

Missing the Mark

Patient safety should be a physician's principal aim. But leaders in the obstetrical community have developed baseless criteria for assessing the causes of brain injury at birth—and have shirked their ethical duty to avoid preventable injuries.

By || **ROBERT L. CONASON AND STEVEN E. PEGALIS**

The civil justice system should fairly compensate people who have sustained preventable injury. The successful pursuit of meritorious medical liability cases promotes patient safety by discouraging substandard care.

Tort liability is premised on the moral concept that each negligent party should be financially responsible for each reasonably avoidable injury. The law also contemplates that the obligation to pay will act as a warning that the law demands the exercise of due care.¹

Our clients who have been harmed by medical error want us to promote safe care for others. Our mission is to help our clients and society. If, by pursuing meritorious medical liability cases, we promote safer care that results in fewer preventable injuries, we are being true to our mission.

The medical profession's ethics are

consistent with this moral and legal premise. All physicians are required to acknowledge that medical errors can occur and harm patients—and to work toward reducing the incidence of potentially harmful errors.² By considering information from past meritorious claims, risk management uses the financial incentive of reducing future liability costs to promote safer care.

We maintain that some medical groups undermine the moral and legal precepts that hold physicians accountable for medical care—especially in cases involving perinatal brain-injured infants. We believe that their arguments, as part of an organized and determined effort intended to “protect” doctors, have the net effect of striking at the heart of the civil justice system.

In 2007, the New York superintendent of insurance convened a task force

to consider medical liability safety and cost issues. Various stakeholders invited to participate included the Medical Society of the State of New York (MSSNY) and the American Congress of Obstetricians and Gynecologists (ACOG), acting on behalf of its member obstetricians, who were reputed to be among the medical specialists “most impacted” by medical negligence lawsuits.³

The MSSNY's position was that the civil justice system no longer serves its fundamental purposes, and traditional tort “reform” measures are only a temporary fix. The society urged the adoption of ACOG's proposed no-fault system for neurologic handicap in children—as a first step toward a no-fault system for all medical liability cases.⁴

During the proceedings, an ACOG physician noted that while scientifically valid studies proved that perinatal brain

injury that results in cerebral palsy (CP) is a “rare” event and not preventable, many ACOG members had paid large sums of money defending lawsuits alleging that their negligence during a patient’s labor and delivery caused an infant’s CP.⁵ According to the physician, this proved that the civil justice system was not working in this subset of serious injury cases—and it might not be working in others.

Proponents of tort “reform” and no-fault legal immunity often use the perinatal brain injury case as an example of how serious injury liability cases cannot be resolved on true merit.⁶ Influential ACOG leaders have written that the medical liability trial amounts to a “free-for-all” and that plaintiff attorneys and their experts use theater rather than science to play on juror sympathy.⁷

But the so-called science that ACOG relies on to make these arguments is flawed. It can be summarized as follows:

- There are specific “essential” criteria for determining whether a disabling brain injury occurred during labor: lab evidence of severe acidosis at birth (the pH must be below 7.0, for example); evidence of specific newborn neurological symptoms (called neonatal encephalopathy); evidence of a specific type of CP; and the absence of any identifiable alternative explanation (such as infection).⁸
- Using these criteria as the measuring rod to identify brain injury that results in CP during labor, ACOG maintains that such injuries occur only rarely.
- The use of the electronic fetal monitor during labor cannot influence the outcome or prevent CP. Despite advances in medicine, CP is not preventable.⁹

The current criteria were created by an ACOG committee chaired by Gary Hankins in 2003.¹⁰ They modify criteria established by a prior ACOG committee, also chaired by Hankins, in 1992.¹¹

But expert testimony that Hankins gave in a 2007 hearing in Florida shows that even he doesn’t believe that the criteria are essential to proving that a child’s cerebral palsy was caused by perinatal injury. In Florida, an obstetrician can opt out of a liability lawsuit and into a no-fault system if a child’s brain damage occurred during labor or birth. In the 2007 case, a defendant obstetrician was seeking to do just that, and Hankins testified that the child’s brain injury in that case occurred during the labor and delivery process as a consequence of acute severe birth asphyxia. He swore that the 2003 criteria were not essential and that each case must be evaluated on its own merits.¹²

In that case, neither the severe acidosis nor the newborn encephalopathy criteria were met. Other information supported the conclusion that there was severe, acute labor-related asphyxia, and there was no identifiable alternative explanation for the child’s injury. Hankins, using deductive reasoning, arrived at a plausibly correct conclusion. He simply used the scientific method, looking at the facts of the case and analyzing what fit and what did not, to determine the most likely cause.¹³

There are known medical reasons why severe acidosis or newborn encephalopathy sometimes occur and sometimes do not occur in cases of acute severe labor asphyxia.¹⁴ Even if other risk factors are present before labor (such as infection and growth restriction), that does not mean the child was not brain-injured during labor. Each case must be evaluated individually, as Hankins did in Florida. An individualized evaluation would understand that prior fetal compromise would make a child more vulnerable to labor stresses.

No scientific studies or data support the ACOG criteria, but obstetricians favor them because few cases of disabling brain damage can be found to

be due to potentially avoidable labor- or birth-related causes if the criteria are rigidly applied.¹⁵

In 1987, ACOG published in its peer-reviewed journal an article in which the obstetrician author wrote that, because “most litigation is based upon events during the delivery process,” he recommended obtaining a sample of fetal blood only when the fetus was depressed so the physician could use that information to help defend a liability case. If the fetus was not depressed, he recommended against obtaining a blood sample because it might be “uncomfortably incriminating.”¹⁶

Collecting or not collecting a sample of fetal blood should be a medical decision based solely on what is best for the child. But ACOG’s editors and peer reviewers impliedly endorsed the article’s recommendations by publishing it.

Using ACOG’s criteria to frustrate children’s valid legal rights also frustrates what can be effective risk-management efforts. What might be a win-win situation (fairly compensating the child and using the information to prevent future similar harm) can become a lose-lose situation.

Skewed Statistics

Statistics have also been used—wrongly—to defend negligent obstetrical care. The perinatal mortality rate (PMR) represents deaths shortly before, during, and shortly after birth. In the 1960s, before the introduction of electronic fetal monitoring and other advances such as the newborn intensive care unit, statistics revealed that the PMR was high (37 per 1,000 births).¹⁷

The statistical incidence of cerebral palsy was comparatively much lower (about 2 to 4 per 1,000 births).¹⁸ Advances in technology produced a dramatic decline in the PMR (of almost 30 per 1,000 births). If only five of those “saved” children survived with cerebral palsy, the cerebral palsy rate would

double. But the rate did not rise at all.

ACOG maintains that the absence of significant decline in the cerebral palsy rate proves that cerebral palsy is not preventable.¹⁹ But this represents a misuse of the statistics. What they show is that far fewer children were injured during labor and birth, fatally and otherwise, proving that good care using new technology can make a difference.²⁰

Statistics have also been used to allegedly prove that cerebral palsy is not “predictive” and therefore cannot be prevented by using electronic fetal monitoring. But this argument ignores the physician’s duty of care to his or her patient. Injury from being an occupant of a moving vehicle is not statistically predictive. For example, even though there is less than a 0.01 percent chance that each occupant of a car will be injured in an auto collision, each driver must place a child in a safety seat and must use due care to avoid a collision.

Complications associated with risk factors sometimes lead to harm. Doctors use risk factors to anticipate and avoid harm. But attributing harm to risk factors rather than specific identifiable complications and stating that cerebral palsy from labor is not a predictive outcome can result in erroneous conclusions.

If stresses during the birth process are excessive, they will cause harm. Disabling brain injury that produces cerebral palsy can be anticipated, and excessive stresses that can produce such injury can be avoided or limited in individual cases.

Ambiguous Advice

Thirty years ago, the American Society of Anesthesiologists (ASA) used information from closed medical liability cases to adopt mandatory minimum standards. As a result, the ASA made the administration of anesthesia much safer, and anesthesiologists dramatically reduced their liability claims and premiums.²¹

In 2008, a group of obstetricians published a study in which they used closed perinatal liability cases to devise and implement a new, “unique” patient safety protocol involving an obstetrical service delivering 220,000 children each year. They stated that their perinatal safety program rejected the use of “purposefully ambiguous” guidelines, which they recognized as a “traditional” approach that helps a liability defense. They used mandatory, unambiguous guidelines coupled with an interactive teaching of electronic fetal monitoring, and they reported fewer bad outcomes, a 50 percent reduction in liability cases, and a “dramatic” decrease in liability costs.²²

There is a clear parallel between what the ASA did 30 years ago—using liability claims to make care safer—and what this obstetrical group accomplished.

In contrast, ACOG’s most recent labor management bulletin (issued in July 2009) is purposefully ambiguous.²³ For example, the committee formulating the guidelines identified certain electronic fetal monitoring information as normal, certain information as abnormal, and certain information as “intermediate.” One member of the committee noted a significant concern with this wording, “fearing its potential legal implications.”²⁴

This ambiguity reflects ACOG’s preoccupation with how the words will be used in the courtroom. Instead, the wording should state unambiguously that issues of uncertainty must be resolved in favor of protecting each child.

ACOG has previously urged its member obstetricians to eliminate the use of the words “fetal distress” to apply to information about the fetal patient based on the electronic fetal monitoring data.²⁵ But the term “fetal distress” has been used to indicate that the fetus is in a precarious condition, which can lead to brain injury or death if it persists. The term was meant to alert medical

professionals that they should not defer action until after it is too late.²⁶

The current guidelines also urge member obstetricians to eliminate the use of the word “hyperstimulation.” Contractions cause labor stresses, and those contraction-induced stresses can become “hyper” (excessive in frequency, duration, or intensity). By focusing on these labor stresses and the ability (or inability) of the fetus to respond to them, bad outcomes for vulnerable children can be avoided.²⁷

Electronic fetal monitoring can reveal hyperstimulation, a precarious situation that can cause fetal distress and, ultimately, brain injury if it persists. ACOG cannot change the reality that this chain of events occurs by eliminating the words “hyperstimulation” and “fetal distress” from patients’ medical records.

Dangerous Disconnect

There is a disconnect between ACOG’s claim that the civil justice system operates as a free-for-all and the due process that actually occurs in the courtroom. We recently represented a child who sustained avoidable perinatal brain injury. Her parents are physicians, but when their child suffered an injury because of medical negligence, they looked to the courts for redress of her injuries and to help ensure that other children don’t suffer the same fate.

Liability cases have improved the safety of medical care. It will be made even safer care as more physicians come to understand that civil justice protects all of us. ▣

Robert L. Conason is the senior partner at Gair, Gair, Conason, Steigman, Mackauf, Bloom and Rubinowitz in New York City. Steven E. Pegalis is a partner at Pegalis & Erickson in Lake Success, New York, and an adjunct professor at New York Law School.

NOTES

1. See e.g. *Bing v. Thunig*, 143 N.E.2d 3, 8 (N.Y. 1957). This case is consistent with the common law of every state.
2. See Am. Bd. Internal Med. Found. et al., *Medical Professionalism in the New Millennium: A Physician Charter*, 136 *Annals Internal Med.* 243, 244–45 (2002), www.annals.org/content/136/3/243.full.
3. The New York State Medical Malpractice Liability Task Force was cochaired by New York's superintendent of insurance, Eric Dinallo, and commissioner of health, Richard Daines. N.Y. St. Ins. Dept., *Medical Liability Task Force Members Announced* (Aug. 3, 2007), www.ins.state.ny.us/press/2007/p0708301.htm.
4. Med. Socy. St. N.Y. & Am. Cong. Obstetricians & Gynecologists, *Submissions to the New York State Medical Malpractice Liability Task Force* (Oct. 16, 2007 & Dec. 19, 2007) (on file with authors).
5. This premise is consistent with current publications. See e.g. Richard L. Berkowitz et al., *A Proposed Model for Managing Cases of Neurologically Impaired Infants*, 113 *Obstetrics & Gynecology* 683 (2009).
6. The term “perinatal brain injury case” usually refers to a case in which the plaintiff alleges that an avoidable brain injury during labor caused cerebral palsy.
7. See James R. Scott, *Expert Witnesses: Perpetuating a Flawed System*, 106 *Obstetrics & Gynecology* 902 (2005).
8. Am. Cong. Obstetricians & Gynecologists, *The Report of ACOG's Task Force on Neonatal Encephalopathy and Cerebral Palsy Has Been Published*, www.acog.org/from_home/Misc/neonatalEncephalopathy.cfm (summarizing ACOG's report, *Neonatal Encephalopathy and Cerebral Palsy: Defining the Pathogenesis and Pathophysiology* (Jan. 2003)).
9. Alastair MacLennan et al., *Who Will Deliver Our Grandchildren? Implications of Cerebral Palsy Litigation*, 294 *JAMA* 1688, 1688–89 (2005).
10. Am. Cong. Obstetricians & Gynecologists, *supra* n. 8; see also Gary D.V. Hankins & Michael Speer, *Defining the Pathogenesis and Pathophysiology of Neonatal Encephalopathy and Cerebral Palsy*, 102 *Obstetrics & Gynecology* 628 (2003).
11. Am. Cong. Obstetricians & Gynecologists, *Tech. Bull.* 163, *Fetal and Neonatal Neurologic Injury* (Jan. 1992). Hankins is also a coauthor of Berkowitz et al., *supra* n. 5, and MacLennan et al., *supra* n. 9.
12. *Bennett v. Fla. Birth-Related Neurologic Compens. Assn.*, No. 06-2422, *Dep. Transcr.* 88–96 (June 13, 2007) and *Hr. Transcr.* 98–101 (July 9, 2007).
13. See e.g. *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262–63 (4th Cir. 1999); *Hardyman v. Norfolk & W. Ry. Co.*, 243 F.3d 255, 261–62 (6th Cir. 2001). These and other similar cases support deductive reasoning based on identifiable data as the approved scientific methodology.
14. See e.g. Marcus C. Hermansen, *The Acidosis Paradox: Asphyxial Brain Injury without Coincident Acidemia*, 45 *Developmental Med. & Child Neurology* 353 (2003).
15. See Robert C. Goodlin, *Do Concepts of Causes and Prevention of Cerebral Palsy Require Revision?*, 172 *Am. J. Obstetrics & Gynecology* 1830 (1995).
16. Richard P. Perkins, *Perspectives on Perinatal Brain Damage*, 69 *Obstetrics & Gynecology* 807, 815 (1987).
17. Richard L. Naeye, *Causes of Perinatal Mortality in the U.S. Collaborative Perinatal Project*, 238 *JAMA* 228, 229 (1977).
18. *Id.*
19. See MacLennan et al., *supra* n. 9.
20. See Bengt Hagberg et al., *Gains and Hazards of Intensive Neonatal Care: An Analysis from Swedish Cerebral Palsy Epidemiology*, 24 *Developmental Med. & Child Neurology* 13 (1982); Alfred L. Scherzer, *The Changing Face of Cerebral Palsy?*, 29 *Developmental Med. & Child Neurology* 550 (1987); see also Kate Himmelmann et al., *The Changing Panorama of Cerebral Palsy in Sweden. IX. Prevalence and Origin in the Birth-Year Period 1995–1998*, 94 *ACTA Paediatrica* 287 (2005).
21. See Jeffrey B. Cooper & David M. Gaba, *No Myth: Anesthesia Is a Model for Addressing Patient Safety*, 97 *Anesthesiology* 1335 (2002); David M. Gaba, *Anesthesiology as a Model for Patient Safety in Health Care*, 320 *Brit. Med. J.* 785 (2000).
22. Steven L. Clark et al., *Improved Outcomes, Fewer Cesarean Deliveries, and Reduced Litigation: Results of a New Paradigm in Patient Safety*, 199 *Am. J. Obstetrics & Gynecology* 105.e1, 105.e6 fig. 4 & 105.e4 (2008).
23. See Am. Cong. Obstetricians & Gynecologists, *Prac. Bull. No. 106, Intrapartum Fetal Heart Rate Monitoring: Nomenclature, Interpretation, and General Management Principles* (July 2009).
24. Catherine Y. Spong, *Electronic Fetal Heart Rate Monitoring: Another Look*, 112 *Obstetrics & Gynecology* 506, 507 (2008).
25. See e.g. Am. Cong. Obstetricians & Gynecologists, *Comm. Op. No. 197, Inappropriate Use of the Terms Fetal Distress and Birth Asphyxia* (Feb. 1998).
26. See generally Richard J. Martin et al., *Fanaroff and Martin's Neonatal-Perinatal Medicine* (6th ed., Mosby 2006).
27. See Clark et al., *supra* n. 22, at 105.e6.