OBSTETRICS

Intrapartum management of category II fetal heart rate tracings: towards standardization of care

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There is currently no standard national approach to the management of category II fetal heart rate (FHR) patterns, yet such patterns occur in the majority of fetuses in labor. Under such circumstances, it would be difficult to demonstrate the clinical efficacy of FHR monitoring even if this technique had immense intrinsic value, since there has never been a standard hypothesis to test dealing with interpretation and management of these abnormal patterns. We present an algorithm for the management of category II FHR patterns that reflects a synthesis of available evidence and current scientific thought. Use of this algorithm represents one way for the clinician to comply with the standard of care, and may enhance our overall ability to define the benefits of intrapartum FHR monitoring.

Key words: fetal heart rate monitoring, neonatal encephalopathy, patient safety

Interpretation and management of fetal heart rate (FHR) patterns during labor remains one of the most problematic issues in obstetrics. Multiple basic science investigations and clinical trials have been published since the introduction of this technique in the late 1950s.[1-7] Unfortunately, this body of work has primarily served to raise more questions than it has answered—as a medical community, we seem to know less than we thought we did 30 years ago regarding the utility of this ubiquitous technique.

In recent years, several specific issues relating to the interpretation and management of FHR patterns have received considerable attention in the medical literature. These include the lack of agreement in interpretation even among recognized experts, the role of FHR patterns as a primary driver of a rising cesarean rate, and the explosion of litigation involving FHR patterns, despite the consistent absence of scientific evidence to support the contention that intervention based on any single FHR pattern or combination of FHR patterns in fact prevents cerebral palsy or other types of neurologic impairment.[8-12]

Against this background, however, there remains in many of us suspicion (albeit based primarily upon anecdotal experience and the original basic science investigations) that at least a portion of the conflicting evidence regarding the clinical utility of intrapartum FHR monitoring results from ad hoc interpretation of terminology, and the lack of standardized protocols for management and intervention based on what are often challenging patterns. In a very real sense, the FHR monitor is a medical device that was introduced into clinical practice without an instruction manual, without the now common premarket testing to support the unrealistic expectations of efficacy, and without clearly defined parameters for use. Under such circumstances, it would be difficult to demonstrate clinical efficacy even of a device with immense intrinsic value, since there has never been a standard hypothesis to test dealing with interpretation and management of abnormal patterns. With respect to the assessment of the clinical value of FHR monitoring, an evolving consensus exists in the maternal-fetal medicine community that it is time to start over and establish some common language, standard interpretation, and reasonable management principles and guidelines.[13-19]

A *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) consensus panel in 2008 proposed a uniform system of terminology in which any FHR pattern is classified as category I, II, or III, based on the presence or absence of well-defined aspects of the FHR.[20] Once universally adopted in clinical practice, these

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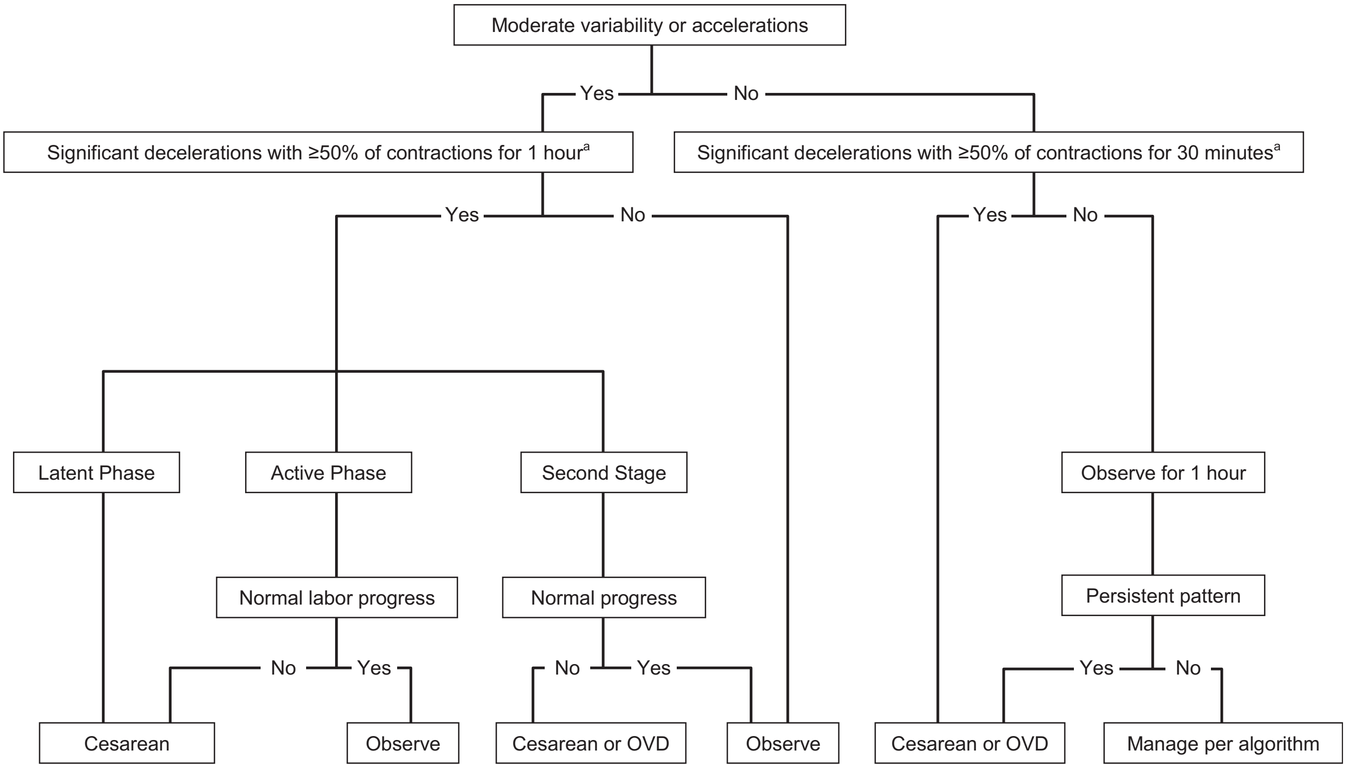
FIGURE 1
Algorithm for management of category II fetal heart rate tracings



OVD, operative vaginal delivery.

[a]That have not resolved with appropriate conservative corrective measures, which may include supplemental oxygen, maternal position changes, intravenous fluid administration, correction of hypotension, reduction or discontinuation of uterine stimulation, administration of uterine relaxant, amnioinfusion, and/or changes in second stage breathing and pushing techniques.

Clark. Category II FHRT. Am J Obstet Gynecol 2013.

definitions should serve as an important first step in both the investigation of the significance of various FHR patterns, and the development of a uniform standard of care in the interpretation and management of such patterns. With this in mind, subsequent recommendations have been developed by the American Congress of Obstetricians and Gynecologists (ACOG) for the management of category I (normal) and category III (pathologically abnormal) FHR patterns.[20,21] Although useful, these recommendations remain insufficient since ≥80% of fetuses in labor demonstrate FHR patterns that fall into category II, patterns for which no specific ACOG management recommendations exist.[21,22]

The management of category II FHR patterns remains the most important and challenging issue in the field of FHR monitoring, and is arguably second only to preterm birth as the most pressing issue in clinical obstetrics. In addition, the overall cesarean delivery rate exceeded 32% in the United States in 2011, and exceeds 50% of all births in some US hospitals.[23] While dystocia and prior cesarean delivery remain the leading indicators for such surgical intervention, the presence of a category II or III FHR in labor is a frequent indication as well.[11,24] For cesarean deliveries, there is a wide variance in the reported indications and their frequency, both between hospitals and among members of the medical staff practicing obstetrics.[24] Concern regarding FHR patterns is perhaps the indication that has the greatest such variance; we believe this observation is directly related to the absence of defined management protocols for category II patterns.

Accordingly, we present a suggested algorithm for the management of category II FHR patterns (Figure 1) along with several important specific clarifications (Table). As outlined in Figure 1, it is reasonable to initiate management of a category II FHR pattern with an assessment of variability and accelerations, thus allowing the clinician to immediately rule out the presence of clinically significant metabolic acidemia. For nonacidemic fetuses, the focus then shifts to assessing the likelihood of developing significant acidemia prior to delivery. While no algorithm can predict all cases of sudden deterioration due to sentinel events, even with category I FHR patterns, analysis of the frequency and nature of decelerations and the progress in labor provides the clinician with a reasonable approach to such decision making (Figure 1).

With category II FHR tracings that do not exhibit moderate variability or

TABLE

Management of category II fetal heart rate patterns: clarifications for use in algorithm

1. Variability refers to predominant baseline FHR pattern (marked, moderate, minimal, absent) during a 30-minute evaluation period, as defined by NICHD.
2. Marked variability is considered same as moderate variability for purposes of this algorithm.
3. Significant decelerations are defined as any of the following:
   - Variable decelerations lasting longer than 60 seconds and reaching a nadir more than 60 bpm below baseline.
   - Variable decelerations lasting longer than 60 seconds and reaching a nadir less than 60 bpm regardless of the baseline.
   - Any late decelerations of any depth.
   - Any prolonged deceleration, as defined by the NICHD. Due to the broad heterogeneity inherent in this definition, identification of a prolonged deceleration should prompt discontinuation of the algorithm until the deceleration is resolved.
4. Application of algorithm may be initially delayed for up to 30 minutes while attempts are made to alleviate category II pattern with conservative therapeutic interventions (eg, correction of hypotension, position change, amnioinfusion, tocolysis, reduction or discontinuation of oxytocin).
5. Once a category II FHR pattern is identified, FHR is evaluated and algorithm applied every 30 minutes.
6. Any significant change in FHR parameters should result in reapplication of algorithm.
7. For category II FHR patterns in which algorithm suggests delivery is indicated, such delivery should ideally be initiated within 30 minutes of decision for cesarean.
8. If at any time tracing reverts to category I status, or deteriorates for even a short time to category III status, the algorithm no longer applies. However, algorithm should be reinstituted if category I pattern again reverts to category II.
9. In fetus with extreme prematurity, neither significance of certain FHR patterns of concern in more mature fetus (eg, minimal variability) or ability of such fetuses to tolerate intrapartum events leading to certain types of category II patterns are well defined. This algorithm is not intended as guide to management of fetus with extreme prematurity.
10. Algorithm may be overridden at any time if, after evaluation of patient, physician believes it is in best interest of the fetus to intervene sooner.

FHR, fetal heart rate; *NICHD*, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development.

Clark. Category II FHRT. Am J Obstet Gynecol 2013.

accelerations, but do exhibit patterns of persistent late or significant variable decelerations, as defined in the Table, significant metabolic acidemia cannot be excluded. Further, these deceleration patterns signify the presence of physiologic stresses that increase the risk of developing such acidemia. In such cases, we recommend expeditious delivery. Examples of the application of this algorithm are demonstrated in Figures 2-5. These examples assume that the 20-minute period shown in the figures is representative of the 30-60 minute observation period referred to in the algorithm. Should the pattern either improve or deteriorate during this time frame, management should be changed accordingly.

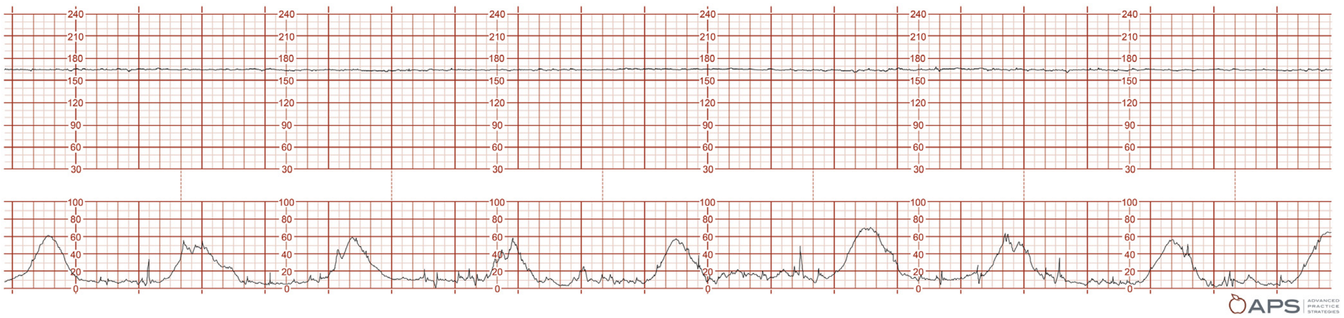
In assessing and implementing this algorithm, we wish to bring specific attention to a number of considerations which we consider to be particularly germane.

1. This algorithm follows the foundational NICHD definitions and recommendations.[20,21]
2. This algorithm should be understood as a next step in the development of management recommendations for category II FHR patterns. The effectiveness and associated intervention rates of this algorithm may be further defined and refined in future studies.
3. Category II patterns identify fetuses that may potentially be in some degree of jeopardy but are either not acidemic, or have not yet developed a degree of hypoxia/acidemia that would result in neonatal encephalopathy.[12,20,21] However, we believe one important goal of intrapartum care is delivery of the fetus, when possible, *prior to* the development of damaging degrees of hypoxia/acidemia. We offer this algorithm to assist the attending physician in accomplishing this goal. We recognize that adherence to the algorithm cannot alter the course for an already injured fetus, or one that experiences an unexpected catastrophic event during labor.

   However, since any algorithm for the management of category II patterns will apply to the majority of fetuses during labor, the algorithm must also avoid unnecessary intervention, and encourage vaginal delivery in women whose FHR patterns suggest minimal risk of significant deterioration prior to delivery. We designed this algorithm with both goals in mind, but with a primary focus on the avoidance of preventable injury.
4. The appropriateness of select conservative attempts to relieve certain category II patterns is well established.[25-29] However, valid scientific evidence affirming the effectiveness of such measures varies widely. For example, while amnioinfusion for relief of oligohydramnios-associated variable decelerations is well supported in the literature, no evidence exists to support the efficacy of maternal oxygen administration in commonly achievable concentrations in increasing fetal tissue oxygenation, or in improving newborn outcomes regardless of oxygen concentration.[28,29] Nevertheless, any of the commonly accepted approaches to relief of abnormal FHR patterns may be appropriately

FIGURE 2

Tracing exhibits minimal to absent variability without decelerations, despite regular contractions



Medication effect has been excluded clinically as part of the initial period of intrauterine resuscitation attempts. While the fetus may have experienced prelabor central nervous system injury, absence of late decelerations excludes ongoing hypoxia in a neurologically intact fetus. However, since such fetuses may not tolerate labor without sudden deterioration and demise, cesarean delivery would be appropriate, per algorithm, if pattern persists for 1 hour.

Clark. Category II FHRT. Am J Obstet Gynecol 2013.

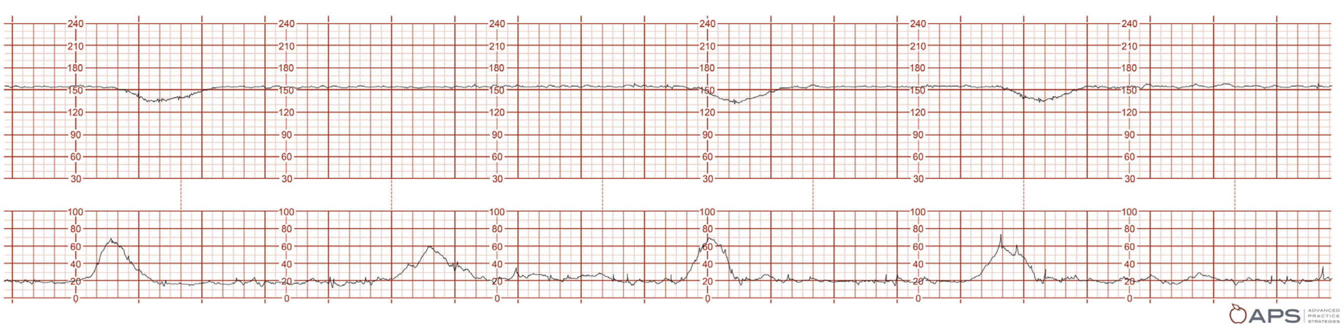
attempted in specific situations. Their effect should be apparent within 30 minutes of application (Figure 1). If the FHR tracing remains category II following these efforts, the algorithm is applied to the pattern observed following these attempts at therapeutic intervention.

Attention should be given to the prompt elimination of excessive uterine activity including tachysystole or prolonged contractions, especially when uterine stimulants (oxytocin or prostaglandin-containing agents) are being applied.[30,31] Oxytocin infusion should be reduced or discontinued in the presence of excessive uterine activity and a persistent category II FHR pattern.[21] Acceptable approaches to monitoring of uterine activity are well described in available literature.[30,31]

5. Recent data suggest that no single quantitative value of fetal arterial pH serves to define a point of hypoxia-induced damage applicable to all fetuses.[32] However, the literature is consistent in its demonstration that for any individual fetus, baseline variability and accelerations will reliably be depressed before the pH has reached a level of acidemia associated with neurologic injury for that fetus, regardless of its quantitative value.[33,34] Hence this algorithm relies strongly on the presence of moderate baseline variability or accelerations. In contrast, conflicting data exist regarding the significance of variability within deceleration nadirs.[35,36] Variability within decelerations alone cannot be reliably used to exclude fetal acidemia and accordingly is not addressed in this algorithm.
6. FHR patterns cannot be interpreted in isolation. Accordingly, we have incorporated labor progress as described in traditional terms (stage I latent phase, stage I active phase and second stage) into this algorithm. This is of significance since the expected remaining length of labor may influence

FIGURE 3

Tracing exhibits minimal to absent variability and late decelerations occurring with >50% of contractions

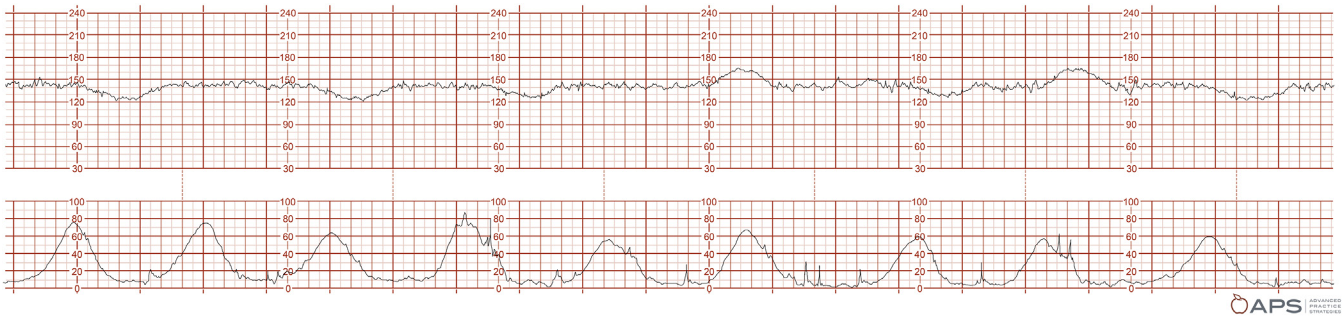


Per algorithm, expedited delivery is indicated regardless of labor progress.

Clark. Category II FHRT. Am J Obstet Gynecol 2013.

FIGURE 4

Tracing exhibits moderate variability and accelerations, thus excluding clinically significant acidemia



Late decelerations represent protective cardiovascular response to contraction-induced reductions in fetal oxygenation. Per algorithm, if labor is progressing normally in active phase or second stage, careful observation would be appropriate. If the fetus is remote from delivery, delivery would be appropriate.

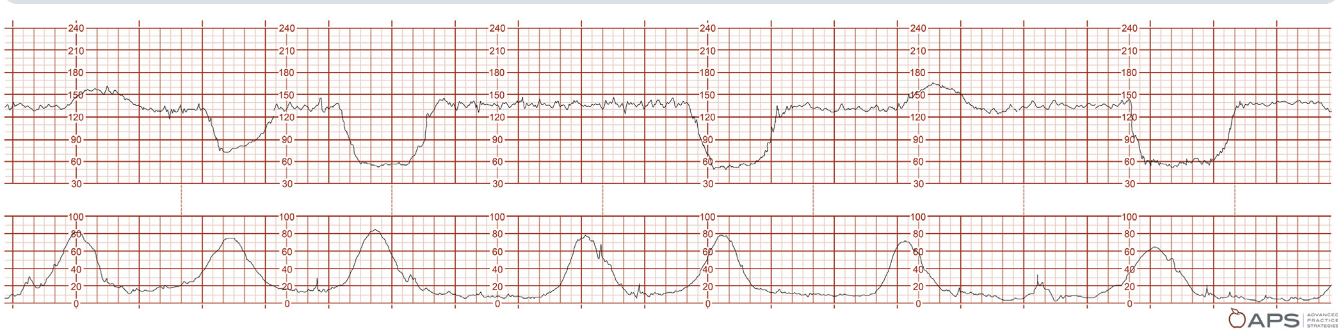
Clark. Category II FHRT. Am J Obstet Gynecol 2013.

the likelihood of, and response to, deterioration of category II patterns. A category II pattern may have a different indicated management when presenting in early first-stage labor than an identical pattern presenting in the late second stage. We acknowledge recent data suggesting that cesarean delivery based on classic definitions of protracted active phase, arrest of dilatation, or arrest of second-stage descent alone may not be necessary, and that longer periods of observation may yield lower intervention rates.[10,37] However, data demonstrating the safety of these more conservative approaches in the presence of persistent category II FHR patterns are lacking. For example, we hesitate to recommend nonintervention for an arrest of active phase dilatation of 4 hours in the presence of recurrent late decelerations, even in the presence of moderate variability. The superb reliability of accelerations and moderate variability in excluding any degree of hypoxia-related central nervous system depression or risk of ongoing hypoxic injury would allow observation of patterns with these features and adequate labor progress regardless of the deceleration pattern (Figure 1). However, intervention in patients with certain category II patterns and slow, but technically adequate labor progression may also be an appropriate option.

7. Some well-defined features of category II patterns (eg, fetal tachycardia or marked variability) are not included in the algorithm-based decision tree for intervention. This does not signify that such patterns are innocuous—indeed, it may be exactly these features of a tracing that mandate consideration as a category II pattern, and the use of this algorithm. However, in such

FIGURE 5

Tracing exhibits moderate variability and acceleration, thus excluding clinically significant acidemia



Significant variable decelerations seen here suggest umbilical cord compression during contraction, which could, over time, lead to significant acidemia. Per algorithm, if labor is progressing normally in active phase or second stage, careful observation would be appropriate. If the fetus is remote from delivery, delivery would be appropriate.

Clark. Category II FHRT. Am J Obstet Gynecol 2013.

cases, it is our expectation that other concerning patterns included in the algorithm will appear prior to the need for intervention.

8. This algorithm is intended to address the challenge of progressive intrapartum hypoxia/acidemia due to the effects of labor contractions on a susceptible fetus. Neither this, nor any other management approach to labor, will ever predict, or prevent, unexpected sentinel events that may occur without warning and rapidly change a FHR pattern from category II to category III. In such situations, even the most expeditious response may be insufficient to avoid neonatal encephalopathy and its sequelae.[38,39] However, 2 clinical situations exist in which category II patterns, while excluding ongoing hypoxia/acidemia, may be harbingers of sentinel events that may rapidly lead to profound hypoxia. These conditions are vaginal bleeding sufficient to suggest possible placental abruption, and any woman undergoing a trial of labor after a previous cesarean.[40-42] In both cases, this algorithm does not apply, as expeditious cesarean delivery is often indicated based on the sudden appearance of decelerations in a context (moderate variability and accelerations) that would be otherwise reassuring.
9. This algorithm does not address the issue of prolonged deceleration, as defined by the NICHD. This definition is too broad to be clinically useful in isolation.[20,21] A 121-second deceleration to 90 beats/min and a 9-minute and 59-second deceleration to 50 beats/min are, from a clinical standpoint, very different, yet both are, by definition, prolonged decelerations. The situations associated with prolonged decelerations also greatly impact the decision making—a prolonged deceleration following an epidural should give rise to a completely different set of management considerations than an identical pattern in a woman laboring with a scarred uterus.[40,42,43] Such variations are legion and cannot be adequately addressed with a single algorithm—indeed, their rarity and physiologic heterogeneity probably preclude meaningful study as a group. We can only comment that tolerance for such recurrent patterns remote from delivery ought to be small unless the etiology is apparent and can be promptly ameliorated.
10. The current NICHD classification system uses the classic descriptions of deceleration patterns initially developed by Kulbi and colleagues.[1] However, because different types of decelerations have unique etiologies, a given fetus may have >1 pathologic process ongoing during labor. One example would be a growth-restricted fetus with oligohydramnios demonstrating both variable decelerations secondary to cord compression and late decelerations due to hypoxia during contractions based on uteroplacental insufficiency. This may give rise to a less well-defined, hybrid pattern of decelerations—for example, late decelerations superimposed upon variable decelerations. Because relatively benign variable decelerations are visually more dramatic than the subtle, yet more concerning, late decelerations, the latter may be easily overlooked. In such cases, the patient should be managed with a focus on the late, rather than the variable decelerations. Such hybrid deceleration patterns differ from the more commonly seen "atypical" variable decelerations that have no correlation with fetal acidemia.[35] It is important for clinicians to carefully evaluate any atypical-appearing variable decelerations in this light.
11. The algorithm presented authorizes judgment in some situations between cesarean delivery and operative vaginal delivery. We wish to emphasize that operative vaginal delivery is not universally applicable, but rather depends on the patient meeting appropriate criteria for vacuum or forceps, as well as operator expertise in use of these techniques.[44,45] Because delivery based on this algorithm will be principally driven by concern for fetal well-being, and because variable levels of expertise in operative vaginal delivery exist among practitioners, we anticipate that cesarean delivery will be the most common procedure elected in many situations. In contrast to some types of category III tracings in which the urgency of intervention may occasionally justify acceptance of some degree of risk for trauma, the vast majority of category II tracings in which delivery is indicated only warrant initiation of delivery within 30 minutes of the decision for delivery. A limited attempt at operative vaginal delivery by an experienced clinician may represent optimal care in some circumstances. However, the physician with limited experience in operative vaginal delivery should not delay preparations for cesarean, nor persist in attempts at operative vaginal delivery without progressive descent with each contraction. Without real expertise in operative vaginal delivery, a deteriorating category II FHRT will often be best managed by prompt cesarean delivery.
12. The most vexing issue in the development of this algorithm was the issue of decreased vs absent variability. We accept the accuracy of data concluding that FHR variability must be absent to reliably reflect a high degree of correlation with severe fetal acidemia.[20,21] However, we caution against delaying delivery of a deteriorating FHR pattern because criteria indicating probable severe metabolic acidemia have not yet been met. We have chosen to treat persistent minimal and absent variability as one for the following reasons.
    a. Variability cannot be considered to be a strictly binary feature of a FHR pattern. It is evident that a fetus with moderate variability (thus excluding concurrent fetal metabolic acidemia)

that devolves to a state of frank asphyxia and severe metabolic academia with absent variability as a result of episodes of intrapartum hypoxia must first pass through a stage of minimal variability, unless the deterioration is abrupt and catastrophic as seen in a sentinel event.

b. While it is possible for apparent variability to be exaggerated with the use of a first-generation external, ultrasound-based heart rate monitoring device, autocorrelation techniques employed with most current monitoring systems have minimized this tendency.[46] Unfortunately erratic signal detection or transient artifact may give rise to periods of apparent "minimal variability" that could be falsely reassuring to some clinicians and lead to delay in delivery. If technically feasible, the fetus with a category II pattern and poor FHR signal quality should be monitored with a fetal scalp electrode.

c. An external FHR monitor that yields a consistent high-quality tracing, or a continuous fetal scalp lead tracing, will generally allow the qualified clinician to distinguish different degrees of variability, even in the presence of classic late or variable decelerations. Unfortunately, such a determination may be rendered more difficult by many of the category II patterns actually encountered in clinical practice. Such difficulties are especially common in the presence of atypical variable decelerations, in which determination of return to baseline may be difficult. In such cases, a "baseline" apparently exhibiting some degree of variability may in fact still be a part of a recovering deceleration.

With exceptional expertise, most of these situations can be appropriately delineated. However, that level of expertise is not universal among practicing obstetricians. Indeed, even among recognized experts there is significant interobserver variation in the differentiation of FHR patterns with minimal vs absent variability.[9] A basic principle of any safety protocol is the direction of such guidelines to the least, not the greatest expected level of user competence. Thus, we have used *moderate* rather than *moderate or minimal* variability as a defining reassuring feature of our algorithm. While we acknowledge that such a decision will lead to intervention in cases that, in hindsight, might be proven to be unnecessary, we believe that following the algorithm as written will avoid preventable neurologic injury due to lack of intervention for a category II FHR pattern, and will be associated with an appropriate intervention rate. Cases of fetal hypoxia/acidemia during labor due to unexpected sentinel events remain largely unpreventable.[38,39]

13. A fetus presenting with persistent minimal to absent FHR variability and absent accelerations but without significant decelerations poses a significant diagnostic and management dilemma. In many of these cases, such a pattern represents preexisting central nervous system injury with marked metabolic acidemia. In other cases, intrauterine events leading to the injury may have resolved (eg, umbilical cord compression) and the fetus will have recovered metabolically, but not neurologically. Developmental anomalies unrelated to hypoxia/acidemia may give rise to a similar picture. Although the benefit of cesarean delivery in improving neurologic outcome in such fetuses has never been demonstrated, these fetuses may be less likely to tolerate the additional hypoxia and acidemia that accompanies even normal labor without intrapartum demise. In the absence of significant decelerations however, the clinician may be assured that while the fetus may *be* damaged, it is not *being* damaged. Under these circumstances, a limited period of observation is appropriate, and is embraced in the algorithm.

14. The algorithm presented here represents a consensus of the best thoughts of 18 authors regarding one reasonable approach to category II FHR patterns given our present scientific understanding. All authors are highly experienced clinicians with significant peer-reviewed research experience and publications in the area of fetal evaluation. They also represent a broad geographic spectrum and experience in both the academic and private practice worlds and represent the disciplines of medicine, nursing, and midwifery. As such, it is reasonable for clinicians to utilize this algorithm in the management of category II FHR patterns; compliance with this protocol is one way to meet the standard of care in the United States. Importantly, as with most other areas of medicine, the establishment of this algorithm as *one* way to comply with the standard of care does not exclude the existence of other equally acceptable approaches. While the authors uniformly agree on the appropriateness of this model for any laboring patient, each of us can think of numerous situations in which alternative approaches to any branch of the algorithm would be equally acceptable.

15. This algorithm is supported by available clinical experience, a substantial body of basic science evidence, and indirect clinical data. Given the current state of obstetric knowledge, we do not believe it is possible to *simultaneously* eliminate preventable fetal neurologic injury and significantly reduce the cesarean delivery rate for abnormal FHR patterns—several decades of such attempts have resulted in the current state of Brownian motion in which neither goal has been measurably achieved. Our goal in developing this algorithm has been to fix one variable in this equation by presenting an algorithm, which if

implemented as one component of good obstetrical care, will assist the clinician in avoiding preventable intrapartum fetal hypoxia, metabolic acidemia, and hypoxic injury based on failure to deliver in the face of certain persistent category II FHR patterns. Of course, as with any set of recommendations, clinical studies directly applying this algorithm both retrospectively to large series of category II patterns, and prospectively to large populations, are needed to potentially improve the efficacy of the algorithm, and to better ascertain the actual intervention rate associated with its application. It is anticipated that such studies may facilitate refinement of this basic algorithm to reduce the intervention rate without incurring preventable morbidity or mortality.

16. We make no claim of the superiority of this algorithm over other approaches that might have been developed. We began with the premise that standardization and simplification of critical care processes are fundamental principles of patient safety. In virtually any human endeavor, particularly one that relies on the performance of multiple team members in an effort to achieve an optimal result, standardization will yield improved results.[47-50] As such, unless one ideal approach to care has been demonstrated to be superior to all others by virtue of well-performed clinical trials, it is not necessary to demonstrate the superiority of one specific approach over others that are, when considered individually, likely to be equivalent. Rather, the adoption by the clinical care team of one appropriate specific management plan will, by virtue of standardization alone, yield results superior to those achieved by random application of several individually equivalent approaches. This is particularly true at the facility level.[47-50] For example, protocols used to guide the provision of cardiopulmonary resuscitation have not been demonstrated to be superior to all others in randomized clinical trials.[51] Yet the near universal adoption of these standard approaches has resulted in improved outcomes for cardiac arrest patients. Such algorithms have, over time, also undergone modification due to advances in clinical understanding based on new data. It is also important to note that in this instance, our algorithm does not seek to replace any established methodical approach to the management of category II patterns. Rather, we suggest that this algorithm will be helpful in the current clinical setting in the United States in which a lack of clear direction has led to divergent decision making regarding cesarean section for FHR abnormalities.[24]

Adoption of this algorithm for the management of category II FHR patterns by the clinician is one approach to achieving compliance with the current standard of care. Application of the algorithm, along with the integration of future evidence-based modifications driven by additional research, will provide clinicians with a standardized, simple, rational, evidence-based, and nationally accepted approach to the management of category II FHR patterns. ■

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The MEDLINE database, the Cochrane Library, and ACOG's own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and January 2009. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician–gynecologists were used.

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- I Evidence obtained from at least one properly designed randomized controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A—Recommendations are based on good and consistent scientific evidence.

Level B—Recommendations are based on limited or inconsistent scientific evidence.

Level C—Recommendations are based primarily on consensus and expert opinion.

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