PATIENT SAFETY SERIES

Electronic fetal heart rate monitoring: applying principles of patient safety

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In 1999, a highly publicized report from the Institute of Medicine identified major deficiencies in the United States health care system, which fueled the rapid growth of the modern patient safety movement. One of the greatest risks to patient safety in obstetrics is poor communication of electronic fetal heart rate monitoring findings. Standardization and elimination of unnecessary complexity are 2 of the cornerstones of improved patient safety. This article describes a standardized, simplified approach to the definition, interpretation, and management of electronic fetal heart rate monitoring that is evidence-based and reflects consensus in the literature.

Key words: electronic fetal heart rate monitoring, interpretation, management, patient safety, standardization

ore than 10 years ago, the Institute of Medicine Committee on Quality of Health Care in America identified standardization as an essential element of effective patient safety initiatives. A growing body of scientific evidence suggests that standardization and elimination of unnecessary complexity can yield statistically significant reductions in adverse outcomes and decrease malpractice claims.^{2,3} Electronic fetal heart rate monitoring (EFM) is only one of many issues to com-

pete for the attention of busy obstetric care providers, yet it consumes a disproportionate amount of time and energy. As one of the most common procedures in obstetrics, EFM has the potential to influence the incidence of preventable life-long brain damage or death. Consequently, it is a common focus for litigation and an obvious choice for standardization and process simplification.

Over the last decade, a number of publications have evaluated and summarized the best available evidence regarding the capabilities and limitations of the technology. 4-12 Together, these publications provide consensus and make it possible to create a multidisciplinary approach to EFM that eliminates unnecessary complexity and minimizes preventable error.

The primary goal of obstetric care is to optimize outcomes for the mother and the newborn infant. An important secondary goal is to minimize medical and legal risks. Both goals require clinicians to practice according to the standard of care, which is defined as care that is reasonable. Reasonableness requires factual accuracy and the ability to articulate a rational plan. This article addresses factual accuracy by encouraging the systematic use of standardized fetal heart rate (FHR) definitions and simplified, evidence-based interpretation. In addition, it provides a simple framework for clinicians at all levels of experience to articulate a rational plan of management. A simpli-

fied, standardized approach to EFM begins by deconstructing it into 3 components: definition, interpretation, and management.

Standardized definitions

In 1997, the National Institute of Child Health and Human Development (NICHD) Research Planning Workshop proposed standardized, unambiguous definitions for FHR tracings that subsequently were endorsed by the American College of Obstetricians and Gynecologists (ACOG), the Association of Women's Health, Obstetric and Neonatal Nurses, and the American College of Nurse Midwives.4,7-9 In 2008, a second NICHD Research Planning Workshop reaffirmed the original definitions, which are summarized in Table 1, and introduced standard nomenclature for normal and abnormal uterine contraction frequency. 10 Normal contraction frequency was defined as ≤5 contractions in a 10-minute window, averaged over 30 minutes. Contraction frequency in excess of this threshold is termed tachysystole. Although the clinical response may differ, these definitions apply to both spontaneous and stimulated contractions. The terms *hyperstimulation* and *hypercon*tractility are defined inconsistently in the literature. Therefore, the consensus report recommended that the terms be abandoned. In the management model given in this article, uterine activity is evaluated and managed in relation to FHR changes as part of clinical assessment of the oxygen pathway. The NICHD Workshop also recommended classifying FHR tracings as category I, II, or III according to the criteria that are summarized in Table 2. Defining FHR patterns accurately and consistently with standardized nomenclature helps to ensure factual accuracy, an essential element of reasonableness, and the standard of care.

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Standardized interpretation

Intrapartum EFM is intended to assess the adequacy of fetal oxygenation during labor. Fetal oxygenation involves the transfer of oxygen from the environment to the fetus and

Pattern	Definition				
Baseline	The mean FHR rounded to increments of 5 beats/min during a 10 min segment, excluding accelerations, decelerations and periods of marked FHR variability The baseline must be for a minimum of 2 min (not necessarily contiguous) in any 10-min segment, or the baseline for that segment is defined as "indeterminate"				
Tachycardia	Baseline FHR >160 beats per min				
Bradycardia	Baseline FHR <110 beats per min				
Baseline variability	Fluctuations in the FHR baseline that are irregular in amplitude and frequency. Variability is measured from the peal to the trough of the FHR fluctuations and is quantitated in beats/min. Variability is classified as follows: Absent – amplitude range undetectable Minimal – amplitude range detectable but ≤5 beats/min Moderate – amplitude range, 6–25 beats/min Marked – amplitude range, >25 beats per min No distinction is made between short term variability (or beat-to-beat variability or R-R wave period differences in the electrocardiogram) and long-term variability because in actual practice they are visually determined as a unit				
Acceleration	A visually apparent abrupt increase (onset to peak <30 sec) in the FHR from the baseline At 32 weeks of gestation and beyond, an acceleration has a peak at least 15 beats/min above baseline and a duration of at least 15 sec but <2 min Before 32 weeks of gestation, an acceleration has peak at least 10 beats/min above baseline and a duration of at least 10 sec but <2 min Prolonged acceleration lasts ≥2 min but <10 min If an acceleration lasts ≥10 min, it is a baseline change				
Early deceleration	In association with a uterine contraction, a visually apparent, gradual (onset to nadir ≥30 sec) decrease in FHR wi return to baseline In general, the nadir of the deceleration occurs at the same time as the peak of the contraction				
Late deceleration	In association with a uterine contraction, a visually apparent, gradual (onset to nadir ≥30 sec) decrease in FHR with return to baseline In general, the onset, nadir, and recovery of the deceleration occur after the beginning, peak, and end of the contraction, respectively				
Variable deceleration	An abrupt (onset to nadir <30 sec), visually apparent decrease in the FHR below the baseline The decrease in FHR is at least 15 beats/min and lasts at least 15 sec but <2 min				
Prolonged deceleration	Visually apparent decrease in the FHR at least 15 beats/min below the baseline lasting at least 2 min but <10 min from onset to return to baseline				
Periodic deceleration	Accompanies a uterine contraction				
Episodic deceleration	Does not accompany a uterine contraction				
Sinusoidal pattern	Visually apparent, smooth, sine wave-like undulating pattern in FHR baseline with a cycle frequency of 3-5 per min which persists for ≥20 min				

the fetal physiologic response if oxygen transfer is interrupted. Intrapartum FHR interpretation can be distilled into 3 basic principles.

Principle 1

Oxygen is carried from the environment to the fetus by maternal and fetal blood along a pathway that includes the maternal lungs, heart, vasculature, uterus, placenta, and umbilical cord. Interruption of the oxygen pathway at one or more points can result in an FHR deceleration. For example, interruption of the oxygen pathway by

compression of the umbilical cord can result in a variable deceleration. 11,13 A late deceleration can result from reduced placental perfusion during a uterine contraction.14 Interruption at any point along the pathway can result in a prolonged deceleration. Although variable, late, and prolonged decelerations have slightly different physiologic mechanisms, they all share a common initiating event: interruption of the oxygen pathway at one or more points.

The first principle of standardized intrapartum FHR interpretation is that all

clinically significant decelerations (variable, late, or prolonged) reflect interruption of the pathway of oxygen transfer from the environment to the fetus at one or more points (Figure 1).

Principle 2

Interruption of fetal oxygenation has the potential to result in hypoxic neurologic injury. Just as the oxygen pathway from the environment to the fetus includes a series of sequential anatomic steps, the pathway from normal fetal oxygenation to potential hypoxic

TABLE 2

Three-tier FHR classification system

Category I

FHR tracings include all of the following:

Baseline rate: 110-160 bpm

Baseline FHR variability: moderate

Accelerations: present or absent

Late or variable decelerations absent

Early decelerations present or absent

Category II

Includes all FHR tracings not included in Category I or Category III

Category III

FHR tracings include

Absent baseline FHR variability plus

Recurrent late decelerations

Recurrent variable decelerations

Bradycardia

Sinusoidal pattern

bpm, beats per minute; FHR, fetal heart rate. Adapted from Macones et al.

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injury includes a series of sequential physiologic steps. The first step, hypoxemia, is defined as decreased oxygen content in the blood. Hypoxemia can lead to reduced oxygen content in the tissues, which is termed hypoxia. Tissue hypoxia can trigger anaerobic metabolism, lactic acid production, and metabolic acidosis in the tissues. Eventually, the blood pH can fall, which causes metabolic acidemia. In 2008, the NICHD Research Planning Workshop identified 2 FHR characteristics that reliably predict the absence of fetal metabolic acidemia.¹⁰

The second principle of intrapartum FHR interpretation is that moderate variability and/or accelerations reliably predict the absence of fetal metabolic acidemia at the time they are observed (Figure 1).

Principle 3

In 1999 and 2003, the International Cerebral Palsy Task Force, ACOG, and the American Academy of Pediatrics published consensus statements that identified specific criteria that must be met before acute intrapartum oxygen deprivation can be considered a possible cause of neurologic injury.^{5,6} Both consensus statements, which were supported by >20 international organizations, concluded that significant fetal metabolic acidemia (umbilical artery pH <7.0; base deficit, ≥12 mmol/L; Figure 1) is an essential precondition to acute intrapartum hypoxic neurologic injury in the form of cerebral palsy.

The third principle of intrapartum FHR interpretation is that acute intrapartum interruption of fetal oxygenation does not result in neurologic injury (cerebral palsy) in the absence of significant fetal metabolic acidemia (Figure 1).

A simplified, standardized approach to management

As illustrated in Figure 1, intrapartum FHR interpretation can be distilled into 3 evidence-based principles that form the foundation for a simplified, standardized approach to FHR management. The management algorithm described in this article was published in 2009 and updated in February 2010 to include the NICHD FHR categories. 15,16 It incorporates the definitions and principles of interpretation discussed earlier but does not include adjunctive tests of fetal status that are currently unavailable for general clinical use in the United States, such as fetal scalp blood sampling, fetal pulse oximetry or fetal ST-segment analysis. The management recommendations are consistent with those proposed by ACOG in November 2010.11

Confirm FHR and uterine activity

The goal of standardized EFM management is to identify and minimize potential sources of preventable error. Reliable information is essential, so the first step is to confirm that the monitor is recording the FHR and uterine activity adequately to permit informed management decisions (Figure 2). If external monitoring does not provide adequate information, placement of a fetal scalp electrode and/or intrauterine pressure catheter should be considered.

Evaluate 5 FHR components

Thorough evaluation of a fetal monitor tracing includes the assessment of uterine contractions along with 5 FHR components: baseline rate, variability, accelerations, decelerations, and changes or

FIGURE 1

Three principles of electronic fetal heart rate monitoring (EFM) interpretation

Environment

Lungs Heart Vasculature Uterus Placenta Cord

Principle # 1

All clinically significant FHR decelerations (variable, late, or prolonged) reflect interruption of the pathway of oxygen transfer from the environment to the fetus at one or more points

Fetus

Hypoxemia Hypoxia Metabolic acidosis

Principle #2

Moderate variability and/or accelerations reliably predict the absence of fetal metabolic acidemia at the time they are observed

Metabolic acidemia

Potential injury

Principle #3

Intrapartum interruption of fetal oxygenation does not result in neurologic injury (cerebral palsy) unless the fetal response progresses to the stage of significant fetal metabolic acidemia (umbilical artery pH <7.0 and base deficit ≥12 mmol/L)

FHR, fetal heart rate.

Courtesy of David A. Miller, MD.

Miller. Electronic fetal heart rate monitoring. Am J Obstet Gynecol 2012.

trends over time. If a tracing meets the criteria for inclusion in category I, it is considered normal. In low-risk patients, the FHR tracing should be reviewed at least every 30 minutes during the active phase of the first stage of labor and at least every 15 minutes during the second stage. 11,17,18 In high-risk patients, the corresponding frequency of review is at least every 15 minutes during the active phase of the first stage and at least every 5 minutes during the second stage. As recommended by ACOG and the Association of Women's Health, Obstetric and Neonatal Nurses, documentation should occur periodically. 11,18 The content and frequency of documentation should be determined by the clinical scenario and applicable institutional policies.

If an FHR tracing does not meet the criteria for classification in category I, a systematic "ABCD" approach can help to ensure that important considerations are not overlooked and that decisions are made in a timely manner (Table 3).

A: assess the oxygen pathway and consider other causes of FHR changes

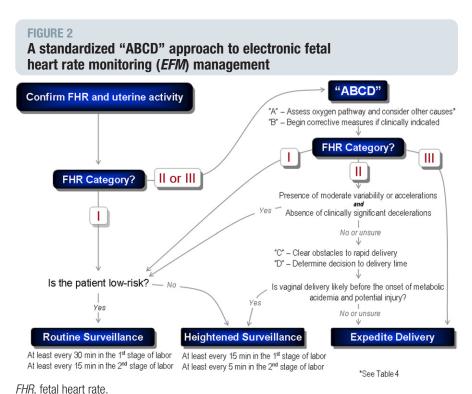
If an FHR tracing moves beyond category I, the oxygen pathway should be assessed systematically (Table 3). In addition, factors that can affect the FHR tracing by mechanisms other than interruption of oxygenation should be identified and addressed as clinically indicated (Table 4).

B: begin corrective measures as indicated

should be addressed with appropriate conservative corrective measures. ^{12,15-19} Table 3 summarizes common measures to consider at each level. Addressing these standard conservative measures in an orderly fashion minimizes reliance on random recall and helps to ensure that important considerations are not overlooked.

Interruption of the oxygen pathway

After beginning conservative corrective measures, the FHR tracing should be reevaluated within a reasonable timeframe. If the tracing returns to category I, surveillance can be resumed. If the tracing progresses to category III despite corrective measures, expedited delivery should be considered. Tracings that remain in category II require additional evaluation. If there is moderate variability



and/or accelerations without significant decelerations, continued surveillance is appropriate (Figure 2). However, some category II tracings are more difficult to interpret, and the clinical team might not always agree on the level of risk. One example is a category II tracing with a normal baseline rate, minimal variability, and no accelerations but no decelerations. Some clinicians might be concerned by the lack of moderate variability or accelerations; other clinicians might be comforted by the absence of decelerations. Fortunately, a standardized approach to management can minimize the controversy that is generated by confusing category II tracings. If any member of the health care team has any question about the presence of moderate variability, the presence of accelerations or the significance of any observed decelerations, the safest and easiest approach is to proceed to the next step.

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C: clear obstacles to rapid delivery

If conservative measures do not correct the FHR tracing, it is prudent to plan ahead for the possible need for rapid delivery. This does not constitute a commitment to a particular

time or method of delivery. It simply serves as a reminder of common sources of unnecessary delay so that they can be addressed in a timely manner. Because many of the considerations that are summarized in Table 2 are viewed by clinicians as "common sense," they usually do not receive the serious, systematic attention that they deserve. Instead, they are left to the vagaries of random recall and frequently are overlooked, which jeopardizes patient safety and invites criticism. One way to minimize the error that is inherent in random recall is to use a simple checklist that organizes potential sources of unnecessary delay into major categories. From largest to smallest, these include the facility, staff, mother, fetus, and labor. Table 2 identifies some examples of potential sources of unnecessary delay at each level.

D: decision-to-delivery time

After appropriate conservative measures have been implemented, it is sensible to take a moment to estimate the time that will be needed to accomplish delivery in the event of a sudden emergency. This step should be addressed by the clinician who ultimately is responsible for per-

Step	"A" Assess oxygen pathway	"B" Begin corrective measures <i>if indicated</i>	Variable	"C" Clear obstacles to rapid delivery	"D" Determine decision to delivery time
Lungs	Respiratory rate Airway and breathing	Supplemental oxygen	Facility	Consider: OR availability Equipment	Consider Facility response time Location and availability of OR
Heart	Heart rate and rhythm	Position changes Fluid bolus Correct hypotension	Staff	Consider notifying: Obstetrician Surgical assistant Anesthesiologist Neonatologist Pediatrician Nursing staff	Consider: Availability Training Experience
Vasculature	Blood pressure Volume status		Mother	Consider: Informed consent Anesthesia options Laboratory tests Blood products Intravenous access Urinary catheter Abdominal prep Transfer to OR	Surgical considerations (prior abdominal or uterine surgery) Medical considerations (obesity, hypertension, diabetes, SLE) Obstetric considerations (parity, pelvimetry, placental location)
Uterus	Contraction strength Contraction frequency Baseline uterine tone Exclude uterine rupture	Stop or reduce stimulant Consider uterine relaxant	Fetus	Consider: Fetal number Gestational age Estimated weight Position Presentation Anomalies	Consider factors such as Estimated fetal weight Gestational age Presentation Position
Placenta	Placental separation Bleeding vasa previa		Labor	Confirm: Adequate UC monitoring	Consider factors such as Arrest disorder Protracted labor Remote from delivery Poor expulsive efforts
Cord	Vaginal exam Exclude cord prolapse	Consider amnioinfusion			

forming operative delivery should it become necessary. The time between decision and delivery can be estimated systematically by considering individual characteristics of the facility, staff, mother, fetus, and labor (Table 2).

Delivery

Management steps A, B, C, and D are relatively uncontroversial, readily amenable to standardization, and represent the overwhelming majority of decisions that must be made during labor. These steps do not replace clinical judgment. On the contrary, they encourage the systematic, timely application of clinical judgment.

Once steps A, B, C, and D have been completed, the clinician must decide whether to await spontaneous vaginal delivery or to expedite delivery by other means. This decision balances the estimated time until vaginal delivery against the estimated time until the onset of metabolic acidemia and potential injury. The former estimate is guided by usual obstetric considerations. The latter is guided by limited data that suggest that metabolic acidemia usually does not appear suddenly but can evolve gradually over a period of approximately 60 minutes. 20 This general statement applies only to normal FHR

tracings that subsequently develop minimal-absent variability and recurrent decelerations with no acute events. 20 The inherent imprecision of these estimates can make the decision difficult. One of the most common preventable errors at this point is to postpone a clinically necessary, but difficult, decision in the hope of spontaneous resolution. Despite the difficulty, a decision must be made with the use of the best available information. If a decision is made to expedite delivery, the rationale should be documented, and the plan implemented. If a decision is made to wait, the rationale and plan should be documented and the decision should be revisited after a reasonable period of time. It is important to recognize that "deciding to wait" is distinctly different from "waiting to decide." The former reflects clinical judgment; the latter suggests procrastination.

Comment

The greatest strength of intrapartum EFM is its ability to predict the absence of metabolic acidemia and hypoxic neurologic injury with an extremely high degree of reliability. Its greatest weakness is its inability to predict the presence of these conditions with any clinically relevant accuracy. The false-positive rate of EFM for the prediction of cerebral palsy has been reported to exceed 99%, which yields a positive predictive value <1%.11 Potential explanations for this imprecision include the relative rarity of intrapartum hypoxic neurologic injury and the mitigating interventions that frequently are triggered by FHR "abnormalities." Although these explanations might be accurate, they do not alter the fact that the positive predictive value of EFM, as it is used in actual clinical practice, is essentially nil. Reasonable management decisions cannot be based on the results of a test that it is virtually always wrong. On the other hand, the negative predictive value of EFM is near 100%. A test that is virtually always right is the ideal foundation for rational decision-making. The interpretation and management method that is described in this article uses the exceptional negative predictive value of EFM to formulate a structured, systematic, nonrandom approach to intrapartum care. Standardization of FHR definitions and simplification of interpretation and management promote safety by reducing unnecessary complexity. This structured approach is consistent with the concept of creating a shared mental model within and between disciplines and is tantamount to the use of team checklists that are seen with other obstetric procedures. Standardization and checklists have been shown to improve outcomes and reduce liability.²¹ In conclusion, this model provides a framework for clinicians of all educational backgrounds to apply and articulate a plan of management that is both reasonable and factually accurate, which meets the 2 essential elements of the standard of care.

TABLE 4

Examples of causes of fetal heart rate changes not directly related to fetal oxygenation

Maternal Fever Infection Medication Hyperthyroidism Fetal Sleep cycle Infection Anemia Arrhythmia Heart block Congenital anomaly Extreme prematurity Preexisting neurologic injury Miller. Electronic fetal heart rate monitoring. Am J Obstet Gynecol 2012.

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