. Mrs. B’s fetal heart monitor strip was evaluated, and the nurse requested internal monitoring for contractions and the fetal heart rate tracing. The fetal heart rate pattern was non-reassuring, and assessment of uterine contractions was difficult. The nurse and Mrs. B’s attending physician concluded that internal monitoring of baby and contractions would be initiated following epidural placement. Mrs. B sat at bedside for epidural placement. Following epidural placement, Mrs. B stated that she felt an urge to push; she was examined and found to be ten centimeters. She was encouraged to push and with the second push the baby decelerated down to 60 bpm and stayed there although interuterine resuscitation was initiated. Mrs. B was rushed to the operating room for a stat cesarean section. When the uterine incision was preformed, the physician had great difficulty locating the baby. Mrs. B had ruptured her upper uterine segment on the posterior side, and the baby was in her abdominal cavity. Baby B was
resuscitated and received apgars of 3, 6, 8 at 1, 5, and 10 minutes. She was brought to the neonatal intensive care unit (NICU), where she was treated with induced hypothermia and transferred to a larger NICU. The physician was able to repair Mrs. B’s uterus, and there was no damage to her other organs, although there was need for a urology consult during the cesarean for a question of damage to a ureter. The surgery lasted 3 hours and recovery another 2 hours. Mrs. B was sent to the main post-anesthesia care unit (PACU) due to the general anesthesia and the need for blood transfusions. She was then transferred to the ICU for 2 days and to a general surgical floor for 5 more days until discharge. Mrs. B did not see her baby until she was discharged. On day 4, Baby B had undergone an EEG and MRI of her head and both were declared normal.

Some points to consider:
1. Mrs. B had a “normal” BP for the entire induction, and there was trace protein in her urine. Her elective induction for preeclampsia was a “soft call” made by her physician.
2. There are very few studies done using Misoprostol on gravid multiparous women or preeclampsics. “According to Wing and Paul (1999), among the maternal factors for exclusion are grand multiparity and previous uterine scar” (Wilson, 2000, p. 579). Wilson goes on to acknowledge that ACOG (1999), and Pfalutz, Schwartz, and Lubarsky’s study (as cited in Wilson, 2000) warn that scarring from previous uterine surgery (not just cesarean section) increase the risk of uterine rupture (2000).
3. Experience shows that Misoprostol can work in 1 hour, and it can also start to work as late as 12 hours after the initial dose, and the dosing seems to have cumulative effect with some patients.
4. Mrs. B should have been internally monitored for contractions as soon as it was possible in order to adequately evaluate the strength of the contractions, especially running high-dose Pitocin following three doses of Misoprostol.
5. Mrs. B’s uterus most likely was very thin due to all of the pregnancies and surgical interventions. Her cervix may have been scarred from the dilatation and curettages and therefore put more strain on her uterus because it was not dilating easily.
6. Mrs. B had a very high pain tolerance as she did not ask for pain relief until 22 hours after her induction began. It is difficult to use pain scale as multips tend to rate pain lower than primips while in labor.
7. Possibly Mrs. B had incurred a puncture through her uterus during one of the dilatation and curettages. Her uterus ruptured on the upper half of her uterus on the posterior side. So Cesarean section scar is not the only risk to ruptured uterus with Misoprostol and/or Pitocin.

Case #2
Mrs. S, Gravida 1 Para 0, 34 weeks gestational age, presented to Labor and Delivery with rupture of membranes and some mild contractions at 07:30 (spontaneous rupture of membranes had occurred at 05:30). Her rupture of membranes was evaluated and documented as positive. Fetal heart rate tracing showed reassuring heart rate with accelerations and moderate variability. She was given 500 million units of Penicillin G prophalactically for unknown group B Beta strep infection status. Mrs. S had been ruptured for 2 hours and was showing some signs of labor, with contractions coming every 3–4 minutes. The attending physician made the decision to augment the labor with Misoprostol 25mcg vaginally, although the cervix was not assessed for dilatation. The physician inserted the Misoprostol into her cervix with an applicator. Mrs. S’s contractions increased in frequency and strength within a half-hour. At 09:00, Baby S’s heart rate decelerated down to the 60s. Nursing interventions were implemented, including oxygen at 10 liters via facemask, increased intravenous fluid rate, and position changes. Baby S did not recover, and a stat cesarean section was called. Mrs. S was given rapid-induction general anesthesia and delivered a baby girl. Apgars were 5, 7, and 9 at 1, 5, and 10 minutes. Baby S went to the NICU for care due to gestational age. Mrs. S had a full placental abruption, which caused the bradycardia.

Points to consider:
1. Labor should not be augmented for at least 2 hours after the water is broken, as most women will begin to contract spontaneously within 12 hours of rupture. Careful consideration needs to be made of the patient’s contraction pattern and fetal heart rate status.
2. There is increased likelihood of placental abruption between 33–35 weeks, with rupture of membranes and with Misoprostol. These all are significant risks for abruption and should be evaluated with great caution.
3. Mrs. S was exposed to major abdominal surgery, risk of infection, possible subsequent cesarean sections, fear, pain, and general anesthesia, all because her physician was not patient enough to let Mrs. S labor without intervention.

Conclusion
Women and infants continue to be put at risk, when safety should come before speed and cost in obstetric health care. On the FDA Web site is a petition with 1,800 signatures, asking for a ban on the use of Misoprostol for obstetric use. The author of the petition, Maddy Oden, lost her daughter and her granddaughter to death (amniotic fluid emboli) 10 hours after a dose of Misoprostol. Should an obstetrician need to reduce time at the bedside lead to unsafe care? Should it matter if it takes a few more hours for a baby to come into the world safely and peacefully? ACOG should consider what is safest for the infants involved and make clear-cut policies, based on evidence, that physicians should be encouraged to follow. Insurance companies need to step in and control the unnecessary expenditures that go along with procedures that are not medically indicated. Hospitals need to reform policies that allow elective inductions and be more concerned with safe patient care and less concerned with loss of revenue from barring these procedures. Patients need to be properly advised
about potential inconvenience of a bad outcome should the “elective” labor not go as planned. Mothers-to-be and their doctors should to allow nature to regain control and stop forcing labor for the sake of convenience.

As LNCs, we need to look at the care given to the obstetric patient and make connections regarding bad outcomes related to medications and procedures. We need to evaluate how informed the patient was in her decisions to induce her labor, and be sure that she received information regarding appropriate alternatives. Women across the country are being subjected to unapproved medications to induce labor, which can lead to devastating effects. When reviewing medical records, LNCs need to not only look at standards of care, but evidence-based practice. By doing this, we can significantly impact the safety of future generations.

References


Tammey Dickerson, RNC-OB FMC CLNC, graduated from St. Francis Hospital School of Nursing. She worked as a Med-Surg nurse for 2 years and has spent the remainder of her nursing career, of more than 24 years, as a Labor and Delivery Nurse. Her clinical background includes all aspects of L&D including antepartum, intrapartum, and postpartum care. She is Advanced Fetal Monitor Certified and has attained Inpatient Obstetric Nurse Certification through the NCC. Presently pursuing her BSN, she will graduate in March 2009 and holds a 4.0 GPA at Chamberlain College of Nursing. She plans on continuing her education with an MSN with a Clinical Leader Focus and certificate in Nursing Education. Dickerson functions as a staff nurse, charge nurse, and preceptor, and has avid interest in obstetric patient safety. She began her LNC career in May 2007 and is the CEO and Founder of Dickerson Legal Nurse Associates. She serves as a consultant and testifying expert for obstetric cases for both plaintiff and defense. As a lecturer in the areas of obstetric liability, documentation, and obstetric expert testimony, she has given presentations to co-workers and chapter members. She is a member of American Association of Legal Nurse Consultants and the Southern New England Chapter of the AALNC. She will hold the position of Education Chairperson of SNE Chapter for 2009. She can be reached at tammeyo@earthlink.net.
The Disclosure of Unanticipated Medical Outcomes: Better Communication, Better Care, Better Patient Satisfaction

Elizabeth S. Bridgeman, BSN RN LNCC, & Andy Malinoski, ARM

KEY WORDS
Disclosure

Communication is the foundation of every aspect of health care. Dangerous situations are created when physicians, nurses, pharmacists, and support staff do not communicate clearly with one another. Good communication skills are essential to help preserve the physician–patient relationship when things do not go as expected. The physician–patient relationship is also vital to the delivery of quality care. Effective, honest, and empathetic communications are a way to preserve that relationship. When physicians communicate openly, the well-being, recovery, and future treatment of the patient can be discussed in a safe and caring environment. This ensures that the patient receives the best care and highest understanding of their options and their current condition in the event of an unanticipated outcome. This article discusses a physician–owned liability insurance company’s approach to creating a disclosure program known as C.A.R.E., led by Robert L. Ghiz, MD, Chairman of the Board of Directors of The Mutual, and Elizabeth Bridgeman, a Certified Legal Nurse Consultant with an extensive background in defense medical malpractice litigation. This leadership structure provides a balanced view and understanding of disclosure combining the physicians’ and a legal nurse consultant’s perspective in defense and trial experience to create and deliver relevant content to the physician audience. The article highlights the challenges created by disclosure and the role of the legal nurse consultant (LNC) as potentially the first person to explain to a patient what actually happened after the review of the medical records.

Formation of the West Virginia Mutual Insurance Company

Faced with the reality that doctors and professional medical liability insurers were exiting the state, the West Virginia Legislature passed a series of tort reforms between 2001 and 2005 that provided legislation enabling the formation of West Virginia Mutual Insurance Company (The Mutual). The company began serving the physicians on July 1, 2004, in response to a medical liability crisis in the state. Prior to the formation of The Mutual, many insurance carriers increased their cost of medical liability insurance for West Virginia physicians. This left physicians with a difficult decision: to stay in West Virginia and be exposed to some of the country’s highest medical liability premiums, or to move to a more “insurance friendly” state. A majority of West Virginia was already recognized by the Federal government as medically underserved. In addition, the legislature also passed legislation allowing physicians the legal right to empathize and sympathize with patients after the occurrence of an undesired outcome or medical error, without the “legal” admission of liability. Most states have similar laws related to expressions of sympathy (See Table 1).

Table 1. Notification Enforcement by State.

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<th>State</th>
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In 2005, the West Virginia Legislature passed the Open Communications Bill. The bill excludes expressions of sympathy after an unanticipated outcome as proof of liability. The bill notes:

No statement, affirmation, gesture or conduct of a healthcare provider who provided healthcare services to a patient, expressing apology, sympathy, commiseration, condolence, compassion or a general sense of benevolence, to the patient, a relative of the patient or a representative of the patient and which related to the discomfort, pain, suffering, injury or death of the patient shall be admissible as evidence of an admission of liability or as evidence of an admission against interest in any civil action brought under the provisions of article seven –b[§§55-7B-1 et seq.], chapter fifty-five of this code, or in any arbitration, mediation or other alternative dispute resolution proceeding related to such civil action. (W.Va. Code 55-7-11 b(1))

Unanticipated outcomes occur in health care every day. The Mutual has found that the manner in which these unanticipated outcomes are communicated to patients is a major factor in regards to improving patient care and reducing the risks associated with an unanticipated outcome. This legislation provided the opportunity for The Mutual to move forward and develop its disclosure program. The company had already instituted many other risk management programs such as on-site office visits, self-assessments, and educational CME seminars for both physicians and physicians’ office staff. In addition to these services, the company saw a need to integrate a full disclosure program into the risk management services it provides.

Development of the Disclosure Program

Believing in disclosure of unanticipated outcomes, what was envisioned by the company was the development of a program to inform, educate, and engage its physician policyholders in the practice of disclosure. This program would be paired with a support mechanism for physicians specifically at the time when things have gone wrong. The program would be designed to maintain the physician-patient relationship, encourage disclosure, and maintain ongoing communication in the presence of an unanticipated outcome. This would be accomplished by providing a framework and advice for the physician as they communicate with their patients in the presence of unanticipated outcomes.

To develop this disclosure program, a study was undertaken of the current “best practice” organizations and resources in disclosure to establish the foundation and design of The Mutual’s flagship risk management program, C.A.R.E. – Communicate and Respond Effectively. The resources studied were the 3 R’s Program, The Sorry Works! Coalition, the work of Thomas Gallagher, MD, and the Institute for Healthcare Communication.

3 R’s (Recognize, Respond, Resolve): The Colorado Physicians Insurance Company (COPIC), formed in 2000, launched the 3 R’s Program as a pilot program to COPIC-insured physicians (COPIC, 2007). The purpose of the program is to assist patients of enrolled COPIC-insured physicians who have experienced an unanticipated medical outcome by facilitating candid early communication between physician and patient, thereby preserving the relationship. The program assists a physician by:

- Responding in a timely fashion to an unanticipated medical outcome;
- Communicating with the patient in an empathetic manner; and
- Arranging for additional care or services the patient might need as a result of the outcome.

The Sorry Works! Coalition: Founded by Doug Wojcieszak in 2005, The Sorry Works! Coalition has quickly become a leading advocacy organization for disclosure, apology when appropriate, and upfront compensation (when necessary) after an adverse medical event (Sorry Works! Coalition, 2007). The Coalition believes and advocates that
the medical malpractice crisis is a customer service crisis – not a legal problem – that can be solved any time by medical, insurance, and legal professionals. Sorry Works! provides the customer service framework in a programmatic approach that encourages communication and problem-solving with patients and families after adverse events. The Coalition provides teaching and training tools to help healthcare and insurance organizations implement and develop successful disclosure programs.

Thomas Gallagher, MD: Dr. Gallagher, a practicing physician, is a nationally recognized speaker and writer regarding medical ethics and disclosure of adverse events. Dr. Gallagher’s research focus is on the disclosure of medical errors. His current work examines patients’ and doctors’ attitudes about medical error disclosure. His focus group study on this topic was published in The Journal of the American Medical Association (Gallagher, Waterman, Ebers, Fraser, and Levinson, 2003). He has also conducted large surveys to understand physicians’ attitudes and experiences regarding communicating with patients, colleagues, and healthcare institutions about medical errors. Dr. Gallagher was the lead author of a review article on disclosure that appeared recently in the New England Journal of Medicine (Gallagher, Studdert, and Levinson, 2007).

Institute for Healthcare Communication: The Institute for Healthcare Communication (IHC) is a not-for-profit organization leading the improvement of healthcare throughout the world (Institute for Healthcare Communication, Who we are, 2007) IHC was founded in 1987 and is based in New Haven, Connecticut. An additional preparatory step in the implementation of The Mutual’s disclosure program included attendance of a three-day disclosure course presented by the IHC. This program addressed each aspect of the communication process using lecture, videos, and large- and small-group practice. It helped The Mutual identify and practice the most effective ways of responding both empathically and non-defensively. The program emphasized the organizational, ethical and risk management aspects of disclosure and its impact on physicians and patients and families (Institute for Healthcare Communication, Disclosing unanticipated outcomes and medical errors, 2007).


After much planning and careful consideration, the C.A.R.E. program was rolled out in November 2006. Enrollment in the program is voluntary and permitted only after the physician attends a seminar covering the specifics of proper and effective disclosure techniques. The seminars are available to Mutual-insured physicians statewide. During the seminar, the physician is briefed on disclosure – often an uncomfortable subject matter for physicians – and is equipped with the knowledge to approach the subject in a way that benefits both patients and physicians.

Continuing Medical Education (CME) credits are granted to those physicians attending the seminar, and the physician earns an additional 2% credit on his or her premium. At the seminar’s conclusion, the physician may enroll in the C.A.R.E. program and be eligible for an additional 3% premium credit. These seminars are conducted throughout the state (30-35 per year) and on an individual basis as physicians need support and advice immediately after an unanticipated outcome.

Since its inception, more than 1,300 physicians have attended C.A.R.E. seminars, and 71% of the attendees have enrolled in the program. Although the program is still in its infancy, there have been successful C.A.R.E. events resolved through the program. In its first year of existence, multiple communication interventions assisted enrolled physicians in communicating more effectively and resolving difficult situations with their patients. The end result is maintaining the physician-patient relationship in the presence of an adverse event, which is the programs’ main goal.

The following are specifics of the C.A.R.E. program for enrollees:
1. The physician must contact C.A.R.E when there is an unanticipated outcome or error and discuss it with a C.A.R.E. representative. The Mutual will decide
if the event meets the qualifications for the C.A.R.E. Program.

2. If the situation meets the C.A.R.E. criteria, the physician must speak with that patient and/or family again and explain what happened, in terms they can understand; why it happened, if they know; what they are going to do about it to prevent this from happening again; and, if there is a medical error, accept responsibility and apologize for the error.

3. If it is an unanticipated outcome with no medical error, the physician should express sincere sympathy or regret for the outcome.

4. If the event qualifies for C.A.R.E., the patient or family member will be given contact information at this time and if they choose, they may call C.A.R.E.

5. Once the patient and/or contacts C.A.R.E., the event is discussed with them to make sure they have no additional questions.

6. Discussions with the patient and/or family include out-of-pocket medical and non-medical expenses they may have incurred due to this unanticipated outcome and/or error.

7. Research is conducted on the medical and non-medical expenses and any other issues that are affecting the patient and/or family as a result of the event.

8. An offer of disbursement is made based upon the findings.

Most of these steps are completed within 10 days of the physician first notifying C.A.R.E. of the unanticipated outcome. This timeframe is in stark contrast to the timeline of most lawsuits that can take much longer to resolve based on the nature of the discovery process.

The personal circumstances for each patient and family member are unique and different. C.A.R.E. reinforces the apology on behalf of the physician in an attempt to meet the immediate needs of the patient. It is important to note that there are no disbursements for "pain and suffering." The Mutual views every C.A.R.E. event on its own individual merits.

The term “event” is used with the program because claims cannot be handled through the C.A.R.E. program. To provide a system of checks and balances, the state’s insurance industry regulator, the West Virginia Insurance Commission, has very specific definitions and requirements for claims such as requiring specific reporting documentation and, generally, attorney involvement. Exclusions to the program, including the following: death, attorney involvement, Board of Medicine complaint, written demand, summons and complaint, in addition to a Notice of Claim with Screening Certificate of Merit. These actions will automatically make the patient ineligible for the C.A.R.E. program.

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**WHAT WILL I LEARN?**

- **Hands on — How to...**
  - Identify and locate appropriate testifying experts.
  - Develop and analyze medical records.
  - Organize, tab and paginate actual medical records.
  - Screen a number of cases for merit.
  - Identify and participate in the standards of care.
  - Identify causation issues, assess damages and any contributing factors that affect the case outcome.
  - Identify any and all potential defendants.
  - Develop time lines and chronologies of medical sequences of events.
  - Prepare case-related medical research.

- **Outcome — What will be done...**
  - Determine if the event meets the qualifications for the C.A.R.E. Program.
  - If the situation meets the C.A.R.E. criteria, the physician must speak with that patient and/or family again and explain what happened, in terms they can understand; why it happened, if they know; what they are going to do about it to prevent this from happening again; and, if there is a medical error, accept responsibility and apologize for the error.
  - If it is an unanticipated outcome with no medical error, the physician should express sincere sympathy or regret for the outcome.
  - If the event qualifies for C.A.R.E., the patient or family member will be given contact information at this time and if they choose, they may call C.A.R.E.
  - Once the patient and/or contacts C.A.R.E., the event is discussed with them to make sure they have no additional questions.
  - Discussions with the patient and/or family include out-of-pocket medical and non-medical expenses they may have incurred due to this unanticipated outcome and/or error.
  - Research is conducted on the medical and non-medical expenses and any other issues that are affecting the patient and/or family as a result of the event.
  - An offer of disbursement is made based upon the findings.
  - Most of these steps are completed within 10 days of the physician first notifying C.A.R.E. of the unanticipated outcome. This timeframe is in stark contrast to the timeline of most lawsuits that can take much longer to resolve based on the nature of the discovery process.
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**CE Hours:**

Course hours can be applied toward renewal.
Challenges Created by Disclosure

Disclosures are difficult to do, both from an emotional and practical perspective. Physicians often feel upset, guilty, depressed and may not be able to forgive themselves when an error occurs. This reaction is common to nature and presents an obstacle for the physicians to overcome. The physician is faced with a variety of fears. A fear of retribution by the legal system, the hospital and the patient can lead a physician to not disclose.

Ethics aside, there may also be a belief in the physician’s mind that the patient will never find out or know the truth. At first it is sometimes easier to deny that an error occurred than to explain completely to a patient what happened.

Disclosure also presents unique challenges because it may be difficult to assess and determine the true cause of an adverse event. This reality complicates the disclosure process, especially when it cannot be determined if a system, another person, or the physician caused the event to occur. The disclosure process may make patients more aware of errors and unanticipated outcomes. Where strong disclosure programs exist, more unanticipated outcomes and events are reported because a process exists to communicate this information to patients. This process allows the facility and physician to learn from this adverse event and determine what to do to prevent it from happening again.

There are environmental barriers to practicing open communications. A “deny and defend” culture encourages a physician to avoid the truth. A culture of blame encourages silence instead of proactive, honest communication.

Increased claim may result from open and honest communication following an unexpected outcome, but the total payout is proving to be less as severity is lessened by the disclosure and resolution process involved. For example, the Lexington, VA, hospital system found a rise in the number of claims once a full disclosure program was introduced, but the amount of money paid out on claims and lawsuits decreased. Currently, the average payout for claims is $16,000.

“Controlling anger is the reason that Lexington, VA, was in the lowest quartile for total payments despite being in the highest quartile for claims. They removed anger from the process and in so doing removed customers’ desire to financially punish the institution. Anger, not greed, is what drives severity” (Wojcieszak, Saxton, and Finkelstein, 2007, page 81).

Role of the LNC

In the medical malpractice arena, the LNC may be the person who ascertains through the review of the medical records and chronological summary what actually happened to the patient. The defense LNC will be summarizing and explaining to counsel what occurred. The plaintiff LNC may be the first person who reviews the medical record with the patient and explains to the patient in language they can understand what happened and how it happened. At this point, most communication is cut off between the patient and the physician involved in the litigation. The patient-physician relationship may be damaged. The anxiety that patient experienced as a result of the unanticipated outcome was neither addressed nor dealt with properly and the anxiety turned to anger. When patients do not get their questions answered from the healthcare system they understandably turn elsewhere for answers.

Conclusion

In the past, physicians were encouraged to minimize conversation and communication with patients and patient’s families when things went wrong. This idea of silence has been ingrained in physician’s psyches and how they practiced medicine. In 2001, throughout the United States the accrediting bodies for hospitals, medical societies and state legislatures have begun to adopt and implement policies and legal statutes that require (and at a minimum recommend) the disclosure of adverse outcomes to patients.

Often on a state statutory level, the protection of the actual apology is paired with tort reforms limiting the non-economic damages that can be sought by patients. Critics of the disclosure movement may view it as a way of blocking a patient’s right for economic damages in the presence of physician negligence. In its purest form, disclosure need not and should not rely on the tort reform movement to achieve its intended goal of open, honest communication. Studies show patients are less likely to sue their physicians if their questions are answered, if they are told the truth, if they are treated with compassion and empathy and the physician-patient relationship is preserved (Gallagher and Levinson, 2005). Dr. Leonard Marcus, Director of the Program for Health Care negotiations and Conflict Resolution, Harvard School of Public Health, states, “Patients harmed by medical errors want three things: an explanation, an apology and an assurance that changes have been made to prevent harm form being done to someone else” (Boothman 2006). In the end, the conversation should be focused on quality care and what is best for the patient. Open, honest and empathetic communication is what we would all expect from our personal physician.

The medical-legal community and the healthcare community should continue to foster the trend of encouraging open and honest communication. If kept separate from the politics of tort reform, apology laws do not protect the act of negligence and are not a barrier to patients’ rights. All entities involved should encourage communication between physicians and patients to bring about better care.

The West Virginia Mutual Insurance Company views the C.A.R.E. program as a valuable tool to assist West Virginia physicians in appropriately communicating unanticipated outcomes. C.A.R.E continues to evolve and serve as a catalyst for physicians’ understanding of disclosure, improving the quality of healthcare available in West Virginia, and ultimately playing a part in reducing the frequency and severity of medical liability claims for The Mutual’s insured physicians.
### Suggested Additional Reading

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<th>Title</th>
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<tr>
<td>American Medical Association Council on Ethical and Judicial Affairs; Southern Illinois University at Carbondale School of Law: Code of Medical Ethics, Annotated Current Opinions: Including the Principles of Medical Ethics, Fundamental Elements of the Patient-Physician Relationship and Rules of the Council on Ethical and Judicial Affairs</td>
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<td>Clinton &amp; Obama: Making Patient Safety the Centerpiece of Medical Liability Reform. Perspective</td>
<td>(in New England Journal of Medicine)</td>
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<td>Kohn, Corrigan, Donaldson: To Err is Human: Building a Safer Health System</td>
<td>(in Archives of Internal Medicine)</td>
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<td>Kraman &amp; Hamm: Risk Management: Extreme Honesty May Be the Best Policy</td>
<td>(in Annuals of Internal Medicine)</td>
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<td>Lazare: On Apology</td>
<td>(in Archives of Internal Medicine)</td>
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<td>Wittman, Park, Hardin: How Do Patients Want Physicians to Handle Mistakes: A Survey of Internal Medicine Patients in an Academic Setting</td>
<td>(in Archives of Internal Medicine)</td>
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### References


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Celiac Disease Approaches the Bench: A Case Study

Bill Sheehan, RN CLNI, Corey J. Speweik, Attorney at Law, & Kathleen Ashton, PhD APRN BC

Does a 23-year-old female patient recently diagnosed with celiac disease (CD), having spent years suffering the disease’s manifestations, have any legal recourse for the missed diagnosis? Are the physicians who treated her for 13 years for anemia, fatigue, bone pain, Reynaud’s disease, and dermatitis – none of whom diagnosed celiac disease – responsible for that suffering? During the period of 1991-2005, was ruling out gluten sensitivity, gluten intolerance, or celiac disease within the standard of care for a patient who presented with the same history and clinical findings as the subject of this case study?

CD has not been extensively researched and is not a well-known disease. It is prevalent, however, as confirmed by information from the Celiac Disease Center at Columbia University in New York, under the direction of Peter H.R. Green, MD. By far the most noteworthy are Green’s stories of patients who have endured this disease for years before being diagnosed, including the anecdote of one patient, an anesthesiologist married to an internist (both of whom work in a major city at a major medical center flooded with physicians in all specialties), whose condition went undiagnosed for 43 years (Green and Jones, 2006). This begs the question: Is this malpractice or misdiagnosis, or both?

The Disease

Celiac disease (CD) is an auto-immune, hereditary disorder resulting in a chronic inflammatory condition of the small bowel. Gluten, a protein that is found in wheat and wheat products, is the culprit. When gluten enters the bloodstream, the body’s immune system produces gliadin antibodies in the intestine. Physiologically, an intramucosal enzyme defect produces the inability to digest gluten. The result is poor absorption of nutrients and atrophy of the villi in the small intestine. Life-long adherence to a gluten-free diet is the best and only known treatment. Failure to maintain the gluten-free diet may result in more advanced and serious disease processes, such as a shortened life expectancy, intestinal lymphoma, pancreatic disease, osteoporosis, infertility, internal hemorrhaging, and others.

The function of the digestive system involves the processes of digestion, absorption, and elimination. During digestion and enzymatic breakdown, the food is passed from the stomach into the duodenum. Intraluminal processes involve biliary and pancreatic secretions that result in enzymatic hydrolysis. Absorption takes place when the food products pass across the villi, which are small hair-like projections in the folds of the small intestine. In patients free of CD, the villi slow the process down and allow for maximum absorption of the nutrients. CD destroys these villi and malabsorption results. Over time, the villi atrophy. The nutrients that are normally allowed to be absorbed into the bloodstream at this time are eliminated.

CD is also referred to as “The Great Imitator,” in that its symptoms are similar to those of many other diseases. The most common symptoms are chronic fatigue, gastrointestinal distress, diarrhea, gastro-esophageal reflux disease (GERD), dyspepsia, iron deficiency anemia, bone or joint pain, Reynaud’s disease, hypocalcemia, and others. Many patients are seen with some or many of these symptoms and diagnosed with irritable bowel syndrome, Crohn’s disease, colitis, or a host of other conditions including anorexia, schizophrenia, and malingering. Many patients have seen physicians in many specialties trying to find a cause for their symptoms, and after being diagnosed, it becomes clear that there is a marked lack of awareness of CD.

This is not a new condition, despite the lack of awareness. In fact, the Omaha-based Celiac Sprue Association (n.d.) reports that Aretaeus of Cappadocia, a Greek physician who practiced in Rome in 250AD, used the term “celiacs” to describe the “sufferers of the bowels.” In 1888, British physician Dr. Samuel Gee presented information regarding CD in both children and adults (Gee, 1888). A discussion of the disease appears in Text-Book of Medical Diagnosis (Anders, 1914). Dr. Willem Karel Dicke wrote about the subject back in 1952 (van Berge-Henegouwen and Mulder, 1993).

The following case consisted of reviewing 13 years of physician visits, hospital treatment and stays, laboratory results, and client interviews, all in an effort to determine whether or not there was in breach in the standard of care and whether the case had merit.

A Case Study

In 1992, a 9-year-old Caucasian female of Irish decent, in otherwise good health, presented to her general practice pediatrician stating that she was constantly tired and it was hard to wake up for school in the morning. She was given over-the-counter (OTC) ferrous sulfate for her iron deficiency anemia and advised to get more sleep. There were no laboratory tests requested at that time. She was also referred to and seen by a dermatologist who placed her on Cefeitin, 125mg twice daily for acne.

This patient had been a professional dancer since age 6 and had been dancing since age 2. She practiced for several hours at least 4 evenings a week. She expended a lot of energy,
and for a midwestern pre-pubescent, she ate a relatively healthy diet, devoid of junk food. She was aware of her image and understood the value of good nutrition.

The scenario continued with little change for several years. The patient saw her pediatrician on a regular basis, and the hematocrit and hemoglobin levels continued to be below normal (Hgb – 8.6 g/dl and Hct – 26.7% with normals of Hgb 11-16g/dl and Hct 31-45%). The physician’s disposition was to take OTC ferrous sulfate, stating, “It’s important that she take it everyday.” The patient complied.

In 1998, at the age of 15, the patient continued to complain of chronic fatigue and also experienced hip pain. Additionally, she experienced gastric reflux disease, which may have begun developing. Born in Los Angeles and having moved to the mid-west, she was symptomatic of Reynaud’s disease because she was experiencing winter for the first time. Regarding the hip pain, her parents were concerned not only about her health, but also about her professional future as a performer. Her pediatrician referred her to a rheumatologist. Blood tests were ordered, and the results were not surprising: Hgb – 9 g/dl and Hct – 28.1%. Her cytomegalovirus (CMV) levels were increased above the normal of 1.8 to 2.55, and her EBV (Epstein-Barr Virus) levels were 2.55 (normal: negative).

This doctor suspected drug-induced Systemic Lupus Erythematosus (SLE). The diagnosis was R/O SLE and arthralgia. The patient was advised to continue with the ferrous sulfate, and she was referred to an orthopedist and a hematologist. The orthopedist ordered and completed a dye study on her affected hip; the results were within normal limits. The hematologist repeated the blood studies with basically the same results. This hematologist, a renowned Professor of Medicine at a very respectable U.S. medical center, practicing hematology for more than 20 years, diagnosed the patient with iron deficiency anemia. The doctor prescribed ferrous sulfate, 325mg 3 times a day and ordered the patient to return in 8 weeks for repeat blood tests.

The patient’s parents were exasperated, the claim forms were piling up, the patient responsibility section on the claim forms amounted to a tidy sum, the whole family was tired of going to doctors, and the patient was still fatigued. In an effort to move on from the pediatrician to an internist, the patient and her parents found a physician with a real desire to find the problem. Blood tests were ordered, and the results were as follows:

- T4: WNL, suggested normal thyroid function
- Electrolyte Panel: WNL, suggested normal kidney function
- Hepatic Function Panel: WNL, suggested normal liver function
- H&H: below normal, suggested anemia
- ANA Titer: 1:80, suggested evidence of Reynaud’s Disease
- Systemic sclerosis, lupus, Sjogrens syndrome and polymyositis were all ruled out.
- She was now left with the diagnosis of iron deficiency anemia.

Although the patient was dealing with fatigue and stomach problems, she was now focused on her career. She auditioned for a Broadway show in New York, and shortly thereafter she was offered a contract. She moved to New York and performed 8 times a week in a Tony Award-winning musical for 4 years. She met new friends and was enjoying her career. At an informal gathering, a friend described his wife, who suffered from CD, as having the same symptoms as the patient. He suggested that she should eliminate wheat from her diet and see if that was the problem.

It was. Within 2 weeks after becoming gluten free, all of the symptoms were gone. She really never knew “normal,” but this new-found energy was great. She researched CD and wanted to be tested. She found a gastroenterologist and scheduled an appointment. She soon realized that she would have to endure the symptoms again, since she had to have a gluten presence in her system prior to the blood tests. She was tested, and to her satisfaction the results were: positive for the endomysial antibody and 23.5 U/ml of tissue transglutaminase – IAG serological markers for celiac disease detected – Celiac disease is highly likely.

The patient began to read every piece of information available on CD. She embraced the gluten-free diet and...
sought out restaurants offering gluten-free menus. In addition to dealing with her new lifestyle, she was determined to find out how she acquired CD. She discovered Celiac disease: A hidden epidemic (Green and Jones, 2006), Wheat free, worry free (Korn, 2002), The gluten-free bible (Lowell, 2006), and the Celiac Disease Center at Columbia University.

In addition, she began to research DNA testing to discover who in the family could be predisposed to CD (Danielle Young, Genetics Counselor, personal communication, June 14, 2007). The CD markers are DQ2 and DQ8. Some 90% of celiac sufferers carry the DQ2 marker, and 8% to 10% carry the DQ8 marker (Kimball Genetics, n.d.). It is important to be tested to know if any children or other family members of celiac sufferers carry the marker. These could be families at risk; if symptoms appear, they can be tested efficiently. If family members carry the marker and are asymptomatic, they can be monitored effectively (Kimball Genetics, n.d.).

The patient and her parents were DNA tested. The mother was negative for DQ2 and DQ8 markers, and her gliadin screens were all negative. She doesn’t have CD, can’t get it, and can’t pass it on. The father tested positive for the DQ2 marker and negative for the DQ8 marker. His serology results were all negative. Both parents are asymptomatic, but the father is pre-disposed and may develop CD in his lifetime. The patient is, of course, DQ2 positive and DQ8 negative.

The patient in this case study just celebrated her 1-year anniversary of a gluten free, healthy lifestyle, and she continues to study the subject in good health. But one has to ask: was any permanent damage done?

Legally Speaking

According to information available at WrongDiagnosis.com (n.d.), one of the world’s leading providers of online medical health information, celiac disease is one of the most difficult diseases to diagnose. Does that preclude physicians from being responsible for misdiagnosis?

In order to litigate a misdiagnosis case, a plaintiff must prove fault in medical malpractice. To prove fault in medical malpractice, four demands must be met:

1. Duty – Was there a duty for the physicians to care for this patient?
2. Breach – Was there a breach of that duty?
3. Causation – Was the breach of the duty of care the legal and proximate cause of the harm to the patient?
4. Damages – Were there damages to the patient due to the physician’s breach?

A duty was formed when the patient first presented to the pediatrician at age 9. There was a duty by the physician to diagnose the disease process, given the symptoms that were presented. There was certainly an established duty between the patient and her four other physicians. In reviewing the medical records, however, it is clear that there was little, if any communication, between the physicians. If phone calls were made, they weren’t recorded in the medical records.

Establishing breach of duty or medical professional negligence would require proof that the physicians’ conduct fell below the standard of medical care. This, of course, would require the testimony of expert witnesses, establishing the applicable standard of care and the fact that the defendants failed to meet that standard. It must be proven that the health care provider failed to do what a reasonably prudent physician possessing the same or similar knowledge and skills would do in the same or similar circumstances. A biopsy of the villi in the small intestine would confirm damage. The fact that there is a pronounced possibility of developing an intestinal lymphoma or other diseases associated with untreated CD would also corroborate damage.

In addition, there are the financial and emotional damages to consider. The damages were, in this case, directly related to the inability of the five physicians to diagnose CD. There was no reasonable way, however, for our patient to know or learn of CD without being diagnosed. Expert witness testimony would support the breach in duty when the standard of care was articulated.

In 1980, the Massachusetts Supreme Court upheld the decision that the cause of action in medical malpractice accrues when the patient learns of the harm as a result of misdiagnosis (Franklin vs Albert, Mass, 1980). Physicians are accountable for their interpretations of screening and diagnostic tests. This case underscores the critical importance of communication between health care providers. It also says that patients have 3 years from the discovery of the harm until they need to file a claim.

The patient in the case study is considering litigation.

Conclusion

A host of materials – for gastroenterologists, attending physicians, RNs, LNCs, allied health professionals, and patients alike – can be found online. Please see Table 1 for a “starter list” of Web sites that helped in the research for this case. There are CD organizations nation-wide that are available to help the patients and the health care providers.

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<th>Table 1. Online Resources for More Information on CD.</th>
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For the LNC consulting on a case involving a patient with CD, it is important to consider that this is one of the most misdiagnosed disease processes because of its many similarities to other diseases. Despite a continued lack of awareness of this disease, attorneys and insurance companies are slowly becoming more familiar with CD. The need for the LNC to learn the specifics also increases. Needless to say, education is the key. It always has been. The LNC needs up-to-date information and education to answer the lingering question: Is this malpractice or misdiagnosis, or both?
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Landzberg, B. *Celiac disease: Could you be missing the diagnosis?* Retrieved February 2007 from http://consultantlive.com/showArticle.jhtml?articleID=193600235

Bill Sheehan, has been an independent certified legal nurse investigator since 2006. He has 25 years of nursing experience and has completed coursework for both CLNI and APLNC. His introduction to the clinical considerations of Celiac Disease began when he was asked to consult on this case. He has authored many scientific articles over the past 20 years and has recently published his first children’s novel. He lives in New York where he is currently writing his second children’s book and a stage play. He can be reached at luminate7@gmail.com.

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Cauda Equina Syndrome

Kara L. DiCecce, MSN RN LNCC

Cauda Equina Syndrome (CES) is a neurological emergency that frequently presents to the chaotic atmosphere of the emergency room or trauma care center. As such, its often insidious presentation and can be easily overlooked, as emergent clinical needs and wound exsanguinations competitively vie for the health care team’s attention. Conversely, it may present as a benign office visit to the family physician in the chronic low back pain patient, where it may be wrongly assumed that the patient presents yet again for narcotics when the patient of record may actually be too embarrassed to talk about a sudden onset of sexual dysfunction. Familiarity with the clinical signs and symptoms, along with a heightened awareness of the legal pitfalls, will serve to provide the LNC researcher with a starting point for case evaluation.

Anatomy

In the average adult, the spinal cord terminates about the level of the L1-L2 vertebrae. Where the Conus Medullaris ends inferiorly and projecting beneath the L2 vertebra are the multiple lumbar and sacral nerve roots known as the “Cauda Equina.” This mass of peripheral nerve roots that, in part, compose the lumbosacral plexus begin tightly gathered but eventually splay out to innervate the sacrum. (See Figure 1.) Translated from Latin, “Cauda Equina” quite literally means “horse’s tail” and gives rise to the name based on the root’s visual appearance. This bundle of nerve roots serves to provide motor and sensory sensation. Unrelieved pressure to this area compresses and paralyzes the nerve roots cutting off sensation and movement.

Etiology

Irrespective of the initiating mechanism, CES is cord compression at the corresponding neurological level leading to nerve root compromise. Left unchecked, this pressure may lead to permanent neurological damage and irreversible deficits. (See Figure 2.)
This compromise may occur secondary to massive disc herniation whether trauma-induced (i.e., fall from significant height, violent trauma, penetrating injury, etc.) or through degenerative progression, as in the case of severe stenosis in an elderly person that may manifest with additional symptoms of neurogenic claudication (Adams, Victor, and Ropper, 1997).

Tumors/malignancies, epidural abscesses, infections, arachnoiditis, sarcoidosis, inferior vena cava thrombosis, lymphoma, and hematomas have been documented as causes of CES as well (Adam et. al., 1997; Beeson, 2007; Grossman, 1996).

While less common in presentation, spinal surgery, pregnancy, congenital spinal stenosis, late-stage ankylosing spondylitis, over-aggressive or improper chiropractic manipulation causing vertebral slippage, and faulty epidural injection technique have additionally been implicated as precipitating factors of CES (Beeson, 2007; Rawlings, 2005).

**Signs and Symptoms**

The more common clinical presentations of CES include:

- Severe back pain and/or severe unilateral or bilateral leg pain;
- Changes in bowel and/or bladder function (primarily urinary retention, as urinary incontinence is thought to be secondary to decreased or absent bladder sensation and resultant overflow);
- Numbness of the perianal and posterior thigh regions (“saddle anesthesia”) and loss of sphincter tone;
- Weakness of motor exam of the lower extremities and decreased reflexes (for instance, absence of great toe flexion or depressed motor strength); and
- Sexual dysfunction (AAOS, 2007; Campbell, 1996; Lee, 1996; Wheeless, n.d.).

**Diagnostic Testing**

Determining or confirming the cause of CES may warrant limiting or expanding individual testing based specific clinical presentation.

- Magnetic Resonance Imaging (MRI) can be used for examining soft tissue and neurological structure. MRI is key for determining cord compression secondary to disc herniation, tumors, or spinal abscesses.
- Plain x-rays may help to determine metabolic bone disease, degenerative processes (disc space height and osteophyte formation), vertebral fractures, or spinal misalignment.
- Bone scan is more predictive for metastases and erosion, as well as infection.
- Computerized Axial Tomography (CAT) Scan is definitive for spinal stenosis and disc disease.

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• Myelography (injection of dye into the subarachnoid space) and radiographic images reveal obstruction of the flow of contrast within the thecal sac or compromise of the exiting nerve roots.

Legal Considerations
• Patients who present to the emergency room setting with dramatic pain patterns secondary to chronic back pain may be easily overlooked as merely drug-seeking, while actually presenting with CES. Adequate time in interviewing the patient and careful documentation regarding the patient’s report of onset of motor or sensory dysfunction is warranted.
• Conservative treatment measures of bedrest and anti-inflammatory medications for chronic back pain should be carefully assessed in the presence of urinary difficulties, such as an inability to provide urine sample while in the ER.
• Conus Medullaris Syndrome (CMS) may be misdiagnosed as CES. For purposes of diagnosing and treatment, the distinction may be academic due to its anatomical location (it is likewise contained in the thecal sac surrounded by spinal fluid). CMS is associated with a less favorable neurological recovery due to higher location of compression on the spinal cord and presents clinically, with no to markedly less radicular pain in the lower extremities (Verdugo, Cea, Campero, and Castillo, 2003). Other (not all-inclusive) clinical considerations are lumbosacral plexopathy and peripheral nerve disorder.
• Patients may be seen during periods of potentially decreased staff/equipment availability on nights, weekends, or holidays.
• The patient may have latent presentation, but the greater the time elapses of unrelied pressure on the roots, the more likely it is that the neurologic damage will be permanent and irreversible. Consensus of the ultimate timeframe for achieving optimal neurological recovery escapes conclusion in the review of literature; however, reports show intervention relieving compression of the nerve roots inside of 24–48 hours is thought to yield improved neurologic outcomes (Rawlings, 2005).
• Violent spinal trauma may result in spinal shock and sacral sparring, but does not apply to lesions below the cord. Resolution of spinal shock is heralded by the return of the bulbocavernous reflex. Without the applicability of spinal shock in a low lumbar burst fracture, absent bulbocavernous reflex is likely CES (Wheeless, n.d.).
• Failure to properly monitor for complications in postoperative spinal surgery (including serials neuro checks) may result in an undetected CES.
• The patient’s history of complaints and presentation, abnormal neurological exam, and sphincter function should be fully documented.
• The patient should receive adequate instruction at discharge to seek emergent treatment if bowel and bladder symptoms develop.
• Indications for use of steroids (such as Depomedrol® or Solumedrol®) to decrease spinal edema (Beeson, 2007) should be well documented.

A Look at Case Law
An intentional search of online case law was conducted using the GOOGLE search engine and keywords (in quotes) “cauda equina syndrome”, “medical malpractice”, “negligence” and “case law” in alternating string searches. A review of the information retrieved provided both formal and informal sources. Reliable sources were extracted by relying on both state (court home page) and federal (Pacer) public document retrieved via online resources. Both published and unpublished reports were entertained. Secondary sources were used only where the information could be adequately traced and verified as to content.

While the majority of available resources were issues on appeal, the initial allegations in litigation were principally based breach in the standard of care, based on a failure to diagnose CES and timely intervene with emergent surgical intervention to provide decompression. A sampling of the preliminary results via Internet retrieval is provided here:
• http://caselaw.lp.findlaw.com/scripts/getcase.pl?court=wi&vol=app2\98-0564&involume=1
• http://www.waranch-brown.com/practiceareas2.htm\anesthesiologist
• http://www.ttthlaw.com/News_Events/TT_H_in_Court/Archive/TT_H_in_Court_Archive/173/vobld\_710/

Potential Experts
• Neurologists, neurosurgeons, and orthopedic surgeons are likely to see the majority of clinical scenarios involving CES. While the neurologist’s involvement may stem from referral or emergent consultation, it is the neurosurgeon or orthopedic surgeon that will be called upon to initiate emergent surgical decompression to prevent or arrest any irreversible damage.
• Obviously, in the trauma or emergency room setting, the responding physician/residents/primary attending would need to be familiar with clinical presentation and emergent nature of spinal cord insults and injuries.
Additionally, from a diagnostic perspective, radiologists and/or neuroradiologists may also be retained.

Could also be retained.

**Damages**

While this list is not all-inclusive of potential damages, permanent neurological impairment of delayed detection of CES may manifest as:

- Urinary retention, requiring repeated daily self-catheterization or urinary incontinence secondary to loss of sensation;
- Bowel retention, requiring enemas for stimulation or manual deimpaction or incontinence due to loss of sensation;
- Foot drop or lower extremity weakness, requiring assistive ambulation or devices;
- Chronic radicular pain;
- Persistent numbness and permanent loss of sensation;
- or
- Sexual impairment or dysfunction.

**References**


Continued on page 30
Questions & Answers

Proper Invoicing for Services Rendered

AALNC Lexington, Kentucky Chapter: Rose Clifford, RN LNCC (President); K.C. Wagner, RN (Director-at-Large); and Donna Hunter-Adkins, BSN RN CCM CLCP LNCC (Past President)

Q: Do you have any suggestions regarding collecting for services I rendered?

A: Begin with a plan of how to format your invoice, develop guidelines to track your billing, implement a follow-up plan, and be professional but with clear expectations for payment.

All successful legal nurse consultants (LNCs) must determine the best way to submit invoices to their attorney clients. There are many ways to format this invoice. When setting up your billing or invoice system, decide upon a numbering system for your invoices. Examples: 00092708 (denotes date of invoice as September 27, 2008) or ABC000123 (denotes company initials and sequential numbering). This system is very easy to keep and track and can be done using a ledger book, notebook or the computer. You should record the date of the invoice, client name and amount of the billing invoice. A separate column is used to document the date the payment is received. You will need a separate column for recording of retainers paid (if any).

For those who wish to keep a more comprehensive billing system, there are several software products on the market. These products are especially helpful with tracking expenses for income tax purposes. You will need to decide if you want to issue an invoice on a monthly basis, at the end of high activity request or send an invoice at the conclusion of the case. If you have an accountant, as is often recommended, you should enlist their input on how best to establish your home billing system.

The following information should be included on the invoice statement:

- Date of invoice.
- Name and address of client.
- Manner invoice was sent (e.g., electronic, fax, U.S. Postal Service)
- Invoice number.
- Employee Identification Number (EIN) or Social Security Number (SSN) [This is necessary for IRS purposes.]
- Invoice statement should reflect legal nurse consultant’s name or company.
- Fees for services should be clearly listed on the invoice.
- Covered service period (e.g., services covering November 1, 2007 through November 30, 2007).
- The services should be either itemized or grouped or flat fee.
- The LNC should inquire if the client wishes the invoice to be presented in a specific manner.
- If the services are itemized, each item should be specified and should include the date of service and the amount of time spent on the service.

Like attorneys, some LNCs bill in increments of 6 minutes (0.1hr); others bill in increments of 15 minutes (0.25 hr). For services that are grouped, such as research, preparation of timelines or expert location, the amount of total time can be documented, rather than listing each time increment spent on the service.

Tips from the Trenches

- When accepting a case assignment, the LNC and the client should agree upon the fee. Be sure to include out of pocket expenses such as mileage, phone, copy, fax, etc. The rate for mileage should be at the current allowable rate per the Internal Revenue Service. See the IRS Web site at http://www.irs.gov (choose the individual/or business tab and enter “mileage” in the search box.) Note: it is considered bad form to raise your fee on cases you have already been assigned. When you make the decision to raise your fee, the change should refer to new cases only and you should inform the client of the fee change.
- Do not forget to subtract the retainer paid, if any, from the final billing. Consider using a credit column to reflect the reimbursement of any portion of an unused retainer.
- The final amount due should be in larger font and should be in a box or in a colored (such as red) font.
- The invoice statement should be clean and easy to read. Be sure to keep a copy of each statement and mark it as a “file copy.”
- The terms should be clearly stated (example: LNC Name sincerely appreciates your business. Payment is due upon receipt of this invoice. A service fee of 1.5% of the unpaid balance will accrue on a monthly basis). This statement can be placed in the footer section of the invoice statement. It is a good idea to establish early
on the contact person for payment. Often the contact person is a legal assistant or office manager who will issue prompt payment whereas the invoice may sit for months on the attorney's desk.

- If payment has not been received after 30 days, a courtesy call to the client’s accounts payable department is in order. In most cases, the payment will be processed as soon as possible. A follow up phone call to ensure that the invoice has been received and there are no questions regarding the billing may be necessary. Keep track of the dates of the contacts made in an attempt to collect the payment. A follow up letter respectfully requesting attention to the matter should be sent. Most attorney clients are honorable and will pay the invoice as soon as possible. As a last resort, the State Bar Association has a separate committee to handle fee disputes. Notifying the attorney client that you plan to notify their Bar Association usually results in prompt payment.

- If you utilize a contract with your attorney clients, you may want to specify that the venue for collection will be your city/state and that expenses related to collecting the debt will be the responsibility of the attorney client.

- If you are an expert witness named in the case, be aware that the invoice is discoverable. You may want to discuss with your attorney client as to how specific the invoice should be prepared. The opposing counsel will have a field day questioning you regarding specific entries.

- Be sure to submit a final invoice immediately upon the conclusion of your services. If the case has settled and the funds have been disbursed, you may be out of luck if you did not submit a bill in a timely manner. Consider adding a line that indicates “the LNC’s payment or Expert’s payment is not contingent upon the outcome of the case. Fee is due upon receipt.”

Tips from the In-House LNC

In-house LNCs, both plaintiff and defense, have ample opportunity to see a multitude of independent contractors’ invoices including invoices from outside legal nurse consultants. The in-house LNC is often privy to attorney conversations regarding the invoices. They see first-hand why some of the invoices are not paid right away and why others are paid immediately. For example, some invoices are not paid immediately because there are a number of forgotten items or inconsistencies frequently seen in invoices that would be helpful in expediting the process of payment.

The following identifiers make the invoice clear and concise:

1. Use your consulting firm letterhead.
2. List a contact number for questions.
3. Include the contracting firm’s case name, case style and/or matter number for which services were rendered.
4. Date each invoice.
5. Clearly identify the name in which the payment check is to be made to (e.g., business name vs. individual).

6. If first time invoicing law firm and the amount is over $600, send a completed W9 form along with the invoice.
7. Include the address where the check is to be sent if different from the letterhead.
8. Include tax identification number. Consider using the invoice to say “thank you for your business and we sincerely appreciate your referrals.”
9. Breakdown and description of services provided should include the hourly rate, dates on which the services were rendered and the amount of time spent on each date for each service.
10. Describe the services rendered (e.g., review of Dr. Smith’s office records, identification of liability issues, fact summary of medical records from XYZ hospital).
11. Make sure the invoice for payment is in accordance with the terms and conditions of the authorized fee agreement.
12. Expenses (if any) should be listed separately from consulting or expert services with a description of each expense including a copy of all receipts over $6.00.
13. Total dollar amount due should be clearly identified.
14. Add terms and conditions including a time frame within which payment is due and any penalties incurred if payment is late.
15. Send the invoice on a regular basis — generally on a monthly time frame
16. Do not wait until the end of the case (some cases take 2-5 years to complete).

Examples of an invoice can be found on page 710 of the first edition of the Legal Nurse Consulting Principles and Practice.

Sending a professional invoice and obtaining timely payment can be a smooth process or a very difficult and intimidating process. Be clear on the terms and conditions of payment prior to the commencement of rendering your services. Remember to talk about the necessary time required within which to provide the services requested and address the money up front including who is responsible for paying your invoice.

Suggested Reading


References


Rose Clifford (Cliffoordrz@aol.com), KC Wagner (kwagner@dbllaw.com), and Donna Hunter-Adkins (Medclaiman@aol.com) are the contributing authors for this issue’s Q&A.
The Journal of Legal Nurse Consulting
Topics Sought for Feature Articles

**Damages/Life Care Planning**
Calculating Damages for Pain and Suffering
Functional Capacity Assessment
Functional Testing: Approaches, Injury Management Integration

**Ethics**
Mental Retardation and (Forced) Contraception
HIV Litigation: Medical-Legal Issues, Treatment
Frozen Embryos/Stem Cells
Sperm and Egg Banks: Issues in Liability
Wrongful Birth
Drug Testing: Workplace, Athletes, Medical-Legal/Ethical Issues

**Law**
Qui Tam and Whistle-Blower Litigation
Expert Panels in Complex Medical-Legal Scientific Litigation
Biomaterials
Conflict of Interest

**Criminal Law**
Correctional Nursing
Death Investigation
Prescription Medications in Death Investigations
Sexual Assault Forensic Examination
Driving Hazards/Doctor’s Liability: Diabetics, Seizure, Alzheimer’s
Insanity Defense
Shaken Baby Syndrome

**Employment Law**
Worker’s Compensation Issues: Fraud, Representing Undocumented Workers, Types of Injuries, Malingering, Assessing Disability, AMA Guidelines, Occupational Asthma

**Medical Malpractice**
Medication Co-prescriptions: Responsibility in Adverse Reactions, Abuse
Medical-Legal Issues in Telemedicine/Teleradiology
Failure to Diagnosis Breast Cancer: Liability, False-Negative Mammograms
Dental Litigation: Temporomandibular Disorders
Missed Diagnosis of MI
Use of EKG and Cardiac Enzymes
Delayed Diagnosis/Treatment of Stroke, CVA: Heparin/TPA Emergency Room Law

**Personal Injury**
Carpal tunnel Litigation
Repetitive Stress Injuries

**Psychiatric Issues**
Malingering: What to Look For
Lack of Supervision and Liability: Suicide

**Toxic Tort**
Carbon Dioxide Poisoning
Mercury poisoning
Lead Poisoning

**Miscellaneous**
School Disability Litigation, IEPs
School Nurse Standards
Autopsy Findings/Terminology
Pharmacy Responsibilities for Patient Education, Informed Consent
Legalization of Marijuana
Athletic Injuries: Medical-Legal and Malpractice Standards in Treatment
Evaluation of Hearing Loss
Ambulatory Care/Outpatient Care Settings
Latex Gloves/Sensitivities
Fraud: Medical Bill Review
The Clinical Maxim: Cauda Equina Syndrome

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Membership in AALNC includes:

• **NetworkNews** – The quarterly newsletter of the American Association of Legal Nurse Consultants is housed in the Members Only section of the AALNC Web site. This member benefit provides important industry news, Association highlights, regional updates, and a dedicated LNCC section.

• **The Journal of Legal Nurse Consulting** – AALNC’s official journal is published quarterly. Members are also able to access past issues online through the JLNC Archives (within the Members Only section).

• **Professional Liability Insurance** – AALNC officially sponsors Professional Liability Insurance offered through Nurses Service Organization. The insurance offered through NSO has many exclusive benefits and features that enhance your protection as a practicing LNC and offers discounts not available elsewhere!

• **eCommunities** – Connect with LNCs and fellow AALNC members across the country through your computer! This online networking tool allows members to communicate with one another through various Discussion Forums – similar to a listserv, but with more capabilities and a more efficient exchange of information.

• **Attorney Awareness** – AALNC has initiated a dedicated marketing campaign to attorneys from all practice specialties. As a member of AALNC, you know that the professional organization for LNCs is working to raise awareness of the specialized skills an LNC brings to each case.

• **LNCLocator** – When attorneys need an LNC, they turn to AALNC’s public online LNC search engine, the LNCLocator. This tool allows attorneys to quickly and easily search for an LNC by geographic area, nursing specialty, or LNC practice area. Being listed in the LNCLocator is a free membership benefit.

• **VerdictSearch** – AALNC members are entitled to receive 30% off any VerdictSearch print publication, including newsletters, books, binders, and indexes, as well as 30% off the annual subscription price of the VerdictSearch Online Database.

For more information about AALNC membership and its countless member benefits, please visit [www.aalnc.org/membership/](http://www.aalnc.org/membership/).
Writing Skills
Kara L. DiCecco, MSN RN LNCC

Initiation to nursing demands from the individual rapid growth in the ability to prioritize responsibilities. Out of necessity, to address the details of bedside care balanced with the need for adequate documentation, nurses quickly assume an adaptive strategy; communication via fragmented sentences. Articles, nouns, and the like are repeatedly sacrificed to hurriedly chart: “Denies shortness of breath.” While generally sufficient to meet the needs of continuous assessment between health care providers, a return to proper sentence structure is expected by both attorneys and patrons of the courts. Discriminating writing skills and attention to detail help to define the LNC’s professional reputation.

The following sites provide resources for confirming correct punctuation and grammar, citation resources, variable report styles, differentiating between primary and secondary sources, and clarification of the inclusions for a resume versus the curriculum vitae (C.V.). This list is provided as a general reference source for the LNC and is not an endorsement of any commercial sites or services. As with any online resource, the reader must confirm its authority and credibility independently.

Writing for Professional Development

http://owl.english.purdue.edu/owl/resource/681/01/
The Online Writing Lab (OWL) at Purdue is the mecca of writing resources. Topics abound on everything from differentiating between primary and secondary resources in citation to sample styles of report writing by discipline; information on correct grammar usage to avoiding plagiarism; manuscript formats and styles for publishing to basic structure of the research paper. This generous contribution to the Web warrants a top place reserved in your bookmarks or favorites. This link at OWL leads you to workplace writers where it covers business writing, CVs and resumes, specific reports and more.

http://med.stanford.edu/careercenter/career_management/resume_writing.html
I always wanted to go to Stanford School of Medicine but I’ll settle for their online career center for right now. This site provides suggestions for C.V./resume development. Nice touch of specifics for medical experience.

From the University of Washington, School of Pharmacy an informative article on writing your C.V. or resume. Complete with examples.

http://www2.hfcc.edu/english/OnlineWritingLab.htm
LA College International provides an extensive menu of writing choices. Starting with the main link, you can explore dictionaries, thesauri, almanacs, global languages, grammar rules, essay writing, grant writing, business plans… well, everything from B to Z as the site says.

Citations

http://www.citationmachine.net/
Landmark’s Son of Citation Machine provides a quick one-stop access to MLA, Turabian, APA and Chicago Manual Writing Styles.

http://www.easbib.com/
An interesting site that provides an automatic citation list in MLA format. (other formats available by subscription) A good confirmation tool to make sure you have included all necessary information in your citation.

http://www.easternct.edu/smithlibrary/library1/citing.htm
This site provides numerous resources in writing courtesy of Eastern Connecticut State University. This link takes you to the Smith Library’s “Citing Your Sources.” Special attention to citing in the electronic age is found a the multiple links provided. Be sure to scroll down to check out the tutorial “Oops, I plagiarized.”

http://www.classroom.com/community/connection/howto/citeresources.html
Excellent coverage of electronic citation styles by Classroom Connect.

http://law.lib.buffalo.edu/departments/info-services/research/webguides/writing.asp
From the University of Buffalo, Charles S. Sears Library. Multiple citation and legal writing resources here. Especially helpful is the link to the American Bar Association’s Universal Citation.

http://www.law.cornell.edu/citation/
An online reference from the Legal Information Institute to at Cornell School of Law for BlueBook Citation (18th edition) by Peter W. Martin.

Punctuation and Grammar

http://www.bartleby.com/141/index.html
Strunk and White is the gold standard for enhancing writing skills in law school. This online version of the well-known, highly-regarded reference will answer many questions about grammar usage and punctuation.

http://owl.english.purdue.edu/handouts/print/grammar/index.html
This is a handy and informative link to grammar instruction complete with downloadable handouts. Everything your eighth-grade English teacher said you would need to know about someday regarding grammar can be found here.

http://www.dianahacker.com/resdoc/home.html
Known scholar in writing, Diana Hacker, makes a available sample papers, finding sources and citation styles in this online reference. She also has several online guides, including how to critically evaluate retrieved sources.

Understanding Primary Sources

http://www.lib.berkeley.edu/instruct/guides/primarystyles.html
Always generous, the University of California Berkeley Library provides an excellent resource for understanding, finding and locating primary resources in writing.

Writing Practicum

http://www.library.unm.edu/govinfo/browse-topics/research-and-writing-tips
The University of Northern Texas offers two informative resources on this page: 1) Government writing 2) Research and writing about the law. Be sure to click up or down levels to see what other resources are available.

http://www.aboutus.org/Portal:Writing_Lab
A dedicated interactive Wiki page (requires free sign in) that will allow you to post works in progress (obviously nothing client related but personal essays, compositions, etc.) and receive feedback and critique to help develop your writing skills. All forms of guides and assistance available.

http://law.wvu.edu/library/research_guides/internet_research_guides
West Virginia University College of Law provides these handy PDF guides on formatting in Word for research and legal writing. A nifty trick with computers.

http://www.gulbransen.net/legal-resources.php
IIts not just legal writing resources you’ll find on David Gulbransen’s web page. On his personal website, David Gulbransen has amassed a comprehensive list of legal links… just some to check out Lawnerds, Introducing Plain Language, and Handbook of Rhetorical Devices.

http://www2.hfcc.edu/english/OnlineWritingLab.htm
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The Journal of Legal Nurse Consulting (JLNC), a refereed publication, is the official journal of the American Association of Legal Nurse Consultants (AALNC). The journal’s purposes are to promote legal nurse consulting within the medical-legal community; to provide both the novice and the experienced legal nurse consultant (LNC) with a high-quality professional publication; and to teach and inform the LNC about clinical practice, current national legal issues, and professional development.

The journal accepts original articles, case studies, letters, and research studies. Query letters are welcomed but not required. A manuscript must be original and never before published, and it should be submitted for review with the understanding that it is not being submitted simultaneously to any other journal. Once submitted, articles are subject to peer review (publication is not guaranteed).

Manuscript format

Manuscripts should not exceed 3,000 words in length. The title page should include the title of the manuscript and the authors’ names, credentials, work affiliations and addresses, daytime phone numbers, fax numbers, and e-mail addresses. One author should be designated as the corresponding author. The title page, the tables and figures, and the reference list should each appear on a separate page. Pages, beginning with the title page, should be numbered consecutively.

Manuscript submission

Manuscripts should be sent to the JLNC Managing Editor via e-mail at JLNC@aalnc.org, as a Microsoft Word attachment. (If not possible, an electronic copy on CD can be mailed to the JLNC Managing Editor; address above.) Use a minimum of formatting: do not use unusual fonts or a variety of type, and do not insert headers or footers except for page numbers. Create a separate file for tables and figures—do not insert them into the text file. Clearly label your e-mail (or CD) with the submission title, word processing program name and version, and name of the corresponding author.

Style and reference guidelines


Reprint permission for copyrighted material

When using figures or tables from another source, the author must obtain written permission from the original publisher and include that as part of the manuscript submission materials.

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Figures and tables

Figures include line drawings, diagrams, graphs, and photos. Tables show data in an orderly display of columns and rows to facilitate comparison. Each figure or table should be labeled sequentially (e.g., Figure 1, Figure 2 or Table 1, Table 2) and should correspond to its mention in the text. All photographs must be black-and-white electronic files.

Manuscript review process

Manuscript submissions are peer reviewed by professional LNCs with diverse professional backgrounds. First-time authors are encouraged to submit manuscripts. Manuscript assistance can be provided upon request to the editor.

Acceptance will be based on the importance of the material for the audience and the quality of the material. Final decisions about publication will be made by the editor.

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Manuscript checklist

Please use the checklist below to be sure that your submission follows JLNC guidelines.

☐ The manuscript is being submitted exclusively to the JLNC and has not been published previously.

☐ Guidelines in the Publication Manual of the American Psychological Association (5th ed.) and The Bluebook: A Uniform System of Citation (15th ed.) (for legal citations) have been followed.

☐ All references cited in the text are included in and agree with the reference list. References in the reference list appear in alphabetical order and include all the elements described in Publication Manual of the American Psychological Association (5th ed.).

☐ Permission for including or reproducing previously published information (e.g., tables and figures) is enclosed.

☐ Numbers and percentages have been checked against one another and the text for accuracy.

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☐ The title page includes the title of the manuscript and the authors’ names, credentials, work affiliations, addresses, daytime phone numbers, fax numbers, and e-mail addresses.

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