Briefly Legal: The Classification of Fetal Heart Rate Patterns, Time for a Change?

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"I speak truth, not so much as I would, but as much as I dare; and I dare a little the more as I grow older."— Michel de Montaigne

Introduction:

In 1964, long before the introduction of fetal monitoring, John Pratt, in an article entitled "Strong Inference," asked why certain systematic methods of scientific thinking may produce much more rapid progress than others. He thought several scientific specialties progressed rapidly while others, including medicine, progressed much more slowly. (1)

"Electronic fetal monitoring (EFM) is the most common obstetrical procedure in the United States; it is used annually by upward of 3.8 million individuals in labor. The ubiquity of EFM ultimately boils down to the need to assess the ability of the fetus to tolerate the hypoxemic, ischemic, and mechanical stresses of labor imposed by loss of amniotic fluid, contractions, and maternal pushing, which may be superimposed on problems of the mother including infection, or problems intrinsic to the fetus or placenta."

In a contemporary article on Clinical Quality Measures in Obstetrics, the authors trace the limited results of numerous efforts to enhance the quality of obstetrical care, including the withdrawal of many indicators of quality once considered necessary. None of the indicators involved the response to FHR patterns. (2)

In attempting to glean wisdom and direction from these widely spaced communications, we offer comments here on the recent "Systematic Review" of the ACOG classification of FHR patterns during labor (Review) and its consequences for the outcome of babies, for the conduct of labor, and in the adjudication of allegations of obstetrical negligence when accountability for injury is sought. (3)

Electronic fetal monitoring (EFM) is the most common obstetrical procedure in the United States; it is used annually by upward of 3.8 million individuals in labor. (4, 5) The ubiquity of EFM ultimately boils down to the need to assess the ability of the fetus to tolerate the hypoxemic, ischemic, and mechanical stresses of labor imposed by loss of amniotic fluid, contractions, and maternal pushing, which may be superimposed on problems of the mother including infection, or problems intrinsic to the fetus or placenta. (6–9) There seems to be no reliable alternative to defining the wellbeing of the individual fetus given the limitations of both intermittent auscultation and newer modalities including fetal pulse oximetry and fetal ST-segment analysis. (10–12)

EFM is not without its limitations. These include significant intra- and interobserver variability (using current terminology) and increased operative deliveries. (13–15) Beyond this, there is widespread disagreement on both its value in terms of improved outcome, as well as the basic glossary of terms related not only to FHR patterns and uterine contractions but to definitions of the feasibility of safe vaginal delivery. (6, 16)

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The ubiquity and longevity of EFM notwithstanding, we are now engaged in a broad debate over the value of EFM, especially as it applies to the nomenclature, the management guidelines, and deliberations in courts and other tribunals. (17–22) In 1991, Freeman opined that EFM was a "modality that is difficult to learn, difficult to interpret. It has become a major factor in obstetrical litigation, where its inexact nature confuses attorneys and lay juries." (23) Beyond litigation, the interpretation of FHR patterns has continued to "befuddle obstetric care providers" as well. (24) Indeed, more than 50 years after its introduction, the level of befuddlement has contributed to calls for the technique to be abandoned clinically and in the courtroom. (20–22)

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The publication of the 3-tier (Category I–III) interpretive and management schema by the American College of Obstetricians & Gynecologists followed a consensus workshop. (25, 26, 6) It is difficult to argue now or then that the publication of these 3-tier guidelines by the ACOG in 2009 and 2010 would improve the problems associated with EFM, improve outcome statistics, or the sense of community on labor and delivery (26–29)

The Category System:

The review attempted to evaluate the rate of adverse neonatal or maternal outcomes in parturients at term according to FHR Categories I–III within 30 to 120 minutes of delivery. The authors reviewed 671 articles but accepted only three disparate, observational studies of term infants reporting outcomes of interest for their analysis. These three reports (two from the US, one from Italy) included 47,648 singletons at 37 weeks gestation: 27.0% of deliveries had CAT I tracings, 72.9% had CAT II tracings, and 0.1% had CAT III tracings. (30–32) It is troubling in several respects that one of the studies, thought by the authors to be of poor quality, contributed more than 80% of the data but had no CAT III tracings. (30)

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Adverse outcomes were based on ***either*** an Apgar score <7 at 5 minutes or umbilical artery pH (UApH) <7.00. Secondary outcomes included several neonatal and maternal outcomes considered adverse. The incidence of an Apgar score <7 at 5 minutes was significantly higher among CAT II deliveries (OR 1.56; 95% CI 1.23–1.99) than CAT III tracings (OR 14.46; 95% CI 2.77–75.39). The incidence of UApH <7.00 was similar among CAT I and CAT II tracings (0.08% vs 0.24%; OR 2.85; 95% CI 0.41–19.55) but was significantly more common with CAT III tracings (31.04%; OR 161.56; 95% CI 25.18–1036.42. Although the incidence was low, hypoxic-ischemic encephalopathy (HIE) occurred with a similar frequency with CATs I and II (0 vs 0.81%; OR 5.86; 95% CI 0.75–45.89) but was significantly more common among those with CAT III tracings (0 vs 18.97%; OR 61.43; 95% CI 7.49–503.50).

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Cesarean delivery occurred with similar frequency with CAT I (13.41%) and CAT II tracings (11.92%) (OR 0.87; 95% CI 0.72–1.05) but was significantly more common among those with CAT III tracings (14.28%) (OR 3.97; 95% CI 1.62–9.75). Unspoken in the presentation of the cesarean section data is the lack of discussion of the timing in the labor of the appearance of the abnormal pattern or its relationship and the feasibility of safe vaginal delivery. (33) Should the FHR abnormality deserving of intervention be found in the 1st stage of labor, vaginal delivery is either not an option or the duration of abnormality is prolonged in the effort to achieve vaginal delivery. In the 2nd stage of labor, operative vaginal delivery may be a reasonable option—avoiding a cesarean section, but again potentially increasing the exposure to a deteriorating FHR pattern.

In addition to those limitations mentioned above, the Category system offers no insight into the source of the abnormal tracing. Thus, decelerations related to maternal hypotension, excessive uterine activity, and fetal growth restriction are not differentiated from those related to impaired umbilical or cerebral blood flow or those related to maternal or fetal infection. The system does not acknowledge a pattern of neurological injury (34), although an ACOG monograph states that if a pattern goes from CAT I to CAT III and the fetus suffers a neurological injury, that injury may be ascribed to the events of labor and delivery. (35) The Category system offers no comments related to the response

(recovery) from the contraction-induced deceleration, likely the most important information to be gleaned in the analysis of FHR patterns. (36) Given these physiological limitations, there can be little surprise that efforts to ameliorate abnormal patterns appear to be of limited value in preventing adverse short- or long-term outcomes. (37, 38) There is an apparent lack of benefit to the increase in cesarean section rate. (5, 39, 25, 40)

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The limitations of the Category system notwithstanding, the authors justify their systematic review, arguing that no previous comprehensive review provides an extensive overview of the differences in the adverse neonatal-maternal outcomes among the different categories. Previous reviews of EFM in the context of intermittent auscultation, amnioinfusion, supplemental oxygen, tocolytics, or deceleration areas related to CAT II patterns do not satisfy these requirements. (41–45, 32)

The authors of the Review aver that they have addressed these shortcomings by including all non-anomalous singletons who reached 37 weeks' gestation with deliveries after labor across two different countries. In addition, they contacted the authors of the publications that met the inclusion criteria to obtain data on several secondary outcomes that were unavailable in the initial publications. The authors further claim that by linking the three categories with the incidence of a low Apgar score at 5 minutes and neonatal acidosis, the co-primary outcomes of the review, they achieve an objective assessment of fetal wellbeing. (46, 47)

These efforts notwithstanding, the frequency of the 3 Categories varied significantly among the studies. Overall, almost three-quarters of FHR patterns in labor were characterized as CAT II and only 0.1% were classified as CAT III. (see below). Some of the secondary adverse neonatal outcomes—treatment for sepsis, HIE, and death within 27 days of birth—increased significantly with increasing Category, but others (*e.g.*, ventilation for 6 hours and neonatal seizures) did not. The rate of cesarean delivery also varied among the three groups, but the rate of postpartum hemorrhage or transfusion did not vary significantly. The maternal characteristics, the proportion of complicated pregnancies, study design, the experience and familiarity with FHR patterns among the physicians and nurses who interpreted and responded to the FHR patterns, and the outcomes that were investigated and how they were defined were all varied across the three studies. In both reports from the United States, (30, 32) the FHR patterns were interpreted by registered nurses. None of the studies were randomized. The small number of cases in one of the included studies (31) and the heterogeneity in the definition of outcomes and some of the assigned categories represent significant limitations of the review.

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In addition, several secondary outcomes were assessed by using the outcomes of only one study. (32) Given the limitations of the data and the limited questions posed by the authors, they caution that the associations, despite their biological plausibility, do not establish causation. They conjecture that the considerable variation in the Categories in these studies resulted from plausible but indeterminable features, including (3):

1. the baseline maternal characteristics
2. antecedent risk factors associated with abnormalities in the FHRTs (e.g., oligohydramnios or intrauterine growth restriction)
3. the intrapartum management of abnormal fetal tracing (e.g., amnioinfusion or oxygen supplementation)
4. the intrapartum complications (e.g., chorioamnionitis or abruption),
5. the interobserver variability in FHRT interpretation

6. the threshold that prompted cesarean or operative vaginal delivery

The Category classification truncates the assessment of uterine activity and ignores the evolution of FHR patterns or uses the individual fetus as its physiological control. It imposes arbitrary definitions of tachycardia and bradycardia and downplays the information contained in the recovery of decelerations. There is no recognition of the importance of fetal behavior or the potential for the prospective identification of fetal neurological injury or intracranial hemorrhage. (34, 48) There is no attempt to evaluate the contraction frequency, strength, and duration linked with adverse outcomes. (44) Nor do they call attention to the need for a more comprehensive assessment of uterine activity than ACOG promulgating the term "tachysystole." Is a Category I pattern with tachysystole still Category I?

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As mentioned above, the CAT system is predicated on the presumed relationship between FHR features and UApH, not the relationship to Apgar score or long-term outcome. Consider this notion and numerous other studies considering Apgar score <7 at 5 minutes **or** UApH <7 as equivalent markers of adverse outcomes. (49) In such a calculus, babies with low Apgar scores but normal UApH values are considered equivalent to vigorous babies with very low UApH values. The risk of adverse outcomes in these two exemplars is quite different. The authors do not compare the Categories according to any combination of these outcome parameters.

Umbilical cord gases may be normal even with severe fetal compromise. When blood has not been flowing efficiently through the umbilical arteries because of occlusion of the umbilical cord or a drop in fetal blood pressure (heart failure), the blood gases of the umbilical arteries at birth may be normal despite the delivery of a lifeless baby. (50) The arterial gases at birth reflect the fetal status before the occlusion or the critical drop in blood pressure. In some instances, e.g., fetal stroke, birth trauma, or acute fetal hemorrhage, the injury may develop rapidly and not be reflected in umbilical cord gases.

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The Apgar scoring system was designed to identify infants who need immediate intervention, not as a tool to reflect or sort out fetal adversities. **Low** scores are never secondary to a metabolic, genetic or prenatal condition but rather reflect intrapartum events. Nevertheless, in defense of inappropriate labor and delivery management, prenatal or a yet unknown genetic disease is put forth in an attempt to defend poor intrapartum management. On the other hand, defense attorneys often use high Apgar scores to dismiss adverse intrapartum events. This is especially common in cases where the fetus experiences head trauma; with head trauma without systemic hypoxia and ischemia, babies will be quite vigorous at birth. Since the hypoxia and ischemia that are experienced in this scenario are regional (limited to the brain) and do not involve the cardiovascular system, the baby appears robust at birth; only hours or days later, as the cytotoxic edema develops, do they develop symptoms of poor feeding, apnea or seizures. Upon further evaluation, they are found to have subdural and retinal hemorrhages and, at times, major changes in head circumference. (51, 52)

The CAT II classification, officially, is "indeterminate;" the patterns satisfy neither the criteria of Categories I or III. This paradigm denies physiological and pedagogical insights. CAT II patterns represent disparate combinations of either decelerations with normal or abnormal baseline features without decelerations. The breadth of the physiological and pathological conditions may present with a CAT II tracing (cord compression, head compression, placental insufficiency, medication effects, prematurity, fetal sleep cycles, existing injury, anomaly, etc.). For example, a tracing with variable decelerations that recover promptly to a stable baseline rate and moderate variability (transient, tolerable cord or head compression) is in the same Category as a tracing with a baseline tachycardia with minimal variability, with absent decelerations (anomaly, drug effect, neurological injury, etc). It seems unreasonable to consider that the metabolic status or the tissue oxygen reserve of each CAT II fetus or the time to decompensation or recovery is the same in each instance. Thus, the presence of a "CAT II" pattern may reflect a normal, healthy, resilient fetus but excludes neither fetal acidosis nor neurological injury. (53–56, 29)

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Combining these disparate features and etiologies into a single classification and offering vague guidelines for their management, including "continued surveillance and reevaluation," (25, 17) appears to have created an unsatisfying "conundrum" for those providers trying to decide what the ubiquitous CAT II tracing means, how to respond, how to counsel patients and defend against the allegation of negligence when there is an adverse outcome. How does one teach, communicate, or use a management recommendation based on CAT II? Published approaches have proven successful. (57) The authors of the Review comment that the incidence of CAT III pattern in their study varies from zero to 9.9%, a differential unlikely to reflect a difference in patients or fetal condition. This improbable range of CAT III tracings is likely related to: 1) an understandable reluctance to identify CAT III tracings—a common problem in malpractice cases, or 2) the understandable confusion imposed by the requirement that CAT III patterns have "absent variability when the technology (using Doppler ultrasonic transducers) does not permit a reliable differentiation of absent and diminished variability. Similarly, tracing interpretation is significantly affected by fetal monitor chart speed concerning variability, accelerations, and decelerations. (58) Ultimately, there is no evidence that the distinction between decreased and absent variability is clinically meaningful; irrespective, it is considered a critical feature of the designation of CAT III.

A sub-analysis of the CAT III in 52 cases led the authors to conclude that the generalizability of the association between CAT III tracings and adverse neonatal outcomes is questionable. They are further unable to comment on whether intrauterine resuscitative measures for the prevention of the development of CAT III, including cesarean delivery done earlier, would reduce neonatal morbidity. (59) Nor could they exclude the Hawthorne effect (improved outcomes derived from clinicians' awareness that their performance was being observed) on the designation of the Category and the associated outcomes. (32, 60, 61)

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We understand that decelerations in the mature fetus represent impaired blood flow. It may represent impaired uteroplacental blood flow without direct impediment to fetal circulation or direct impairment of the umbilical or cerebral circulations. The deceleration, however, only points to the mechanism of the insult; the fetus' ability to deal with that insult is measured by the impact of the deceleration on the baseline rate and variability during the recovery. (36)

The most prominent missing data in the review is understanding the FHR tracing when the patient is admitted for surveillance. Because the three reports included in the analysis focused narrowly either on the last 30 or 120 minutes of labor, the authors could not comment on the FHR patterns before these periods. It is difficult to make sense of these statistics or understand the benefits of intervention without first knowing the Category of the tracing on admission and its evolution throughout labor, including the effect of pushing in the 2nd stage of labor. (62, 63) An adverse outcome with a Category III tracing is understandable. The adverse outcome is likely unpreventable if the tracing is Category III on admission. (64)

Let us set out to create a "perfect," physiologically understandable, teachable classification of FHR patterns. The most superficial

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assessment begins with the notion that tracings either show decelerations or not. In addition, they either have normal baseline features (a stable HR, in the normal range with normal variability) or not (unstable rate, bradycardia, tachycardia, altered variability). Thus, as a minimum, we have a 4-part classification. A fifth classification might be applied to the agonal pattern where, in addition to absent variability and unclassifiable decelerations, there is an unstable, falling baseline FHR. A sixth classification might be applied to fetal arrhythmias, which can sometimes be found. There would be no plausible physiological basis for a 3-tier classification in analyzing FHR responses to uterine contractions. Beginning with the minimum 4-tier classification, it becomes possible to assign pathophysiological explanations as we trace the evolution of patterns. It enables us to focus on restoring normal homeostasis or timely intervention rather than the need to satisfy some elusive level of fetal acidemia before injury has occurred.

If this scenario were "perfect," *the initially normal fetus* would reveal reliable evidence of early compromise, corrective measures would be undertaken promptly, and the fetus would either return to homeostasis or be delivered expeditiously unharmed. If such a system existed, there would be no relationship between evidence of compromise and the outcome because all preventable adverse outcomes were indeed prevented by timely intervention. On the other hand, if the test were worthless, with no correlation between the test results and the outcome, there would again be no relationship between the indicators of distress and the outcome.

The finding of a significant correlation between certain surveillance features and adverse outcomes provides information that the test is not "perfect," as defined above. Under the circumstances where the normal fetus starts with a reassuring pattern (Category I) that evolves to a certain Category II or III tracing and an adverse outcome, in most instances, this often represents a clinical failure—the failure to timely interrupt the deleterious effects of contractions, or pushing, or alteration in the maternal condition. This may develop because the signs were not acted on promptly, or the trajectory of deterioration was not appreciated. There is no evidence that FHR patterns during labor will fail to detect abnormalities in the availability of oxygen or impediments to the heart or brain perfusion early, before the appearance of acidemia. In the rare case, the injury (stroke) in the form of the sudden, unpredictable transition from CAT I to CAT III may occur so quickly as to preclude timely intervention, even with assiduous care. (34)

Why has EFM failed to live up to its expectations? (61, 62) Part of the answer seems to lie in the promulgation of the Category system, a system that permits "allowable" acidosis to develop before responding, in the hopes that the response is sufficiently timely to avoid injury when we do not know the trajectory of deterioration.

Rigorous studies did not accompany the introduction of the FHR CAT system. A greater deficiency was the failure to understand the provenance of intrapartum fetal injury based on the assessment of both immediate and long-term outcomes, not just injury associated with a very low pH. Although ACOG guidelines accept the evolution of CAT I to CAT III as confirmation of an intrapartum injury, most babies injured during labor had CAT II, not CAT III FHR patterns. (54) The majority of these are not acidemic at birth. The measurement of UApH is simple to obtain. We fall back on it as a measure of outcome because no measurements of greater relevance, such as fetal blood pressure or cerebral perfusion, are available. FHR patterns, correctly interpreted, provide information about these parameters. (67)

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However, if the test of EFM's value rests with the correlation with pH or base deficit (BD) at the time of birth and not with meaningful immediate (requirements for resuscitation, etc) and long-term outcome (cerebral palsy, seizures, ASD, etc), then the wrong question is being asked. On the other hand, if EFM has no preventive value except to increase the cesarean section rate, what can be the justification for EFM or intermittent auscultation?

We must remove the notion of waiting for presumed acidosis before intervention. The monitor should be used as an instrument of preventive care rather than one geared to rescuing the fetus from a hostile, presumably acidemic environment. (68) Intervention

based on the provenance of the alterations must begin earlier with the expectation of converting the CAT II to a CAT I tracing. (24) In this recommendation, ensuring adequate fetal reserve at the outset of monitoring is essential. Additional measures include the avoidance of excessive uterine activity with the informed use of oxytocin, irrespective of FHR pattern, and titrating the use of the mother's expulsive efforts according to the response of the fetus. These should be considered as primary instruments to prevent or improve abnormal FHR patterns and minimize the need for urgent intervention. Interestingly, the need for urgent intervention in a patient undergoing a trial of labor is not a measure of the quality of obstetrical care in any of the monitored indicators of obstetrical quality. (69)

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It would seem that these modest initiatives must be taken early, and their trajectory assessed with each contraction. Withholding intervention until the pattern reaches CAT III determines fetal acidemia is more important than a normal fetal outcome. The fact that most CAT III tracings are not acidotic is irrelevant. The pattern reflects a lack of fetal homeostasis from which the fetus does indeed deserve rescue.

The review's authors concluded that "although the incidence of an Apgar score <7 at 5 minutes and umbilical artery pH <7.00 increased significantly with increasing FHR CAT, about 98% of newborns with CAT II tracings do not have ***these*** adverse outcomes. This argument, presumably to sustain the use of the Category system, parallels an argument to tolerate prolonged pushing in the 2nd stage of labor despite the increased risks of seizures and HIE (70). This raises another issue potentially impacting the interpretation of the data: the relationship of outcome to the duration of any abnormal FHR pattern. A European, multicenter, randomized controlled trial study compared the effects of "moderate" versus "intensive" pushing in ***nulliparas*** in the 2nd stage of labor with an epidural and a "normal" FHR pattern. Irrespective of the outcome of the study, the standard of care required that the *midwife* call an obstetrician ***after 30 minutes of pushing*** to discuss operative delivery (71)

It can come as no surprise that the review ultimately concludes that the 3-tiered FHR tracing interpretation system provides "***an approximate, but imprecise,*** measurement of neonatal prognosis." In addition to the limited, if any, according to some, benefit of this classification of FHR patterns on outcome statistics and its apparent impact on the induction of an increased rate of cesarean sections discussed above, we must consider the impact on the allegation of malpractice based on the interpretation of the EFM tracing. This ubiquitous concern appears in many articles on EFM and in the majority of medico-legal allegations of preventable fetal injury worldwide. (72, 73) Finding FHR Categories "approximate, but imprecise" potentially undermines their probative evidence in the courtroom, a benefit to the defense—at the expense of understanding accountability for the preventability of fetal harm.

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Why have the authors of the review not called for the abandonment of this flawed, unphysiological approach to fetal surveillance? We seem to have been "befuddled" for way too long; we need to make better use and stronger inferences from the data that we do have. There seems to be no better way to reduce allegations of negligence than to improve outcomes.

Keywords: EFM, Classification of FHR patterns, fetal distress,

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