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Electronic Fetal Monitoring, Cerebral Palsy Litigation, and Bioethics: The Evils in Pandora's Box

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Abstract

Pandora opened the box releasing death and all other evils into the world. She hastened to close the lid but the whole content had escaped except for one thing at the bottom of the box - HOPE. Paraphrase of the Greek Myth in Hesiod's Works and Days.

Edward Hon opened the Electronic Fetal Monitoring (EFM) Pandora's Box in the 1950s. Although perhaps noble in original purpose, the unintended EFM consequences over the last half century resulted in more harm than good to mothers and babies in most of the industrialized world. EFM became the standard of care not because it was scientifically efficacious, but because it was promoted by physicians with undisclosed conflicts of interests and because obstetricians desperately wanted to believe that a machine would solve the age old cerebral palsy malady and at the same time protect physicians and hospitals from the then new and costly cerebral palsy birth injury lawsuits. EFM became the standard of care at the same time that bioethics became medical reality replacing the medical profession's Hippocratic paternalistic ethic with patient autonomy and informed consent in virtually all aspects of medical practice except for the use of EFM. The use of EFM without informed consent has continued for fifty years with no outcry from the bioethical world. This article explores this ongoing medical and ethical calamity, and discusses why even today EFM use continues disguised as a safety device when in fact its use is primarily as protection for physicians and hospitals from cerebral palsy lawsuits.

Keywords: Cerebral palsy; Bioethics; Fetal monitoring

Introduction

A modern day Pandora's Box - electronic fetal monitoring (EFM) - was opened by Dr. Edward Hon in the 1950's. Unintentionally, he released multiple evils into the obstetrical world with his promotion of EFM as the beginning of the end of fetal distress in labor [1]. Hon's initial intent was perhaps noble in purpose but quickly became tainted with conflict of interest, avarice, medical paternalism, unscientific optimism, and arrogance [1-4]. As a result, Hon unleashed a machine that for fifty years has been disguised as a safety device for birth that in fact is nothing more than a scientific fraud causing infinitely more harm than good to obstetrical care givers, hospitals, mothers and their babies [1-22].

Hon, however, was only the instigator. In true O. Henry like irony, almost the entire obstetrical world became active participants in Hon's EFM conflict of interest, avarice, medical paternalism, unscientific optimism, and arrogance, declaring EFM a necessity for safe birth when in fact EFM was and is today primarily used as protection for doctors and hospitals from cerebral palsy (CP) lawsuits [3-5,10,14,23-25]. Those coming after Hon not only sustained the evils Hon unleashed but added an even more deleterious EFM evil - a total compromise of the ethical principle by which any great profession should be measured - honesty [5,10,23,26,27].

How Did It All Begin?

EFM began because of a century old conventional wisdom that taught birth caregivers that fetal heart rate was a direct measure of acute hypoxia and past and present brain function and damage, and that CP was virtually always due to "birth asphyxia" [1-5,7,8,10-12,14,22,23,26,27]. But conventional wisdom is not science. And although these hoary myths are today still widely believed by the public, trial lawyers, many birth caregivers, and numerous physicians, they are nothing more than myths, fables, and fairytales [26].

Nevertheless, these birth myths were the foundation of Hon's effort to automate fetal heartbeat counting, which was the essence of fetal surveillance in labor [1-5,26-30]. This untested theory, still prevalent today, claimed that when a fetus's heart beat was out of the presumed normal range, that indicated the beginning of asphyxia, and there was a limited amount of time to rescue the fetus with forceps and later by C-section before brain damage became irreversible [26-30].

Hon classified various EFM patterns by comparing them to outcomes using Apgar scores and published what became a universally accepted classification of normal-abnormal fetal heart rate patterns [26-30]. Other researchers confirmed Hon's work [26-30] and by 1970 EFM machines were in demand in hospitals around the world [1-5,28,30]. Although EFM entered clinical practice without clinical trials, with no instruction manual, no clearly defined parameters for use [31], based on a catastrophic misunderstanding of fetal physiology [32], and based on a non-existent scientific foundation [1-5], it was nevertheless routinely used in all labors and was labeled by physicians as a mandatory safety device. Mothers were given no choice or informed consent [1-5,10,26,33,34].

Hidden From the Light

Unknown to most early EFM purchasers and the physicians users, was the fact that Hon was the founder of Corometric Medical Systems one of the first EFM machine manufacturers [1-4]. Corometric became wildly successful with sales skyrocketing based on Hon's research and the optimism the inventor and his colleagues expressed in reports of their research: Hon said 90% of all fetal distress is caused by umbilical cord compression and EFM will save 20,000 babies per year [1]; two Hon colleagues wrote, in 1975 before EFM had been subject to even one clinical trial, that EFM alone would reduce by half intrapartum deaths, mental retardation, and CP [35].

But Hon and many of the investigators writing propitious EFM research articles creating the demand for EFM in every labor, were undisclosed Corometric Board of Directors members, stock holders, investors, and patent holders, and Corometric was the undisclosed financial arm of much of Hon's and others' research [1-4]. By 1975 EFM was viewed as such an important part of a safe birth that University of Southern California, where Hon had moved his EFM research, rejected an EFM randomized controlled trial (RCT) on the ground that withholding EFM from the control group was unethical [1-4,36]. Corometric was eventually sold after experiencing fantastic sales [1-4]. Hon and his insiders held more than half the stock [1-4].

EFM Naysayers

Before EFM was a concept there were a few CP causation conventional wisdom critics convinced that CP-neurologic birth related conditions were not labor-birth related at all but rather were congenital in origin [11]. Difficult birth was a symptom of pre-existing developmental anomalies [11]. Chief among these conventional wisdom non-believers was Sigmund Freud [11].

Around the time EFM was becoming the standard for hospital birth a significant challenge was made to the fetal heart beat reflects fetal distress theory. Benson and colleagues, having studied almost 25,000 labors, concluded there was no single reliable fetal heart rate indicator of fetal distress [1,37] while others demonstrated that most fetal heart rate patterns deemed abnormal were associated with normal cord pH and even the most dramatic patterns resulted in very few neonates born acidotic [1,13].

But Hon and his followers and the vast majority of contemporary obstetricians ignored naysayers [1-5]. They wanted to believe in the illusion that they had discovered the simple rule-of-thumb formula that solved CP's neurologic complexities as well as other birth related maladies. Thus, the majority of the medical establishment eschewed the scientific method to prove EFM efficacy in favor of antidotes and clinical impressions [1-4]. Adding to the belief in EFM illusion was the technology revolution overtaking medicine in the 1960s-1970s. Obstetrics was still stuck in the non-technology dark ages with fetoscopes and humans manually counting fetal heart beats. Thus as the world and medicine became increasingly beguiled by computers, the space race, and technology in general, obstetricians also wanted to believe a computer like machine was a simple solution to a problem vexing mankind since the world began [1-5,10,12,22,27,32]. Most believed EFM was a real *deus ex machine* [18].

The first RCT was accomplished by a non Corometric associated believer in EFM's efficacy [1,2]. Albert Haverkamp, a Denver obstetrician, wanted to prove EFM's worth to a few skeptical obstetricians and mothers but was surprised to find EFM was no better than intermittent auscultation but significantly increased the numbers of C-sections [1,4]. Between 1976 when Haverkamp's RCT was published and 1995 eleven more RCTs found essentially the same results [1-5,10,14,18,28-30].

Medicialized Birth

But it was too late. The majority of the obstetrical world fiercely believed in Hon's invention and its fairytale like promises. The believing obstetrical community attacked the non-believers and the RCTs with a vengeance [1,2] denigrating the contrary evidence as well as personally attacking the non-believers [1,2]. Even today, obstetricians reject contrary EFM evidence and continue using EFM in almost all labors in the industrial world [1,3-20]. And, almost uniformly without mothers' informed consent, Why? [38-44].

Two primary reasons

First, modern society's belief, induced by the medical profession, that birth cannot safely be accomplished without a physician, hospital, and nurses overseeing the event [3-5, 9,24,45,46]. Also, most of modern society have been convinced by physicians that medical technology like EFM is indispensable to safe birth just like technology is necessary to most all other aspects of medicine [3,5,9,24,45,46]. But, the created need for doctors, hospitals, nurses, and technology at

birth had an unintended consequence. When the medical profession created the idea that birth was only safe when a physician and nurse were present in a hospital with the latest technology, they also created the idea that the physician, hospital, nurse, and technology guaranteed a perfect outcome. So, if an untoward outcome occurs, the obstetrician and other care givers are obviously to blame because they and their technology failed to produce the perfect birth.

The second reason is trial lawyers. When Hon and others were touting EFM as the beginning of end of fetal distress, [1] CP, intrapartum deaths, and mental retardation, 1-5, 35 crafty trial lawyers were listening intently. Before EFM there were few birth injury lawsuits because there was no evidence of what took place in labor except the obstetrician's or nurse's recollection of what was heard during auscultation. EFM changed that dynamic and changed it dramatically. EFM created a computer like permanent record of every second of labor, a record that could be reanalyzed in a courtroom by a hired physician expert who, using Hon's and other's own EFM assertions, could pin point the exact time a physician should have intervened in labor by C-section in order to have saved a child from CP and other neurologic abnormalities [1,7,8,10,12,14,15,17,19,23-27].

The Perfect Storm

EFM was ushered into clinical practice as the standard of care at the same time that the world's industrial societies and their courts were radically shifting responsibility for life's tragedies from individuals to others in society [5,10,14,23,26,27,47]. Expanding legal liability and liberal evidence rules opened the pocketbooks of exponential numbers of defendants from manufacturers, drug and medical device makers, governments, and individuals, in particular doctors and hospitals for medical malpractice [5,10,14,23,26,27,47,48]

Combining the new liberal liability theories and evidence rules with EFM's guarantee that medicine had found the key to the cause and prevention of CP and other birth maladies, gave trial lawyers a roadmap to prosecute any case where a child had CP or almost any other untoward birth outcome [5,14,26,27,48].

Trial lawyer reasoning was simple: EFM predicted and easily demonstrated fetal distress at a time when intervention in labor would save a fetus from a lifetime of neurologic devastation. Thus, any case of CP was obvious medical malpractice on the part of a physician or nurse who could not or did not understand EFM pattern interpretation that predicted the very life altering event that had occurred [5,14,26,27,48-52].

Paid courtroom EFM "experts" willingly repeated the trial lawyer mantra pointing to the very minute EFM tracings allegedly predicted disaster. And in courtrooms around the world these "experts" delivered thousands of babies by simple C-sections, always without complications, saving every child from the tragic life that they were living, something the

defendant doctors, nurses and hospitals could have done if they had simply paid attention or been better educated.

So began the CP-EFM litigation crisis that continues today still based on the same myths repeated by courtroom "experts" now for a half century [1,5,6,7,10-12,17,19,26]. Doctors, their birth related professional organizations (BRPOs), and hospitals could have halted the crisis at its beginning. But they chose instead to ignore reality and in the process compromised their ethics, honesty, and integrity.

Heads in the Sand

The BRPOs', doctors', and hospitals' response to the CP-EFM litigation crisis was a shameful phenomenon unseen in medicine's long history - defensive medicine - medical procedures performed not for patients' benefit but for protection of doctors, nurses, and hospitals from CP lawsuits [3-5,10,14,23,26]. And while defensive medicine was a reaction of medicine in general to the medical malpractice crisis engulfing all of medicine [50-52] obstetrical defensive medicine was especially egregious.

Obstetricians' defensive reaction to CP-EFM lawsuits was not a reassessment of scientific fundamentals while EFM use was restricted, but rather was an exponential increase in EFM use in the grossly mistaken belief that EFM was indeed a *deus ex machina* [18] that actually protected them from lawsuits [5,10,14,23,27]. More important, this belief that EFM was protection persisted even as the scientific evidence proving EFM's scientific foundations were almost non-existent and EFM was causing harm to mothers and babies from unnecessary C-sections, mounted higher and higher [1-10,12,14,16-21,24-34].

In 1970 C-sections occurred 6% of the time [14] while today C-sections occur in one in three births in the USA and even higher in other countries [5,6,14,53-55]. Much of the increase is due to EFM's documented 99.8% false positive rate [21] and birth caregivers fears of CP lawsuits [53-57]. That fear, stronger than the hoary Hippocratic ethical prescription to first do no harm [58], inspired the modern obstetrical mantra, "no one gets sued for doing a C-section. They get sued for not intervening [25]."

But this mantra ignored not only the EFM research belatedly begun after EFM was made the standard of care, but also ignored the belatedly begun CP researchers' [12] rapidly increasing evidence proving CP is caused by genetic mutations or by adverse environmental factors of pregnancy and rarely by physicians and nurses [1,5,7,8,10-12,15,17,19,22,23,26,31,32]. Perhaps most egregious of all, those physicians living by this C-section mantra ignored the present and future risks C-sections impose on mothers and their children, [5,7,8,10,12,13,23-27,53-57] and ignored the undeniable fact that EFM and C-sections have not reduced the incidence of CP or any other birth neurologic malady at any time in its fifty years of existence [1-6,10,12-14,16-21,23-34,36,37,58].

But obstetrical groupthink [59] went further than merely ignoring medical facts. In order to use EFM for fifty years knowing the potential harms to mothers and children from unnecessary C-sections while never giving mothers the informed consent that modern bioethics mandated, obstetricians rationalized that EFM protected them from lawsuits and, therefore, regardless of potential harms or ethical infelicity, their conduct was not only expedient but was the right and good thing to do.

Paradise Lost

Post World War II saw not only the birth of the atomic age, economic prosperity, technology revolution, space exploration, medical breakthroughs unthought-of a decade earlier, social revolution, the birth of EFM, and a thousand other dramatic changes across the spectrum of human existence, there was also the birth of an ethics revolution [26,60-63].

A new deontology emerged stimulated in part by the dramatic revelation of decades of medical experiments conducted without patients' knowledge or consent, [26,61,62,64], a deontology conceived by philosophers, theologians, scientists, legal scholars, and physicians questioning the ethics of the rapid expansion of science and medical procedures, and seeking to preserve core human values in these advances. By 1970 the new deontology had a name - bioethics - and before the decade was out bioethics was a separate, distinct discipline with its own literature, research centers, teachers and medical school departments in major universities across the globe [26,60-63].

Bioethics differed radically from the centuries old Hippocratic ethics - physician centered ethics of benign paternalism - wherein the physician's duty was to choose the best treatment for the patient using the physicians' judgment even if the patient disagreed [26,60-63]. The new deontology's core principle was patient centered - autonomy - each person's freedom to choose what is in their best interest. Autonomy's essential partner was informed consent, wherein the physicians' duty was to provide the medical treatment choices so the patient could choose what to do with her own body, even if the physicians disagreed [26,60-63]. And, of course, with informed consent came an obligation of physician honesty, something unrequired of physicians by Hippocratic ethics [26,60,65].

When EFM entered clinical practice obstetricians comfortably operated on the Hippocratic principle of making all choices for mothers in labor without asking or explaining [38-42]. Literally the doctor knew best. And in the case of EFM obstetricians around the world accepted EFM as the beginning of the end of CP, mental retardation, and fetal intrapartum death just as the EFM proponents promised [35]. Therefore why was there any necessity to explain or give mothers a choice for an essential, necessary safety device? [26].

While the new informed consent deontology spread rapidly to virtually all medical specialties, [60-63] it did so despite the concomitant medical malpractice litigation crisis and

malpractice insurance availability crisis that began in the mid-1970s, fueled by the courts' liberalized liability and evidence rules. And the new ethics continued to spread in every decade until today [5,7,9,10,12,14,26,27]. Obstetricians, however, were the EFM informed consent exception that proved the rule.

Self-Centered Ethics

When EFM was introduced into clinical practice bioethics' informed consent was in its infancy. Obstetricians practiced in the Hippocratic paternalistic atmosphere. In 1978-1979, however, following the first EFM RCTs and the accompanying EFM criticisms among which were excessive unnecessary C-sections, [1-5,10,26,33,34] the National Institute of Child Health and Human Development (NICHD) formed a Task Force to investigate, among other things, intrapartum fetal distress predictors one of which was EFM.

The Task Force report's summary, conclusions and recommendations were concurrently published in three prominent medical journals [43,66,67]. The Task Force, made up of physicians, ethicists, the public, and other scientific specialties [43,66,67], recognized there was no evidence EFM was superior to auscultation, that EFM could result in inappropriate C-sections, and that physicians should give mothers a choice of fetal surveillance after providing detailed EFM informed consent benefit-risk information both during pre-natal care and again on admission to the labor suite [43,66,67].

Obstetricians and hospitals ignored the Task Force. EFM use continued rising [14]. It was being used in almost every pregnancy, and no choice was offered or informed consent given. By 1984 physicians' insistence on using EFM, their systemic failure to provide mothers a choice of fetal monitoring methods, and their refusal to give EFM informed consent, had become a prominent controversy in legal and medical circles [42].

In 1987, the International Federation of Gynecology and Obstetrics (FIGO), a global professional society, published its first EFM guidelines [44]. FIGO mirrored the 1979 NICHD Task Force including the directive to physicians to provide mothers with EFM informed consent and a choice of monitoring methods: "Mothers should have the opportunity to discuss the use of electronic fetal heart rate monitoring during antepartum care and again upon admission to hospital in labor, so that they are able to give or to withhold informed consent [44]."

Obstetricians and hospitals, however, ignored FIGO as well, continued increasing EFM use, continued ignoring their patients' autonomy, the increased risks of unnecessary C-sections, as well as the ever mounting CP-EFM research findings. Bioethicists, the champions of autonomy, were silent regarding the obstetrical community's EFM postmodern ethical relativism [5,10,26]. This bioethical silence is curious since pointed reminders appeared in the literature over the years, including as recently as 2015 [38], that mothers were entitled

to informed EFM choice [39-42]. None of these reminders, however, came from bioethicists [5,10,26].

How Much Evidence is Enough?

The CP-EFM research effort began in earnest in 1968 [37]. Since 1985, that research has been remarkably consistent in its conclusions that CP is rarely caused by health providers, and that EFM is decidedly unhelpful and even dangerous [1-23,26-34,68]. Just as consistent has been the obstetrical community's obstinate, intransigent, remorseless refusal to acknowledge the research and acknowledge EFM is causing more harm than good to mothers and babies [13,20].

The obstinacy continued in 2014 when ACOG and AAP, in a report endorsed by major worldwide BRPOs, conceded that EFM after fifty years of use offered no long-term benefits, did not predict neurologic injury or CP, and that C-sections as a method to reduce neonatal encephalopathy and CP were a failure [69]. These overdue confessions were unaccompanied by demands that EFM use be curtailed, that mothers be provided EFM informed consent, fetal surveillance choice, or warned that EFM use created C-section overuse that had substantial current and future dangers [5,7,10,17,19,20,26,27,31,55,56,68].

The ACOG-AAP report ignored another comprehensive Cochrane Collaboration EFM assessment in 2013, concluding that EFM use caused significantly more C-sections and instrumented vaginal births, but did not reduce the incidence of CP, infant mortality, or any other measures of infant well-being [68]. This Cochrane assessment also concluded that mothers should be given EFM informed consent in particular about EFM's increased C-sections and instrumented vaginal births, the adverse effects of operative births, and that EFM had no impact on CP or perinatal mortality [68].

ACOG-AAP also ignored the growing consensus in the maternal fetal medicine community that EFM had no common language, standard interpretation or management principles, and that it was time to start over on a technology that had never been proven efficacious [31].

The ACOG-AAP further ignored the long established fact that EFM pattern interpretation is subjective, inconsistent, impossible to standardize, poorly reproducible [7,10,18] as well as four decades of documented inter-intra observer disagreement so consistent as to suggest a decided lack of objectivity [6], warnings that EFM as a screening tool for absence of injury is merely a coin toss [13,16] and prominent warnings that EFM was causing more harm than good [13,20].

Unanswered questions

So the question is why would the BRPOs of the world ignore obvious evidence of EFM harm, ignore informed consent, ignore the violation of mothers' bioethical autonomy, and ignore the reality that most of the birth profession is lying daily to mothers and themselves about EFM dangers and forcing mothers to undergo a medical procedure that has the potential for current and future harm?

One obvious answer to these questions is a near fifty year CP litigation crisis wherein CP verdicts and settlements became so astronomical that obstetricians and hospitals came to fear lawsuits [5-8,10-12,14,15,17,19,26,70,71] more than they respected their patients' bioethical rights and their own bioethical obligations to their patients. As a result of fear, physicians willingly compromised their ethical integrity representing EFM as a safety device when in fact its use is primarily to protect doctors and hospitals from lawsuits. This dishonesty, with themselves and their patients, is unbecoming of a profession supposedly dedicated to healing by proven evidence based science rather than self-protection by deceit.

But fear of lawsuits is not the only answer. BRPOs could have stopped the CP litigation crisis at the beginning by declaring EFM is not the standard of care for fetal surveillance [5,14,23,26,27,47]. In fact the CP litigation crisis could be stopped today if BRPOs declared EFM to be experimental [5,14,23,26,27,47]. So the real question is, if the crisis could have been stopped and can be stopped today why have BRPOs not protected the birth care givers of the world and at the same time protected their patients from unnecessary C-sections? Lay people as well as physicians have asked that question [5,14,23,26,27,72,73].

There is simply no obvious answer. Somewhere there are, like Hon, undisclosed conflicts that are more important than patient wellbeing and bioethical obligations.

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