

Electronic Fetal Monitoring

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“Electronic Fetal Monitoring [EFM], or cardiography [CTG], has been used worldwide for over half a century, making it the most common obstetric procedure. While financial investment in technology is considerable, there are repeated questions of whether the money is well spent and whether the technology is more harmful than beneficial. (1-3, 4-6)”

Malcolm Gladwell has said: The key to good decision-making is not knowledge. It is understanding. We are swimming in the former. We are desperately lacking in the latter. _ Malcolm Gladwell (2008). “Outliers: The Story of Success”, p.31, Hachette UK

Electronic Fetal Monitoring [EFM], or cardiography [CTG], has been used worldwide for over half a century, making it the most common obstetric procedure. While financial investment in technology is considerable, there are repeated questions of whether the money is well spent and whether the technology is more harmful than beneficial. (1-3, 4-6)

In these articles by Sartwelle, a malpractice lawyer, and others, including respected medical authors, they allege that research to date has shown that EFM has neither prevented adverse short or long-term outcomes nor has it ameliorated any measure of fetal adversity, including C.P. Further, they allege, that EFM has almost no scientific foundation and was untested by clinical trials. It comes “without an instruction manual, without premarket testing to support the expectations of efficacy, without clearly defined parameters for use, and proper informed consent from the patient.” (7) In the face of such failures, the technology, by itself, has increased the C-section rate with its attendant risks and morbidity not only in the present pregnancy but for future pregnancies as well. (8) These authors question why EFM became a standard of care and why it is allowed to continue. Whether the authors are lawyers or physicians, the ratiocinations about the limitations of EFM inexorably lead to allegations of the predatory comportment of plaintiff attorneys and their experts in pursuing “brain-damaged baby” lawsuits alleging obstetrical negligence based on EFM.

They argue that the problem lies with the trial lawyers and their “experts” who use EFM-CP junk science to blame caregivers for causing C.P. In this scenario, ubiquitous experts abetted by unprincipled lawyers have helped create a worldwide litigation crisis threatening bankrupt healthcare systems. (9, 10, 11) Indeed, these allegations of obstetrical negligence have, in turn, created

an industry of defensive medicine that has diverted time, attention, and considerable expense to counter the allegations. This issue is highlighted by the recent disclosure from the United Kingdom of the extraordinary expenses related to payouts for alleged obstetrical negligence. National The situation has been called a lottery, a cash cow for lawyers and their experts.” Sartwelle (3, 12, 13) We can agree, however, not that the awards are necessarily excessive or unjust, but that adverse outcomes need to be curtailed.

Mr. Sartwelle, a defense attorney, is one of the best-known assailants of EFM. He enumerates the scientific, clinical, ethical and judicial failures of EFM in various articles and discusses various solutions. - not so much to improve perinatal outcomes, but rather to protect the physician from allegations of negligence and the predations of lawyers and their experts. (12, 14-18) He questions why this litigation picture continues in the face of a technique (EFM) that he and others believe is based on junk science.

Where does the blame lie for this unhealthy, counterproductive situation? As these authors claim, does it lie with the purveyors of the technology or the medical societies? Or does it lie with the failure of the judicial system that continues to accept testimony about interpreting FHR patterns? Is it the fault of the ethical community or plaintiff experts in EFM who say that it must be someone's fault since there is a bad outcome? It is alleged that experts for the plaintiff become experts “after the fact when the outcome is known. (10-12, 17, 19) Is it the fault of defense experts who find exculpation for harm with the argument that whatever the doctor did was right because they would not have done it if it were not? Whatever happened to equipoise? Irrespective, there is little evidence that the problems of EFM and their potential for harm are being ignored or suppressed. (5, 9, 20, 21)

“From the medical standpoint, proposed solutions involve changing the classification of fetal heart rate patterns, modifying the scheme of management, abandoning the technique, or, perhaps more appealing, reengineering the interpretation of patterns such that the original, well-intentioned myths adopted prematurely by health care providers, litigators, and patients could be put into context. (22-27)”

There is no limit to the number and breadth of the proposed solutions. From the medical standpoint, proposed solutions involve changing the classification of fetal heart rate patterns, modifying the scheme of management, abandoning the technique, or, per-

haps more appealing, reengineering the interpretation of patterns such that the original, well-intentioned myths adopted prematurely by health care providers, litigators, and patients could be put into context. (22-27)

Legal solutions that have been put forth include no-fault, requiring patients to sign binding arbitration agreements, and giving up the right to sue for medical malpractice as a condition of care. (28) Sartwelle et al. claim that professional medical societies, such as the ACOG, might summarily curtail the use of EFM by declaring it as some unproven technique not yet justified in routine clinical practice. A partial concession has come with recommendations that in the “low-risk pregnancy,” auscultation (presumably with EFM backup) is the desired form of fetal surveillance. There is no evidence that this approach is better overall, but at least the cesarean section rate seems lower. (29) Endorsing IA and removing EFM as the standard of care, presumably for any and all indications, need not forbid the use of EFM, but such a designation will allow the practitioner to use the technique. It helps litigation defense by removing the onus of not using the device.

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There are also recommendations that the testimony of plaintiffs’ experts be challenged legally with Daubert or Frye constructs. The purpose of a Daubert challenge is to expose bias and self-interest concerning the reliability and admissibility of expert opinions. A successful Daubert or Frye challenge seemingly permits the notion that, legally, EFM is “junk science.” (8, 30, 31) Evaluating the challenge calls for trial judges to consider (1) whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, (2) whether their opinions were developed expressly to testify, and (3) if the testimony is not based on independent research, there is proof that the proffered conclusions have been subjected to scientific scrutiny through peer review and publication. Further, it emphasized that “differential diagnosis is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated.” (30) The methodology for establishing a differential diagnosis was summarized as follows: 1) The expert needs to compile a list of competing causes that are generally capable of causing the patient’s adverse outcome. 2) After ruling in all potential causes that are generally capable of causing the outcome, the expert must eliminate potential causes based on a continuing examination of the evidence until the most likely cause is found. 3) The expert must provide reasons for rejecting alternative causes using scientific methods and procedures, and their elimination must be based on more than subjective beliefs or unsupported speculation.

This *seemingly* logical remedy partly fails because there is too much accepted science behind FHR patterns and too few alternatives. EFM has become the de facto, accepted standard of care required by most hospitals/institutions. Given their frequency of use and the attention and scientific underpinnings given to FHR patterns (as opposed to the management of these patterns), it seems complicated to reverse the position for litigation by attacking EFM as junk science. As a practical matter, there would seem to be no option for a Daubert challenge when a practitioner, with

proper informed consent from the mother (risks, benefits, alternatives), decides not to use EFM and writes a note stating that he/she understands that the standard of care prescribes the EFM, but with proper informed consent he is desisting. Nothing is limiting this option today – without a Daubert challenge.

Those who would curtail EFM in judicial litigation assume that intermittent auscultation (I.A.) is a scientifically proven alternative. Unfortunately, there is no evidence that auscultation is reliable, gives meaningful interpretations, or can be used as a reliable basis for intervention or review. A study of auscultation versus no surveillance found no difference in outcome. (32) Thus, carried to extremes, the lowest cesarean section rate would come from no monitoring. I.A. leaves no reliable record (a tracing) whose interpretation can be challenged. However, since there is no evidence that EFM will fail to detect hypoxia, it may be argued that I.A. failed to detect what would have been evident on EFM.

“Succinctly put, the classification of FHR patterns and the management scheme based on those patterns are attempting to protect the fetus from the problems of labor (excessive uterine activity, prolonged labor, malposition, etc.) while simultaneously using the same approach to protect the health care providers from allegations of negligence. Thus, the classification of FHR patterns (Categories I-III) is unworkable and widely disparaged. Management guidelines based on that classification prove vague, poorly reproducible, and of limited benefit. (7)”

There is an issue not articulated by any of the parties that seems fundamental to our present circumstances. Succinctly put, the classification of FHR patterns and the management scheme based on those patterns are attempting to protect the fetus from the problems of labor (excessive uterine activity, prolonged labor, malposition, etc.) while simultaneously using the same approach to protect the health care providers from allegations of negligence. Thus, the classification of FHR patterns (Categories I-III) is unworkable and widely disparaged. Management guidelines based on that classification prove vague, poorly reproducible, and of limited benefit. (7) To defend against allegations of negligence, the organization promulgated, in a widely disseminated monograph, (33) unrealistic and indefensible “essential criteria” for the relationship of intrapartum events and subsequent C.P. that would not (and did not) withstand a Daubert challenge. (33) Nevertheless, Sartwelle and others remain anchored to earlier notions of the mechanism(s) of injury when EFM was first promulgated, predicated on using FHR patterns to predict the severity of fetal acidosis. This mechanism did not apply to many, if not most, of those children injured during labor and delivery. (34) They use these issues of the classification and response to EFM patterns to camouflage their primary notion that C.P. and related handicaps are not

preventable by the actions of the obstetrical care provider. (2, 12)

Do fetuses suffer preventable neurological consequences from the events of labor and delivery? The evidence seems inescapable that they do, and manifold evaluations from many countries involving experimental and human experience, even data from malpractice cases, affirm the compelling relationship of intrapartum events to subsequent, often devastating ones. These contributions also reveal the preventability of both fetal and maternal injury. Despite the limitations of implementation, these countervailing data gave practitioners backing for the continued use of EFM in the belief that it was helpful, if not perfect. The allegation that the practitioner continued using EFM “in the grossly mistaken and naive belief that EFM...was a defense to the rising tide of C.P. lawsuits. (10, 11, 17, 19) - a technology that caused more harm than good.

Paying attention to their allegations should have made Sartwelle and others realize that they and the ACOG were (“unintentional”) co-conspirators. Both camps want to eliminate malpractice suits passionately. Given the role of EFM in such litigation, the question is not their shared objectives; they have different paths to the objective with very different constraints. Sartwelle does it by edict - legal, medical, or ethical. ACOG does it by vagueness or distractions - creating classifications of FHR patterns and management protocols that are so vague that they, in their perspective, offer the best opportunity to counter an allegation of negligence. (12, 14, 35-37)

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There can be no failure to recognize that the specialty, if not its society, began to publicly acknowledge EFM's flaws and limited benefits while still condoning its widespread use. In 2003, for example, Clark et al. (6) warned of the lack of benefit of EFM with “overwhelming evidence of EFM harm.” His four remedies included a) publication of the lack of benefits; b) revision of EFM category II designation; c) official publication that C.P. litigation is

based on junk science; and 4) obstetricians need to realize EFM is based on myth, not reality. The demand for immunity is apparent. What is also clear is that his debatable criticisms and recommendations DO NOT call for the abandonment of the technique, to do more research, or to provide better training, and there was no call to revisit the original precepts for EFM. Indeed, Clark et al. later offered a reclassification of the scheme of managing Category II FHR patterns that was ultimately deemed unhelpful. (7, 38) They also found that since FHR patterns did not correlate well with fetal acidosis, the use of EFM was at fault, not the use of pH (see below). (39)

Unfortunately, EFM cannot be dismissed as “junk science.” There is too much science behind the patterns; however, the management schemes are flawed. (40, 41) However, given the long-standing perspective on what it was expected to accomplish, there is not enough science behind its implementation (not the patterns) to simultaneously improve patient outcomes and reduce allegations of negligence.

There is a need to understand that EFM tells you about fetal behavior, including neurological responsiveness. It will not fail to tell you about hypoxia-ischemia, including stroke, infection, hemorrhage, and trauma. It cannot be used, however, without understanding the maternal condition and the feasibility of safe vaginal delivery - irrespective of FHR pattern. A normal pattern does not permit you to maintain labor when vaginal delivery is futile. Finally, EFM is an instrument of preventive care, not rescue.

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In these deliberations, several issues reflect mistaken notions. One such notion states that the expert sets the standard of care. Not quite; experts are only supposed to put forth opinions about the reasonable precepts of care as outlined in published guidelines of professional societies abetted by the enlightened interpretation of the literature in the context of the individual patient circumstances. They may not testify about their own standard of care or information they only know. They are there to opine on the propriety and reasonableness of the care in the light of the extant standards. It is inappropriate to believe that there is a single definable standard of care clinically and in courtrooms. Indeed, mutually exclusive options for care may each fall within a reasonable standard of care (elective cesarean section or attempted vaginal delivery) may each fall within an acceptable standard of care for

the fetus in breech presentation.

Another example of the problem of correlation is the notion that serious injury during labor will be manifested during the immediate neonatal period. From the time of Freud, but more obviously in recent times, it has been recognized that isolated cognitive defects can be related to adverse intrauterine environments during labor and delivery. Indeed, it is widely understood that *“the outcome of neonatal encephalopathy includes cognitive deficits as a prominent feature, even in the absence of cerebral palsy, and that this is associated with the watershed pattern of injury and white-matter damage.”* (42)

Removing EFM as the standard of care, however, does not countermand its use. Given the inability to use A.I. as frequently as required, it might still be useful as a labor-saving monitoring device. Physicians could still make labor decisions based on EFM output. It simply requires a reversal of informed consent; now, informed consent must be obtained (not given) when using EFM since it is not the standard of care. If physicians explain how EFM might assist their decision-making, even if EFM is not the standard of care, many women, given a choice, will follow their doctor's advice. Will certification in FHR pattern interpretation still be required?

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The criticisms of plaintiffs' lawyers and their experts, the professional associations, the purveyors of equipment, the literature, etc, notwithstanding Sartwelle's efforts, go far beyond removing EFM from the clinical armamentarium. The fundamental reason behind these distractions about EFM's failures and limitations is that “we cannot prevent C.P.” (43) He fails to give the profession credit for recognizing many potential causes of C.P. - including infection, trauma, coagulation disorders, malformations, and genetic disorders. Irrespective, asphyxia and hypoxic/ischemic injury are among the most common and potentially preventable causes. (44-46) Further, the newest version of the ACOG/AAP monograph (47) (2014) accepts the notion that injury can be attributed to labor events if there is an evolution in the EFM of a Category I pattern to a Category III pattern. Using similar logic that insists on a normal tracing at the outset of labor to establish previous normalcy (an uncommon prerequisite in most studies of EFM), various studies underscore not only the intrapartum timing of injury, but the duration of abnormality preceding harm and the likelihood of finding a low pH at the time of delivery. (25, 27, 48-51)

Ultimately, various authors have found that elective cesarean section has a beneficial effect on neonatal outcomes. (51-53) By eliminating labor, elective cesarean section eliminates many of

the risk factors for neonatal encephalopathy encountered during labor, including maternal fever, fetal malposition, and prolonged labor, along with other catastrophic events in labor. Ideally, EFM attempts to eliminate those differences by enhancing the safety of pursuing vaginal delivery. It seems perverse, therefore, to administer magnesium sulfate during labor to prevent neurological injury during labor and then argue that labor does not contribute to injury or that it is unpreventable. (54-56) The use of unvarnished, published “criteria” or data cobbled together by selective use of the literature by the experts of either side, clinically or in a courtroom, is not a substitute for an evidence-based, reliable weighting of the evidence. While careful reading of the literature easily refutes arguments to ban the monitor, it uncovers problems related to its implementation.

Thus, the proper interpretation of FHR patterns can provide the clinician with an opportunity to assess the potential for injury, but that assessment must rest with the establishment of certain prerequisites. The most obvious is that the baby is demonstrably normal on admission. As detailed above and elsewhere, (57) some babies are already injured on admission with no expectation that the conduct of delivery will prevent subsequent harm. Under circumstances where the initial tracing is demonstrably normal, EFM patterns almost invariably provide the window of opportunity for the obstetrician to understand the evolution to a threatened fetal environment irrespective of any confirmatory metabolic acidosis and the opportunity to moderate by conservative measures (if possible) the abnormal FHR patterns. If this fails to occur, tracings provide an understanding of the urgency of intervention if fetal decompensation and compromise are to be prevented. In published studies, this window ranges from minutes (occasionally) to hours (far more commonly), subject to the severity and nature of the compromise. In most cases, the window of opportunity to predict and confirm the asphyxial exposure tends to be longer rather than shorter. (24, 25, 58)

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There is persuasive evidence that obstetrical negligence during labor causes adverse outcomes, including C.P. It is not something to be proud of, but it is something to learn from, using the knowledge gained to improve care in the future. In a study of alleged malpractice during labor resulting in harm in Sweden between 1990 and 2005, Berglund reported 177 infants who suffered from severe asphyxia due to malpractice around labor, concluding that the most common causes of such obstetrical errors were failing to perform a timely delivery, increasing Pitocin in the presence of pathological FHR patterns, failing to supervise fetal well-being, overlooking signs of fetal asphyxia, and selection of a non-optimal choice of mode of delivery. ^{59,60} Our personal experience suggests that these circumstances still prevail a quarter-century later.

Despite the longevity of EFM, it is still recognized that outcomes will benefit from better training and education of clinicians in its use abetted by the implementation of unambiguous guidelines for the management of abnormal patterns, improved communication and collaboration between physicians and nurses, and implementation of special drills and training to teach personnel how to respond to emergencies. (61) EFM will come closer to achieving its

maximum potential when adequate training in relevant, uniform terminology and more rigorous standards are designed only to improve outcomes.

Hypoxic-ischemic brain damage comes in different forms, ranging from mild to severe, and varying combinations of hypoxia and ischemia. While the final outcome depends on the duration, the severity of the exposure, and the fetus' resources, the impact of such factors as the strength and frequency of uterine contractions and maternal pushing, the position and attitude of the fetal head during labor among other factors that likely influence fetal tolerance to the hypoxic and ischemic stresses encountered during labor and delivery. (62) It is also necessary to remember that the diagnosis of neurological injury acquired around the time of birth (and irrespective of the pH of the umbilical artery) has ramifications beyond medico-legal considerations. Neuroprotective therapies are capable of reducing the adverse effects of hypoxic-ischemic intrapartum injury. (63, 64) Ultimately, while similar degrees of insult may, in fact, not be similar at all – it will be up to the fetus, perhaps, to tell us what is and is not tolerable. (65, 66)

“Ultimately, it would seem that the interpretation of reliable, physiological information directly from the fetus must play a role in determining the urgency of intervention and the timing, mechanism, and preventability of intrapartum injury. Someone who understands its voice has to speak for the fetus.”

Properly interpreted and with timely (preventive, early, not necessarily operative) intervention acted upon, the tracing benefits the current situation by improving the outcome and the defensibility of actions by diminishing the risk of adverse outcomes, the need for emergency delivery, and allegations of negligent care. Its deficiencies notwithstanding, it seems irresponsible to refer to EFM as “chicanery worthy of a snake oil salesman” and to encourage professional societies to call for its abandonment of EFM since doing so will make it easier to defend lawsuits. (43) Ultimately, it would seem that the interpretation of reliable, physiological information directly from the fetus must play a role in determining the urgency of intervention and the timing, mechanism, and preventability of intrapartum injury. Someone who understands its voice has to speak for the fetus.

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