iMedPub Journals http://www.imedpub.com

DOI:10.4172/2472-1786.100021

Abstract

Journal of Childhood & Developmental Disorders ISSN 2472-1786 2016

Vol. 2 No. 2: 13

# Cerebral Palsy and Electronic Fetal Monitoring: Rearranging The Titanic's Deck Chairs

# Thomas P Sartwelle<sup>1</sup> and James C Johnston<sup>2</sup>

- 1 Beirne, Maynard & Parsons, LLP, Houston, TX, USA
- 2 San Antonio, TX, USA

#### Corresponding author: James C Johnston

johnston@GlobalNeurology.com

1150 N Loop 1604, San Antonio, TX, USA 78248.

Tel: 2062013618

**Citation:** Sartwelle TP, Johnston JC. Cerebral Palsy and Electronic Fetal Monitoring: Rearranging The Titanic's Deck Chairs J Child Dev Disord. 2016, 2:1.

**Keywords:** Cerebral palsy; Electronic fetal monitoring; Medical ethics; Medical malpractice; Standard of care

Electronic fetal monitoring (EFM) has repeatedly proven clinically ineffectual, caused more harm than good to mothers and babies alike, and trapped obstetricians

into daily violations of fundamental medical ethics. EFM is also the foundation for the continuing worldwide cerebral palsy (CP) birth injury litigation crisis which

routinely results in lottery-like verdicts and settlements which only benefit trial

lawyers. Birth-related professional organizations (BRPOs) have had the power to stop EFM's clinical proliferation, deal with the ethical violations, and put an end

to the undeserved verdicts and settlements against physicians unjustly blamed for causing CP. These organizations have done nothing. This article reviews the myths behind EFM, explains why CP-EFM litigation is so successful, outlines the ethical dichotomy created by this scientifically flawed procedure, and proposes a solution

to change the clinical standard of care, linking EFM to the Daubert exclusionary

evidence doctrine recognized throughout the world's courts, thereby ending CP-

Received: February 25, 2016; Accepted: March 28, 2016; Published: April 04, 2016

## Introduction

EFM litigation.

Electronic fetal monitoring (EFM) has been a birth myth for fifty years. Yet, EFM is the standard of care in the world's industrialized nations despite overwhelming evidence that it is ineffectual [1-11] rife with interpretive errors [11-18] and has a 99% false positive prediction of fetal distress [1-3, 10, 19-21] and has markedly increased the C-Section rates with resultant harm to women and newborns alike [1, 3, 4, 9, 10, 22, 23]. EFM is a waste of time for uncomplicated labors [1, 4, 8, 23]. It is no better than a coin toss as a test for absence of injury [3]. But EFM today remains the most common obstetrical procedure [4, 21, 24, 25], even as evidence against its efficacy continues to mount [2, 4, 10, 21, 26-28].

A lesser but significant harm propagated by the EFM birth myth has been the worldwide obstetrical malpractice litigation crisis centered around cerebral palsy (CP) and neurologic birth injuries allegedly preventable by EFM use [2, 4, 9-11]. This crisis was spawned primarily by EFM "courtroom experts" specializing in courtroom deliveries of neurologically perfect neonates [4, 9, 10, 21]. According to the myths spun by these experts, thousands of children could have been delivered free of neurological deficits by thousands of defendant physicians and nurses if only these providers had been more attentive to or better educated in proper EFM use. EFM propelled CP and neurological birth injury litigation to lottery-like payouts where single-plaintiff jury verdicts exceed \$100 million [4, 21, 29], verdicts on a par with business litigation cases [4, 21, 30]. The litigation lottery elevated failure to diagnose and treat fetal asphyxia into the most common claim in obstetrical malpractice litigation [5, 21, 31, 32].

CP-EFM litigation continues unabated today [2, 4, 9, 10], essentially turning physicians into a de facto social welfare insurance scheme and slowly driving caretakers away from obstetrics [4, 9, 10]. CP children and their families have nowhere to turn other than to the inefficient and costly cerebral palsy litigation industry created and nurtured by trial lawyers and their courtroom EFM experts [4, 9, 10, 21, 33].

More important than a continuing obstetrical malpractice crisis is the ethical quagmire created by daily EFM use [34]. The fact that EFM is scientifically bankrupt and harmful has been ubiquitous knowledge within the medical community for more than four decades [1, 4, 21, 22, 34], yet this vital information has never been routinely communicated to expectant mothers. Women in labor are given no choice regarding EFM use. Physicians merely perpetrate the myth that EFM is necessary for a safe delivery, and today EFM is used in 85% of 4,000,000 annual births in the United States alone [4, 21]. Why? Because physicians perceive EFM is protection from lawsuits, another misguided almost fifty year old birth myth [4, 21, 34]. Thus for EFM's entire life physicians have simply ignored bedrock ethics principles—autonomy, beneficence, and non-maleficence—while making irrational decisions based solely on fears of being sued [3, 4, 9, 10, 21, 34]. This open and obvious ethical malfeasance remains unaddressed by medical ethicists as well as the world's birth-related professional organizations (BRPOs) [34, 35].

Could BRPOs have stopped EFM's clinical proliferation, erosion of professional ethics, and courtroom theatrics? Yes. But they never tried [34, 35]. If BRPOs became EFM thought leaders today, could they change the EFM clinical, ethical, and litigation landscape? Yes. But it will take time and effort. Not because the solutions to these myths are complicated, but rather because the belief in myth is so strong among lay people and physicians alike [2, 4, 10, 21, 36, 37].

The solution? BRPOs worldwide must declare EFM unreliable and that its use is not the standard of care in labor rooms or courtrooms. This declaration would place EFM interpretation into the non-empirical category thereby requiring mothers to be given the autonomy they deserve through an informed consent for EFM use. With informed consent physicians could continue using EFM as a labor saving device rather than using intermittent auscultation, the only other method of fetal surveillance. Additionally, such a declaration would link EFM to the universally applied Daubert doctrine excluding junk science like EFM from use as evidence in courtrooms the world over, thereby depriving EFM "courtroom experts" of the only device they claim caregivers can use to predict and prevent CP.

This declaration can be accomplished by an international task force of all industrialized countries publishing a consensus report in plain declarative language based on the uncontradicted evidence that EFM does not and never has predicted or prevented CP or any other birth related malady. A task force declaration would accomplish several desperately needed steps. First, it would end the medical paternalism that has forced EFM on mothers since its introduction into clinical medicine, and allow physicians and patients to finally engage in true informed consent which is the bedrock of bioethics, and allow obstetricians to reset their ethical compasses to true north. Second, it would be the beginning of the end of the CP cottage industry from which only trial lawyers profit, by providing courts with up-to-date evidence by which they could decide Daubert challenges to the EFM "evidence" that has been misused for so long against physicians and nurses accused of causing a child's CP.

### A short CP history: The myths begin

In 1893, Van Winkle published his fetal distress criteria. He set forth what were thought to be abnormal fetal heart rates reflecting fetal distress [38]. London orthopedic surgeon William John Little had studied fetal distress consequences half a century earlier, concluding that cerebral palsy and related neurologic

birth maladies were caused by oxygen deprivation during labor and delivery—asphyxia neonatorum [39]. Little's hypothesis, first published in 1843, coupled with Van Winkle's speculation, led to a theory that fetal heart changes represented fetal asphyxia [40-42]. If the infant developed CP, cognitive deficits, epilepsy, or any other deficits or impairment, then the cause was asphyxia. The cure was quick delivery. Thus, intermittent auscultation became the standard of care. And assisted deliveries became standard for any suspected fetal asphyxia [21, 38, 39].

Little's and Van Winkle's speculation was accepted uncritically by generations of physicians for more than a century. Speculation quickly morphed into medical dogma: asphyxia caused CP; early delivery in the face of detected asphyxia prevented CP. Obstetrical maneuvers and forceps were utilized until anesthesia and antibiotics made C-sections the intervention of choice [4, 21, 39].

Until the 1970s physicians thought of asphyxia as a benign means to explain to heartbroken parents the cause of their child's CP, mental retardation, or seizures [21, 39]. Until the first medical malpractice litigation-insurance availability crisis occurred in the mid-1970s, physicians had no idea that they would be blamed for causing or failing to detect birth asphyxia or both, and failing to intervene and rescue the fetus from permanent life-altering neurologic devastation [4, 21, 39]. Thus, as medical technology rapidly advanced in the first half of the twentieth century, physicians' attention was focused not on proving the foundational asphyxia causes CP dogma, but on devices to better hear fetal heart beats so interventions could occur more quickly. Unbeknownst to those physicians, birth-related medicine was on the verge of a perfect litigation storm that was about to give birth to defensive medicine-ethical relativism turning physician self-interest into virtue—and deliver to trial lawyers a machine as valuable as the world's supply of gold and silver-electronic fetal monitoring.

#### A short EFM history: The myths multiply

In the 1950s, questions arose regarding a human's ability to accurately count fetal heart beats, giving birth to the EFM concept [38]. Counting heart beats accurately was crucial to the fetal distress-asphyxia-rescue doctrine [38]. And as society became beguiled by computers, the space race, and other technological advances, medicine led the way with unimaginable technological innovations allowing heretofore unthought-of victories over myriad diseases. Labor and delivery also succumbed to technology's infallibility charms. Introduced into clinical practice without clinical trials in 1970, the electronic fetal monitor was nonetheless advertised by two EFM experts in a 1975 journal article to be the machine that would reduce by half intrapartum deaths, mental retardation, and CP [43].

These experts cited three "facts" justifying their optimism that EFM would be CP's nemesis. In retrospect, these "facts" are naive in the extreme. The "facts," however, reflected physicians' assurance that medicine's ability to intervene and alter unwanted birth outcomes had been consummated at last despite the fact that EFM was never subjected to clinical trials and the underlying theory that asphysia caused CP was utterly unproven nineteenth century speculation. The three basic facts these experts cited to support EFM use: labor stress could cause fetal death, and therefore, one could assume it also caused brain damage; half of institutionalized, severely retarded individuals had been shown to have experienced events attributable to delivery; and asphyxia induced in primates produced similar pathology to human CP [43].

More than anything else, this article illustrates how EFM advocates sidestepped the scientific method, branded their machine a success, and created one of the longest enduring medical myths. No doubt EFM was noble in purpose. But its introduction into clinical medicine based on little more than nineteenth century anecdotes and nonsense spawned an illegitimate worldwide litigation epidemic of blame harming mothers and babies, eroding medical ethics and providing trial lawyers with undeserved riches [1, 3, 4, 9, 10, 21, 39].

#### The perfect storm: CP-EFM litigation

As EFM was being introduced into clinical practice in 1970, a sociological phenomenon was also taking place—high stakes medical malpractice litigation. In the late 1960s, medical malpractice cases accelerated quickly, both in terms of frequency of claims per physician and claim severity, resulting in the first medical malpractice insurance crisis in the 1970s [21]. The causes of the crisis were many and varied and are still somewhat mysterious. What is not mysterious is the fact that birth injury litigation accelerated exponentially and continues today to represent an international malpractice epidemic despite overwhelming evidence it is ineffectual and despite so-called tort reform [4, 9, 10, 34, 44]. The question is why. Why does CP-EFM litigation remain so successful?

The answer is because EFM delivered to trial lawyers CP litigation's crown jewel—a permanent computer-like tracing that could be analyzed and reanalyzed by EFM courtroom "experts" in front of lay judges and juries. Birth injury lawyers were no longer dependent on an obstetrician's recollection that auscultation had revealed a normal heart rate pattern. With EFM, the courtroom "experts," years and sometimes a decade or more after birth, could pinpoint on the tracing the exact time the fetus allegedly suffered asphyxia. The courtroom expert quickly "delivered" a neurologically perfect child, as opposed to the actual child in the courtroom, strapped to a wheelchair, blind or deaf or both, mentally challenged, and being fed through a plastic syringe connected to a stomach tube. Is it any wonder CP-EFM birth-injury verdicts can exceed \$100 million?

The medical malpractice crisis also delivered a medical phenomenon previously unseen in medicine's history—defensive medicine—prophylactic medicine administered solely for physicians' and hospitals' protection from trial lawyers. EFM became and is today merely an unscientific legal prophylactic [1, 2, 4, 11, 21, 35, 39, 44, 45].

#### EFM: a waste of time? [8]

EFM use rose exponentially through the years: in 1980, it was used in 45% of all labors; in 1988, 62%; in 1992, 74%; in 2002, 85% [24]. But EFM was a classic oxymoron. As clinical use increased,

along with hospitals' financial investment in EFM monitoring equipment, so did the evidence proving that EFM's scientific underpinnings were based on "a catastrophic misunderstanding of fetal pathophysiology," [36] that outcomes were no better than auscultation [1, 3-5, 11, 21, 46] that EFM had a 99% false positive rate [19] and the rate of CP was the same despite the increasing rate of surgical delivery [20, 47-49]. Summarizing thirty years of EFM clinical use, MacDonald concluded: EFM "promised much, but has achieved little" [50].

Studies also revealed other EFM deficiencies. EFM is not a monitor; it merely records data and that data requires interpretation [4, 9, 10, 26-28, 51]. Interpretation is an art. Interpretation always leaves room for bias, especially-as with EFM-when there is little objective substantiating data supporting the interpretation [1-4, 9, 10, 21, 52, 53]. Studies of the EFM "experts" revealed their precise, dramatic courtroom interpretations did not exist. Experts frequently disagreed with each other and themselves. Inter-observer/intra-observer variability was the rule, not the exception-exactly the opposite of the experts' courtroom testimony. When tested, the experts identified harmless fetal rate changes as fetal distress and ominous tracings as reassuring [7-12, 14-18, 53]. Decisions regarding C-sections were no better. One day experts advised immediate C-section, but days later, based on the same data, they advised vaginal delivery [4, 20-22, 53].

The EFM courtroom "experts" were also subject to another bias hindsight. As had been demonstrated for years [53, 54] knowing that there is a poor patient outcome causes "experts" to be much more likely to criticize another obstetrician's management and find evidence of fetal asphyxia on heart rate tracings [53, 55].

These courtroom "experts" were and are charlatans [4, 21, 39].

#### **CP-EFM myths today: Idée fixe**

Despite the continually mounting uncontradicted evidence that trial lawyers and their EFM courtroom "experts" are engaged in a sham; despite a five-decade failed effort by BRPOs to make EFM relevant and clinically useful; despite the fact that all but trial lawyers and their courtroom "experts" concede that physicians rarely cause CP; that EFM does not predict CP or neurologic injury; that EFM has not reduced the incidence of CP or neonatal encephalopathy in term infants; that EFM is in large part responsible for the high C-section rate with the attendant morbidity and mortality of that major abdominal operation; and despite recognition that no intervention based on any single or combination of fetal heart rate patterns reduces the risk of CP in any population [4, 10, 11, 24, 56] and despite contemporary medical observers' recognition that EFM has caused more harm to mothers and babies than it has even helped [3, 23] judges and juries worldwide continue believing trial lawyers and their "experts" and awarding CP mega-verdicts, and physicians continue clinging to EFM use in virtually every labor and delivery, thereby daily violating medicine's basic ethics principles [4, 34, 35] Why? Why has one machine given birth to defensive medicine, daily ethics violations, and simultaneously created a worldwide CP litigation epidemic?

Those questions are a riddle wrapped in an enigma [57]. But

the answers are at least partially intertwined with the deeply rooted myths surrounding the causes of CP [35, 37] a widely held misunderstanding of fetal pathophysiology [36] physicians' persistent belief in the myth that EFM inoculates them from lawsuits [4, 21, 45, 58] and the common human need to blame someone or something for cerebral palsy [37, 49].

Little's hypothesis—asphyxia neonatorum—is that one every person on earth, including physicians, consciously or unconsciously, accepts as true-oxygen deprivation causes brain injury. It matters little that medicine today has almost no real knowledge concerning the length of time and degree of hypoxemia required to produce CP or any other neurologic injury in a previously healthy fetus [56, 59-61]. It does not matter either that fifty years of CP-EFM research has repeatedly proven asphyxia to be a cause of only a tiny fraction of CP cases, while the same research identified a multiplicity of antenatal-post-natal causative factors, a number of which are silent and impossible to recognize until years later [1-11, 21, 39, 56, 59-63] in addition to the most recent genetic studies revealing the large number of plausible mutations, de novo and inherited, contributing to cerebral palsy causation [10, 64, 65]. The public, trial lawyers, and a surprising number of physicians, including obstetricians, still believe the oxygen-deprivation-is-the-sole-cause-of-perinatalbrain-damage and CP myth [47-49, 66-71].

Equally surprising is physicians' tenacious EFM use for every pregnancy, a use they believe confers a magic protection from trial lawyers [4, 21, 39, 45]. The direct opposite is true, as has been pointed out for years in the legal and medical literature [4, 21, 35, 39, 45, 72, 73]. But these observations are unheeded by most obstetricians, who continue to believe EFM's "own ubiquity suggests that it is the exclusive standard of care" [45] and believe in its protective ability even though "EFM has historically been more of a tool for plaintiffs' lawyers than a safe harbor for the defense" [45].

#### An unexplored ethical minefield

In EFM's fifty years of clinical use, medical ethics were all but forgotten. As the uncontradicted evidence accumulated, demonstrating EFM's scientific foundation was nonexistent, its false positive rate exceeded 99%, EFM did not predict CP or reduce the CP rate, EFM increased the C-section rate, harmed women and children, wasted money and time, offered no lasting benefit to children, was subject to inter-intra observer interpretation variability, inconsistency, and bias, and whose interpretations had never been standardized and were poorly reproducible, and was, even as a screening test for the absence of injury, no better than tossing a coin, not one BRPO or medical ethicist suggested EFM should be abandoned because using a medical modality with no clear medical benefit that does harm to mothers and babies and whose use is actually for the purpose of protecting doctors from lawsuits, was unethical.

Why? The ethical principles that EFM use violates are plainly visible to anyone who cares to see them.

#### Willful blindness

Certain core principles known to all physicians form the basis

of today's medical ethics (bioethics) [74-76] three of which are violated daily with routine EFM use: autonomy, beneficence, and non-maleficence [74-76].

Autonomy—physicians sharing decision-making with patients—is the principle of informed consent [74-76] the essence of which is the physician providing information to the patient so that the patient, not physician, makes an informed decision about her medical treatment. And EFM is medical treatment. Life and death decisions are made based on EFM interpretation. In light of fifty years of accumulating evidence demonstrating EFM is no better than flipping a coin, no better than intermittent auscultation, pregnant women deserve an understanding of their choices. But BRPOs simply ignored providing choice. For almost half-a-century national and international meetings, conferences, and task forces assessed and re-assessed EFM. Virtually all concluded that there was no consensus on EFM common language, interpretation, or management, and each ended with the mantra, more research is needed, while conceding that there was no evidence to support interventions based on any single or combined EFM pattern that could prevent CP or any other neurologic injury [2, 3, 10, 11]. And the same was true of the 1999 International CP Consensus Statement and the 2003 ACOG-AAP Consensus CP Statement [4, 21]. Out of the hundreds of thousands of words BRPOs wrote about EFM, none addressed the autonomy issue. This silence continued even when a few tiny voices labeled EFM a classic autonomy issue begging to be addressed [77-79].

Not content to ignore just the insignificant voices, BRPOs also ignored a 1979 National Institute of Child Health and Human Development Task Force and a 1987 FIGO EFM Guideline both of which specifically recognizing EFM's inherent limitations and mandating that patients should be apprised of EFM's limitations before labor began and allowed to choose between EFM and intermittent auscultation [80, 81]. BRPOs are also ignoring the 2013 Cochrane Collaboration EFM Review, a contemporary EFM informed consent advocate [6].

BRPOs equally ignored EFM's destruction of the ethical principles of beneficence, acting in the patient's interest, and nonmaleficence, do no harm. These principles were expediently replaced with physicians' postmodern ethic of self-interest, what is now called defensive medicine, which is nothing more than a euphemistic phrase for protecting physicians and institutions from lawsuits. Through the decades of EFM use, there was an occasional honest reference to the principle driving EFM useprotecting doctors from lawsuits [80-83] but there was no protest from BRPOs, individual physicians, or, notably, ethicists, regarding the gross reversal of the fiduciary physician-patient relationship demanding that physicians act not in their interest, but in the patient's interest. Astoundingly, mothers and babies have knowingly been subjected to five decades of EFM inspired C-sections and the documented significant mortality-morbidity risks [1-4, 9-11, 19-23, 44, 84] from those unnecessary surgeries and, as recently discovered, subjecting children born from those operations to possible chronic immune diseases, asthma, diabetes, cancer, and neurodevelopmental maladies [85-88] primarily in the name of liability avoidance. So despite hundreds of books and journals devoted to medical ethics-bioethics,

publishing millions of eloquent words, despite thousands of conferences giving voice to patient autonomy and the death of medical paternalism, the medical establishment failed to live by its own principles. Rather than allow mothers to choose EFM after informed consent, physicians chose for them, not because EFM protected mothers and babies, but because it protected physicians and hospitals. Thus medicine's promise that a patient will have full ownership over her body and be able to make medical decisions after being fully informed by her physicians [74-76] is merely empty rhetoric. Benign paternalism may be dead [74-76] but physicians' self-protection despite the evidence of EFM's uselessness is alive and well.

#### EFM 2015: rearranging the titanic's deck chairs

For five decades medicine has attempted to make EFM heel to its demands that it predict cerebral palsy and finally live up to its creators' dreams [43]. All of these efforts have failed [2, 3, 10, 11, 23, 34, 44]. Every conference and every task force dedicated to CP-EFM concluded, after intense study, that another conference or workshop was needed before EFM unanimity could be reached. There was a consistent lack of agreement concerning definitions, nomenclature, pattern interpretation, and interventions that continues today [1-3, 10-11].

Recently FIGO published updated EFM Guidelines [89]. There is little difference between what is written in the new guidelines than what has been written after every other similar effort to make the EFM square peg fit the EFM is clinically useful very round hole. It simply does not fit. No matter how often or how extensively EFM pattern definitions and interpretations are massaged or nuanced or how much is written about the alleged failure of past RTCs to truly test EFM efficacy [89] that does not change the forty years of indisputable EFM research: EFM is a poor measure of past or present fetal brain function and damage [10]; trained physicians frequently disagree with each other's EFM interpretations and with their own interpretations [26-28, 53, 90, 91]; EFM has a 99.8% false positive rate despite fifty years of use [1-11]; EFM does not predict or prevent CP [1-11]; obstetrical societies of the USA, Canada, Australia, and New Zealand acknowledge that EFM provides no long term benefit for children [56]; and maternalfetal medicine scholars conceded that despite half a century of trying to make EFM viable, it is time to start over because EFM is contradictory, highly unreliable, difficult to teach, subjective, impossible to standardize, and poorly reproducible [11]. Importantly, contemporary efforts to supplement EFM to make it useful---fetal pulse oximetry [92], STAN [93], arterial cord blood pH and base excess measurements [94, 95], have failed to make EFM anything more than what is has always been junk science.

Despite this reality none of the CP-EFM workshops ever called for abandoning EFM or declaring it unreliable. Nor was there condemnation of EFM courtroom experts and their pseudoscientific testimony, despite the well published dramatic verdicts being handed down against doctors and nurses accused of misinterpreting the magic black box that the courtroom experts testified was able to predict the future. Most distressing of all, however, was the unanimous failure of any organization or physician to recognize the ethical quicksand of EFM use. Thus, in 2014, when a major international task force published a peer-reviewed, updated study on issues involving causes of CP, neonatal encephalopathy, and neurologic outcomes [56], one would have expected the task force to conclude that EFM was unreliable for labor rooms and courtrooms alike, and that EFM use so profoundly violated bedrock ethical principles that it must stop as soon as possible. But the task force said not a word to help their colleagues in the trial lawyers' crosshairs, nor did they focus on the inherent dangers of EFM-induced C-sections, nor expectant mothers' lack of informed consent when a scientifically bankrupt machine is used to monitor their labors, nor any other words dedicated to restoring the ethical principles which have guided medicine for so long. One must wonder why a task force of international experts would bypass all of these transparent issues merely to end up rearranging deck chairs on a sinking ship.

#### **Evading responsibility**

The ACOG / AAP Second Edition 2014 [56] was a revision of the 2003 Task Force report [59]. The 2014 version was initiated in 2010 with a simple charge: Update the 2003 report "to the current state of scientific and clinical knowledge relating to neonatal encephalopathy and neurological outcome [56]. The Second Edition acknowledged what most Ob / Gyn societies had been forced to recognize [11]: "There are no long-term benefits of EFM as currently used"; "no evidence exists demonstrating that electronic FHR monitoring reduces the rate of neonatal encephalopathy"; "there is no evidence in the current literature to support the ability of practitioners to predict neonatal neurologic injury, cerebral palsy, or stillbirth using EFM"; "there remain important improvements to be made in terms of system-wide use of technology (including education), as well as adoption of uniform nomenclature"; and "cesarean delivery as an obstetrical intervention to reduce neonatal encephalopathy and cerebral palsy has been considered unsuccessful" [56].

Incredibly, the Task Force, acknowledging EFM's total, complete impotency, also wrote the following: "All women in labor should be monitored in an attempt to prevent 'asphyxial' injury and intrapartum death" [56].

This is an alarming statement, and an absolutely bewildering position. While the statement does not say all women should be monitored by EFM, it is well known that most labors in the industrialized world and certainly in the USA are monitored by EFM not auscultation. Thus, this Task Force does not condemn EFM and in fact provides a backward endorsement to EFM while at the same time acknowledging EFM's unfitness, disability, frailty, and uselessness for the very purpose for which it was invented. This position should be exceedingly disconcerting to both the medical and lay communities. It completely ignores the ethical minefield of using a medical modality that has no clear medical benefit except for the self-interest of the physician using the machine. It disregards the fact that mothers are uninformed about the potential uselessness of the procedure and its potential for harm. And it completely ignores the elephant in the room---the innocent physicians and nurses unjustly blamed for causing CP in illegitimates lawsuit around the world. The Task Force chose to be blind to reality. Why?

Certaintly the Task Force knows the fear of all those involved in ministering to laboring mothers and their newborns every day: the fear that they will be the next target of a seemingly unending lawsuit, with multiple healthcare providers blaming each other, and culminating in a headline-making, career damaging CP megaverdict [2-4, 9, 10, 63]. This "blame game" atmosphere has permeated obstetrics and neonatology since the first CP-EFM verdict, exponentially increasing over the intervening years. One would believe that BRPOs would have addressed this blame-game issue, because it it is their members who were not only being sued, but are also doing the finger-pointing in the courtroom [4-6]. But BRPOs have not protected their members [63] or tried to stop the CP-EFM litigation cottage industry despite the now overwhelming evidence that CP is rarely caused by birth and EFM is tantamount to junk science. Moreover, these organizations have disregarded medicine's continued acknowledgement that "we still lack reliable assessment tools of fetal and neonatal status, which are both sensitive and specific to intrapartum insult that correlates with long-term outcome. The critical hypoxic or ischemic threshold for neuronal necrosis in developing brains remains unknown" [56].

And, importantly, the Task Force disregarded the scholarly voices that have repeatedly pointed out EFM's clinical impotency and clarified the real reason behind its use—physicians' misguided impression that EFM is a prophylactic against lawsuits [4, 9, 10, 21, 39, 45].

Why would the Task Force ignore every healthcare provider involved in delivering babies and their now universal fear of CP lawsuits, and blatantly disregard the ethical concerns of EFM's continued use without informed consent?

#### We have met the enemy and he is us

There is no discernible answer to the question. During the four years of ACOG/AAP Second Edition 2014 development several dozen medical authors began to loudly echo the original voices of the courageous few who in the beginning said that EFM would not work because of its false premise [4, 21] These modern voices [1-6, 10, 11, 23, 44, 48, 49, 52] were completely ignored, despite the fact that EFM'S shortcomings were openly discussed, along with the fact that there was an explosion of CP-EFM litigation. Some thought leaders even pointed out that within the maternal-fetal medicine community there was an evolving consensus that it was time to start over and establish common EFM language, standard interpretation, and reasonable management principles and guidelines [11]. ACOG / AAP Second Edition 2014 ignored them as well.

The Task Force also said not one word concerning the charlatans in the courtrooms unjustly accusing physicians, or the lack of agreement in EFM interpretation even among experts. Nor did it recognize EFM's primary role in the rising cesarean-section rate, much less opine on the ethical quagmire under their feet. Task Force 2014, rather than recognize and deal with the evacuation of a sinking ship, chose to use its efforts to rearrange the deck chairs so that when at last the ship goes under the chairs will be in perfectly straight alignment.

#### Can anything be done?

Yes. To end the CP-EFM litigation crisis, BRPOs must change the EFM standard of care. Changing the standard of care begins by admitting the obvious—EFM is unscientific and there is a need to start over [11]—and by each BRPO officially declaring EFM is not the standard of care in labor rooms or courtrooms.

Such declarations would mark the beginning of the end of CP-EFM litigation, because it would link EFM to the Daubert doctrine—an exclusionary evidence doctrine applied in most of the world's courts—a doctrine that bars junk science from courtrooms [4, 96-98].

Some will protest that BRPOs cannot simply change the EFM standard of care because trial lawyers will accuse BRPOs of being self-serving. Maybe. But even so, it should be BRPOs, and not trial lawyers, who determine standard of care. For the last fifty years, physicians and BRPOs have, because of fear of lawsuits, defaulted and allowed trial lawyers to dictate the standard of care for mothers and babies. Today is the day that should stop. As is well known, physicians must testify in each individual lawsuit what the standard of care is for that particular procedure. It is also well known that consensus statements from a worldwide body of experts, in plain declarative language, understandable to judges and juries, accompanied by a literature analysis weeding out past, stale, unscientific opinions, would be more persuasive to juries and judges than testimony of individual physicians. Task Force 2014 [56] failed to take advantage of the unique opportunity presented to it. It not only failed to hear the voices of the medical profession, but also failed in its obligation to insist on the application of ethical principles that BRPOs avoided for so long while trying to rescue EFM. Rescue is no longer an option. It is time to recognize that EFM is not the deus ex machine [52] it was touted to be, is not the magnum opus of obstetrics, and is, in fact, a medical failure rivaling the century-long miasma-versusgerm theory of disease, a medical imbroglio famous for a majority of medicine taking the head-in-the-sand approach to science.

The question arises how would labors be monitored if not with EFM? The answer is that EFM would still be clinically usable as a labor saving device but mothers would have to be given true informed consent and be told that EFM pattern interpretation is experimental and does not predict or prevent CP or other birth maladies. Most will undoubtedly choose EFM if their physicians encourage it. But at least they will know the truth about EFM and the pressure on obstetricians to quickly do a C-section because of a worrisome EFM pattern will be relieved.

## Conclusion

EFM was introduced into clinical practice with no instruction manual, no clinical trials, with unrealistic expectations of efficacy, and without clearly defined use parameters. Fifty years of trial and error have not cured its shortcomings. By omission and blindness, BRPOs have allowed trial lawyers to use EFM like a Saturdaynight special perpetually pointed at obstetricians and the myriad healthcare providers routinely caring for laboring mothers and their babies. The EFM gun makes every potential birth the one that will result in years of litigation, multiple defendants pointing the finger of blame at each other, and the very real possibility that at the end there will be a career-damaging, headline-making jury verdict. It is little wonder, then, that most physicians view a quick cesarean-section as the only choice when the machine indicates even a slight possibility of a birth problem. Far better to choose early cesarean-section with its complications and risks for mothers and babies than to risk being sued for acting slowly. The failure of BRPOs to act has made this decisional dilemma a daily occurrence and has created an ethical nightmare for innocent care providers: birth decisions made based on fear—the fear of being sued—are neither rational nor ethical.

It is far past time for BRPOs to confront electronic fetal monitoring reality, stop rearranging the deck chairs, abandon the EFM ship,

and start over. BRPOs must come to grips with the fact that EFM undeniably creates an epic medical-ethical dichotomy—it harms mother and babies, in direct opposition to the promise care providers made—first, do no harm.

# Funding

The authors received no financial support for the research, authorship or publication of this article.

# **Conflict of Interest**

The authors report no conflicts of interest with respect to the research, authorship, and/or publication of this article.

## References

- 1 Grimes DA, Peipert JF (2010) Electronic fetal monitoring as a public health screening program, the arithmetic of failure. Obstet and Gynecol 116: 1397-1400.
- 2 Badawi N, Keogh JM (2013) Causal pathways in cerebral palsy. J Paediatrics and Child Health 49: 5-8.
- 3 Constantine MM, Saade GR (2012) The first caesarean: role of fetal distress diagnosis. Semin Perinatol 36: 379-383.
- 4 Sartwelle TP, Johnston JC (2015) Cerebral palsy litigation: change course or abandon ship. J Child Neurol 30: 828-841.
- 5 Graham EM, Adami RR, McKenney SL (2014) Diagnostic accuracy of fetal heart rate monitoring in the identification of neonatal encephalopathy. Obstet and Gynecol 124: 507-513.
- 6 Alfiredic Z, Devane D., Gyte GML (2013) Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour. Cochrane Database of Systematic Reviews 5.
- 7 Graham EN, Ruis KA, Idartman AL, Northington FJ, Fox HE, et al. (2008) A systematic review of the role of intrapartum hypoxiaischemia in the causation of neonatal encephalopathy. Am J Obstet and Gynecol 199: 587-595.
- 8 Khalil A, O'Brien P (2006) Fetal heart rate monitoring is it a waste of time? Obstet and Gynecol of India 56: 481-485.
- 9 MacLennan A, Hankins G, Speer N (2006) Only an expert witness can prevent cerebral palsy. O&G 8: 28-30.
- 10 MacLennan AH, Thompson SC, Gecz J (2015) Cerebral Palsy: Causes, pathways, and the role of genetic variants. Am. J. Obstet Gynecol 213: 779-788.
- 11 Clark SL, Nageotte MP, Garite TJ (2013) Intrapartum management of category II fetal heart rate tracings: toward standardization of care. Am J Obstet Gynecol 209: 89-97.
- 12 Umstead MP, Permezel M, Pepperell RJ (1994) Intrapartum cardiotocography and the expert witness. Aust & NZ J Obstet Gynecol 34: 20-23.
- 13 Larssen A (1994) The role of the obstetrician in preventing fetal asphyxia. In: H.C. Lou (eds.) Brain Lesions in the Newborn 361.
- 14 Gaffney G, Sellers S, Flavell V, Squier M, Johnson A, et al. (1994) Casecontrolled study of intrapartum care, cerebral palsy, and perinatal death. Brit Med J 308: 743-750.
- 15 Borgatt L, Shrout PE, Divon MY (1988) Reliability and reproducibility of non-stress test readings. Am J Obstet Gynecol 159: 554-558.
- 16 Hruban L, Spilka J, Chudacek V (2015) Agreement on intrapartum cardiotocogram recordings between expert obstetricians. J Eval Clin Pract 21: 694-702.
- 17 Spilka J, Chudacek V, Janku P (2014) Analysis of obstetricians decision making on CTG recordings. J Biomed Informatics 51: 72-79.
- 18 Trimbos JB, Keirse MJ (1978) Observer variability in assessment of antipartum cardiotocograms. Brit J Obstet Gynecol 85: 900-906.
- 19 Nelson KB, Dambrosia J, Ting TY, Grether JK (1996) Uncertain value of electronic fetal monitoring in predicting cerebral palsy. N Engl J Med 334: 613-618.
- 20 Scheller JM, Nelson KB (2008) Does cesarean delivery prevent cerebral palsy or other neurological problems of childhood? Obstet Gynecol 83: 624-630.

- 21 Sartwelle TP (2012) Electronic fetal monitoring: a bridge too far. J Legal Med 33: 313-379.
- 22 Lilford R, DeGroot HA, Moore PJ, Bingham P (1990) The relative risks of cesarean section and vaginal delivery. Brit J Obstet Gynecol 97: 883-892.
- 23 Clark S, Hankins G (2003) Temporal and demographic trends in cerebral palsy facts and fiction. Am J Obstet Gynecol 188: 628-633.
- 24 Am. Coll. Obstetricians and Gynecologists. Practice Bulletin 106; Intrapartum fetal heart rate monitoring: nomenclature, interpretation and general management principles (July 2009).
- 25 Macones GH, Hankins GD, Spong CY, Hauth J (2008) National Institute of Child Health and Human Development Workshop Report on Electronic Fetal Monitoring. Obstet Gynecol 112: 661-666.
- 26 Westerhuis M, Van Haren E (2009) Inter- and intra-observer agreement of intra-partum ST analysis of the fetal electrocardiogram in women monitored by STAN. BJOG 116: 545-551.
- 27 Chauhan SP, Klauser CK (2008) Intra-partum nonreassuring fetal heart rate tracing and prediction of adverse outcomes: interobserver variability. Am J Obstet Gynecol 199: 623.e1-623e5.
- 28 Ojala K, Makikallio K (2008) Inter-observer agreement in the assessment of inter-partum automated fetal electrocardiography in singleton pregnancies. Acta Obstetricia Gynecologica Scandinavica 87: 536-540.
- 29 U.S. Dept. of Health & Human Services, Office of the Asst. Sec. Planning and Evaluation (2002) Confronting the new health care crisis: improving health care quality and lowering costs by fixing our medical liability system.
- 30 Lucchese DR (2007) Defending the perinatal brain injury lawsuit. For the Defense 49: 65-69.
- 31 CRICO Strategies (2010). Annual benchmarking report, malpractice risks in obstetrics.
- 32 Jacobson PD (2004) Medical liability and the culture of technology. Pew Project on Medical Liability.
- 33 American College of Physicians (2014) Medical liability reform: Innovative solutions for a new health care system. Philadelphia: American College of Physicians, Policy Paper.
- 34 Sartwelle TP, Johnston JC, Arda B (2015) Perpetuating myths, fables, and fairytales: A half century of electronic fetal monitoring. 01: e28-e34.
- 35 Sartwelle TP, Johnston JC. Neonatal encephalopathy 2016: opportunity lost and words unspoken. J Matern Fetal and Neonatal Med 29: 1372-1375.
- 36 Beller FK (1995) The cerebral palsy story: a catastrophic misunderstanding in obstetrics. Obstet Gynecol Survey 50: 83-84.
- 37 Obladen M (2011) Lame from birth: early concepts of cerebral palsy. J Child Neurol 26: 248-256.
- 38 Freeman RK, Garite TJ, Nageotte MP (2003) Fetal Heart Rate Monitoring. In: Williams & Wilkins (3rd eds.) Philadelphia, PA: Lippincott.
- 39 Sartwelle TP (2009) Defending a neurologic birth injury: asphyxia neonatorum redux. J Legal Med 30: 181-247.
- 40 Courville CB (1954) Cerebral palsy. San Lucus Press, Los Angeles CA.
- 41 Cardwell VE (1956) Cerebral palsy. Assoc for the Aid of Crippled Children. New York, NY.

- 42 Ford FR (1944) Diseases of the nervous system in infancy, childhood, and adolescence. Thomas Springfield, Boston MA.
- 43 Quilligan EJ, Paul RH (1975) Fetal monitoring: is it worth it? Obstet Gynecol 45: 96-100.
- 44 Donn SM, Chiswick ML, Fanaroff JM (2014) Medico-legal implications of hypoxic-ischemic birth injury. Sem Fetal Neonatal Med 19: 317-321.
- 45 Lent M (1999) The medical and legal risk of the electronic fetal monitor. Stan L Rev 51: 807-837.
- 46 DiGuiseppi C (1996) Intra-partum fetal monitoring, ch. 39. Guide to Clinical Prevention Services. In: US Dept Health and Human Services (2nd eds.), Report of the U.S. Preventive Services Task Force, pp: 433-441.
- 47 Miller R, Depp R (2008) Minimizing perinatal neurologic injury at term: is cesarean section the answer? Clin Perinatol 35: 549-559.
- 48 Graham EM, Petersen SM, Christo DK, Fox HE (2006) Intra-partum electronic fetal heart rate monitoring and the prevention of perinatal brain injury. Obstet Gynecol 108: 656-666.
- 49 Thacker SB, Stroup DF (2003) Revisiting the use of the electronic fetal monitor. The Lancet 361: 445-446.
- 50 MacDonald D (1996) Cerebral palsy and intra-partum fetal monitoring. N Engl J Med 334: 659-660.
- 51 Jenkins HML (1989) Thirty years of electronic intrapartum fetal heart monitoring: discussion paper. J Royal Soc Med 82: 210-214.
- 52 Greene MF (2006) Obstetricians still await a deus ex machina. N Engl J Med 355: 2247-2248.
- 53 Sabiani L, Le Du R, Loundou A (2015) Intra- and interobserver agreement among obstetric experts in court regarding the review of abnormal fetal heart rate tracings and obstetrical management. Am J Obstet Gynecol 213: 856 e1-8.
- 54 Caplan RA, Posner KL, Cagney FW (1991) Effect of outcome on physicians judgment of appropriateness of care. JAMA 265: 1957-1960.
- 55 Zain HA, Wright JW, Parrish GE, Diehl SJ (1998) Interpreting the fetal heart rate tracing: the effect of knowledge of neonatal outcome. J Reproductive Med 43: 367-370.
- 56 American College of Obstetrics & Gynecology & American Academy of Pediatrics (2014) Neonatal encephalopathy and neurologic outcome (2nd eds.).
- 57 The Churchill Society (1939) The Russian Enigma. BBC Broadcast, London.
- 58 Romergryko GG, Matthew AK, Xiaofeng J, Robert DS, Mary AP, et al. (2011) Management of Brain Injury After Resuscitation From Cardiac Arrest. Neurol Clin 26: 487-ix.
- 59 American College of Obstetrics & Gynecology & American Academy of Pediatrics. Neonatal encephalopathy and cerebral palsy: defining the pathogenesis and pathophysiology (2003).
- 60 MacLennan A (1999) A tutorial for defining a causal relation between acute intra-partum events and cerebral palsy: international consensus statement. Brit Med J 319: 1054-1059.
- 61 National Institute of Child Health & Human Development; National Institute of Neurological and Communicative Disorders and Stroke; US Department of Health & Human Services. Prenatal and perinatal factors associated with brain disorders (JM Freeman ed. 1985).
- 62 Ellenberg JH, Nelson KB (2013) The association of cerebral palsy

with birth asphyxia: A definitional quagmire. Develop Med Child Neurology 55: 210-216.

- 63 Maso G, Piccoli M, DeSeta F (2015) Intrapartum fetal heart monitoring in labor: a critical appraisal. Minerva Ginecologica 76: 65-79.
- 64 Schnekenerg RP, Perkins EM, Miller JW (2015) De novo point mutations in patients diagnosed with ataxic cerebral palsy.
- 65 Moreno-DeLuca A, Ledbetter DH, Martin CL (2012) Genomic insight into the causes and classifications of the cerebral palsies. Lancet Neurol 11: 383-392.
- 66 Am Acad Ped & Am Coll Obstet and Gynecol (1992) Guidelines for Perinatal Care (3rd eds.).
- 67 Phelan JP, Martin GI, Korst L (2005) Birth asphyxia and cerebral palsy. Clin Perinatal 32: 61-76.
- 68 Ramin SM (2000) New concepts in cerebral palsy-introduction. Semin In Perinatol 24: 195.
- 69 Pschirrer R, Yeomans E (2000) Does asphyxia cause cerebral palsy? Semin In Perinatol 24: 215-220.
- 70 Morgan MA, Hankins GD, Zinberg S, Schulkin J (2005) Neonatal encephalopathy and cerebral palsy revisited: the current state of knowledge and the impact of American College of Obstetricians and Gynecologists task force report. J Perinatal 25: 519-525.
- 71 Hankins GD, Erickson K, Zinberg S, Schulkin J (2003) Neonatal encephalopathy and cerebral palsy: a knowledge survey of fellows of the American College of Obstetricians and Gynecologists. Obstet Gynecol 101: 11-17.
- 72 Sachs BP (1989) Is the rising rate of cesarean sections a result of more defensive medicine? In: VP Rostow, RJ Bulger (eds.) Medical Professional Liability and the Delivery of Obstetrical Care 2: 27-40.
- 73 Friedman EA (1986) The obstetrician's dilemma: how much fetal monitoring and cesarean section is enough? N Engl J Med 315: 641-643.
- 74 Veatch R (2012) The Basics of Bioethics (3rd eds.) Pearson Education Inc.
- 75 Beachamp T, Childress J (2008) Principles of biomedical ethics. Oxford Press (6th eds.).
- 76 Jonsen AR (2000) A Short history of medical ethics. Oxford University Press.
- 77 Heelan L (2013) Fetal monitoring: creating a culture of safety with informed choice. J Perinatal Education 22: 156-165.
- 78 Wood SH (2003) Should women be given a choice about fetal assessment in labor? MCN Am J Matern Child Nurs 28: 292-298.
- 79 Gilfix MG (1984) Electronic fetal monitoring: physician liability and informed consent. Am J Law Med 10: 1-48.
- 80 Zuspan FP, Quilligan EJ, Iams JD, Van GHP (1979) NICHD Consensus Development Task Force Report. Predictors of intrapartum fetal distress—the role of electronic fetal monitoring. J Pediatrics 95: 1026-1030.
- 81 International Federation of Gynaecology and Obstetrics and Family Health International (1987) Guidelines for the use of fetal monitoring. Int J Gynaecol Obstet 25: 159-167.
- 82 Robinson B, Nelson L (2008) A review of the proceedings from the 2008 NICHD workshop on standardized nomenclature for cardiotocography. Rev Obstet Gynecol 1: 186-192.

- 83 Wolfberg A (2012) The future of fetal monitoring. Rev Obstet Gynecol 5: 132-136.
- 84 Villar J, Carroli G, Zavaleta N (2008) Maternal and neonatal individual risks and benefits associated with caesarean delivery: multicenter prospective study. BMJ 335: 1025-1036.
- 85 Borre YE, O'Keeffe GW, Clarke G (2014) Microbiota and neurodevelopmental windows: implications for brain disorders. Trends In Molecular Med 29: 509-518.
- 86 Fridrich MJ (2015) Unraveling the influence of gut microbes on the mind. JAMA 313: 1699-1701.
- 87 Sevelsted A, Stokholm J, Bonnelykke K (2015) Cesarean section and chronic immune disorders. Pediatrics 135 : e92-e98.
- 88 Almgren M, Schlinzig T, Gomez-Cabrero D (2015) Cesarean delivery and hematopoietic stem cell epigenetics in the newborn infant: implications for future health? Am J Obstet Gynecol 211: 502-503.
- 89 Ayres-de-Campos D, Spong CY, Chandraharan E (2015) FIGO consensus guidelines on intrapartum fetal monitoring: cardiotocography. Int J Gynaecol Obstet 131: 13-24.
- 90 Sholapurkar SL (2016) Imperative for improvements and international convergence of intrapartum fetal monitoring: A bird's eye view. World J Obstet Gynecol 5: 102-109.

- 91 Ugwumadu A (2014) Are we (mis)guided by current guidelines on intrapartum fetal heart rate monitoring? Case for a more physiological approach to interpretation. BJOG 121: 1063-1070.
- 92 Greene MF (2006) Obstetricians still await a deus ex machina. N Engl J Med 355: 2247-2248.
- 93 Belfort MA, Saade GR, Thom E (2015) A randomized trial of intrapartum fetal ECG ST-Segment analysis. N Engl J Med 373: 632-641.
- 94 Olofsson P (2015) Determination of base excess in umbilical cord blood at birth: accessory or excess? Am J Obstet Gynecol 213: 259-261.
- 95 Cahill AG (2015) Umbilical artery pH and base deficit in obstetrics. Am J Obstet Gynecol 213: 257-258.
- 96 The scientific reliability requirement was articulated in Daubert vs. Merrill Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).
- 97 Hammond CB, Schwartz PA (2005) Ethical issues related to medical expert testimony. Obstet Gynecol 106: 1055-1058.
- 98 Johnston JC, Sartwelle TP (2013) The expert witness in medical malpractice litigation: through the looking glass. J Child Neurol 28: 484-501.