

FETAL ASPHYXIA: STANDARDS OF CARE AND LEGAL CERTAINTY

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Fetal asphyxia is a medical event that can have profound medical-legal implications. It can, of course, cause tragic and irreversible brain damage for the child. It can, accordingly, have profound liability consequences for the obstetrician and other healthcare providers involved. Quite naturally, the significance of such cases has led some to wish for clear “national standards” that can be enforced to control the outcome of the resulting medical negligence cases. Although a few courts have accorded essentially controlling authority to certain practice guidelines, guidelines and standards are more typically viewed as establishing minimum standards---and as being only evidentiary on the ultimate issue of compliance with the standard of care.

This paper focuses on pronouncements by the American College of Obstetricians and Gynecologists (ACOG), journal articles, and sponsored studies that have attempted to delineate standards of care and to describe criteria for evaluating fetal asphyxia. But---at the end of the day---the analysis of those standards and criteria themselves demonstrate that there are no fixed, immutable standards that apply. Experts conscientiously disagree as to the significance of particular criteria; scientific knowledge advances, and that which seemed quite established is supplanted. Moreover, the objectivity of certain sources---and this writer would give particular emphasis in that regard to ACOG---is subject to reasoned debate.

I.

DEVELOPMENT OF ACOG GUIDELINES

In July, 2004 the American College of Obstetricians and Gynecologists (ACOG) released a national survey purporting to confirm that the “medical liability insurance crisis has worsened.” According to ACOG, one in seven ACOG Fellows reported that they have stopped practicing because of high-risk liability claims. One in two Fellows had reported being involved in a claim in the last four years, and about three in ten Ob/Gyns had been sued for care provided during their residency. The top four obstetric allegations were: neurologically impaired infant (34%), stillbirth/neonatal death (15%), other infant injury-major (7%) and delay in failure to diagnose (7%).

However, ACOG also reported that the majority of those cases were not successful. Almost half (49.5%) were dismissed, dropped or settled without payment. Of the cases that did proceed to court, doctors successfully defended the cases 8 out of 10 times.¹

In contrast to these figures, recent studies have indicated that most Ob-Gyn's are not at fault in most cases of newborn brain injuries such as cerebral palsy (CP) and encephalopathy.² One of the hoped-for goals of the report is to "stem the tide" of lawsuits against obstetricians, according to one of the co-issuers of the report.³ Plaintiffs' attorneys took a different view. They see the report as "dangerous, intellectually indefensible and morally irresponsible" by promoting the argument that fetal distress in labor almost never causes brain injury to the fetus, which may cause obstetricians to ignore early signs of fetal distress.⁴

The recent report follows another study in 1997 which also suggested perinatal hypoxic-ischemic injury, secondary to intrapartum asphyxia, rarely resulted in CP.⁵ In support of that conclusion, the study cited several factors: (1) increasing evidence that in most cases the brain injury associated with CP is not related to perinatal events, (2) improved survival of very low birth weight infants who are at risk for developing hemorrhagic ischemic cerebral injury, (3) limitations of current markers of perinatal stress used to identify infants during labor at greatest risk for developing hypoxic-ischemic injury secondary to intrapartum asphyxia, and (4) the lack of specific postnatal interventions to treat infants who develop hypoxic-ischemic encephalopathy.

The report also stated a potential goal of the information. A wider dissemination of knowledge regarding the origins of CP, and the relative infrequency of preventable intrapartum asphyxia as a cause, "should serve to restrict the number of cases reaching litigation to those few with potential merit."⁶

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¹ ACOG News Release, *Medical Liability Survey Reaffirms More Ob-Gyn's are Quitting Obstetrics*, July 16, 2004.

² ACOG Task Force, *Neonatal Encephalopathy and Cerebral Palsy: Defining the Pathogenesis and Pathophysiology*, January 2003.

³ Kight Ridder, Tribune Business News, *Disputed Study Finds Doctors Not to Blame in Most Cases of Cerebral Palsy*, January 31, 2003.

⁴ Ibid.

⁵ Perlman, *Intrapartum Hypoxic-Ischemic Cerebral Injury and Subsequent Cerebral Palsy: Medico-Legal Issues*, Pediatrics, Vol. 99, June 1997.

⁶ Ibid.

The issuance of these reports will undoubtedly add fuel to the litigation fire. On the one hand, defense attorneys and their experts will point to such reports as supporting a lack of causation between an asphyxia-related injury and alleged malpractice. Plaintiffs' attorneys will fight hard to keep such studies out of evidence, or point to erroneous conclusions or data relied upon by the reports.

The ACOG Task Force set forth four "essential" criteria to establish an acute intrapartum event sufficient to cause cerebral palsy. These criteria were modified from the criteria established by the International Cerebral Palsy Task Force.⁷ The factors are as follows:

1. Evidence of a metabolic acidosis in fetal umbilical cord arterial blood obtained at delivery (pH <7 and base deficit=12 mmo/L).
2. Early onset of severe or moderate neonatal encephalopathy in infants born at 34 weeks or more of gestation.
3. Cerebral palsy of the spastic quadriplegic or dyskinetic type.
4. Exclusion of other identifiable etiologies such as trauma, coagulation disorders, infectious conditions, or genetic disorders.

Additionally, the Task Force set forth other criteria that suggest an intrapartum timing of the injury, but are nonspecific to asphyxial insults:

1. A sentinel (signal) hypoxic event occurring immediately before or during labor.
2. A sudden and sustained fetal bradycardia or the absence of fetal heart rate variability in the presence of persistent, late, or variable decelerations, usually after a hypoxic signal event when the pattern was previously normal.
3. Apgar scores of 0-3 beyond 5 minutes.
4. Onset of multisystem involvement within 72 hours of birth.

⁷ MacLennan A., *A template for defining a causal relation between acute intrapartum events and cerebral palsy: international consensus statement*. BMJ 1999; 319:1054-9

5. Early imaging study showing evidence of acute nonfocal cerebral abnormality.⁸

These new standards have been applied in recent litigation. In Wolfe v. Virginia Birth Related Neurological Injury Compensation Program (Va. 2003) 580 S.E.2d 467, the mother of an infant diagnosed with cerebral palsy appealed a decision of the commission denying her benefits under the state act. Extensive testimony was admitted that the hospital staff monitored the labor consistent with the ACOG standards. More importantly, the defense expert testified that the infant did not meet the four ACOG standards for a diagnosis of birth asphyxia.

Although cord pH results were not available, the infant did not meet the multi-organ damage or Apgar score requirements. The Apgar scores were 4 at one minute, 4 at five minutes and 6 at ten minutes. A CT scan performed one day after birth showed small left and right frontal lobe hemorrhages, but those findings were absent on MRI two days and twenty-three days after birth. Testing revealed no evidence of cardiovascular, gastrointestinal, renal, hematologic, or pulmonary failure. Although testimony was presented that perinatal anoxia was the cause of the injury because no other cause could be found, the court relied heavily on the fact that the ACOG standards were not satisfied. Therefore, benefits were denied.

One important fact apparently was not presented to the commission. The International Task Force uses a five-minute Apgar score between 0-6, whereas ACOG uses 0-3. The infant would have met the International Standard, and the only factor missing was the multi-system involvement. It is unclear how this might have affected the determination, but this may present one area where expert testimony might divide on the significance of the Apgar score. The ACOG Task Force did not explain the rationale for using the lower value.

II. ACOG GUIDELINES DO NOT AUTOMATICALLY ESTABLISH THE STANDARD OF CARE.

The Wolfe decision placed considerable emphasis on the ACOG criteria. However, whether its rationale will be adopted nationwide is doubtful. Experts

⁸ ACOG Task Force, *Neonatal Encephalopathy and Cerebral Palsy: Defining the Pathogenesis and Pathophysiology*, January 2003.

should take note of the cautionary language in the Task Force recommendations, particularly when arguing against their applicability. The Task Force noted:

“The Task Force recognizes that this summary will require updating as the scientific database and knowledge on this topic expands. Only with more complete understanding of the precise origins and pathophysiology of neonatal encephalopathy and cerebral palsy can logical hypotheses be designed and tested to reduce their occurrence. As such, we recommend several important areas of research that are detailed in the text of the full document. We encourage those engaged in research to pursue these areas, and others to exert influence to the degree possible to propel this to a high priority for funding and study.”⁹

This language acknowledges that even the task force understands that the “standards” are not absolute. The majority of jurisdictions have either held outright, or implied in appellate decisions, that ACOG standards may set a minimum threshold, or be indicative of the standard of care, but are not necessarily controlling.

A. DIRECT APPLICATION OF ACOG GUIDELINES ON THE STANDARD OF CARE.

Some jurisdictions, such as California, recognize the standards by statute. For instance, California Code of Regulations, Title 22, Section 51348.1(a) (1), entitled “Comprehensive Perinatal Standards of Care,” provides that “Services shall be provided in conformance with: ‘Standards for Obstetric-Gynecological Services, Sixth Edition,’ herein incorporated by reference in its entirety and available from the American College of Obstetricians and Gynecologists.”

Some other jurisdictions put great emphasis on the ACOG guidelines as determinative of the standard of care. In *Craig v. Oakwood Hospital* (Mich. 2002) 643 N.W.2d 580, malpractice allegedly resulted in cerebral palsy and severe mental retardation to the infant. The plaintiff’s experts testified that, as a result of prolonged contractions caused by an overdose of Pitocin, hypoxia to the fetus occurred. The defendant doctors claimed the trial court improperly allowed the plaintiff to establish the standard of care by cross-examining the defense experts on ACOG bulletins and the AMA Drug Evaluation, at times reading directly from the

⁹ ACOG Task Force, Executive Summary, *Neonatal Encephalopathy and Cerebral Palsy: Defining the Pathogenesis and Pathophysiology*, January 2003.

documents. The defense doctors testified that the standard of care did not require internal monitoring during the administration of Pitocin in 1980. The appellate court found no error in allowing the ACOG bulletins, which stated that internal monitoring was necessary, and the article from the AMA, which suggested the use of Pitocin in this labor was not in accordance with the standard of care. The court held that the use of the written materials was appropriate for impeachment purposes.

Other medical studies may also be used to provide causation testimony. In Mitchell v. Palos Community Hospital (Ill. 2000) 740 N.E.2d 476, the defendant sought to introduce evidence of an expert on an analysis of the infants nucleated red blood cell (NRBC) count to establish that the fetus suffered a pre-emergency room visit placental abruption. The expert had authored numerous articles on the relationship between NRBC's and fetal asphyxia. On a Frye motion challenging the scientific validity of the findings, the court found no error in allowing the testimony. The defense experts testified that using the level of NRBC's, along with other factors, to determine the timing of the fetal injury or placental abruption, was generally accepted in the medical community, and that the articles had been published in prestigious medical journals, and that the theory had been put into practice at Children's Memorial Hospital in Chicago. Thus, defendant was able to establish the requisite degree of scientific reliability.

B. OTHER JURISDICTIONS DO NOT ALLOW ACOG GUIDELINES ALONE TO ESTABLISH THE STANDARD OF CARE.

However, that view does not predominate. Compliance with the ACOG standards alone does not necessarily let the OB/GYN "off the hook." For instance, in Liberatore v. Kaufman (Fla. 2003) 835 So.2d 404, plaintiff alleged she suffered severe vaginal and cervical lacerations as a result of a vacuum extraction, and the subsequent bleeding resulted in a hysterectomy and removal of her ovaries. The defendant's attorney questioned his expert regarding an ACOG bulletin, and used the bulletin to establish the standard of care. The expert testified that he was familiar with the ACOG bulletins, and further opined that the defendant doctor's care and treatment had complied with the guidelines set forth in those bulletins. Another defense expert testifying regarding the use of Pitocin indicated the ACOG bulletins do not establish the only standard of care, but they do establish one standard of care. The expert said:

"This is not the only way to manage a problem, there may be other ways which are equally appropriate, but certainly no one can claim if someone

did it according to one of these bulletins that this would be a violation of the standard of care.”

Under Florida law experts cannot bolster their testimony by testifying that a treatise agrees with their opinion. Instead, authoritative publications can only be used to cross-examine or impeach an expert. Thus, the appellate court found the direct use of the ACOG bulletins to be prejudicial error.

In another Florida case, Kirkpatrick v. Wolford (Fla. 1998) 704 So.2d 708, the defendant in a malpractice case involving the death of a newborn sought to introduce certain ACOG technical bulletins and committee opinions. The defense experts testified that the ACOG materials were “authoritative.” The plaintiff’s experts testified the ACOG materials were not “in and of themselves, authoritative” and that “the general obstetric community does not recognize them as per se authoritative.” The trial court admitted the use of the ACOG materials, and the appellate court upheld this determination. Florida law did not require the materials to be “per se” authoritative. As long as there is some credible evidence to conclude that a text is authoritative, the trial judge has discretion to admit the text for purposes of cross-examination.

The expert does not need to be familiar with the guidelines. In Ornoff v. Kuhn and Kogan Chartered (D.C. 1988) 549 A.2d 728, a medical malpractice case was brought against a gynecologist in the District of Columbia arising out of the performance of a laparoscopy. The patient contended that she suffered “life-threatening” internal bleeding resulting in the necessity of a total hysterectomy. The plaintiff’s medical expert was a hematologist, who opined that the doctor was negligent because a simple blood clotting factor screening test was not performed, which would have revealed the patient had a Factor XI blood deficiency, which would have contributed to the bleeding. The defendant contended the hematologist was not competent to testify as to the standard of care of OB/GYN’s performing laparoscopies, and in particular, that the expert did not know the ACOG standards and guidelines. The trial court excluded the testimony based in large part on the expert’s unfamiliarity with the ACOG standards.

The appellate court overturned the trial court’s decision, finding that “a physician need not be a specialist in the field of which he speaks in order to testify as an expert.” Thus, the hematologist could testify to the standard of care in performing surgery (in the context of hematology), the effect a breach would have on a person with a Factor XI blood deficiency and any causal linkage between the hematoma and a violation of the standard of care.

The same view was expressed in a Rhode Island case, DeBar v. Women and Infants Hospital (R.I. 2000) 762 A.2d 1182. The plaintiffs alleged the doctor did not timely order an emergency caesarian section, which resulted in the death of the baby. An autopsy revealed that the baby had aspirated meconium into her lungs, and the cause of death was determined to be cardiac arrest as a result of the meconium aspiration and bilateral pneumothorax.

The plaintiff's Ob-Gyn expert opined that the treating doctor fell below the standard of care, and that the baby would have survived long enough to be viable. However, he could not opine as to whether the infant may have eventually died as a result of the consequences of the disease because he was not a pediatrician. Plaintiffs then offered the testimony of a board-certified pediatrician and pediatric neurologist, who was prepared to testify that an earlier C-section, based on certain decelerations on the FHM strip, would have allowed the infant to survive. However, the trial court granted defendant's motion to exclude this testimony because the doctor was not an expert in the field of obstetrics or fetal monitoring.

The appellate court found this to be reversible error. Although the Rhode Island statute provided that "only experts who qualify in the field of the alleged malpractice" were allowed to provide expert testimony, the court reasoned that the wording of the statute did not require the expert to practice in the same field. As long as the expert was familiar with the procedure performed, through experience, observation, association or education, the expert was competent to testify to the standard of care. The court relied on other jurisdiction that had adopted the same rule. [Pool v. Bell (Conn. 1989) 551 A.2d 1254; Fitzmaurice v. Flynn (Conn. 1975) 356 A.2d 887; Letch v. Daniels (Mass. 1987) 514 N.E.2d 675.]

These cases show that there is no absolute rule to determine when ACOG guidelines will be permitted to establish a standard of care. Much depends on the expert witness, who, depending on the issue, may or may not agree with the proposition that ACOG standards control. However, even if the standards are not controlling, one party should expect that, at the very least, its expert will need to confront the standards if the level of care fell below the guidelines.

III. THE ROLE OF CLINICAL PRACTICE GUIDELINES TO ESTABLISH THE STANDARD OF CARE.

An emerging trend in malpractice litigation is the use of clinical practice guidelines (CPG's) to establish a standard of care. Although CPG's were not designed to establish a standard of care, their use as such is becoming more prevalent. Historically, many CPG's were issued by malpractice liability carriers and health insurers.¹⁰ The AMA refers to its CPG's as "parameters," defining an acceptable low and high range for the level of care. However, liability concerns also came into play, as noted by the following pronouncement:

"In essence, it is hoped that practice parameters will enable physicians to provide high-quality medical care more effectively and efficiently, thereby responding to society's need to control health care expenditures without sacrificing the quality of care. It is expected that practice parameters will help physicians reduce the amount of unnecessary or inappropriate care for patients [and] reduce the amount of avoidable injuries caused by substandard care and the amount of defensive medicine."¹¹

Even though avoidance of litigation may not have been the primary motivating factor, such pronouncements ["reduce avoidable injuries"] give the plaintiff's attorney ammunition to argue that compliance with the CPG's is necessary to fall within the standard of care. If treating providers, health insurers or hospitals adopt, for instance, the cerebral palsy guidelines, then the further incorporation of those guidelines will undoubtedly be used to argue that they are sufficient to establish a standard of care. From a practical standpoint, the defendant doctor would have a difficult time convincing a jury that she is required to comply with one set of standards, but not another.¹²

Currently, the majority of jurisdictions treat CPG's as being admissible in the same way as a learned treatise. Experts are allowed to testify as to the role of the CPG's in a particular case, but the weight given to the guidelines is not determinative

¹⁰ See, John D. Ayres, *The Use and Abuse of Medical Practice Guidelines*, 15 J. Leg. Med. 421 (1994); Arnold J. Rosoff, *The Role of Clinical Practice Guidelines*, 5 Health Matrix 369 (1995).

¹¹ Edward B. Hirshfield, *From the Office of the General Counsel: Should Practice Parameters Be The Standard of Care in Malpractice Litigation?*, 266 JAMA 2886,2887 (1991).

¹² Michelle M. Mello, *Of Swords and Shields: the role of clinical practice guidelines in medical malpractice litigation*, Univ. of Penn. L.Rev., 1/01.

of a standard of care.¹³ The effect depends on how the experts are willing to characterize the guidelines. However, exceptions do exist. Some courts have recognized CPG's as establishing a rebuttable presumption of the standard of care.¹⁴

IV. THE LEGAL RISKS OF THE ELECTRONIC FETAL HEART MONITOR.

Electronic fetal heart monitoring is the most-widely used method of monitoring the heartbeat for signs of fetal distress. The EFM strip is perhaps the most used piece of evidence in a fetal brain injury or death case, and much time is devoted to experts analyzing the strip for signs of distress, and nurses are cross-examined at length on whether events were properly charted and reported. One study concluded that the focus on EFM's efficacy in preventing and predicting intrapartum distress had diverted attention away from exploring other factors that may contribute to maldevelopment or injury to the infant's brain.

Even definitions may play an important role in a malpractice case. Consider the use of the term "nonreassuring" in the context of interpreting fetal heart rate patterns. In 1997, the National Institute of Child Health and human Development established four clearly-defined terms to describe the variability of a fetal heart rate:

1. Absent variability.
2. Decreased or minimal variability.
3. Normal or moderated variability.
4. Increased or marked variability.

Instead of using such terms, however, one commentator noted that medical students tend to generalize patterns as either "non-reassuring" or "fetal distress" when they really mean a variant heart rate pattern. Malpractice lawyers are quick to seize upon the "nonreassuring" term to claim the treating provider was not doing enough in the face of noted fetal distress.¹⁵

¹³ Sam A. McConkey, *Simplifying the Law in Medical Malpractice: The Use of Practice Guidelines as the Standard of Care in Medical Malpractice Litigation*, 97 W.Va. L. Rev. 491 (1995).

¹⁴ Marshall B. Kapp, 'Cookbook' Medicine: A Legal Perspective, 150 Archives Internal Med 496 (1990).

¹⁵ Sherry Boschert, *Watch your language: don't write 'nonreassuring' in chart*. OB GYN News (9/15/04).

Electronic fetal monitoring is a significant advancement that can be beneficial in providing care to a mother and her unborn child. It is one tool among many available to the practitioner. The American College of Obstetricians and Gynecologists' approach to electronic fetal monitoring is subject to skeptical review. Rather than appropriately evaluating the medical benefit of EFM, ACOG has tended to view it contentiously¹⁶:

- It assessed auscultation to be of equivalent efficacy and benefit as electronic fetal heart monitoring.
- In downplaying its benefits, ACOG implicitly encouraged healthcare providers not to use a medical advance that can be of significant benefit to fetal health and well-being.
- Its pronouncements permitted fetal heart monitor strips to be destroyed---their destruction being deemed to be within the standard of care.

ACOG's history in regard to electronic fetal monitoring is consistent with other actions taken by the organization which reflect on its objectivity. Those actions include semantic fights that are litigation-based rather than scientifically based---specifically issuing a full-blown ACOG Committee Opinion taking issue with the use of the phrases "fetal distress" and "birth asphyxia."¹⁷ It has adopted a set of ethical standards relating to expert witness testimony and applies it unilaterally in regard to plaintiffs' experts. It has become an advocate for "tort reform" and publicly aligns itself with political candidates and political parties.

V. CONCLUSION

The search for certainty is illusive. Firm, bright line, nationally applied standards are not often to be found. Scientific knowledge advances---and those advances appropriately inform the quality of care to be provided to patients. "Standards" change and "standards" are subject to significant debate within the scientific community. Noted scientists may, for instance, find that base excess is a significant criterion for assessing fetal asphyxia. Others would argue for ph level---some wanting a ph of 7.0 or below and others arguing for a level of 7.1 or below.

¹⁶ ACOG Technical Bulletin, Number 207, July, 1995.

¹⁷ ACOG Committee Opinion , Number 303, October, 2004.

Medicine---like law---is best informed by the full application of the best and most up-to-date research available. That fact should be encouraged.