**FRI Addendum materials**

Methods

The medical, obstetrical, and fetal risk factors follow standard guidelines from ACOG (addendum Table 1). Likewise, the definitions of baseline heart rate and variability, and decelerations are shared by various organizational guidelines (addendum Table 2). The “basal heart rate” is determined at the outset of monitoring and corresponds to the “baseline rate at that time”. 1 The baseline rate is the heart rate sustained for 10 minutes at any subsequent time and compared to the basal rate. By this strategy, we are able to determine, relative tachycardia (sustained baseline >15bpm over basal rate) and relative bradycardia (sustained baseline > 15 bpm below the basal rate). We also define “recovery” from a deceleration as the prompt return of the FHR pattern to the previously normal baseline rate and variability.

Two other variables were measured but are NOT included in the FRI score: Point “A” corresponds to that time in the tracing where the fetus is manifesting early deterioration (decompensation), and that intervention is called for, but not necessarily delivery. The hallmark of Point A is the failure of the deceleration to return promptly to the previously normal baseline rate and variability; i.e., the recovery is prolonged or associated with rising or falling baseline rate and diminution or exaggeration of baseline variability. Intrauterine resuscitation (IR) includes discontinuation of oxytocin, cessation of pushing, support of BP with lateral positioning, IV fluids and oxygen by mask as one can no longer certain of the health of the fetus in the context of the estimated feasibility of safe vaginal delivery. Point “B” is the pattern seen after neurologic damage to the fetus has occurred. 2 This pattern was identified – irrespective of Category (II-III) or perceived presence of fetal acidemia. Points A and B were determined blindly by one of the investigators (BSS) who did not participate in the FRI risk scoring of the labor, tracings, or statistical analysis. These are by definition somewhat subjective and require extensive experience so are not applicable to a universally used screening approach. They were calculated to provide internal benchmarks for comparisons to traditional monitoring interpretation.

For contractions, we define **abnormal uterine activity** (AUA) more broadly than simply the frequency of contractions (tachysystole). Beyond the frequency of contractions (>5/10 minutes averaged over 30 minutes), the tracing may qualify for AUA based on criteria for the duration of the contraction, the intervals between them is shortened, or the tone is elevated (addendum tables 1, 2). Specifically, in the 2nd stage of labor, we consider the maximum average number of contractions to be 4 per 10 minutes rather than 5 in 10 minutes or 7 in 15 minutes. 1 3

These features are combined into an 8-parameter algorithm (addendum Table 3). If all 8 are normal: 8/8 = 100%; 2/8 = 25%, etc. While EFM category values including AUA are dynamic and modified as parameters change, the clinical risk factors are generally unidirectional (e.g. diabetes, ruptured membranes)- i.e., once satisfied they remain in the equation (or calculus). To facilitate clinical interactions, FRI Scores >50% are labelled “Green zone,” between 50% and 26% are “Yellow zone,” and ≤25% are “Red zone” which is defined as screen positive “at risk status” demanding affirmative attention (and written evaluation). In “version 1.0” employed here, the 8 factors are weighted evenly. With more data, we anticipate that modifications to the weighting will further improve statistical performance over existing methods.

Time intervals were calculated for the length of labor, length of 2nd stage, time of first onset of abnormal EFM characteristics until delivery, Points A, Point B, and presence of Category III tracing. Additionally, the total time of each EFM characteristic, lowest FRI and its duration, last FRI score, its appearance, and duration of time during labor were determined. We previously have shown that the FRI has much improved statistical performance metrics in identifying CP compared to ACOG category I-III system or the earlier ACOG monograph criteria.

Graphic representation of the differences between the early and late groups are shown in addendum Figure 1.

**Addendum Table 1**

**RISK FACTORS**

**Maternal Risk factors**

1. Decreased cardiac output / vascular perfusion of the placenta
   1. Cardiac Disease with risk of decreased cardiac output in pregnancy
   2. Hypertension (Chronic and Pregnancy induced]
   3. SLE, etc.
2. Oxygen carrying capacity
   1. Pulmonary disorders (e.g. Asthma]
   2. Anemia and Hemoglobinopathy
3. Infection (chronic and acute]
4. Chronic debilitating Disease
5. Malabsorption / Poor weight gain
6. Endocrine – Diabetes and Thyroid disorders
7. Advanced Maternal age
8. Drug abuse, addiction, and smoking
9. Obesity – BMI >35
10. Short Stature (<5’2”]

**Obstetrical Risk Factors**

1. IUGR/Macrosomia
2. Oligohydramnios
3. Polyhydramnios
4. Bleeding and abruption
5. Previous c/section
6. Placental and umbilical cord anomalies
7. Rupture of Membranes (PPROM, SROM, AROM)
8. Dystocia (Protraction and arrest disorders of labor)
9. Malpresentation

**Fetal Risk Factors (Demographic]**

1. Abnormal Dopplers/BPP
2. Genetic disorders
3. Fetal arrhythmia
4. Meconium passage
5. Chorioamnionitis
6. Second stage of labor- pushing
7. Amnioinfusion
8. Discontinuation of Pitocin due to fetal intolerance
9. Conversion patterns (Acute prolonged tachycardia (>170 bpm]
10. Ominous overshoots
11. Bradycardia (<100 bpm]
12. Missing important data in labor (e.g. lack of EFM in second stage]

**Addendum Table 2A:**

**Electronic Fetal Monitoring Classification**

**Features of Fetal Heart Rate Patterns –**

**Fetal Heart Rate**

**Basal rate – Normal, stable heart rate at the outset of monitoring**

**Baseline rate heart rate at any moment in time – averaged over 20 minutes – caveat**

Normal - Rate between 110 to 160 bpm\*

Abnormal – Baseline tachycardia\* >160 bpm,

Baseline bradycardia\*-- <110 bpm,

\*Duration of at least 10 minutes

**Baseline variability – variability assessed between uterine contractions and absent pushing**

Normal variability - >5 <25 bpm

Abnormal variability

Decreased / Absent FHR variability <5 bpm

Sinusoidal, or nodal

Increased FHR variability >25 bpm

**Accelerations** –

**Normal** - at least two FHR accelerations of >15 bpm (at peak] and 15 seconds duration (from onset to offset - associated with normal baseline variability and stable baseline rate]

**Abnormal -** Abnormal - Pathological –

Overshoots – increase in baseline FHR rate following contractions associated with decreased variability and absence of “shoulders.”

**FHR decelerations –**

**Early / mild variable – either term suffices**

Decelerations confined to the time period of the contraction.

**Variable decelerations – Abrupt decelerations >30 bpm**

**Late decelerations – any amplitude, but must be recurrent and proportion in amplitude and duration to the amplitude and duration of the underlying contractions.**

**Prolonged decelerations – Deceleration lasts longer than 2 minutes.**

**Decelerations – “Recovery”** –

**Normal:** Each deceleration is modified by whether or not it has “recovered,” i.e., it has returned promptly to the previously normal baseline rate and variability. This must be affirmatively demonstrated. It cannot be assumed, if there are technical issues.

**Abnormal:**  (not recovered]

Prolonged overshoot >15 seconds

Recovers to higher rate or increased variability

Progressively rising rate until next contraction

Slow return to the baseline.

**Conversion pattern** – an abrupt alteration in baseline rate and/or variability – usually in association with ongoing variable decelerations or prolonged deceleration (see examples]

**Dropped data** –

First stage of labor With previously normal tracing – allow 20 minutes

With previously abnormal tracing – immediate evaluation and possible intervention

2nd stage of labor – Failure to determine or establish a baseline rate ***immediately*** following deceleration x 2 is considered pathological. Assigned to Point A

**Addendum TABLE 2b**

**Features of Uterine Activity (UA] –**

***Normal (20 minutes]*** ***Abnormal***

Frequency ≤ 8 contractions >8 UC (tachysystole]

Duration <90 seconds >90 seconds

Increased Tonus With toco Coupling / prolonged >120 sec

With IUPC >20 mmHg

Interval A Interval – peak to peak <2 minutes

Interval B Interval – offset of UC to onset of next UC <1 minute

Rest time >50% <50%

**Addendum Table 3**

**COMPONENTS OF THE FETAL RESERVE INDEX**

1. Fetal Heart Rate – includes relative and absolute definitions of tachycardia and bradycardia
2. Baseline variability
3. Accelerations
4. Decelerations
5. Uterine activity
6. Maternal risk factors
7. Obstetrical risk factors
8. Fetal risk factors (separate from EFM]

**Addendum FIGURE 1**

FIGURE LEGEND

T ED: total emergency deliveries

E CS: emergency Cesarean sections

RED: percentage of cases reaching Red zone.

IR: intrauterine resuscitation

Still ECS: % of patients requiring ECS despite IR.

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**APPROACHES TO EFM INTERPRETATION**

There have been numerous comparisons of various proposed classifications of FHR patterns. In this short addendum, we categorize a number of them. From our perspective, all of these have yielded suboptimal results because they have focused on the EFM, per se, and have not included the expanded focus that we suggest.

These have included several large scale randomized trials using competing classifications and in several cases ancillary data from STAN analysis. Indeed, some authors have created separate algorithms for 1st and 2nd stage of labor. (e.g. INFANT trial) 1 2,3

Bhatia et al compared the FIGO-2014 and the UK (NICE-2007, 2014) classification systems.in which observers classified ten cardiotocography traces according to the three guidelines. The κ values were 0.38 (FIGO 2015), 0.37 (NICE 2007), and 0.34 (NICE 2014). The percentage agreement was identical across the three systems for normal (100.0%) and very high for intermediate/ or suspicious (80.9%). By contrast, the percentage agreement for abnormal or pathological findings was only 47.6% for NICE 2014, 76.2% for FIGO 2015, and 91.0% for NICE 2007 guidelines. Among 210 observations, intervention was deemed necessary for 48 (22.9%) for FIGO 2015, 29 (13.8%) for NICE 2014, and 56 (26.7%) for NICE 2007 guidelines. Thus, from a clinical perspective, these metrics are very problematic.

Ghi et al compared the accuracy of RCOG and 4 cardiotocographic patterns classification systems in predicting fetal acidemia in the second stage of labor. Both systems showed moderate accuracy in identifying acidemic fetuses during the second stage of labor. The occurrence of unclassifiable findings was significantly more common among acidemic fetuses. 5

One of the more problematic features of EFM and the prediction of either outcome or the need to intervene is the fact that foreknowledge of fetal outcome certainly often influences the retrospective interpretation of cardiotocographic tracings and subsequent management recommendations. Indeed, when provided with information on adverse fetal outcome, healthcare professionals provide a more pessimistic evaluation of basic tracing features, overall classification, and clinical management recommendations. 6 Furthermore, neither fetal behavioral states nor the options of using FHR patterns for defining fetal neurological injury have not been included in contemporary classifications. 10 11

Di Tommaso and colleagues compared the accuracy of five different classification systems for interpreting EFM when predicting neonatal status at birth (umbilical cord arterial pH). They found that the 5-tier classification of Parer and Ikeda and NICHD classifications had the highest sensitivity in detecting umbilical cord arterial pH ≤7.15, but that the high sensitivity of the NICHD classification is hindered by an unacceptably high percentage of "non-informative" traces (Category II) (80%) which from a statistical metric perspective renders the system essentially useless

Gyamfi Bannerman et al compared the 2-tier (ACOG), 3-tier (NICHD) and 5-tier systems. They found that the 3-tier and 5-tier systems were similar in fetal heart rate interpretations for tracings that were either very normal or very abnormal. Whether one system is superior to the others in predicting fetal acidemia remains unclear. 8

Parer measured agreement among 5 “expert” clinicians and a computerized method with the use of a strict fetal heart rate classification method. These clinicians achieved moderate-to-substantial levels of agreement overall using a strictly defined method to classify fetal heart rate tracings. The results of the computerized method were similar to the conclusions of these clinicians. 9

Two systems for computerized CTG analysis were recently evaluated in multicenter randomized controlled trials in the United Kingdom. Nunes, et al 12 compared the Omniview-SisPorto® 3.5 system for which traces were viewed on a central station with real-time alerts for features suggestive of fetal hypoxia/acidosis. In 7,730 randomized term patients this approach did not reduce the rate of metabolic acidosis or obstetric intervention, except for a very high risk group of women with pre-existing or pregnancy complications for whom it may have conferred benefit.

The INFANT Trial used the INFANT (K2 Medical Systems) – a decision-support software developed to run on the Guardian system, which is an electronic informatics system for managing information during labor, **13,14** It was an unmasked RCT, involving about 23,000 patients in the computer assisted group and about an equal number of those cared for using standard clinical care. No differences were found in the incidence of poor, immediate, neonatal outcomes or developmental scores at 2 years of age. Thus, neither trial found evidence that visual-aid computerized analysis of CTG or CTG + STAN reduced the likelihood of adverse outcomes compared with standard care. Further, both studies found lower than expected incidences of various components of the composite adverse outcome. (see below) The methodological issues included multiple comparisons, variability of strengths of findings and plausibility, and the evaluation of the significant findings in secondary outcomes.

Several recent fetal monitoring trials have reported unexpectedly low rate of poor outcomes resulting in the studies being underpowered to detect the predefined difference 18, 2. Therefore, there is an urgent need to improve knowledge and training about the appropriate response to CTG abnormalities, including timely intervention 19

Many recent authorities have lamented that EFM just doesn’t perform as well as needed. The question then is: it the specific algorithms used by the evaluated systems that do not work? While the fault could lie with the specific algorithm and system of alerts it seems more likely that the failure lies elsewhere in the failure to take into account other data from labor such the progress of labor, the presence of maternal fever, chorioamnionitis, meconium, which are known to modify the clinicians’ interpretation and response to the FHR. It seems unnecessary to note that algorithms mimicking clinicians cannot be expected to work better than the best clinical experts, Such is the premise of the FRI, i.e., other significant factors must be incorporated in the evaluation.

What needs to be appreciated and improved is the *effectiveness* of EFM in routine clinical care. Real impact needs to be evaluated for not only adverse neonatal outcomes but also emergency intervention rate and the rate of “necessary” cesarean section.

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