PERINATAL BRAIN INJURY: THE LEGAL RIGHTS OF A DISABLED CHILD

By Steven E. Pegalis, Esq.

Plaintiff's attorneys who screen a possible medical liability case based on a preventable perinatal brain injury have an ethical responsibility not to pursue a meritless case. There is also a financial incentive to motivate the non-pursuit of the meritless case as one can anticipate a spirited defense adversarialism and likely a financial loss. If, however, a child has sustained a preventable, disabling perinatal brain injury, the ethical mission of the plaintiff's attorney is to try to financially secure the child's future and, importantly, to also create a legal accountability that motivates safer care going forward.

Infortunately, defense adversarialism has for many years been using a pseudo-medical science created for litigation to defend against meritorious cases. This pseudoscience has been used to the detriment of disabled children who truly have had meritorious legal cases and, therefore, should be compensated for their injuries. Such pseudoscience has also been linked to a lip service rationalization that the legal system has been victimizing doctors. What has been missing is a medical professionalism grounded in concepts that embrace and link legal accountability to professionalism as a pathway to justice and greater safety.

I hope this paper will help untangle pseudoscientific pitfalls that can, but should not, deflect plaintiff's attorneys from their ethical missions.

A HISTORICAL CONTEXT

In 1987, an article was published in the peer review journal of the American College of Obstetricians and Gynecologists (ACOG).² ACOG is the official journal of the national organization acting on behalf of obstetricians. The author states: "Because most litigation is based upon events during the delivery process, we would recommend cord blood gas analysis only with neonatal depression. In this way, the obstetrician might be best protected in the Courts." This author adds: "On the other hand,... nearly 20% of the infants appearing vigorous at birth would have shown cord blood gas data of an uncomfortably incriminating nature in the absence of neonatal depression."

The paper refers to an "epidemic of malpractice litigation" and stresses "...that injury is frequently attributed to perinatal causes when in fact the obstetrician could not possibly foresee and circumvent it." The author cites "the dramatic recuperative powers of many infants ... compared with minimal provocations frequently associated with handicap, underscoring the concept of prior injury or unique fragility."⁵

Thus, we see the seeds of a preposterous pseudoscience. It is true that some children compensate, and then decompensate to the point of near death, and yet survive without residual brain damage. The scientific point is that the causal pathway to disabling brain injury from, for example, perinatal asphyxial stresses in healthy full-term infants usually cross an injury threshold "late" in the process often making the injury very preventable when such injury does occur. Associating "minimal provocations" with handicap linked to "unique fragility" has no scientific validity. Preterm children, growth restricted children, and/or septic children are compromised and therefore vulnerable to continued and/or superimposed additional stresses. It is this vulnerability that creates a professional duty to use that data to protect the child. These children do not have a "unique fragility." Continued and/or superimposed additional stresses are not "minimal provocations," but rather can be causes of preventable injury that could have been foreseen and circumvented.

Some obstetrical medical authors have claimed that medical science established that the "vast majority" of brain injury is not preventable, yet plaintiff's attorneys sue in almost all cases of cerebral palsy (CP).6 Some of these same authors have contended that judges, jurors and family members cannot appreciate that high-tech gadgets, such as the electronic fetal monitor (EFM), cannot reasonably predict or influence the outcome. They add that, although birth can be a hazardous journey, the EFM "does not help," as cerebral palsy is "not currently preventable."

Plaintiffs have been accused of using "hired guns" as medical experts, who give "biased, outdated, or simply wrong testimony." Thus, the legal system is allegedly flawed.⁸ Why flawed? Because, allegedly, plaintiffs use sympathy (as if the seriously disabled child is an uninvolved bystander) and, allegedly, use "a seemingly

reasonable explanation."9 The "seemingly reasonable explanation" that allegedly misleads judges and juries is the plaintiff's attorneys' claim that EFM really does have a purpose. These attorneys also claim that physicians, who are responsible to protect the unborn child during the hazardous journey leading toward birth, really do have important responsibilities that include an ability to prevent disabling brain injuries.

Plaintiff's attorneys have been accused of bringing meritless perinatal brain injury cases. If true, that would mean that plaintiff's attorneys are unethical and that the civil justice system is incapable of resolving these cases on the merits. This hypothesis has created a rationalization that is all too often used to justify the creation of mandatory causation criteria and the creation of medical literature concerning the utility of EFM data to be used to discourage or defeat valid legal claims.

THE RISE AND FALL OF CAUSATION CRITERIA

In 1992, ACOG published a list of specific criteria they maintained <u>must</u> be present before a plausible link could be made of a "possible relationship between perinatal asphyxia and neurologic deficit." ¹⁰

The premise was that most disabled children were alleging in their case that brain injury and neurologic deficit were due to asphyxia (hypoxia with metabolic acidosis) and that the asphyxia occurred during the perinatal time interval (at around the time of birth). Often during the perinatal time interval, the physician would be "on duty" during labor (intrapartum time interval) watching the baby with the EFM. If the causation criteria were not met, the defense would maintain that the injury occurred before the provider was on duty and the use of the EFM could not have influenced the outcome.

There never has been any scientific validity to these criteria and similar criteria created in 2003. Using data to predict handicap in large populations of children (e.g. low Apgar Scores and metabolic acidosis), doctors noted that extremes would better predict bad outcomes just as for example auto collisions at 75 mph would more likely produce injury in comparison to collisions occurring at 35 mph. The point, however, is that the individual auto collision at any speed can cause serious injury and that the absence of signs of asphyxial extremes do not make individual children immune and do not support a factual premise to assign a brain injury to silent, secret influences occurring when the doctor was off duty.

One medical author describing the 1992 criteria, noted that the list has appeal to obstetricians because, when applied to a child disabled with cerebral palsy pursuing a liability case against an obstetrician, few cases would be due to perinatal asphyxia. That medical

author noted that obstetricians who had, as a group, been supporting tort reform that would limit their liability should have a rebirth of enthusiasm for prevention of cerebral palsy.¹¹

In 2003, an ACOG Task Force issued a new document entitled "Neonatal Encephalopathy and Cerebral Palsy" (referred to as NECP (2003)). That new document included a similar criteria list, some of which were "essential" and therefore mandatory before "an acute intrapartum event" could be sufficient to cause CP.¹² This list of allegedly "essential" mandatory criteria has also been used to discourage the pursuit of perinatal brain injury cases and to defend against such cases that have been pursued.

A second Task Force convened by ACOG published in 2014 a new document entitled "Neonatal Encephalopathy and Neurologic Outcome, Second Edition," (referred to as NENO (2014). NENO abandons the use of any "all" and "must" and "essential" causation criteria list. The newest document states that it is now known that there are multiple potential causal pathways that lead to cerebral palsy in term infants and that knowledge gaps still preclude a definitive test or set of markers that accurately identifies an infant in whom neonatal encephalopathy is attributable to an acute intrapartum or peripartum event. The new document now favors a "broader perspective" that would assess "likelihood" from a "comprehensive evaluation of all potential contributing factors." 13

The NENO (2014) document notes that the healthy term fetus is able to mount a series of compensatory mechanisms that protect the brain from hypoxia-related damage. The compensatory responses include increased cerebral blood flow. However, hypoxia of sufficient length or severity will overwhelm compensatory mechanisms leading to the crossing of a critical threshold producing irreversible disabling damage.¹⁴

The knowledge gaps referred to in the 2014 document existed prior to 1992. There has never been a definitive test or a definitive set of markers that can define when a threshold for brain injury was passed. Yet, with ACOG's full support, mandatory rigid criteria lists were created and used in the medical-legal arena representing the pseudo-science referred to. The ironic twist is that such has been at odds with the physician's ethical mission and has been working against safer care which can reduce the incidence of perinatal brain injuries.

How to Understand and Use These Medical Facts

Neonatal encephalopathy (NE) describes neurologic dysfunction in the early days of life.

If a full term, or preterm newborn following birth, does exhibit signs of encephalopathy, it is and has been

known – with no gaps in knowledge – that hypoxic, infectious, traumatic and cardiovascular stresses, experienced by the unborn child, which stresses occurring in isolation or occurring in combination can overwhelm intrinsic compensatory mechanisms and can cross a threshold producing disabling brain injury.

It is these intrinsic fetal compensatory capabilities that create the time and the opportunity to identify the stress or combination of stresses that potentially can produce the brain injury. The NENO (2014) document notes that "it is important to identify the earliest instigating factors in neonatal encephalopathy because for primary preventive strategies to be successful, intervention must occur as early as possible in the causal pathway before any pathologic damage takes place." It has always been, not just important, but crucially mandatory to "identify" a potential problem as early as possible because it is and has been mandatory to act before disabling brain injury occurs.

Liability for physical harm (e.g. brain injury) exists if unreasonable care "increases the risk of ... harm." 16

Thus liability would exist if the medical facts reveal a failure to identify an early "instigating" factor (or factors) and a failure to intervene if such failure to act was unreasonable and did in fact increase the risk of harm (i.e. a perinatal brain injury that actually did occur).

THE EFM

A collaboration of ACOG, District II, New York State Department of Health and the Health Education and Research Fund, Inc. initiated in New York State a two-year quality improvement program with the goal of improving fetal outcomes and reducing liability exposure. The goal of providing excellence in electronic fetal monitor (EFM) ".... is of critical importance because EFM can warn the obstetric team of potential fetal complications, enabling clinicians to take action to avert or mitigate adverse outcomes." ¹⁷

The project concluded: "appropriate utilization and a standardized approach to interpretation of EFM can warn the obstetric team of potential fetal complications that may lead to injury, including brain injury or death." Thus the goal of the project was to improve fetal outcomes and reduce liability exposure.¹⁸

NENO (2014) states that "the interplay of antenatal complications, inadequate placental perfusion, and intrapartum events can lead to adverse outcomes." Therefore, the EFM monitoring is to assess "fetal well-being." According to NENO (2014), although labor and delivery most often proceeds uneventfully, at any moment the labor process can produce events and conditions that can lead to potential fetal insult or injury. Yet according to NENO (2014), there is no ability to predict neonatal neurologic injury, cerebral palsy, or stillbirth using EFM.¹⁹

What is it that ACOG physicians wish to communicate with regard to alleged lack of predictability? When hypoxic and other stresses become excessive and are allowed to cross a threshold of irreversibility, one can then predict with 100% certainty that the child will be disabled. Thus, the way to reduced liability exposure is to improve outcomes.

The Hospital Corporation of America (HCA) and others have published safety initiatives for perinatal care. ²⁰ They cite how they included mandatory EFM courses so that providers could and would use the EFM data to take action to avert or mitigate adverse outcomes such as perinatal brain injury. The HCA study complains that "...there currently exists no organization exerting an effective national leadership role in these areas" though their safety approaches have produced a precipitous decline in adverse perinatal outcomes. ²¹ The HCA and other institutions have used adverse outcomes learned from closed cases to make their care safer.

The HCA study noted that most money paid in conjunction with obstetric malpractice cases is a result of actual substandard care resulting in preventable injury.²² As plaintiff's attorneys who have pursued perinatal brain injury cases, we have known for many years that substandard care has resulted in preventable injury. Other than carefully screening our cases and other than diligently pursuing meritorious cases we have had no ability to enact safety practices that can prevent that which is preventable. It is gratifying to see that despite delays for so many years, the relatively recent use of closed liability cases has resulted in fewer children being injured.

PATIENT SAFETY

NENO (2014) calls for a "no blame" safety culture. NENO emphasizes accountability while allowing reporting safe from blame, humiliation and retaliation. It notes a concern that error disclosure will lead to disciplinary action and lawsuits but do concede an ethical obligation to be honest with the patient.²³

Pursuit of the meritorious case is not intended to generate humiliation or retaliation. Fairly and fully compensating the child and creating the kind of accountability that can, and has, reduced the incidence of these tragic cases is how our civil justice system can and should work. Pursuit of a lawsuit is not an "evil." It is a vehicle for justice and accountability.

CONCLUSION

Plaintiff's attorneys now have fewer perinatal brain injury cases because safety initiatives, using EFM and other data linked to strategies learned from studying past meritorious closed cases, has reduced the incidence of adverse outcomes. The motivations linked to

legal accountability along with intrinsic professionalism can, and has, worked together to produce safer care as measured by fewer legal claims and therefore less legal expense. Thus, motivations to be safer through accountability, rather than eliminating these motivators through tort reform immunity has been effective.

Will ACOG physicians and others abandon a hostility toward the legal advocates who represent their patients? There must be a reason why EFM data has been part of the safety projects. There must be a connection between safety initiatives cited herein and fewer adverse outcomes such as perinatal brain injuries.

In a paper published in the New England Journal of Medicine, the author called for a judicial recognition of an explicit "right to safety" for hospital patients with a correlative duty of hospitals to implement patient safety measures as a motivation for the development of systems to improve patient safety. Why? Because increased liability risk is what hospitals respond to.²⁴ The task force that created NENO (2014) had no representation by any advocate for the legal rights of brain injured children. If ACOG convenes another task force in the future, perhaps it will include advocates for safety motivated by the legal accountability that directly corresponds to a proven capability that has reduced the incidence of perinatal brain injury.

BIOGRAPHY

Steven Pegalis is founding member of Pegalis & Erickson, LLC representing plaintiffs in catastrophic medical malpractice actions with special concentration in perinatal brain injury cases. He is a member of the Board of Trustees and is an Adjunct Professor teaching Medical Malpractice at New York Law School. He is the author of the three volume text: The American Law of Medical Malpractice (now in its 3rd Edition). He has written and lectured on the subject of trail advocacy, technique and patient safety. He moderates the Annual Pegalis and Erickson Lectureship on the Intersection of Law and Medicine to Promote Patient Safety at New York Law School and co-directs the NYLS Health Law and Patient Safety Project.

ENDNOTES

- 1 See e.g. Ethical Rules #1200.23 [Rule 3.1] Non-meritorious Claims and Contentions. Prohibiting the knowing advancement of a claim or defense that is unwarranted.
- 2 Perkins, R.P. Perspectives on Perinatal Brain Damage Obstet. Gynecol 69:807, 1987.
- 3 Supra 2, at p. 815.
- 4 Supra 2, p. 815.

- 5 Supra 2, p. 807.
- 6 R. Berkowitz et al., A Proposed Model for Managing Cases of Neurologically Impaired Infants, 113 OB & GYN 683 (2009).
- 7 A. McClennon et al., Who will deliver our grandchildren? Implications of Cerebral Palsy Litigation, 294 JAMA 1689 (2005).
- 8 S.R. Scott, Expert Witness: Perpetuating a Flawed System, 106 OB-GYN 902 (2005).
- 9 See R. Berkowitz, Footnote #6.
- 10 ACOG Technical Bulletin No. 163: Fetal and Neonatal Neurologic Injury (1992).
- 11 Goodlin, R.C., Do Concepts of Causes and Prevention of Cerebral Palsy Require Revision? Am.J. OB/GYN, 1995; 172:1830-6.
- 12 NECP (2003).
- 13 NENO pp. xxi and xxii.
- 14 NENO, pp. 21, 24.
- 15 NENO, p. 6.
- 16 Restatement (Second) of Torts #323.
- 17 See, Best Practices in EFM Definition, Interpretation and Management, Final Report May 2011, Collaboration of HANYS, ACOG and NYS Disab.
- 18 *Id*.
- 19 NENO (2014), pp. 87-91.
- 20 Clark, S.L. et al, Patient Safety in Obstetrics The Hospital Corporation of America Experience. 2011 Am.J. Obstetrics & GYN 204(4): 283-287.
- 21 See Footnote 20 at p. 285.
- 22 Clark, S.L., et al. Reducing Obstetric Litigation Through Alterations in Practice Patterns. OB-GYN 2008; 112:1279-83.
- 23 NENO, pp. 197-199.
- 24Annas, G.J. The Patient's Right to Safety Improving Quality Care Through Litigation Against Hospitals, 2006 N.Eng.J.Med. 354:19.