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FORUM



# Further Reducing OB Risks

Issue Editor: Deborah LaValley, BSN, RN, CPHQ

# Commentary: Carrots, Not Sticks: Using Malpractice Insurance Premium Incentives to Promote Patient Safety

**by John L. Mc Carthy**

Jack Mc Carthy is President of CRICO/RMF

This issue of *Forum* focuses on many key facets of risk for women (and their babies) receiving obstetrical care. Despite the best intentions, training, and experience, highly-skilled clinicians make mistakes that sometimes lead to tragic outcomes. Poor obstetrical outcomes, even when the standard of care was met, can result in lawsuits that are difficult to defend. At CRICO/RMF, our goal is to find the best way to help obstetrical care providers make care safer and concurrently reduce their risk profile.

Recently, the Centers for Medicare and Medicaid Services (CMS) announced[1] that Medicare will not reimburse costs relating to certain types of hospital acquired infections—one more example of negative incentives being applied to the health care setting. I am not confident that negative incentives are effective. Instead, CRICO/RMF (a provider-sponsored company) remains committed to positive incentives as a way to foster change. Our approach has definitely been carrots, not sticks, and the results have exceeded expectations.

CRICO/RMF's incentive program originated with a professional liability insurance (aka malpractice) premium discount for anesthesiologists who participated in simulator training and completed online CME courses related to patient safety. In 2003, we initiated the OB Risk Reduction Program.[2] Last year we introduced an incentive for office-based practices and, next year, we will begin a program to encourage surgeons to take the fundamentals in laparoscopic surgery exam. While some insurance programs might find it easier to simply raise premiums for clinicians who make mistakes, our choice is to offer training programs to sharpen provider skills and to recommend systems-based approaches to mitigate risk and improve patient safety. The relatively modest financial incentives simply make our carrots easier to swallow.

Let's look at the "interim" results:

**Anesthesia:** After five years, an independent actuary determined that a 19 percent rate differential (decrease) was appropriate for anesthesiologists with simulator training. In addition, anesthesia department chiefs are moving to make simulator-based training a mandatory requirement for credentialing. If approved, CRICO will act in concert by making the training a condition of coverage.

**Obstetrics:** Based on the success of the anesthesia incentive, CRICO approved a 10 percent premium discount to obstetricians who engaged in simulator and team training, as well as some directed self-study. Since our pilot in 2003, more than 85 percent of attending obstetricians have participated; in 2006, residents

and certified nurse midwives were added to the incentive plan. Early results show a drop in malpractice claims frequency and a downward trend in adverse outcomes.

**Office Practice:** CRICO/RMF conducts office practice evaluations (OPEs) to assess real-time risk identified in office-based malpractice claims—in particular, diagnosis-related processes. By focusing on a) management of abnormal test results, b) referral management, and c) patient assessment, the OPE program provides office-based physicians with a proactive tool for maintaining effective and safe care. Practices that comply with criteria in six key categories receive a premium discount. Those that fall short of the incentive goal are given an opportunity to address areas of concern and undergo re-evaluation. At this early stage, malpractice trends cannot be linked to the office practice incentive, but CRICO/RMF's initiation of this and other incentive programs is based on an expectation of reduced risk and fewer patient injuries.

CRICO/RMF is committed to continue working with the clinical leaders in the Harvard-affiliated medical institutions. These institutions are rapidly adopting the components of our premium discount programs and moving toward their inclusion in credentialing standards. Based on our success to date, a number of other specialties are working with us to adopt similar programs. Perhaps, if we can hand out enough carrots, then someday CMS will put away its sticks and, instead, focus its resources and clout on helping to reform the expensive and counter-productive tort system. ■

References

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# Obstetrics-related Malpractice Cases 1997–2007

**by Deborah LaValley, BSN, RN, CPHQ, and Jock Hoffman**

Ms. LaValley is a Program Director for Loss Prevention/Patient Safety for CRICO/RMF and Issue Editor of Forum. Jock Hoffman is Editor of Forum.

Birth-related malpractice is rare. For more than 99 percent of women who give birth at a CRICO-insured hospital, the care she and her newborn receive meets an acceptable standard (i.e., no malpractice is affirmed).[1] Of course, the outcome may not always be "perfect," but any suboptimal result is not deemed to be anyone's "fault."

Nevertheless, even with that remarkable level of care and safety, the obstetrical leaders and clinicians practicing in the CRICO-insured hospitals aim to do even better. Given the high volume of deliveries in CRICO-insured settings (>25,000 per year) even a miniscule percentage of errors translates into an untenable number of preventable adverse outcomes. Those rare "substandard" events deserve scrutiny for opportunities to minimize recurrence. This issue of *Forum* explores obstetrics-related claims asserted over the past decade in an effort to identify common themes among such events.

Obstetrics-related cases constitute about seven percent of all malpractice cases asserted against CRICO-insured providers since 1997, and more than 14 percent of CRICO's total incurred costs (*see* Table 1). That variance is not unusual: obstetrics-related claims that a) involve an adverse outcome to a newborn, or b) impact a woman's continued ability to reproduce, can be more difficult to defend and more costly to resolve than other type claims.

Among CRICO's perinatal cases, the most frequent allegation (31 percent of cases) was that the clinicians failed to recognize and respond to fetal distress. Another third of the cases challenged the decisions made by physicians and nurses (i.e., clinical judgment) regarding the management of labor and/or delivery. Not surprisingly, inadequate communication—both among clinicians and between clinicians and delivering women—is frequently found to be a contributing factor in cases alleging "mismanagement" of labor and delivery. In the May 2005 issue of *Obstetrics and Gynecology,* White et al. show that poor communication is a significant factor in dissatisfaction with obstetric and gynecologic care and a motivation for filing obstetrics-related malpractice lawsuits.[2]

Obstetric providers understand that each adverse event—especially those that might have been better managed—is a personal tragedy for the parents and clinicians involved. Working to prevent the recurrence of errors, and also to better understand how to prepare for, and respond to, unexpected (sometimes unexplainable) circumstances, is motivated by the gravity of those unfortunate events. For more than 20 years, the CRICO-insured institutions have collaborated to instill and maintain a culture of safety in their labor and delivery units through the development of guidelines, team training, and ongoing case review and quality improvement.

Table 1

**CRICO Obstetrics-related Cases[a]**
**Asserted 1997–2007 (N=167 cases)**

From 1997–2007, events related to labor and delivery accounted for:
- 7% of all CRICO cases
- 11% of all CRICO clinician defendants
- 14.5% of all total incurred losses[b]

| Cases | All CRICO Cases | Obstetrics-related |
|---|---|---|
| Claims and suits | 2,405 | 167 |
| Defendants | 4,926 | 448 |
| Closed cases | 1,827 | 118 |
| Closed with payment | 532 (29%) | 37 (31%) |
| Total incurred losses | $839,000,000 | $122,000,000 |
| Average indemnity payment[c] | $536,000 | $1,200,000 |
| **Defendants** | **All CRICO Cases** | **OB-related Cases** |
| Staff physicians | 2,060 | 199 |
| Residents | 433 | 54 |
| Fellows | 109 | 2 |
| Nurse midwives | 27 | 26 |
| Registered nurse | 296 | 40 |
| Institutions | 1,708 | 116 |
| Other | 308 | 11 |
| **Total** | **4,941** | **448** |

a Includes birth-related cases naming a CRICO-insured provider or institution asserted between January 1, 1997 and March 31, 2007
b Aggregate of expenses, reserves, and payments on open and closed cases
c Average of all cases with an indemnity payment

Efforts to improve teamwork in Labor and Delivery units have had significant impact on how clinicians communicate and work together to mitigate error. As that culture evolves, obstetrics leaders continue to expand their patient safety focus to address some even more difficult malpractice challenges: EFM interpretation, cervical insufficiency, preterm deliveries, and stillbirths. Those risk areas, as well as concerns related to anesthesia and informed consent, are explored throughout this issue of *Forum*.

CRICO/RMF's commitment to obstetrical patient safety continues on numerous other fronts, including the OB Risk Reduction Program (i.e., premium incentive),[3] online CME courses,[4] updating and revising the *Clinical Guidelines for Obstetrical Providers*,[5] team training for certified nurse midwives, and the September 2007 OB Symposium.[6] ■

References

1. CRICO-insured hospitals deliver approximately 25,000 births annually; birth-related malpractice claims average fewer than 17 per year.
2. White AA, Pichert JE, Bledsoe SH, Irwin C, Entman SS. Cause and effect analysis of closed claims in obstetrics and gynecology. *Obstet Gynecol.* 2005;105:1031-1038:
3. www.rmf.harvard.edu/high-risk-areas/obstetrics/ob-risk-reduction-program/general-information.aspx
4. www.rmfcme.com
5. www.rmf.harvard.edu/files/documents/obguide_06.pdf
6. www.rmf.harvard.edu/events/ob-symposium-2007-description.aspx

Table 2

**CRICO Obstetrics-related Cases[a]**
**Asserted 1997–2007 (N=167 cases)**

Almost two-thirds (65 percent) of the obstetrics cases involved a high-severity injury.[bS]

- 63% derive from mismanagement of labor and/or delivery
- 31% allege a delay in responding to fetal distress
- 20% involve misinterpretation of diagnostic studies (e.g. EFM strips)
- 20% reflect a breakdown in communication among clinicians

| Top Allegations | Cases | Incurred Losses[c] |
|---|---|---|
| Delay in treatment of fetal distress | 52 | $57,700,000 |
| Improper choice of delivery method | 23 | $12,708,000 |
| Improperly managed labor (other) | 14 | $15,659,000 |
| Delay in delivery (induction/surgery) | 14 | $9,075,000 |
| Improper management of pregnancy | 12 | $6,624,000 |
| Improper performance of vaginal delivery | 11 | $4,287,000 |
| Retained foreign body | 10 | $449,000 |
| Improper performance of operative delivery | 4 | $4,693,000 |
| **Top Risk Management Issues[d]** | **Cases** | **Percent of Cases** |
| Management of labor and delivery | 106 | 63% |
| Misinterpretation of diagnostic studies | 34 | 20% |
| Communication among providers re: patient condition | 34 | 20% |
| Management of pregnancy | 25 | 15% |
| Failure/delay ordering diagnostic test | 24 | 14% |
| Patient monitoring | 19 | 11% |
| Insufficient documentation: clinical rationale | 17 | 10% |
| Inadequate consent process | 16 | 10% |
| Communication language barrier | 13 | 8% |
| Lack of/inadequate assessment/note re: clinical information | 13 | 8% |
| Failure to obtain a consult | 12 | 7% |
| Inadequate assessment/premature discharge | 12 | 7% |

a Includes birth-related cases naming a CRICO-insured provider or institution asserted between January 1, 1997 and March 31, 2007
b Includes death and permanent grave, permanent major, and permanent significant injuries.
c Aggregate of expenses, reserves, and payments on open and closed cases
d A single case may involve multiple risk management issues

# An Early Warning System

**by Roxane Gardner, MD, MPH**
Dr. Gardner is an Obstetrics Specialist for CRICO/RMF.

CRICO/RMF[1] is sponsoring a perinatal adverse event (pilot) project aimed at creating an early warning system to supplement obstetrics-related claims data and facilitate more timely actions towards improving obstetric care across Harvard-affiliated perinatal units.

Over time, CRICO/RMF has generated a multi-dimensional approach in its effort to reduce obstetrics-related risk, the cornerstone of which is regularly meeting with the obstetrics chiefs of Harvard's affiliated Labor and Delivery units and their associated nurse managers and certified nurse midwifery directors. Malpractice claims data are periodically reviewed at these meetings, informing the development of programs aimed at standardizing obstetrical care and strengthening CRICO/RMF's system-wide efforts to reduce obstetrical errors and adverse events.

The "chiefs" meetings began in the late 1970s, giving rise to the Clinical Guidelines for the Obstetrical Services of the CRICO-insured Institutions.[2] Specific programs to cultivate teamwork skills have also been developed and are key elements of an obstetric risk reduction program, rewarding specific, prescribed risk reduction activities with a malpractice premium discount. These measures have contributed to a malpractice claim rate (for CRICO-insured obstetrical clinicians) of <1 per 1,000 births. Despite significant reductions in claims asserted and closed with payment over time, we still see opportunities to address recurring risk management issues (see Table 2). Because obstetrics-related claims are based on outcomes and process failures originating anywhere from three to, in some cases, more than 10 years prior to when the claim is asserted, the Harvard obstetrics chiefs posed the following question:

Instead of relying on "after-the-fact" malpractice claims data, can consistent, systematic reporting of perinatal adverse events by institutions result in an early warning system that promotes safer, high quality care of mothers and babies CRICO-wide?

To find out the answer, the chiefs have agreed to pilot such a system in hopes of designing a better way to more promptly identify and address perinatal risks emerging at each institution. Armed with that information, the participating institutions[3] will have better opportunities to learn from each other in a safe environment—in real-time, instead of after-the-fact.

With CRICO/RMF serving as the clearinghouse for data collection and analysis, the chiefs agreed to a set of quality metrics selected from adverse perinatal events data currently collected by the obstetric QA committees and reportable to the Commonwealth of Massachusetts. A subcommittee of the Harvard obstetrics chiefs committee will review the collated data and present its findings to the group at large in 2008.

References

1. CRICO/RMF is the patient safety and medical malpractice company serving the Harvard medical community since 1976, dedicated to assisting clinicians in delivering the safest health care in the world.
2. The OB guidelines are revised and updated on a regular basis. The most recent version, approved for use in 2006, is available at http://www.rmf.harvard.edu/files/documents/obguide_06.pdf
3. Beth Israel Deaconess Medical Center, Brigham and Women's Hospital, Cambridge Health Alliance, Harvard Vanguard Medical Associates, Massachusetts General Hospital, Mount Auburn Hospital, Newton-Wellesley Hospital, and North Shore Medical Center

# Delayed Response to Fetal Distress

A newborn died shortly after birth following a prolonged labor with signs of fetal distress.

**by Deborah LaValley, BSN, RN, CPHQ**

Ms. LaValley is a Program Director for Loss Prevention/Patient Safety for CRICO/RMF, and Issue Editor of Forum.

CASE STUDY

## Key Lessons

- Clinicians faced with situations unfamiliar or worrisome need to consult with others who are more experienced or knowledgeable, or simply offer a fresh perspective.
- Physicians covering for others need some process to gain an understanding of any aspects that may place the patient at increased risk of problems.
- Teams in which providers do not trust each other—and thus do not communicate well—decrease the individual provider's ability to work.

## Clinical Sequence

*Monday 11:00 a.m.* An obese, 33-year-old mother of four (G6, SAB1, P4) with pregnancy-induced hypertension (controlled with atenolol), hypothyroidism, asthma, and gestational diabetes contacted her obstetrician's office stating she was full term and "in labor."

*Monday 1:00 p.m.* After evaluation at the hospital, the patient was discharged home.

*Tuesday 9:00 a.m.* The patient returned to the hospital and was admitted to Labor and Delivery.

*10:30 a.m.* The patient was triaged by a certified nurse midwife whose vaginal exam revealed the patient was 3cm dilated/ 50 percent effaced/-4 station.

*10:45 a.m.* The patient was assessed by the attending OB/GYN. The baby had a fetal heart rate (FHR) 130–140 and was in a transverse lie. The attending OB/GYN decided to attempt an external version to reposition the baby. The patient was informed of the risks and benefits of the procedure, and signed a consent for the version and possible cesarean section.

*11:30 a.m.* During the placement of an epidural (which was difficult), the baby moved into the vertex position; the version was cancelled. During a repeat ultrasound, which confirmed the baby's vertex position, membranes were (artificially) ruptured; fluid was clear. The attending OB/GYN attempted to place a scalp electrode (for better FHR capture) but was unsuccessful despite several attempts. Another OB/GYN was able to place the electrode.

*12:30 p.m.* The attending OB/GYN told the nurse that he wanted to get a scalp pH. As they waited for Respiratory to arrive, the FHR dropped into the 70s and the attending OB/GYN decided to do a cesarean section.

*12:40 p.m.* The FHR returned to its baseline (110–120s) and went up into the 130-140s with scalp stimulation. The cesarean section was cancelled. Vaginal exam revealed 6–7cm dilated /75 percent effaced/-3 station; no evidence of cord prolapse.

*1:00 p.m.* The FHR dropped and a cesarean section was again planned for. Then when the FHR recovered, the cesarean section was again cancelled.

*1:00–3:00 p.m.* Over the next two hours the FHR gradually began to increase with variable decelerations noted. The patient was repositioned and the attending OB/GYN was notified. The nurse caring for the patient—concerned about the attending's management of the patient's labor—informed her head nurse, who discussed the case with the physician.

*4:00 p.m.* The baby's baseline FHR increased to 180.

*4:20 p.m.* The FHR dropped into the 90s with variable decelerations. For the next 45 minutes, the attending OB/GYN attempted to obtain a scalp pH, during which time the FHR continued to drop with recurring deep decelerations. The nurse paged another OB/GYN to attempt the scalp pH (against the wishes of the attending), but he was unavailable.

*4:45 p.m.* The patient was fully dilated; a scalp pH revealed severe acidosis. The patient was brought to the OR, but the attending OB/GYN felt that a vaginal delivery would be quicker; he declined a vacuum to assist in the delivery.

*5:00 p.m.* The baby was delivered vaginally with a tight double nuchal cord; Apgars were 1, 3, and 5. After the delivery, Pediatrics was called; a pediatric resident arrived three minutes later. The baby was brought to the NICU and placed on life support for continued signs and symptoms of metabolic acidosis, hypoxemia, and disseminated intravascular coagulation (DIC). The birth cord pH was 6.86. Four days after delivery, the parents elected to remove the life support and the baby died shortly thereafter. Results of the autopsy showed no evidence of any congenital or developmental abnormalities. The case did meet all of ACOG's criteria for an acute intrapartum hypoxic event.[1]

## Allegation

The parents alleged that the attending OB/GYN failed to diagnose and treat fetal distress, resulting in the delivery of their baby with severe hypoxic ischemia, and his death.

## Disposition

The case was settled in the high range (>$500,000).

## Analysis

1. During this woman's labor, the physician demonstrated inexperience and indecision, frequently changing his plan of action. He did not trust his knowledge that this was an ominous fetal heart pattern, and backed off the plan to deliver by cesarean section. In the end, that decision appears to have impacted the child's condition.

Although physicians need to respond to the circumstances as they present themselves, those faced with situations unfamiliar or worrisome need to consult with others who are more experienced or knowledgeable, or simply offer a fresh perspective. If you are experiencing uncertainty, do not hesitate to request a consult.

2. This patient had a complicated obstetrical history and numerous health issues. The attending OB/GYN met her for the first time on the day she was admitted to Labor and Delivery.

   Physicians covering for others need some process to gain an understanding of the patient's history, status, and any aspects that may place the patient at increased risk of problems. Once any risks are identified, the care plan can be appropriately personalized. Without that information on hand, the covering physician is left to rely on standard procedure and the patient's ability and willingness to share crucial information.

3. Communication within the care team broke down and may have delayed decisionmaking. The OB/GYN's reluctance to seek a consult, and the nursing staff's inability to resolve discordance, hindered a prompt and proper response to the fetal distress.

   Inadequate communication among providers regarding the plan of care for a patient is a common path for substandard care. Teams in which providers do not trust each other—and thus, do not communicate well—decrease each individual provider's ability to work effectively. In a well functioning team, individuals are better able to anticipate the needs of the others, including the patient.

4. The patient's primary nurse expressed to her supervisor concern about the course of events and the OB/GYN's plan, but her discomfort was not resolved after the supervisor spoke to the physician.

   Obstetrical nurses have an independent responsibility to the patient and the unborn child and need support and training that encourages and enables them to activate the chain of command when:

   - there is a significant change in the FHR baseline,
   - the attending obstetrician fails to provide care in accordance with the accepted standard of care,
   - the nurse disagrees with the attending obstetrician's interpretation of the fetal heart monitor, or
   - the attending obstetrician prepares an inadequate treatment plan.

   Once the chain of command is activated, failure to continue until the issue of concern is appropriately resolved jeopardizes the patient's safety and the clinical team's liability.

Note

1 The American College of Obstetrics and Gynecology defines an acute intrapartum hypoxic event as one which meets the following criteria:
   - pH of <7,
   - early onset of severe or moderate encephalopathy,
   - Apgar scores of 0–6 for longer than five minutes,
   - early evidence of multisystem involvement, and
   - early imaging evidence of acute cerebral abnormality.

## Optimizing Outcomes, Reducing Risk for the Obstetric Patient

This issue of Forum addresses many opportunities for the improvement of obstetrical care and the reduction of malpractice claims against obstetrical clinicians. Below is a brief summary.

**Patient Assessment**
- Preconception: promote smoking cessation and weight control.
- Prenatal: obtain full medical and obstetrical history.
- Patients with history of preterm births: maintain vigilance, e.g.,
  - monitor cervical length with periodic transvaginal ultrasounds, and
  - consider administering weekly 17 alpha-hydroxyprogesterone.

**Consent**
- Discuss proposed actions, risks, benefits, and alternatives with the patient and her partner early on and throughout the patient's pregnancy.
- Discuss with the patient her plans and expectations for childbirth.
- Confirm with the patient and her partner that the patient is the one best able to make decisions during labor.

**Stillbirth**
- Initiate preconception counseling regarding weight, aiming to optimize weight prior to pregnancy.
- Encourage smoking cessation.
- Control blood glucose levels.
- Fetal ultrasound: evaluate for presence of congenital anomalies.
- Minimize higher order multiple gestations (triplets or more).
- Monitor fetal growth with periodic fetal ultrasounds for high risk pregnancies.
- Assess fetal activity using fetal kick counts.
- Have a low threshold for fetal evaluation with reports of decreased fetal activity.

**Shoulder Dystocia**
- Be familiar with the evidence-based risk factors for shoulder dystocia:
  - history of previous shoulder dystocia,
  - macrosomia,
  - gestational diabetes,
  - small maternal stature, and
  - operative vaginal delivery: forceps or vacuum.

**Quality Measures**
- Select and monitor pertinent process and outcome indicators to identify opportunities for improving quality and safety of obstetric care in the ambulatory and hospital setting.
- Provide education and "practice" opportunities for providers (e.g., simulation, team training, effective communication, emergency response drills, use of guidelines/algorithms).
- Perform routine rounds in Labor and Deliver two or more times a day to facilitate situation awareness, cross-monitoring, and collective appreciation for the plan of care.

**Miscellaneous**
- Periodically evaluate staff cognitive skills, such as with written examinations as specified by ACOG, AWHONN, ACNM, or AAFP.
- Convert to computer-assisted medication prescribing and order entry and electronic medical records.

# EFM Expertise

**by Marian Dwyer, RN, MA, CPHRM, ARM**

Ms. Dwyer is Director, Patient Safety & Loss Prevention, for MCIC Vermont, Inc.

Electronic fetal monitors (EFMs) provide obstetrical clinicians with a mechanism for monitoring the fetal heart rate (FHR) pattern and presumably the baby's tolerance to the events of labor and delivery.

The information captured and recorded by these EFMs can also be a critical factor in medical malpractice claims involving obstetrical care. Medical experts testifying on behalf of plaintiffs frequently allege failures or delays in recognizing fetal or maternal abnormalities on EFM tracings. Disputing such allegations can prove challenging because of inconsistent interpretation and documentation practices historically employed by obstetrical clinicians.

Certainly, the validity of EFM as a diagnostic tool (either prospective or retrospective) has been challenged by clinicians as strongly as it has been touted by plaintiffs' attorneys.[1] While that vigorous debate continues, however, the fact remains that electronic monitoring is ubiquitous—both in the Labor and Delivery units and in the courtroom. Indeed, obstetric-related malpractice cases are often decided based on the interpretation of EFM strips. Physicians and nurses who lack standardized EFM training and terminology may find themselves at greater risk for allegations of mismanagement of labor and delivery.

The absence of a common EFM nomenclature is one factor contributing to differing interpretations and miscommunication. As fetal heart monitors have evolved over the past several decades, there has been no concurrent evolution of a standard language for defining or describing FHR patterns or maternal contraction patterns. In the 1990s, an interdisciplinary group was convened by the National Institute of Child Health and Human Development (NICHD) specifically to address the absence of standard EFM definitions. Prior to that, there was no single standard, unambiguous set of definitions; physician and nursing literature typically referenced differing nomenclature for describing FHR patterns seen on electronic monitors. Most nurses and doctors acquired their EFM interpretation skills through on-the-job training rather than as a component of formal didactic education.

In 1997, the NICHD workgroup established unambiguous definitions for FHR tracings announced via publication of two seminal articles.[2-3] Over time, the American College of Obstetricians & Gynecologists (ACOG) and the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) formally endorsed the NICHD definitions (now commonly referred to as the *NIHCD Terminology*). Widespread adoption of these standardized FHR definitions within clinical settings has been slowly taking place.

## EFM Certification

In 2003, the MCIC Vermont[4] committee overseeing claims and risk management sought to address the issue of EFM strips from a loss prevention perspective. As part of a comprehensive patient safety initiative designed to reduce obstetrical liability risk at MCIC hospitals, we established an Obstetrical Leadership Committee comprising medical and nursing perinatal leaders from all 11 insured hospitals. Recognizing the regularity with which communication breakdowns contributed to medical malpractice claims, the committee sought to standardize communication among obstetrical clinicians.

This aggressive undertaking comprised several components, including formal adoption of the nationally recognized nomenclature for interpretation of all EFM (i.e., the NICHD terminology). Due to the variations in training and practices for interpreting EFM tracings, the committee recommended, as a first step, that all obstetrical nurses and physicians at MCIC insured hospitals complete a one-time, standard EFM certification program. MCIC's intent was to ensure that all insured obstetrical caregivers demonstrated competence in the use of NICHD terminology and applied consistent definitions when interpreting EFM patterns. This recommendation was subsequently endorsed by the MCIC board of directors as a condition of insurance for all hospitals and obstetricians.

Other components of the MCIC Obstetrical Safety Initiative included the establishment and funding of five perinatal safety nurse positions (one per shareholder) and administration of a pre and post intervention safety attitude questionnaire to all staff. A formal training program on team communication skills and the development of select practice guidelines were also essential elements of the initial initiative.

## Obstacles

Having all designated obstetrical physicians, nurse midwives, and registered nurses—more than 1,000 individuals—obtain EFM certification proved challenging. The first obstacle was determining what EFM program would satisfy the objective. Since we found only one national certification examination for EFM interpretation, MCIC began discussions with the vendor, National Certification Corporation (NCC).[5] A representative pilot group of physicians and nurses from MCIC hospitals collaborated with NCC to ensure that the EFM certification examination (and the testing process) was appropriate for all members of the perinatal teams.

The actual process of having all designated obstetrical clinicians satisfactorily pass the exam and acquire certificates of "Added Qualification in Electronic Fetal Monitoring" took more than

two years to achieve. Simultaneous to our undertaking at MCIC hospitals, NCC rolled out a program allowing certification exams on-site at the hospitals. Although this allowed for flexibility, and was intended for the convenience of the test takers, the actual testing process placed an administrative burden on the hospitals. Fortunately that burden was lightened by the diligence, creativity, and perseverance of the perinatal safety nurses.

## Perinatal Safety Nurses

In addition to coordinating all aspects of EFM test administration, including proctoring exams, the perinatal safety nurses provided or facilitated refresher courses and EFM training programs for all interested clinicians. One of the side benefits to the (occasionally cumbersome) process of preparing and taking the EFM certification exam was that it provided an excellent forum for fostering interdisciplinary communication among perinatal team members. For many physicians and nurses, this program helped solidify the sense of a shared competency. In several settings, the resulting interdisciplinary collaboration helped the perinatal team members recognize shared patient safety values—a key component for ensuring a safe clinical environment.

Of course, not everyone was enthusiastic about taking an EFM certification exam. Some clinicians opted to move ahead with retirement or relocation plans. A few individuals were assisted with job reassignments to post partum units or other clinical areas where fetal monitoring skills were not needed. Some hospitals chose to formally incorporate EFM certification into their credentialing requirements, and this typically eased program implementation. Obtaining EFM certification was established as a requirement for all current and future staff. The Obstetrical Leadership Committee (a subcommittee MCIC's Patient Safety Committee) is discussing options for ensuring ongoing EFM competency.

The long term impact of our obstetrical safety initiative at MCIC hospitals, and specifically the program focused on EFM competency, on our liability risk will take many years to evaluate. However, from an anecdotal perspective there is widespread agreement that efforts aimed at promoting a culture of safety and specifically standardizing communication practices is going a long way to ensure a safer environment for mothers and babies in MCIC hospitals. ■


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2. *Am J Obstet Gynecol.* 1997;177(6):1385-90.
3. *JOGNN.* 1997;26(6):635-40.
4. MCIC Vermont, Inc. provides medical professional and general liability insurance coverage to New York-Presbyterian Hospital, Cornell University, Columbia University, The University of Rochester, The Johns Hopkins Hospital and The Johns Hopkins University, and Yale New Haven Hospital, Yale University, Bridgeport Hospital, Greenwich Hospital, Highland Hospital, Johns Hopkins Bayview Medical Center, and Strong Memorial Hospital.
5. www.nccnet.org/public/pages/index.cfm?pageid=332




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**CRICO/RMF**
101 Main Street
Cambridge, MA 02142

E-mail: Forum@RMF.Harvard.edu

Fax: 617.495.9711

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# Stillbirth: Common Causes and Prevention Strategies

**by Ruth Fretts, MD, MPH**

Dr. Fretts is Chair of the Stillbirth Review Committee, Brigham and Women's Hospital, Boston.

Stillbirth, while infrequent, occurs 10 times more often than sudden infant death and accounts for a large proportion of all perinatal losses. In the United States during 2002, the stillbirth rate was 6.4/1000 total births (approximately 26,000 stillbirths nationwide). That year, there were also about 28,000 infant deaths (7.0/1000 live births), and 19,000 neonatal deaths (4.7/1000 live births).[1] Black women have more than twice the rate of stillbirth compared to white women; while some of this increased risk can be attributed to access to, and quality of, medical care, other factors probably play a role as well.[2]

Fetal death can be stratified according to gestational age, into early losses (20–28 weeks) and late fetal death (>29 weeks). Presumably, this approach was used initially to divide those pregnancies that might be saved (i.e., late losses), from very early term losses, the majority of which would not be salvageable. Recent advances in neonatal care make this division somewhat arbitrary, but the causes of fetal death *do* vary according to gestational age. The prevention of a proportion of early losses is associated with prenatal diagnosis of congenital anomalies and the availability of abortion. A large proportion is also related to premature rupture of membranes and infection, complications that have proven difficult to prevent. Multiple gestations, either spontaneous or related to reproductive technologies, are also associated with an increased risk of stillbirth and preterm birth; these fetal losses occur throughout pregnancy with higher risks both in early and late pregnancy.

## Causes of Stillbirth

Between 24 and 27 weeks of gestation, the most common causes of stillbirth are related to infection (19 percent), abruption (14 percent) or significant lethal anomalies (14 percent); 21 percent are unexplained. After 28 weeks of gestation, the most common category of stillbirth is that of "unexplained." (*see* Table 1.).[3] The proportion of fetal deaths that have no known cause after complete pathological evaluation increases as gestational age advances. Deaths unexplained by fetal, placental, maternal, or obstetric factors—which represent from 25–60 percent of all fetal deaths—are one of obstetrics' most distressing outcomes.

### *Medical Risk Factors*

Hypertension and diabetes are two of the most common medical conditions to complicate pregnancy (7–10 percent and 3–5 percent, respectively, *see* Table 2). Historically, both of these conditions have been shown to be responsible for a significant proportion of fetal deaths. Optimal management, including counseling, preconceptual care, and close medical management of these conditions *has* been shown to reduce the risk for perinatal death to a level only marginally elevated above that of the general population. Management of patients remains a challenge, however, because of the increased risks of abruptio placenta, of intrauterine growth restriction, and of superimposed preeclampsia—which often necessitates early delivery. Other medical conditions associated with an increased risk of stillbirth include systemic lupus erythematosis, and congenital and acquired thrombophilias (Table 2).

Table 1

**Common Causes of Stillbirth by Gestational Age**

| 24–27 weeks | | 28–36 weeks | | 37+ weeks | |
|---|---|---|---|---|---|
| Infection | 19% | Unexplained | 26% | Unexplained | 40% |
| Abruption | 14% | Fetal malnutrition | 19% | Fetal malnutrition | 14% |
| Anomalies | 14% | Abruption | 18% | Abruption | 12% |

From Fretts 2005 Etiology and Prevention of Stillbirth

### *Non-medical Risk Factors*

Nationally, black women consistently have had approximately twice the risk of stillbirth when compared to white women. Even when evaluating only women who had received adequate prenatal care, Vintzileos et al, found that African American women still had twice the risk of stillbirth when compared to whites. The excess of stillbirth was attributed to higher rates of diabetes, hypertension, placental abruption, and premature rupture of membranes.[2] Given that black women are a relatively high-risk group for stillbirth, increasing their access to prenatal care and the identification and management of medical and socioeconomic risk factors for stillbirth remains important.

### *Advanced Maternal Age*

Advanced maternal age remains an independent risk factor for stillbirth, even after accounting for medical conditions that are more likely to occur in older women.[4] Prior to prenatal diagnosis, older women were more likely to have a stillbirth related to congenital anomalies. In recent years, the only type of stillbirth that was statistically more common in older women was the "unexplained" category of fetal demise, and these were likely to occur late in pregnancy.[5-8]

### *Obesity*

The prevalence of maternal obesity has also been increasing steadily and is associated with an increased risk of fetal macrosomia and perinatal mortality.[9-10] The reasons for this association are speculated to be due to behavioral and socioeconomic issues, as well as obstetric factors. Obese women are more likely to smoke and to have pregnancies complicated by gestational diabetes and preeclampsia. However, even when controlling for these factors, pre-pregnancy obesity remains a significant risk factor for stillbirth. The association between

Table 2

**Medical Disorders Associated with Stillbirth Risk**

| Condition | Estimated Stillbirth Rate |
|---|---|
| All Pregnancies | 6–7/1,000 |
| **Hypertensive Disorders** | |
| chronic hypertension | 5–25/1,000 |
| superimposed preeclampsia | 52/1,000 |
| PIH/mild preeclampsia | 9/1,000 |
| severe preeclampsia | 21/1,000 |
| eclampsia | 18–48/1,000 |
| HELLP syndrome | 51/1,000 |
| **Diabetes Mellitus** | |
| gestational diabetes | 5–10/1,000 |
| type 1 diabetes | 6–10/1,000 |
| type 2 diabetes | 35/1,000 |
| systemic lupus erythematosus | 40–150/1,000 |
| **Chronic Renal Disease** | |
| mild renal insufficiency | 15/1,000/1,000 |
| moderate and severe renal insufficiency | 32–200/1,000 |
| **Thyroid Disorders** | |
| stable treated hyperthyroidism | 0–36/1,000 |
| uncontrolled thyrotoxicosis | 100–156/1,000 |
| subclinical hypothyroidism | 0–15/1,000 |
| overt hypothyroidism | 15–125/1,000 |
| cholestasis of pregnancy | 12–30/1,000 |

Modified from Simpson, 2002

Table 3

**Maternal Risk Factors/Causes for Stillbirth**

**Ranked by estimated attributable risk/importance (developed countries)**

| | |
|---|---|
| 1 | Congenital/karyotypic anomalies |
| 2 | Growth restriction/placental thrombosis |
| 3 | Decreased fetal movement |
| 4 | Medical diseases (e.g. diabetes, hypertensive disease/ preeclampsia, systemic lupus erythematosus, renal disease, thyroid disorders, thrombophilias, cholestasis of pregnancy) |
| 5 | Congenitally acquired infections (e.g. Group B streptococcus, parvovirus 19) |
| 6 | Smoking |
| 7 | Multiple gestation |

Adapted from McClure et al, 2006

elevated pregnancy BMI and stillbirth at term appears to increase as the gestation advances. Sleep studies of pregnant women have shown that obese women spend more time snoring, have more apnea-hypoxia events, and have more episodes of oxygen desaturation than non-obese pregnant women.[11-14] Snoring has also been associated with pregnancy-induced hypertension and fetal growth restriction.[15] In the United States, in addition to advanced maternal age and low socioeconomic status, as discussed above, the most prevalent risk factor for stillbirth is pre-pregnancy obesity.

## Prevention of Stillbirth

Prevention of stillbirth requires an ongoing audit process to evaluate losses in order to assess systematic or common errors of management. Globally, smoking cessation during pregnancy is an important area of stillbirth prevention. And, as previously stated, prenatal diagnosis—with the availability of abortion, and the minimization of multiple gestations—are also important strategies to reduce stillbirth (Table 3).[16] After 28 weeks of gestation, the two most common types of stillbirth are related to growth restriction and to those that are otherwise unexplained. The Confidential Inquiry into Stillbirths and Infant Death of Northern Ireland found that the failure to adequately diagnose and manage fetal growth restriction was the most common error, followed by failure to recognize additional maternal medical risk factors.[17] Given that deaths of intrauterine growth-restricted fetuses represent one of the most common types of stillbirths, a significant opportunity remains to improve outcomes. Assessment of fetal growth by ultrasound should be considered for at-risk patients. A customized growth chart more readily identifies the growth-restricted fetus, and reduces "false-alarms" in the constitutionally small fetus.[18] Ideally, serial ultrasounds should be reported together so that the history of intrauterine growth over time can be more readily appreciated. The threshold to perform an ultrasound in the obese patient should be low, since fetal growth is often difficult to estimate clinically.

Risk factors of unexplained stillbirth include advanced maternal age, pre-pregnancy obesity, low educational attainment, and—in some studies—primiparity.[5-8] The risk of unexplained stillbirth rises after 37 weeks, and more so for primiparous women. Women 35–39 years of age have a 1/156 risk of stillbirth after the 37th week of pregnancy, compared to 1/269 for women less than 35 years of age. The risk is higher for women age 40 or older, where 1/115 women will experience a stillbirth after week 37.19 Currently, no guidelines specifically address women of advanced maternal age later in pregnancy, but a decision analysis predictably estimates that, while a strategy of antepartum testing could reduce late stillbirths, it would also lead to a higher intervention rate, including an increased risk of induction and cesarean section.[20]

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Another area of prevention that has not previously been emphasized is the role of kick counting. In a quality improvement study in Massachusetts (Brigham and Women's Hospital, and Newton Wellesley Hospital), we evaluated the outcomes of pregnancies complicated with the complaint of decreased fetal movement. The rate of stillbirth in those pregnancies that were complicated with decreased fetal movement was four-fold above the general population. While providers were prompt at referring patients for evaluation with this complaint, 50 percent of women waited two days or more before reporting to their provider that they noticed decreased fetal movement. The most common evaluation was a non-stress test (94 percent); only 18 percent of women were evaluated with an ultrasound. In the pregnancies that reported decreased fetal movement and ended in a stillbirth, 44 percent were severely growth restricted. A strategy of evaluating fetal growth with an ultrasound could potentially increase the opportunity of detecting growth restriction prior to fetal demise. There was also a disappointing aspect of the study: of 16 women who had stillbirths after reporting decreased fetal movement, three had had prompt and *reassuring* antepartum testing—but had stillbirths anyway. All three cases involved additional risk factors that were overlooked, including unidentified growth restriction at term, post-dates, and a previous stillbirth.

## Summary

Clinicians need to be able to assess each patient's risk for adverse outcomes, including stillbirth, and should have a low threshold to evaluate fetal growth in at-risk pregnancies. Decreased fetal movement represents a high-risk condition, as does late pregnancy. A strategy of antepartum testing in patients with increased risk should serve to decrease the risk factors of late fetal loss, but is associated with higher intervention rates and their inherent risks. ■

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# The Birth Plan Dilemma

**by Elizabeth (Biddy) Fein, CNM**

Ms. Fein is Director of Midwifery for Harvard Vanguard Medical Associates in Boston.

The birth plan presents a conundrum for both patients and obstetrical providers. Is it a helpful tool, or is it a hindrance to safe care? Why do some providers roll their eyes at the very idea of a birth plan? Are families spending too much time stylizing their ideal birth?

Millions of women are confronting these questions every day, on the Internet and in the books they read. Many childbirth educators, providers, and friends encourage pregnant women to write a birth plan. The challenge for obstetricians and certified nurse midwives is to employ the birth plan as a tool to improve patient safety (mother and baby) as well as satisfaction.

If a birth plan is used by the patient as a treatise from which deviations represent failure, then it (the plan) becomes a hindrance. Under *those* circumstances, providers may give silent credence to the notion that the length of a birth plan correlates directly with one's likelihood for a cascade of interventions that ends in cesarean. On the other hand, if informed consent is the hallmark of safe care, then the birth plan represents a tool that provides an opportunity to discuss common practices, dispel myths, and share clinician preferences. It is also a vehicle for women to work through their anxieties about labor, hospitalization, birth, and parenting. When used to facilitate open communication, a birth plan has enormous value and can enhance the patient-provider relationship.

For a woman anticipating a hospital birth, quite possibly while surrounded by caregivers she has not met, a birth plan provides her with a tool for communication at a vulnerable time. If she and her provider have taken the time to review the plan prenatally, then they may minimize surprises or unreasonable/unattainable requests. Much like a pre-admission history and physical, a birth plan can open the clinician-patient dialogue and quickly foster a supportive relationship with the hospital providers.

Providers strive for high quality/safe care; expectant parents want control over their birth experience. These goals can be mutually met by use of a realistic birth plan that allows discussion of common practices and interventions using evidence-based medicine. Applaud a patient who comes to you with a birth plan, capture this opportunity to listen, learn, and educate. Discuss your own practices and find the congruence with her desires. Clinicians who remain flexible (when appropriate) establish a tone and rapport that may become critical if the patient encounters difficulties during labor and delivery…or experiences a less than optimal outcome.

Numerous example birth plans can be found on the Internet. While they vary in scope, most offer similar categories in which patients can delineate their requests and preferences. The accompanying sample illustrates common components. ■

## Sample Birth Plan

The following example birth plan (adapted from birthplan.com) illustrates the categories and types of preferences an expectant mother might indicate.

**Labor**
I would prefer to avoid an enema and shaving of pubic hair.

I wish to be able to move and change position at will throughout labor.

I would like to be able to have fluids by mouth throughout the first stage.

I would prefer to keep the number of vaginal exams to a minimum.

**Monitoring**
I do not wish to have continuous fetal monitoring unless it is required by the condition of my baby.

**Labor Augmentation/Induction**
I do not wish to have the amniotic membrane ruptured artificially unless signs of fetal distress require internal monitoring.

I would prefer to be allowed to try changing position and nipple stimulation before pitocin is administered.

**Anesthesia**
I do not want any kind of anesthesia offered to me during labor, but I would like it available if I specifically request it.

(Custom note regarding use of an epidural.)

**Cesarean**
If my obstetrician determines that a cesarean delivery is indicated, I would like to obtain a second opinion…if time allows.

I would like my partner present at all times if I require a cesarean delivery.

I wish to have an epidural for anesthesia.

If my baby is not in distress, my baby should be given to my partner immediately after birth.

**Episiotomy**
I would prefer not to have an episiotomy unless absolutely required for the baby's safety.

**Delivery**
I would like my partner and/or nurses to support me and my legs as necessary during the pushing stage.

I would like a mirror available so I can see my baby's head when it crowns.

Even if I am fully dilated, and assuming my baby is not in distress, I would like to try to wait until I feel the urge before beginning to push.

I would like to have my baby placed on my chest immediately after delivery.

**After Delivery**
I would like to have my baby examined and bathed in my presence.

If my baby must be taken from me to receive medical treatment, my partner or some other person I designate will accompany my baby at all times.

I would like a private room if available.

After the birth, I would prefer to be given a few moments of privacy to urinate on my own before being catheterized.

**Breastfeeding**
Unless medically necessary, I do not wish to have any bottles given to my baby (including glucose water or plain water).

I do not want my baby to be given a pacifier.

**Photos**
I would like to make a video recording of labor and/or the birth.

# Midtrimester Fetal Loss and Extreme Prematurity: Strategies for Prediction and Prevention

**by Jack Ludmir, MD**

Dr. Ludmir is Professor and Chair, Obstetrics and Gynecology, Pennsylvania Hospital; Director Obstetrical Services, Hospital University of Pennsylvania; Vice Chair, Obstetrics and Gynecology, University of Pennsylvania Health System.

Preliminary data for babies born in 2005 show a prematurity rate of 12.7 percent, representing a two percent increase in premature births in the last 15 years (*see* Figure 1).[1] Perinatal mortality and morbidity occur most commonly in babies born before 37 weeks and, in particular, before 32 weeks gestation. For those babies that survive being born at the threshold of viability (23–26 weeks), prematurity-related disorders such as hearing and visual impairment, cerebral palsy, and developmental delay are of significant magnitude—despite advances in neonatal intensive care.[2]

The causes for preterm delivery at extremely early gestational age or during the midtrimester of pregnancy (18–26 weeks) are complex and usually involve a combination of factors. Traditional simplistic approaches to causality such as cervical incompetence (painless dilation)—recently referred to as cervical insufficiency, preterm contractions, and/or infection have been replaced by the concept of the "spontaneous preterm birth syndrome" comprising anatomic and functional components.[3] The notion that the cervix functions as competent or incompetent during gestation has been replaced by the concept of functional cervical competence along a continuum during gestation, with the cervix responding differently to a multitude of factors such as contractions, infection, and inflammation.[4]

Because the underlying processes resulting in very early spontaneous preterm birth are often poorly understood, finding one specific prevention and management scheme has been unsuccessful and, for the most part, empirically based. Regardless, the birth of an extremely premature baby that dies during the perinatal period—or that survives with significant sequalae—is a common cause of malpractice claims naming an obstetrician.[5] Honest discussions with patients about the current knowledge limitations in predicting and preventing prematurity can potentially reduce liability…if the patient understands that an adverse outcome can occur despite a specific management plan.

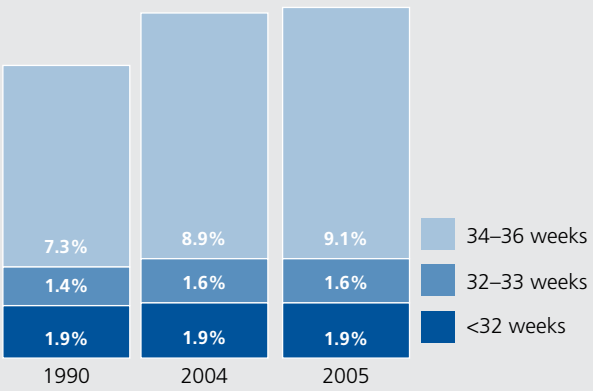
Based on our experience, interventions taken during pregnancy to prevent the delivery of an extremely premature fetus require the following: recognition of clinical risk factors for preterm birth, appropriate ordering/interpretation of diagnostic tools, and management of signs or symptoms.

## Clinical Risk Factors for Preterm Birth

A majority of cases of preterm birth may not have an identifiable risk factor. Nevertheless, failure to recognize a risk factor when present, and failure to come up with a management plan once a risk factor is identified, can result in an allegation of mismanagement if an adverse outcome occurs. The following risk factors for preterm birth should be considered and identified during the initial prenatal visit and subsequent care:

Figure 1

**United States Rate of Prematurity**




Source: CDC/NCHS

- history of preterm delivery (less than 37 weeks);
- vaginal bleeding;
- infection: systemic and genital tract;
- maternal ethnicity (higher risk for African American women);
- short cervical length as measured by transvaginal ultrasound;
- cervical or uterine abnormalities;
- multiple gestation;
- assisted reproductive technologies: not only due to the increase in multiple gestations, but an increased rate of preterm births in singletons; and
- lifestyle-related factors such as smoking.

The first and most important risk factor is an obstetric history characterized by preterm delivery before 37 weeks gestation.[6] The recurrence risk for preterm birth is as high as two to four-fold and should be addressed with the patient. One of the few (appropriately studied) management schemes proven effective in reducing a subsequent preterm birth in patients with history of spontaneous preterm delivery has been the use of weekly 17 alpha-hydroxyprogesterone (resulting in a 40–50 percent significant reduction in prematurity).[7] These findings apply to singleton gestations only. Unfortunately, a recent study did not demonstrate benefit of this medication when used in twin gestations.[8]

## Failure to Order or Interpret Diagnostic Tools Correctly

The last 25 years have witnessed the introduction of better diagnostic modalities to help in the prediction of the patient at risk for preterm delivery. When the home monitor to detect uterine contractions was first introduced, it was done so

without appropriate scientific evaluation. The rationale for its use was that early identification of contractions with treatment could result in prematurity reduction. Appropriately conducted studies have determined that this device is of no value and should be abandoned. Transvaginal ultrasound of the cervix with measurement of cervical length at different gestational ages has been correlated with the risk for preterm delivery: the shorter the cervix in pregnancy, the greater the risk.[9] Unfortunately, once a short cervix (less than 2.5cm) is identified early in gestation, no specific intervention has proven beneficial.

Other diagnostic tests available to the clinician include fetal fibronectin and screening for bacterial vaginosis. Although early enthusiasm advocated the use of these tools for screening purposes, currently their use can be only justified in patients with symptoms. Even if the sensitivity of the different diagnostic modalities to predict preterm delivery is high, the specificity and positive predictiveness of these tests are low, precluding their use in low risk populations.

### Mismanagement of Signs or Symptoms

Because no sign or symptom is specific for cervical insufficiency or preterm labor, common pregnancy complaints such as abdominal cramps, pressure, spotting, backache, and/or increase in vaginal discharge, *could be* manifestation of a pathologic process associated with preterm delivery. Ignoring these complaints—particularly in patients with risk factors—can result in significant patient anger and frustration if an adverse outcome occurs, and can trigger a malpractice claim.

The following cases, based on actual closed malpractice claims, illustrate the above categories.

#### *Case 1*

A 31-year-old presented for prenatal care at eight weeks gestation. A prior pregnancy two years before had good dates based on LMP and first trimester ultrasound. At 36 weeks/2 days, her membranes ruptured and she went into labor, delivering within five hours a liveborn female, 2,689g with Apgars of 8/9. Both mom and baby were discharged home on the second post partum day without complications. The patient's gynecologic and medical histories were unremarkable.

During the index gestation, the patient had routine prenatal care; no discussion of the significance of her prior (preterm) delivery was documented in the medical record, nor was a specific management plan. At 20 weeks, an ultrasound for fetal anatomy was normal; cervical length was not reported. Two days after this ultrasound, the patient was seen for a routine prenatal visit. She had no complaints and was told to return in four weeks for another routine prenatal visit. At 22 weeks/5 days, persistent pelvic pressure and increased vaginal discharge prompted the patient to call her obstetrician. He told her that these symptoms were normal in pregnancy and not to worry. The next day, the patient presented to the hospital, where she was found to be 4cm dilated with bulging membranes and uterine irritability. Emergency cerclage was discussed, but her obstetrician opted to wait at least 24 hours to rule out infection. When the patient was brought to the OR for the procedure, she was found fully dilated and proceeded to deliver quickly a 520g female who survived for three hours. The placenta was sent to pathology and revealed chorioamniontis and funisitis. A year later, a claim was made with the following allegations:

- failure to recognize prior preterm delivery (36 weeks/2 days) as a risk factor,
- failure to order appropriate diagnostic tests (ultrasound of the cervix at 20 weeks during routine fetal survey), and
- failure to manage the pregnancy correctly (i.e., telling the patient her pelvic pressure and vaginal discharge were normal symptoms of pregnancy).

The case went to trial with the plaintiff expert arguing that the standard of care was breached because there was no (documented) discussion of the greater risk for prematurity and the obstetrician should have performed a cervical evaluation during the 20 week visit—which would have revealed cervical shortening, leading to a cerclage and a good outcome.

The defense argued that regardless of any sonographic cervical findings, placing a cerclage in this patient would not have prevented her preterm birth. The presence of significant infection in the placenta and the umbilical cord, the defense stated, was consistent with infection as the cause for preterm delivery, and no intervention would have been beneficial.

After two days of deliberation, the jury found the clinician negligent, but could not link that negligence to the outcome (i.e., no causation), and thus, rendered a defense verdict.

This case clearly illustrated the three points discussed above:

**Failure to identify risk factors.** The patient had previously delivered prematurely (36 weeks/2 days). Even though the baby did well and went home with mom, the patient was still at risk for preterm birth in a subsequent gestation. The recurrent risk for preterm birth should have been discussed and documented in the chart.

**Failure of using diagnostic tests.** Although this patient had an ultrasound for fetal anatomy, no description of cervical length was documented. Controversy reigns about the need to visualize and document cervical length in every patient. Not every patient needs an assessment of cervical length in mid-gestation, but if the patient is at risk for prematurity it seems reasonable to assess the cervix at the time of fetal survey. Include in this category patients with prior history of preterm birth, history of cervical surgery, fibroids, multiple gestation, and any patient with symptoms.

**Mismanagement of pregnancy.** This patient had called with significant symptoms of pelvic pressure and increased vaginal discharge. Without an assessment, the patient was told that

these represent normal symptoms of pregnancy and told not to worry. Patients at risk deserve to be evaluated with an exam. Even though the use of emergent cerclage for patients with bulging membranes is controversial, the literature suggests that aggressive management with cerclage (i.e., without delay) results in longer prolongation of pregnancy compared to bed rest alone, as long as signs of infection (sometimes difficult to assess) are not present.[10]

*Case 2*

A 29-year-old G2P1 presented for her initial prenatal visit at eight weeks gestation. Her prior pregnancy was uneventful and delivered at term. In between gestations, the patient developed abnormal cervical cytology and underwent a shallow cone biopsy (depth of 4mm) with subsequent negative cytologies. During the initial prenatal visit, the cervix felt normal on inspection and palpation. Because of her prior cervical surgery, the patient was identified as high risk for prematurity, and a management protocol of frequent visits with cervical evaluation was instituted to detect cervical shortening or dilation. The patient was seen every two weeks with assessments of her cervix by scan and digital examinations. Her pregnancy remained uneventful until 27 weeks, when her membranes ruptured. The cervix appeared closed and long on speculum evaluation. She was managed conservatively and was given steroids to enhance fetal lung maturity and antibiotics to prolong latency. After three days of observation, the patient developed a fever with signs of clinical chorioamnionitis and was delivered by cesarean section of a liveborn male, 1,280g with Apgars of 6/8. The baby had a prolonged hospitalization in the intensive care unit. At the age of two, he was diagnosed with cerebral palsy. A malpractice claim was made alleging mismanagement of pregnancy resulting in a premature baby.

During trial, the plaintiff's expert supported the allegations of negligence and causation by maintaining that: a) patients with a prior cone biopsy are at risk for cervical insufficiency (incompetence) and b) prophylactic cerclage performed at 12–14 weeks would have prevented the premature rupture of membranes.

The defense argued:

1. The patient was informed of the potential greater risk for prematurity secondary to her 4mm deep cervical biopsy. The literature does not show greater risk for cervical insufficiency unless the cone depth is greater than 20mm.[11]
2. A management protocol of frequent cervical assessment was established. During the evaluations, the cervix did not demonstrate shortening, dilation, or any signs of insufficiency. Furthermore, the cervix was closed and long at the time of the membranes rupture.
3. Preterm rupture of the membranes is an unpredictable and unpreventable event (the most common cause being subclinical infection). To date, no management protocol has been found effective in preventing this situation.

The jury found in favor of the defense.

Despite the adverse obstetric outcome, the patient's clinicians followed the standard of care. He identified her history of prior cervical surgery as a risk factor for prematurity and established a management protocol of frequent cervical evaluations (and instructed the patient about potential signs and symptoms for preterm labor). The literature does not support any specific management protocol under these circumstances; patients with a history of a shallow cone biopsy are not at greater risk for cervical insufficiency. Prophylactic cerclage for such patients is not supported by any evidence. In fact, to date, no management protocol has been proven to decrease the risk of preterm rupture of the membranes

Prematurity prediction and prevention continues to be a great challenge in modern obstetrics, with few strategies scientifically proven to reduce the risk. Knowledge and documentation of risk factors, understanding the value of diagnostic tools, and listening to patients' signs and symptoms can minimize liability and reduce risk even in cases with adverse outcomes. ■

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# Three Typical Claims in Shoulder Dystocia Lawsuits

**Henry Lerner, MD**

Dr. Lerner practices obstetrics and gynecology at Newton-Wellesley Hospital in Massachusetts.

At the end of a busy day, your office manager comes in holding a thick envelope. You don't like the look on her face. As she hands it to you, you see the return address is a law firm. The envelope holds a summons indicating that a malpractice lawsuit is being filed against you. The name of the patient involved seems only vaguely familiar. When you review the chart, you see that it was a delivery with a mild shoulder dystocia—four years ago.

As an obstetrician who has been in practice for more than 28 years, had numerous shoulder dystocia deliveries, and reviewed close to 100 shoulder dystocia medical-legal cases, I have seen the above scenario played out frequently. In some cases, the delivery was catastrophic and the obstetrician was unsurprised by the lawsuit. In most cases, however, the delivery was just one of hundreds or thousands the doctor has done over the years…and forgotten. Whatever the circumstances, the receipt of this suit letter will initiate a years-long process with which, unfortunately, obstetricians are too familiar.

## The Three Most Common Claims

It is worthwhile to examine the three types of claims most commonly made in shoulder dystocia lawsuits, how they are "packaged" by plaintiffs' attorneys, and what might make such claims valid or fallacious. Understanding this may help physicians (and their defense teams) determine when a plaintiff's claim has validity—and should be settled expeditiously—and when such claims are not valid. Such understanding will also lead to the best approaches for countering nonvalid claims.

Almost all shoulder dystocia malpractice suits imply that the delivery was *mishandled* by the obstetrician or midwife. By far the most common type of injury leading to suit is a brachial plexus injury, resulting in some degree of permanent paralysis of one or both shoulders, arms, or hands of the infant. However, some suits claim neurologic damage due to asphyxia at the time of delivery, or even fetal death.

The three most commonly claimed deviations from the standard of care are as follows:

### 1. The physician/midwife should have been able to predict that a shoulder dystocia was going to occur.

#### *Allegation*

Given certain risk factors (*claimed* to have been present and to indicate an increased risk), the clincian should have known that a shoulder dystocia was likely to occur. Knowing this, the clinician should have avoided this risk by performing an elective cesarean section, or should have interrupted labor at some point and delivered the baby surgically.

The plaintiff's lawyer and expert witnesses will *claim* that it was the physician's duty to assess whether the baby was at increased risk for shoulder dystocia at delivery. Plaintiffs will enumerate a series of factors gleaned from their history and medical records which they will *claim* indicate that they were at increased risk for shoulder dystocia. Such factors include:

Prelabor risks (alleged):

- Suspected big baby
- Gestational diabetes
- Large maternal weight gain
- Large uteri fundal height measurement
- Small pelvis
- Small maternal stature
- Previous large baby
- Known male fetus

Risks during labor (alleged):

- Arrest of first stage of labor
- Deceleration of end of first stage of labor
- Prolonged second stage of labor
- Use of pitocin
- Use of either vacuum or forceps for delivery
- Tasks plaintiffs claim the clinician had a duty to perform
- Obtaining an ultrasound in the last few weeks of pregnancy to assess fetal weight
- Assessment of blood sugars throughout pregnancy (beyond indicated ACOG guidelines)

#### *Facts*

In fact, careful evaluation indicates that there are only five, literature-supported, risk factors for shoulder dystocia:

- history of previous shoulder dystocia,
- macrosomia,
- gestational diabetes,
- small maternal stature, and
- use of vacuum or forceps at delivery.

All other alleged factors either are not consistently linked with shoulder dystocia or are based on fetal macrosomia.

#### *Defense*

The key to refuting such claims involves:

1. Being familiar with the literature on shoulder dystocia as expressed in textbooks, ACOG bulletins, and significant journal articles.
2. Knowing that even with the valid risk factors, "risk" is a relative term. A given risk factor could produce a 10 percent increase in risk or a 10-fold increase. Never let a plaintiff's attorney concatenate a series of risks factors without having him or her define—or having you

tell him or her—exactly what *percentage* increase risk is involved with each factor. Contend any statement that a certain factor is a risk factor if the literature shows it is not. Also, be sure to point out what the sensitivity and false positive value of each risk factor is, in order to put each in context as a clinical predictive tool.

3. Always remember that shoulder dystocia in and of itself is not the risk with which a physician has to be primarily concerned in deciding which mode of delivery to recommend to a patient. The key factor is the risk of *permanent brachial plexus injury.*

Shoulder dystocias occur in about one percent of all deliveries, with the percentage rising for babies over 4,000g (10 percent) and 4,500g (20 percent). Brachial plexus injuries, in general, occur in 10 percent of all shoulder dystocia deliveries. Of these, only 10 percent remain permanent. So, although the risk of a patient encountering a shoulder dystocia may range from 1–20 percent, the risk of her fetus experiencing a permanent brachial plexus injury is approximately 1/100th of that. Published studies (Rouse) show that even in the highest risk patients—those with macrosomic babies and gestational diabetes—the risk of permanent brachial plexus injury is only 1 in 450.[1] While this number is higher than the risk of permanent brachial plexus injury in the general population (1 in 10,000), it still means that 99.8 percent of babies in this highest risk category would not experience a permanent brachial plexus injury via vaginal delivery. Jurors may need to be taught that this fetal risk must be weighed against the risk involved in the performance of an elective cesarean section, especially when the mother is obese, has diabetes, or has other risk factors that patients at high risk for shoulder dystocia often do.

Thus, in refuting the first of the common shoulder dystocia claim, the defense team must know which of the claimed risk factors are valid and must determine, based on a given patient's medical history, her specific predelivery risk for permanent brachial plexus injury. This number is what needs to be presented to the jury when arguing whether or not a cesarean section should have been offered.

### 2. There were enough risk factors present that the mother should have been given the option of having a cesarean section.

Although this claim involves several of the items discussed above, the specific import here is the issue of informed consent.

#### *Allegation*

The plaintiff will claim that, in general, mothers will do everything possible to ensure the safety of their infants. ACOG documents will be quoted relating to patient's rights to be notified of risks. It will further be claimed that, had the patient in this case only known that there was *any* risk of injury to her child, she would of course have opted for cesarean section. Therefore the physician or midwife was negligent in not specifically discussing the risk of shoulder dystocia with his or her patient and not having offered a cesarean section as an option for delivery.

#### *Defense*

The legitimate and proper responses to this claim are:

1. Evaluate the factors claimed by the plaintiff to see if they are, in fact, genuine risks.
2. Demonstrate that the standard of care is *not* to discuss all risks with patients. For instance, if the risk of having a serious car accident on the way to the hospital while in labor is 1 in 10,000, it would not be obligatory for the physician to warn the patient about this and to offer her another means of transportation. Similarly, if the risk of a permanent brachial plexus injury—not just of a shoulder dystocia occurring—in a specific case is relatively rare, then it is not necessarily a physician's obligation to discuss this risk with his or her patient. In the same vein, a physician is not obliged to discuss the rare risks of amniotic fluid embolus or postpartum hemorrhage leading to hysterectomy for each and every one of his or her obstetrical patients.
3. There is a general consensus—documented in surgical textbooks[2]—that the level of risk at which a physician is obliged to discuss the possibility of a complication with his or her patient is roughly 1 in 100. As noted above, even in the most high-risk cases, the risk of permanent brachial plexus injury does not exceed 1 in 450.

This does not mean that, for a patient with gestational diabetes and a suspected very large baby, no consideration should be given to discussing cesarean section. Neither does it mean that one should blithely perform instrumental vaginal deliveries on such patients. What it does mean, however, is that exaggerated claims of the physician's duty to inform a patient about rare risks are neither truthful nor the standard of care.

### 3. The permanent brachial plexus injury suffered by the plaintiff could only have occurred because the doctor pulled too hard when encountering a shoulder dystocia and did not act according to the standard of care by correctly performing other maneuvers.

#### *Allegation*

With this claim, the plaintiff's lawyer is invoking the hoary old legal theory of res ipsa loquitor: the thing speaks for itself. The lawyer and his or her expert witnesses will *claim* that all permanent brachial plexus injuries are due to "excessive" trac-

tion. They will *claim* that this is, physiologically, the only way such injuries can occur. They may *claim* that, had a physician performed all the proper maneuvers, the "excessive force" they say was used would not have been necessary and thus the baby would not have suffered the injury it did.

### *Defense*

This is the most difficult of all of the three claims to refute. The jury is presented with a child who has a permanent injury. From what they are told by the plaintiff's obstetrical, neurological, and neurosurgical expert witnesses, it makes a certain amount of sense that the injury was caused by the delivering clinician's actions in pulling on the fetal head in an improper way in an attempt to resolve the shoulder dystocia.

The refutation of such claims involves showing that there are no data to support them; they are, in fact, totally unproven. No reliable study has shown a linkage between traction applied to the fetal head and permanent brachial plexus injury, much less that *all* such injuries are based on clinician traction. Furthermore, much evidence can be presented that contradicts the assumption that all permanent brachial plexus injuries are due to excessive physician force, for example:

- documented cases exist of permanent brachial plexus injuries that involved no shoulder dystocia;
- likewise, cases of permanent brachial plexus injuries following cesarean section deliveries have been noted;
- the forces of labor and maternal expulsive efforts themselves can cause stretching of the brachial plexus;
- the forces of labor and maternal expulsive efforts themselves generate pressure on the brachial plexus four to nine times higher than that exerted by a physician;[3] and
- recent eyewitness and/or video documentation exists of two deliveries, one involving a temporary and one involving a permanent brachial plexus injury, where there was a) no shoulder dystocia and b) no physician contact with the baby at birth.[4] Thus, claims by plaintiffs' attorneys and their physician expert witnesses that excessive physician traction is the only etiology of permanent brachial plexus injuries can not be substantiated.

A further caution: never allow the pejorative term "excessive traction" to go unchallenged. Excessive means "too much." Yet a permanent brachial plexus injury may and frequently does occur with the clinician applying what he or she perceives as the same amount of force he or she uses for all deliveries. Given other forces involved in the delivery process and the biologic variability of each infant for susceptibility to brachial plexus injury, a claim that a particular brachial plexus injury is the result of an inappropriate amount of force being used by the deliverer—except in the rarest cases of documented extraordinary traction—is unproven and untenable.

## An Uphill Battle

Medical legal cases involving shoulder dystocia and brachial plexus injuries are among the most challenging faced by physicians and their defense teams. It is often an uphill battle convincing a lay jury that a young child facing a lifetime disability should not be awarded money whether or not negligence was involved. Furthermore, when payouts at jury trials do occur, they are often in the $1–$3 million range, enough to make many insurance companies shy away from taking shoulder dystocia cases to trial. This is unfortunate, because experience shows that, when an adequately prepared defense team with knowledgeable expert witnesses and a physician who can convincingly show that he or she provided excellent care presents its case, outcomes are overwhelmingly favorable for the defense. ■


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# Quality Initiatives to Improve Obstetrical Patient Care

**by Karen Mueller, RN**

Ms. Mueller is the Labor and Delivery Nurse Manager for Newton-Wellesley Hospital (Massachusetts).

A colleague on the Labor and Delivery unit at Newton-Wellesley Hospital (NWH)[1] once stated that "in order to precipitate a change you have to precipitate a crisis." While this was in reference to a marriage, it could also ring true in clinical practice. It certainly felt that way in 1997 when two maternal deaths in one week at NWH[2] had everyone examining the hospital's quality issues: the Department of Public Health, Health Care Financing Administration, the Joint Commission, and several internal committees.

One of the first questions we asked was, what, from the patient perspective, constitutes "quality"? Yes, we want to provide superior care, but how does that actually translate to patients? Although we had many quality programs already in place, we still discovered opportunities for improvement. Logically, low frequency, high-risk situations were areas that needed the most attention.

Self reflection almost always reveals flaws that we otherwise can not, or do not want, to see. When the NWH obstetrical care staff studied the status quo, it became obvious that we were not as prepared as we could have been for code situations. Therefore, NWH instituted a mandatory annual competency for all staff to practice initial steps in providing care to a patient who has had a respiratory or cardiac arrest. NWH also instituted annual mock maternal codes involving the hospital code team. Daily code cart checks are another part of this readiness effort as it enables staff to become familiar with the location and contents of the code carts on each unit.

Since our crisis in 1997, a committee comprising nursing and medicine has met monthly to review cases and identify systems and quality issues that need to be improved or changed. Established quality indicators extrapolated from the delivery data is one vehicle for getting cases to the committee. The present indicators include, but are not limited to:

- babies with an Apgar score <7 at 5 minutes,
- all birth injuries,
- maternal hemorrhage requiring blood transfusions,
- hysterectomy following delivery,
- maternal readmittance to the hospital after discharge,
- maternal and or newborn transfers to tertiary centers, and
- surgical infection rates.

Any staff member on the unit is able to send a case to the committee. The goal is to precipitate changes *before* a crisis. The committee has been instrumental in changing many maternal/child health policies, as well as some policies that involve maternity patients in other areas of the hospital. For example, we discovered that not all the obstetrical providers were comfortable with neonatal resuscitation, so we conducted drills for all the obstetricians and midwives to help them practice.

The above-mentioned committee reports to the Perinatal Care committee, which meets quarterly. That committee comprises nursing, medicine, social work, laboratory, education, risk management, and administration. It is here that many of the quality indicators are reported and reviewed, and significant deviations are examined. In addition, twice daily rounds by the chief of Obstetrics (or designee), the obstetrical anesthesiologist, and the nurse in charge of Labor and Delivery further help to identify significant patient issues and opportunities to put a quality plan of care in place.

## Team Training

NWH developed and particpiated in the obstetrics simulation scenarios at the Center for Medical Simulation in Cambridge.[3] A vast majority of NWH-affiliated obstetricians, midwives, and nurses have participated in the training. The focus is on how the teams function during an emergency; effective communication and role identification are emphasized. Participation in these scenarios was a segue to the perinatal team training in which all the Partners Healthcare perinatal units were involved.

Using the airline industry as a model, perinatal team training focuses on error prevention and safety. Once again the emphasis is on effective communication. The SBAR (Situation, Background, Assessment and Recommendation) method of information transmission is imparted to the staff, as is a method of communication that will be used when the need for further clarity is apparent. SBAR training is reinforced through monthly sessions where the staff are given clinical scenarios and then asked to develop an SBAR communication of their needs. The staff appreciates the opportunity to perform these exercises since, for many, this mode of communication does not come naturally.

In September 2007, NWH began mandatory shoulder dystocia drills for all staff involved in deliveries. As practice makes perfect, the many available maneuvers to release the entrapped shoulder will be performed over and over, so all will be comfortable and feel prepared when the real situation occurs. After completion of these drills, NWH will turn its attention to constructing drills for post partum hemorrhage. NWH has also offered the STABLE (Skin, Temperature, Airway, Blood Pressure, Labs, Emotion) program to its nursing staff. The aim is to improve the quality of care given to both our normal and compromised neonates. ■

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# Informed Consent Challenges in Obstetrics

**by Elizabeth J. Buechler, MD**

Dr. Buechler practices obstetrics and gynecology at Harvard Vanguard Medical Associates and is Chair of the CRICO/RMF Obstetrical Providers Guidelines Committee.

The ethical purpose of informed consent is to reinforce patient autonomy.[1] A collaborative informed consent process demonstrates respect for the patient and the patient's right to decide what medical interventions are appropriate. The optimal consent process occurs over time in which the medical provider and the patient discuss the proposed actions, risks, benefits, and alternatives. The process requires disclosure of pertinent information, comprehension by the patient, and voluntary agreement.

The patients in this study reported that having enough information and shared decision making were important to them. Having information did not detract from the labor experience or reduce the possibility of achieving a normal birth.

Obstetrics, however, brings some unique challenges to informed consent. During the antenatal period, obstetrical providers and patients should discuss the patient's plans and desires for the childbirth experience (*see* Fein, page 11). Each discussion should also include an explanation of obstetrical interventions that might occur, many of which are neither planned nor desired (e.g., vacuum extraction, cesarean section). With the wide variety of possibilities, a detailed discussion of the risks and benefits of each one is not practical or desirable. A written consent form should acknowledge a diverse discussion and formalize the patient's consent for care and treatment during labor and delivery. An example is in the appendix of the CRICO/RMF Clinical Guidelines for Obstetrical Providers.[2]

## Too Much or Not Enough

Given that a full discussion of all the possible actions is impractical, a number of questions arise.

- How much information *should* be provided in the antenatal period and how do patients view this consent?
- Can the laboring women, in pain, exhausted, distracted, and (frequently) medicated give true informed consent?
- What is the role of the partner, doula, or other support persons during the labor?
- What happens when the wishes of the mother have the potential to adversely affect the fetus?

Little scientific study has been devoted to determining how much information a woman should receive about possible interventions during labor. Many believe that excessive focus on possible complications and treatments can increase anxiety. Others propose that women would rather have detailed information so that they are less fearful of potential unknown complications. A 1999 study of nulliparous patients in spontaneous labor at term sought to identify what factors contributed to a positive labor experience.[3] The patients in this study reported that having enough information and shared decision making were important to them. Having information did not detract from the labor experience or reduce the possibility of achieving a normal birth.

But how much of the consent discussions is recalled and how do patients view the consent process? Unfortunately, patient recall of the details of a consent form is likely to be low. A study related to transfusion[4] showed that most patients remembered signing a consent form (80 percent), but a majority did not remember having a discussion of transfusion risks. Recall was improved for those patients who received written information in addition to oral discussion. A second study questioned 732 patients who had undergone obstetric or gynecologic surgery in the preceding year.[5] One in 10 patients reported not knowing what she agreed to at the time of written consent; 40 percent reported that they only signed the form so they could get their operation. Three-quarters of patients *did* report that signing the consent helped make them aware of risks of their operation. These studies highlight the importance of providing an antenatal patient with a written summary of potential events and risks. Repeated conversations covering the important aspects of labor care may help increase recall.

Studies of a woman's capability to assess risks while in labor are rare. The majority of studies concerning the quality of informed consent in labor are recorded in the anesthesia literature, evaluating women's competence in giving consent for an epidural. A small (82 women) study in 1988 indicated that patients had reasonable recall of the consent process.[1-2] Only two women felt, retrospectively, that they were unable to give valid consent. A second study of 60 actively laboring women assessed understanding of epidural risks after the request for epidural but before pain relief.[6] The authors concluded that the ability to understand risks was not affected by pain, anxiety, opioids, or duration of labor. Based on these and other studies, we can conclude that laboring women are able to provide competent consent and should be engaged in ongoing discussions of medical events and proposed interventions, risks, and benefits.

## Labor Support

The role of the other participants in labor support may be a challenge to the clinician. The partner or doula may be disturbed by deviations from the original birth plan and, on occasion, may try to interfere with decision making of the patient. To minimize this type of conflict, the obstetrical clinician, patient,

and partner (or other support person) need to address this during the antenatal period. The clinician should confirm that the patient is the person best able to make a decision about the conduct of childbirth and that those decisions may change based on the reality of the labor. Medical providers and labor support persons all need to acknowledge the patient's right to autonomy and decision making during labor.

### Mother or Child?

Conflict between the needs of the baby and the mother is rare, but is one of the most challenging and difficult situations faced by obstetrical providers. Both the American College of Obstetrician-Gynecologists (ACOG) and the American Academy of Pediatrics have issued statements reviewing the ethics of intervention when a pregnant woman declines care that the obstetrical providers believe to be critical to good fetal outcome. The ACOG document mentions three basic choices for the care providers: 1) agree to respect the patient's decision making; 2) decline to participate further and transfer care to another provider; or 3) seek intervention of the courts.[7]

An anecdote provided by a practicing obstetrician may illuminate the issues more clearly. Several years ago, a colleague reported a difficult situation. While covering the hospital for his group practice, a patient he had not met was admitted in labor. The fetal tracing was concerning and he recommended an urgent cesarean section. The patient refused. About two hours later, he delivered the baby vaginally. The baby was depressed at birth and ultimately died. My friend was very distressed by this situation.

Two years later, I met a woman in a social setting who told me about her difficult experience in childbirth. Two years previously, she had been newly arrived in this country with limited English skills. Her cultural background made dealing with a male clinician very difficult. Her labor was premature and her husband was out of town. A male physician, whom she had never met, came into the hospital room when she thought all was going well. He insisted on a cesarean section. Surprised, confused, upset—and not understanding that the baby was really at risk—she refused. I recognized her story, an unfortunate confluence of failed communication, different cultural expectations, language constraints, and perhaps impatience on the part of the care provider.

This anecdote demonstrates many of the issues that may contribute to conflict. Almost all women are willing to accept medical interventions to improve the fetal outcome. Careful explanation, cultural awareness, and sensitivity to the patient's concerns will usually help the care team through these challenges. In the event that a simple resolution cannot be reached, the obstetrician should attempt to explore other, mutually acceptable, resolutions. Consultation with an ethics committee may be helpful, if time permits. If resolution can still not be achieved, most clinicians would agree that the patient is ultimately entitled to refuse intervention for herself and her child.

To minimize the risk of "uninformed" patients, the process should start during the antenatal period via formal discussions and written consent. At that time, the obstetrical providers should explain potential procedures and review their general approach to childbirth, while asking about the patient's preferences. Once the labor is underway, the clinicians should continue to provide information in a clear manner, offering alternatives. When challenged by the patient or her support persons, the clinician needs to remain calm and work to diffuse hostility, which often arises from fear and anxiety. Luckily, in the majority of cases, the interests of the mother and the interests of her unborn child coincide. ■

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# Informed Consent for Epidural Anesthesia: Vignettes from Labor and Delivery

**by William Camann, MD**

Dr. Camann is Director of Obstetrical Anesthesia at Brigham and Women's Hospital, Boston.

**Case A:** A healthy primigravida woman presents to the Labor and Delivery unit at term gestation in active labor, cervical dilation 5cm, and she is in severe pain from uterine contractions. She did not attend any prenatal childbirth education classes. She asks for epidural analgesia.

*Is informed consent possible under these circumstances?*

**Case B:** A healthy woman is in active labor at term gestation. She has a "birth plan," dated three months ago and signed by both herself and her husband, which states: "I am not to receive an epidural in labor, even if I ask for one." She is now at 8cm cervical dilation, in severe pain, and insisting on an epidural. She says "Forget the birth plan, I didn't know it would hurt this bad!" Her husband says "You didn't want this, you can do it without the epidural!"

*What is the next step?*

How does an obstetric anesthesiologist handle these situations? How do pregnant women actually receive information about labor pain relief options, and what do they do with this information? Is informed consent possible, and/or valid, when obtained during active, painful labor?

The process of obtaining informed consent in the above situations is problematic because the stresses of labor, both physical and psychological, may be alleged to impair judgment and understanding of both spoken and written information. The process of informed consent should include disclosure of the details of the procedure, risks, benefits, and alternatives, and a competent patient should be able to understand this information. Ideally, a woman will have studied a variety of resources prior to labor and have a realistic understanding of the available options before her delivery date.

In practice, this often does not occur: it is not unusual for a woman in labor to have had either cursory or no formal prenatal education, or to have obtained information from a variety of less-than-reliable sources. A recent survey indicated that only seven percent of women received prenatal education from an anesthesiologist. The remainder received information from an obstetrician (15 percent), prenatal class (21 percent), friend (20 percent), or "other."[1] Adding to the difficulty is that much of the information given in typical childbirth classes favors non-drug (so-called "natural" childbirth) methods of pain relief. Consequently, women who arrive in labor anticipating a natural childbirth are often faced with the uncomfortable reality that non-drug methods of pain relief are inadequate.

One study, conducted at Brigham and Women's Hospital, showed that, among women who anticipated receiving an epidural prior to labor, 95 percent eventually got the epidural. However, among those whose pre-labor expectations were for natural childbirth, a full 50 percent still received an epidural.[2] Another study revealed that, among women who entered labor anticipating natural birth, but who eventually received an epidural, there were low levels of satisfaction with the birth experience, despite excellent pain relief.[3] Such evidence stresses the importance of establishing realistic expectations with regard to labor pain relief.

## A Painful Process

Does painful active labor preclude a proper informed consent process? There is consensus among obstetric anesthesiologists and the courts that women in labor can indeed understand information provided to them and thus give valid informed consent. Although labor may not be the ideal time for a full discussion of pain relief options, it is indeed possible. What level of risk needs to be disclosed is less certain. A recent survey indicated that:

- 31 percent of pregnant women want to know about risks that occur with a frequency of at least 1/100.
- 2 percent wanted to hear about risks that occur with a frequency less than 1/1000.
- 12 percent did not want to hear any discussion of risks, and
- 52 percent wanted to hear about potential complications, but did not want to be told the incidence.[1]

The complications of most concern to mothers were seizure, death, paralysis, and effects on baby; but in the majority of cases, these potential outcomes would not change their decision to receive an epidural. Side-effects considered least important were headache, confinement to bed, and prolongation of labor.[2] In addition, recall of risks enumerated during labor is equal to that of other patient populations.[4] However, the discussion that takes place prior to receiving an epidural for labor analgesia must be tailored to the perceived differences in level of disclosure desired. This requires judgment, skill, maturity, and experience. There is no easy formula, and confounding issues include, but are not limited to, cultural influences and "soft" interpersonal cues dictated by the brief relationship established between the patient and anesthesiologist.

**Patient A,** above, represents a relatively common scenario encountered on a Labor and Delivery unit. A "reasonable" patient, given the appropriate information, would consent to an epidural, and the procedure may be carried out after a discussion (documented) with the patient and her agreement to proceed, using the ethical principle of beneficence. In other words, to withhold the most effective form of analgesia from a patient who is in severe pain and asking for relief, simply because a complete and formal "informed consent" process has not been undertaken, would be neither humane nor reasonable.

*Continued on page 23*

# A Difficult Labor: The Practice of Obstetrics and Gynecology

by Hal C. Lawrence, MD, and Albert Strunk, MD

Dr. Lawrence is Vice President for Practice Activities for the American College of Obstetrics and Gynecology (ACOG).
Dr. Strunk is Vice President of Fellowship Activities for ACOG.

Broadly speaking, the two main challenges currently confronting Obstetrics and Gynecology are:

1. optimizing obstetric outcomes and maintaining quality, life-long gynecologic care; and
2. sustaining the OB/GYN workforce.

Optimizing obstetric and gynecologic care requires implementation of relevant new technologies, regular assessment of clinical competency, meaningful health care quality assurance, and improved patient safety. Maintaining and increasing our professional workforce means attracting more residents, improving the lifestyle of the practicing obstetrician, and developing fair and just alternatives to our current tort system.

To improve health care quality, physicians must enhance skills in clinical assessment and the use of new treatment and diagnostic technologies. The day-to-day practice of obstetrics is impacted by the increasing numbers of pregnant women who are judged to be at high risk. The national obesity problem, increasing maternal age, and the number of patients now having multiple gestations as a result of fertility treatments have contributed to the growing group of high-risk patients. The continuing evolution of obstetric ultrasound will facilitate their care.

Preconception screening, as well as prenatal screening, now gives prospective parents more information and more reproductive choices before and after conception. However, the number of genetic diagnoses for which we can now screen requires more time from the obstetric provider to make sure patients are accurately counseled and screened, and the available screening options will only increase in the future.

Another challenge facing OB/GYNs is an increased emphasis on assessments of competency and professionalism. In cooperation with the American Board of Medical Specialties, the American Board of Obstetrics and Gynecology will introduce a new Maintenance of Certification program in January 2008, focused on four major areas:

- professional standing;
- lifetime learning/self-assessment;
- cognitive expertise; and
- continuous quality improvement.

Cognitive expertise will be evaluated by written examination every six years; the other components will be evaluated annually. Also, the Joint Commission will soon implement six competencies for hospital credentialing of physicians. These mimic those developed by the Accreditation Council of Graduate Medical Education (ACGME) for residency training.

## Reducing Errors

Medical error is often based on the failure of systems, rather than the failure of individuals. Use of computer-assisted medication prescribing (to ensure correct drug/dosage and the absence of contraindications and drug interactions), surgical simulation training, and emergency response drills can improve patient safety. So, too, can the improved screening of medical students and residents for interpersonal and communication skills (as well as relational attributes such as empathy and caring). ACOG's Patient Safety and Quality Improvement department continues to collaborate with other groups on relevant OB/GYN initiatives. These include sharing ACOG records and formats with EMR/EHR software manufacturers at no cost and liaison relationships with the Certification Commission on Health Information Technology (CCHIT) and Integrating the Healthcare Enterprise (IHE).

The challenge of maintaining and increasing the workforce of OB/GYNs has received increased emphasis since 2004, when the percentage of United States senior medical school graduates matching in available ACGME-approved residency programs fell to 65 percent. The factors most commonly cited by medical students for not choosing OB/GYN are:

- insufficient time for family and leisure,
- irregular work hours,
- low pay,
- litigation/fear of litigation, and
- cost and availability of liability insurance.[1]

On the positive side, no other specialty combines a diversity of practice which, in addition to obstetric and gynecologic care, offers elements of reproductive endocrinology, internal medicine, mental health, urogynecology, and oncology. Moreover, practice in institutional and large group settings has ameliorated many quality-of-life and liability-related issues for new residency graduates. The 2007 increase in U.S. medical school graduates entering OB/GYN programs (to 72.5 percent of available positions) is a cause for cautious optimism.

Improving the lifestyle for those who practice obstetrics and gynecology is, of course, part of our task in recruiting to the specialty. It is also an important element in preventing burnout and keeping established OB/GYNs in obstetrics longer. According to ACOG's 2006 liability survey, the average age of physicians leaving obstetrics for a gynecology-only practice was 43 years for women and 52 years for men. In addition, OB/GYNs sense a loss of control and a loss of mastery in clinical practice, which results in an overall loss of satisfaction in having done a job

*Continued from page 21*

well. Because of time constraints, OB/GYNs frequently feel unable to give their best to each patient, unable to be confident that they have done all that needs to be done, and unable to be certain that a diagnosis is correct. This challenge will be addressed in part by new technologies. For example, computer and PDA-based treatment algorithms will improve the quality of differential diagnosis, and electronic records and prescribing software will expose drug contraindications and minimize drug interactions before the prescription is written.

### The Cost of Doing Obstetrics

In terms of keeping the office open, no other specialty labors with the levels of diminished reimbursement and extraordinarily high liability insurance costs presently experienced by OB/GYNs. For instance, in 10 of 50 states, 2006 malpractice insurance premiums average between $107,000 and $192,000 and may be as high as $299,000.[2] Depending upon geographic locale and prevailing rates of reimbursement for a single delivery, an OB/GYN might perform between 75 and 150 deliveries a year just to pay his or her premium.

Yet another level of impact is the stress and fear engendered by lawsuits. Current research indicates that, in cases of neonatal encephalopathy, only 10 of 100 cases are related to intrapartum events.[3-4] Of those 10 cases, an undetermined number are of a type which does not permit any effective intervention by the clinician and cannot therefore be judged of negligent cause. Yet, babies with neonatal encephalopathy often represent potential multi-million dollar lawsuits.

While all areas of medicine are facing difficulties, OB/GYNs struggle in the face of economic stresses from diminished reimbursement and increased professional liability costs. We all hope that new technologies for both clinical care and practice management will be successful in improving the efficiencies and cost-effectiveness of the physician's office. As patients' diagnoses become more complicated and the number of services they need continue to expand, much is expected from these potential developments. ■

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**Patient B** represents a less common and more complex situation. This patient wishes to change her mind. Regardless of the reasons for her initial choice not to receive an epidural, that decision was made at a time when the patient was not in labor and not in pain. Is this truly an informed decision? Perhaps not. It has been suggested that true informed consent for pain relief cannot be completely "informed" until the patient actually experiences the severity of the pain.[5-6] Hence, perhaps the process of consent for pain relief in labor should actually be a two-part procedure, with a discussion prior to labor focusing on risks, and during labor focusing on benefits. A very realistic scenario is that a woman who initially refuses an epidural based on risks may eventually ask for and receive one based on benefits. True adherence to the principles of autonomy includes recognition of one's right to withdraw consent; everyone has the right to change his or her mind at any time.

Ideal circumstances would have all pregnant patients exposed to a comprehensive array of information regarding labor pain relief options, prior to the stresses of actual labor itself. Many obstacles preclude full implementation of this goal. Enhanced advocacy of extensive and unbiased sources of information in the prenatal education process would be of benefit.

Women in labor enjoy multiple pain-control choices, and the safety record of currently used techniques is remarkable. According to a recent statement by the American College of Obstetricians and Gynecologists, "many techniques are available for analgesia in laboring patients. None of the techniques appears to be associated with an increased risk of cesarean delivery. The choice of technique, agent, and dosage is based on many factors, including patient preference, medical status, and contraindications. Decisions regarding analgesia should be closely coordinated among the obstetrician, the anesthesiologist, the patient, and skilled support personnel."[7] ■

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# Additional Reading

**by Judith Jaffe, MSLIS**
Ms. Jaffe is Knowledge Manager for CRICO/RMF.

*The following additional resources related to obstetrical patient safety were selected from the PubMed (Medline) database of indexed biomedical literature published from 2000 through July 2007. Links are provided to abstracts and full text, where available.*

## Anesthesia

American College of Obstetricians and Gynecologists. ACOG Committee Opinion. Safe use of medication. Number 331, April 2006. *Obstet Gynecol.* 2006 Apr;107(4):969–72.

American College of Obstetricians and Gynecologists. ACOG practice bulletin. Obstetric analgesia and anesthesia. Number 36, July 2002. American College of Obstetrics and Gynecology. *Int J Gynaecol Obstet.* 2002 Sep;78(3):321–35.

## Birth Plans

Lothian J. Birth plans: the good, the bad, and the future. *J Obstet Gynecol Neonatal Nurs.* 2006 Mar–Apr;35(2):295–303. PubMed abstract

Perez PG, Capitulo KL. Birth plans: are they really necessary? Pro and con. *MCN Am J Matern Child Nurs.* 2005 Sep–Oct;30(5):288–89.

Simkin PP. Birth plans: after 25 years, women still want to be heard. *Birth.* 2007 Mar;34(1):49–51.

## Cervical Incompetence

American College of Obstetricians and Gynecologists. ACOG practice bulletin. Cervical insufficiency. *Obstet Gynecol.* 2003 Nov;102(5 Pt 1):1091–99.

Berghella V, Seibel-Seamon J. Contemporary use of cervical cerclage. *Clin Obstet Gynecol.* 2007 Jun;50(2):468–77. PubMed abstract

## Fetal Heart Monitoring

Dellinger EH, Boehm FH, Crane MM. Electronic fetal heart rate monitoring: early neonatal outcomes associated with normal rate, fetal stress, and fetal distress. *Am J Obstet Gynecol.* 2000 Jan;182(1 Pt 1):214–20. PubMed abstract

Hendrix NW, Chauhan SP, Scardo JA, Ellings JM, Devoe LD. Managing nonreassuring fetal heart rate patterns before cesarean delivery. Compliance with ACOG recommendations. *J Reprod Med.* 2000 Dec;45(12):995–99. PubMed abstract

## Guidelines/Standards

Pearlman MD. Patient safety in obstetrics and gynecology: an agenda for the future. *Obstet Gynecol.* 2006 Nov;108(5):1266–71. PubMed abstract

Committee on Professional Liability, American College of Obstetricians and Gynecologists. ACOG Committee Opinion #309: Coping with the stress of medical professional liability litigation. *Obstet Gynecol.* 2005 Feb;105(2):453–54.

## Informed Consent

Davila GW. Informed consent for obstetrics management: a urogynecologic perspective. *Int Urogynecol J Pelvic Floor Dysfunct.* 2001;12(5):289–91. PubMed abstract

## Nursing: Quality Measures

Simpson KR, Knox GE. Essential criteria to promote safe care during labor and birth. *AWHONN Lifelines.* 2005 Dec-2006 Jan;9(6):478–83.

Simpson KR, James DC, Knox GE. Nurse-physician communication during labor and birth: implications for patient safety. *J Obstet Gynecol Neonatal Nurs.* 2006 Jul–Aug;35(4):547–56. PubMed abstract

## Shoulder Dystocia

Crofts JF, Bartlett C, Ellis D, Hunt LP, Fox R, Draycott TJ. Training for shoulder dystocia: a trial of simulation using low-fidelity and high-fidelity mannequins. *Obstet Gynecol.* 2006 Dec;108(6):1477–85. PubMed abstract

Gherman RB, Chauhan S, Ouzounian JG, Lerner H, Gonik B, Goodwin TM. Shoulder dystocia: the unpreventable obstetric emergency with empiric management guidelines. *Am J Obstet Gynecol.* 2006 Sep;195(3):657–72. PubMed abstract

Ouzounian JG, Gherman RB. Shoulder dystocia: are historic risk factors reliable predictors? *Am J Obstet Gynecol.* 2005 Jun;192(6):1933-35; discussion 1935–38. PubMed abstract

## Stillbirth: Predictors

Smith GC. Predicting antepartum stillbirth. *Curr Opin Obstet Gynecol.* 2006 Dec;18(6):625–30. PubMed abstract

Sharma PP, Salihu HM, Oyelese Y, Ananth CV, Kirby RS. Is race a determinant of stillbirth recurrence? *Obstet Gynecol.* 2006 Feb;107(2 Pt 1):391–97. PubMed abstract


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