

Briefly Legal: Fetal Heart Rate Patterns, Cerebral Palsy, and Accountability: Response to Dr. Steven Clark's Current Commentary in Obstetrics & Gynecology

Barry Schiffrin, MD, Maureen E. Sims, MD

Introduction

This commentary represents a response to several articles commenting on the deficiencies of electronic fetal monitoring (EFM) and other indicators of intrapartum injury and their use in the courtroom. (1, 2) Because of its breadth, we focus more specifically on a recent "commentary" published in **Obstetrics & Gynecology**, the official publication of the ACOG, by Dr. Steven Clark, a prominent maternal-medicine physician, who covered a broad range of issues, but emphasized four major points, (3)

"This commentary represents a response to several articles commenting on the deficiencies of electronic fetal monitoring (EFM) and other indicators of intrapartum injury and their use in the courtroom. (1, 2)"

- "First, we need to get our own house in order. Publications describing electronic FHR monitoring must clarify the documented lack of benefit of such monitoring in preventing neurologic injury in language that cannot be misinterpreted."
- "Second, revising the category II designation is badly needed."
- "Third, professional organizations should make clear that any allegation that cesarean delivery in an individual patient based on any single or combination of FHR features not associated with a recognized sentinel event would likely have reduced the risk of cerebral palsy in a child represents the very definition of "junk science." Such opinions are not only not generally accepted in the scientific community, but universally rejected."
- "Finally, obstetricians need to realize that we are unique among medical specialties in our willingness to perform hundreds of thousands of major operative procedures each year without any evidence of benefit but with strong evidence of non-benefit. Initial enthusiasm for accepting this technology without demanding firm evidence of benefit has left current practitioners in an untenable situation in which myth has replaced reality. However, we are realistically prevented by the current legal system from getting off this train, even if our own anecdotal biases could be overcome."

Believing that the EFM lacks immediate or long-term benefits, Dr. Clark challenges fundamental precepts of monitoring and the provenance of CP relating to the events of labor and delivery and questions whether EFM should be abandoned. He also raises ethical questions about the continued teaching of the precepts and principles of fetal monitoring and its continued application in the clinical setting. In addition to editors of journals and directors of professional societies, part of the blame for this situation, it seems, lies with the legal system: in the courtroom, the interpretation of EFM along with clinical, neuroradiological, and neonatal data are permitted as part of the fact pattern to assist in determin-

ing the timing, mechanism, and preventability of a perinatal injury to the fetus or newborn. Taken to its most fundamental allegations, this and other articles raise fundamental questions about the value of obstetrical care using current EFM guidelines while at the same time attempting to reduce, based on medical uncertainty and dogma, legal accountability for adverse outcomes. (1)

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These articles challenging the use of EFM in major journals reflect broader distress over EFM in the obstetrical community. Despite the prolonged duration and ubiquity of its use and various modifications to the classification of FHR patterns over the past 50 years, there has been no apparent reduction in the rate of CP, while there has been a dramatic increase in the cesarean section rate – often considered unnecessary. To be sure, there is wide variability in the interpretation of FHR patterns and the responses thereto.

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The recent version of **Up-To-Date** avers no certain benefit to the use of EFM, insisting that it is equivalent to intermittent auscultation. (4) In a publication on the evaluation and response to Category II patterns, the 18 authors confess, "As a medical community, we seem to know less than we thought we did 30 years ago regarding the utility of this ubiquitous technology." They also aver that "Unfortunately, this body of work [EFM research] has primarily served to raise more questions than it has answered." (5) In a subsequent study, their proposed scheme to manage Category II patterns was found to be of very limited benefit. (6) Thus, under circumstances where FHR patterns continue to confound and be-

fuddle obstetric care providers, the perception is redolent that experts of “dubious experience” expound with existential “certainty” on the interpretation of patterns in the courtroom. As one author put it, “only individuals who know the outcome seem to be proficient at its interpretation.” (2)

It is necessary to understand both the “befuddlement” of obstetric care providers and the sometimes overwrought allegations, pro, and con, on the use of EFM and the search for advantage in the medico-legal arena to look at Clark’s positions from a different perspective. In this appeal, we try to be mindful of the principle that the absence of definitive evidence cannot be interpreted to mean the absolute absence of a relationship and that “strong inference” may point the way to definitive proof. We are also mindful of Einstein’s caution about trying to solve problems using the same tools (or dogma) that have created the problem.

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Revising Category II FHR patterns

As emphasized by many authors, the currently popular, three-category classification of FHR patterns (Category I-III) was introduced in 2008 without proper vetting, attention to fundamental physiological principles, or reasonable editorial oversight. Indeed, the editorial accompanying the original publication, written by one of the authors, avers that attorneys were consulted about promulgating these guidelines (7). There is even the suspicion that the classification was designed more to protect the physician than the fetus.

The definition of terms and their collection into a therapeutic classification were based upon a presumed relationship of intrapartum hypoxic-ischemic fetal injury derived exclusively from systemic fetal hypoxia developing slowly during labor, resulting in a severely compromised newborn with severe derangements of pH (<7.0) and BD (>12) and very low Apgar scores at 1 and 5 minutes of age and specific forms of cerebral palsy (CP). (8, 9) Presumably, failure to meet these “essential criteria” required the conclusion that intrapartum events were not responsible for the adverse outcome. In 2014, this position was modified, and the “essential criteria” were removed. (10) Nevertheless, adherents continue to rely on the 2003 criteria in courtroom testimony – for the defense.

Dr. Clark and his colleagues, among others, have shown the limited value of determining pH for assessing the quality of obstetrical care or predicting immediate or subsequent disability. (11) The classification of FHR patterns based on the presumed relationship to acidemia imposed arbitrary definitions of “baseline heart rate” (perversely, the rate at present), tachycardia and bradycardia and

derived no insight from the recovery of the fetus from the individual deceleration. There is no recognition given to the evaluation of fetal behavior or the potential for the prospective identification of fetal neurological injury or intracranial hemorrhage. (12, 13) The guidelines attach little importance to the comprehensive assessment of uterine activity and other mechanical forces and ignore the concept of using the individual FHR pattern over time as its control or in association with clinical circumstances. (13, 14)

Teleologically, the fetus must have robust defenses to adapt not only to the hypoxemic nature of recurrent uterine contractions during labor but must also defend against the pressures on the fetal head created by contractions and the passage through the birth canal. These defenses are evident in the vagally-mediated responses when hypoxic or ischemic threats are present. (15) (Lear) From a pathophysiological standpoint, however, there is no plausible way to beneficially use a 3-tier classification of FHR patterns to provide insight into the fetal responses to the various stresses it encounters during labor.

“A thoughtful interpretation of FHR patterns takes advantage of the presence of normal cyclic fetal behavior as a measure of fetal neurological integrity as well as the relationship of the rapidly responding heart rate (decelerations) to the intermittent mechanical/ischemic and hypoxemic stresses of uterine contractions and passage through the birth canal.”

A thoughtful interpretation of FHR patterns takes advantage of the presence of normal cyclic fetal behavior as a measure of fetal neurological integrity as well as the relationship of the rapidly responding heart rate (decelerations) to the intermittent mechanical/ischemic and hypoxemic stresses of uterine contractions and passage through the birth canal. Fetal (and neonatal) behavior is assessed by rest/activity cycles of greater and lesser heart rate variability (HRV) and accelerations with epochal fetal activity or contractions. Decelerations in the heart rate pattern announce an interruption of blood flow to the fetus (e.g., excessive uterine activity, maternal hypotension, etc.) or compromised blood flow within a fetal vessel (e.g., umbilical, placental, carotid) and appear before any change in pH. Accordingly, assessing the impact of the decelerations is less dependent upon the duration or amplitude of the deceleration than on its impact on subsequent heart rate and variability, much as we determine cardiovascular competence (tolerance/reserve) in the adult from the rapidity of its recovery from an imposed stress. In the fetus during labor, that stress (hypoxic, mechanical) is created by uterine contractions. Category I patterns represent normal baseline features (a stable FHR, moderate variability, cyclic accelerations, and absent decelerations) and, despite Dr. Clark’s assertion to the contrary, provide information about fetal neurological responsiveness and behavior and reasonably, the adequacy of fetal blood pressure and cerebral blood flow. The evolution to a Category III represents abnormalities of baseline rate and variability and the presence of decelerations. The fetus is being compromised by impaired blood flow, to which it meets with robust but not insurmountable nor in-

exhaustible defenses but may not yet be injured. Dr. Clark does not recognize any specific pattern of injury or nuance in interpreting patterns. Although unique patterns of fetal ischemic neurological injury have been identified (Category II or III), there is no controlled study of the relationship. (12, 16) .

“As agreed to by Dr. Clark and others, combining these disparate features and etiologies into a single classification and offering vague guidelines for their management, including “continued surveillance and reevaluation” (4, 20), appears to have created an unsatisfying clinical milieu with considerable uncertainty on how this should be managed.”

Category II (present in 75-80% of laboring fetuses) is represented by an abnormality of either decelerations OR baseline features – but not both. Given the breadth of physiological and pathological conditions (some mutually exclusive) that may present with a Category II tracing, it is unreasonable to consider that the metabolic status, the tissue oxygen reserve, or the time to decompensation is the same for each fetus, or in the case of abnormal baseline features without decelerations that the problem is indeed asphyxial. (17) A “Category II” pattern does not exclude fetal acidosis or neurological injury. (16-19) As agreed to by Dr. Clark and others, combining these disparate features and etiologies into a single classification and offering vague guidelines for their management, including “continued surveillance and reevaluation” (4, 20), appears to have created an unsatisfying clinical milieu with considerable uncertainty on how this should be managed. Irrespective, both more and less detailed guidelines are promulgated by obstetrical societies – creating a conundrum not only for obstetrical care providers but for the various stakeholders involved in improving care and assessing preventability. Dr. Clark’s proposed 3-category classification of tracings, with its limited detail, is offered with neither evidence nor logic to support its acceptance.

Cerebral Palsy and the Consequences of Obstetrical Care

Before the middle of the 19th century, the prevailing notion was that abnormal babies either survived intact or died. Beginning with the work of Little and later Freud and others, there evolved the notion of a “third option,” related to a life-long physical and/or mental handicap whose genesis arose prenatally or at the time of birth. (21) In the 21st century, we acknowledge that fetal death and certain postnatal disabilities may be related to hypoxia-ischemia during the birth process.

It is generally accepted that EFM reduces fetal death compared to auscultation and that asphyxial harm suffered during labor may lead to subsequent CP in the previously normal fetus. The prevention of intrapartum fetal death would seem to be a compelling reason to use EFM. Dr. Clark forgot this notion and found no evidence (to a p-value < 0.05) that EFM reduces disability in the form of CP, which he embraces as the only long-term consequence of asphyxial harm during labor and delivery. He does not mention epilepsy, autism spectrum disorder (ASD), or perinatal stroke, each of which has an association with intrapartum events. (22) By no means are the studies definitive – in part related to the problem

of accurately timing the mechanism and severity of fetal/neonatal neurological injury – but the associations do exist. We have also come to understand that the breadth of intrapartum injury may not be gleaned simply from an evaluation of the neonate and that significant injury may occur without immediate signs or symptoms in the newborn. Injuries sustained intrapartum may manifest as behavior and executive function problems later in life. (23)

Do fetal injury and death share a common pathway, differing only in duration/severity? Evidence suggests that severe systemic acidosis is a better predictor of subsequent death, while FHR patterns (which reveal fetal neurological function – see below) correlate better with injury than acidosis. Ischemic mechanisms during labor and delivery (e.g., increased intracranial pressure during pushing) may threaten (regional) cerebral blood flow but may not be accompanied by systemic asphyxiation. In the face of pre-existing fetal compromise, pushing, for example, will exaggerate any ischemia and the potential for harm. While inferential data seems compelling in these areas, definitive studies are lacking.

Dr. Clark does not confront these issues because he and the other commentators recognize no mechanism of subsequent injury other than that occasionally associated with severe hypoxia/acidemia. Even recent, highly regarded reviews of the subject (15) fail to consider other mechanisms of injury other than progressive asphyxiation, which ultimately compromises cardiac output, reducing cerebral blood flow (ischemia) with the potential for injury or death.

It is widely understood that the ultimate mechanism of hypoxic-ischemic injury is cerebral ischemia, facilitated, but not caused by, systemic hypoxia. In the experimental animal, it is very difficult to produce neurological injury without some specific hypotensive intervention (exsanguination) or ischemic compromises such as arterial ligation of a carotid vessel – a model of injury that, unlike systemic hypoxia, restricts blood flow, oxygen, and substrate (glucose) availability to the brain. (24) Further, consider that the model of injury which serves as the underpinning of therapeutic hypothermia (TH- cooling) resulted from studies in the lamb fetus subjected to direct, the primary interruption of the carotid circulation without preceding systemic hypoxia or acidemia. (25) Dr. Clark opines that except for injury suffered during a sentinel event, babies manifesting abnormal tracings during labor and neonatal depression were likely injured prior to labor. If true, they would be denied TH, which requires implementation within 6 hours of the presumed injury.

Cerebral Palsy

Dr. Clark anchors his arguments about the lack of long-term benefits of EFM to a simple notion that: given the apparent stability of the rate of CP over the past several decades, the failure to change that statistic despite the rising cesarean section rate and the widespread use of EFM (however misguided) must mean that cesarean section and EFM and care during labor do not impact the occurrence of CP.

Cerebral palsy is an umbrella term encompassing disorders of movement and posture attributed to non-progressive disturbances occurring in the developing fetal or infant brain. Cerebral palsy cannot be diagnosed at birth but is associated with diverse risk factors, causes, and timing and is diagnosed in approximately two per 1000 children. As such, it seems clear that no single strategy will prevent all CP. A recent Cochrane review addressed the issue of the impact of obstetrical interventions on preventing CP. (26) The authors point out that there has indeed been a changing pattern of risk in obstetrics over the last several decades; labors are longer, mothers are heavier and older, and they suffer from hypertension and diabetes. They are more frequently induced, have more complications, spend much more time on labor and delivery, and are more likely to be delivered by cesarean section.

If neonatal care is the reference point, CP rates have remained constant in the face of the increased survival of premature infants due to antenatal corticosteroids and MgSO₄ and other medical advances, perhaps including intrapartum EFM cesarean section and new treatment modalities. Irrespective, as a group, premature infants remain at increased risk of CP and other disabilities. The survivability of term babies has also profited from modern NICU care and the benefits of monitoring and TH. The Cochrane review reminds us that not all interventions are beneficial and that using the CP rate to assess the quality of obstetrical care is problematic when we have not agreed on the timing or mechanism of the injury. The authors of this review underscore the urgent need for "long-term follow-up RCTs of interventions addressing risk factors for CP that are rigorous in their design and aim for consistency in CP outcome measurement and reporting to facilitate pooling of data, to focus research efforts on prevention."

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The Preventability of CP

When the issue of the preventability of CP or any other long-term outcome arises in a medico-legal encounter, population-based statistics (meeting a p-value < 0.05 – a probability > 95%) are of limited assistance. The question before the court relates to whether the injury in this particular baby was preventable by reasonable conduct of the obstetrical care providers based on a probability of 51%. As suggested above, it is too often believed that adverse outcomes for the obstetrician or pediatrician/neonatologist rest entirely with the obstetrical expert opining on some "pathognomonic squiggle" in the FHR pattern. This notion, however, has little to do with actual medico-legal jurisprudence, where many prerequisites must be met and agreed upon. (1, 27)

A risk factor is not the same as the diagnosis of CP. For example, IUGR is a well-known risk factor for subsequent CP. IUGR is also a risk factor for the appearance of abnormal patterns in labor. Irrespective, CP does not develop in most babies with IUGR. Is it reasonable to affirm that the baby with IUGR is less tolerant of the hypoxemic effects of contractions during its time in labor than the time it spends in utero without the challenge of frequent, hypoxemic uterine contractions? By any reasonable construct, the fresh appearance of decelerations in an IUGR fetus during (early) labor represents a deterioration of its tolerance (reserve) – its ability to tolerate the hypoxemic effects of contractions. Dr. Clark decries the conceptual term "fetal reserve" as "imaginary." He also considers the time spent in labor no more relevant to the outcome than the time before labor. These positions seem contradictory given his concession to the hypoxic nature of labor.

To be able to opine that an intrapartum injury was preventable by

reasonable medical conduct, certain prerequisites must be present:

- There must be an injury whose timing and mechanism can be reasonably elucidated. In this respect, Dr. Clark's reference to the FHR patterns of an anencephalic has no bearing on the discussion of the standard of care or causation because it is not an acquired injury, it is not reasonably influenced by the obstetrical care and will not appear as an allegation in a court of law.
- Irrespective of risk factors, the fetus must be neurologically normal at the time of the initiation of monitoring, and the injury must be affirmatively timed to the events of labor and delivery using various clinical, obstetrical, and neuroradiological techniques.
- The mechanism of an injury must be biologically plausible and not be related to an earlier injury, a congenital anomaly, or an obvious metabolic or genetic disorder.
- There must be agreed-upon signs and timetables of intervention that are undertaken in a timely and predictable manner. Irrespective of a sentinel event, the injury must not develop so obscurely or quickly, or without sufficient warning (as some injuries do) as to preclude reasonable intervention.
- It seems necessary to add that you cannot create a management protocol that provides both "assistance" to the fetus and a "defense" to the obstetrical care personnel against the allegation of negligence when that protocol is violated.

"WAs mentioned above, FHR patterns may be used to help time injury, but only in conjunction with consistent clinical and radiological information. In studies of the FHR patterns preceding the subsequent development of CP, Evans et al. insisted that the fetus usually behaves on the initial tracing and that there be no clinical, obstetrical, or radiological evidence of earlier injury even in retrospect. (16) "

As mentioned above, FHR patterns may be used to help time injury, but only in conjunction with consistent clinical and radiological information. In studies of the FHR patterns preceding the subsequent development of CP, Evans et al. insisted that the fetus usually behaves on the initial tracing and that there be no clinical, obstetrical, or radiological evidence of earlier injury even in retrospect. (16) Thus, an abnormal tracing on admission or an anomaly or other basis to believe that an injury had occurred prior to labor or by a non-preventable mechanism will compromise the allegation that the injury occurred during labor and delivery irrespective of changes in fetal heart rate pattern throughout labor. Consider a case where the fetus enters labor with a normal Category I FHR tracing, is of normal weight and activity pattern, and demonstrates a normal amount of clear amniotic fluid volume. In association with excessive uterine activity and exuberant pushing, the FHR pattern deteriorates and shows evidence of injury during the 2nd stage of labor (a "conversion" pattern). (12) (16) At birth, the baby is depressed to various degrees with a variable pH and BD in cord blood. Apgar scores are modestly depressed. The infant seizes

on the first or second day of life. Further, the newborn shows a normal head ultrasound examination on day 1 of life (DOL1), followed on DOL 5 by an MRI showing basal ganglia-thalamic injury (BGT) or watershed (white matter injury) or a combination of the two with restricted diffusion. Reasonably the child has suffered an acute, recent, intrapartum injury.

Dr. Clark seems to discredit this exercise in jurisprudential truth-finding by underscoring the perceived limitations of the obstetrical, neuroradiological, and neurological deliberations among the caretakers that go into assigning the timing and mechanism and preventability of fetal neurological injury. He assails the use of both FHR patterns and neuroradiological investigations to inform such conclusions – except in the presence of a sentinel event. He insists that without evidence of normal pre-labor neurologic development and function (he does not offer an opinion on how this is best obtained), neither intrapartum FHR patterns nor abnormal postnatal imaging can be viewed as reliable indicators of the timing or preventability of such injuries. He argues that those fetuses who suffer a sentinel event will show unmistakable patterns (his new Category III), which are also detectable by auscultation and will not fail to spur the clinician to action.

Consider the question: how safe are automobiles? Why is the death toll from automobile accidents rising if cars are safer than previous? If cars are safer, that benefit can be overridden by poor or inattentive driving habits. Some may imagine safer cars promote faster speed and more reckless conduct behind the wheel. Reasonably, it is the habits of the driver that contribute to the adverse outcome statistics. Even Dr. Clark agrees that practitioners frequently do not use EFM wisely; they are poorly educated in the interpretation of tracings using Categories I-III for the management of labor, i.e., “they frequently act based on the FHR pattern alone without considering the clinical circumstances” such as progress in labor or associated maternal high-risk conditions.

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Clearly, FHR patterns do not fail to detect asphyxia; and presumably cannot fail to reduce its consequences; therefore, inarguably, they should make labor “safer”(28-29). How shall we evaluate the role of EFM under current circumstances when its underpinnings are suspect?. That will depend on the evidence, but how does one determine the predictive accuracy of EFM while it is used (sometimes inappropriately) by the practitioner to influence the conduct of labor and the timing and route of intervention. It becomes unreasonable to demand that EFM should both predict and prevent the adverse outcome.

Fetal monitoring in the courtroom

Finally, we come to using FHR patterns in allegations of obstetrical malpractice. This concern is so ubiquitous that it appears in many, if not most, articles on fetal monitoring. This is not without cause; the substandard response to FHR patterns is a conspicuous mainstay of preventable injury worldwide, whether the tribunal is the courtroom or in organizational reviews by medical authorities. (30, 31) Clark decries the introduction of the FHR tracing

as evidence in the courtroom. As shown above, he avers that the allegation that an adverse outcome would have been avoided by a different response to the FHR tracing is “junk science.”

Fueling the discontent are trials in cases where the child suffers from a life-long neurological handicap that result in large monetary awards and where the decision hung on “the disputed interpretation of the FHR pattern. (1) Discussions elsewhere highlight the relationship of large awards to the comportment of the defense and how large awards relate in part to the jury’s disappointment with the actions of the defense that diminish the honor of the medical profession.” (27) Indeed, it is rarely the medical issues that cause those runaway verdicts that create so much distress in the medical community, but rather, the humanity of the defendant that prevents “runaway” verdicts. It is inspiring and, we believe, award-limiting) when the defendant offers some solace (healing) to the parents while holding open the option of having learned something from the experience that will benefit a future patient. Arguing arrogantly and dogmatically that nothing different will be done in the future is a formula for large awards.

Imagine going into court or even an administrative hospital or governmental meeting to justify current practices armed with the arguments offered by Dr. Clark. The defense argues that tracings cannot be interpreted so that babies benefit, except perhaps with a sentinel event. The profession cannot show that obstetrical care matters; monitoring has no other effect than harmfully increasing the cesarean section rate. Would not the mindful stakeholder ask why monitoring was used in the first place, why are all these guidelines for management based on FHR patterns in vogue, and why have so many evaluations worldwide found so much intrapartum injury they consider preventable? (30) Fetal heart rate tracings are but one component of the compendium of perinatal data. While better evidence is urgently needed, it would seem that we need to focus on fundamental notions of what is being monitored with EFM and the importance of optimizing perinatal care using evidence – not dogma.

“However, we also have the inferential keys to understanding the imperfect but informative language of FHR patterns and the broad adoption of a less defensive posture that reorients our priorities so that we are more offended by bad outcomes than the specter of malpractice litigation. We must increase our support for the obvious concept that what we do as obstetrical care providers does matter – and that accountability – vulnerability to the allegation of professional negligence - acknowledges that value.”

Conclusion

Obstetrical health care providers continue to look for guidance in the poorly conceived, defensive three-tiered classification of FHR patterns (Categories I, II, and III) that are largely unrelated to our understanding of fetal-maternal physiology and predicated on

the notion of EFM as an instrument of rescue from “threatening” acidemia. In this, we can all agree. However, we also have the inferential keys to understanding the imperfect but informative language of FHR patterns and the broad adoption of a less defensive posture that reorients our priorities so that we are more offended by bad outcomes than the specter of malpractice litigation. We must increase our support for the obvious concept that what we do as obstetrical care providers does matter – and that accountability – vulnerability to the allegation of professional negligence – acknowledges that value.

We must at least consider employing measures to keep babies out of harm's way in the first place and attempt to convert category II to a category I tracing. (2) In this recommendation lies the likely reengineering of the approach to EFM as an instrument of preventive care rather than one geared to rescuing the fetus from a hostile, presumably academic environment. (32) In this respect, it seems especially necessary to scrupulously avoid excessive uterine activity irrespective of heart rate pattern and titrate the mother's expulsive efforts according to the fetus's response. We must attempt to minimize the need for urgent intervention – an effective measure of the quality of obstetrical care. There appears to be no clinical virtue to seeing how close one comes to catastrophe or a sentinel event before intervening (rescuing) – enlightened surveillance matters both to the outcome and the profession's self-esteem.

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Barry Schiffrin, M.D,
Western University of Health Sciences, Pomona, California
Formerly, Professor of Obstetrics & Gynecology
Keck School of Medicine, University of Southern California, Los Angeles



Corresponding Author:

Maureen E. Sims, M.D.
Professor of Pediatrics
Geffen School of Medicine,
University of California, Los Angeles
Los Angeles, California
email: mes@g.ucla.edu