KEEPING LABOR SAFE
Re-engineering the interpretation and responses to fetal heart rate patterns.
New Jersey Symposium Nov 2018

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Time to change our thinking

DISCLOSURE
MIE has US patents on process described in this paper.
UNCOVERING WHAT WE NEED TO KNOW FROM WHAT WE SHOULD SEE

• For nearly 50 years, we have interpreted fetal status in labor as a function of the EFM, per se.
• We have ignored other key pieces of information about the timing and mechanism of fetal injury that didn’t fit the prevailing theory of pathogenesis.
• If you don’t ask the right questions,.....
• In genetic screening, we routinely amalgamate different components (US, biochemistry, and molecular) into one unified score of risk.
• For EFM to maximize fetal outcomes, we need to do the same.

THE PROBLEM - cerebral palsy

• Approximately 4 million births a year in USA.
• Approximately 144 million births world-wide
• Cerebral palsy (CP) occurs in about 1/700 singleton pregnancies and 1/100 twin pregnancies – about 6,000 babies per year in USA.
  • Over 200,000 world-wide
• A tripling of the Cesarean section rate from <10% in the 1970s to
• > 30% currently in USA has not lowered the CP rate.
• Major differences of opinion as to how much of CP incidence is “pre-ordained” before entering labor, and how much can be attributable to events in labor.
Lack of infrastructure worsening
Fewer eyes watching
Celebrated awards become floor not ceiling
However, there is malpractice

80% of sub-standard care never litigated
Majority of filed cases unfounded
Cadre of “experts” who will say anything on both sides

PREVENTION OF CEREBRAL PALSY

- Electronic fetal monitoring (EFM), developed in 1969, is now used in >95% of all laboring hospital patients.
- Uncoordinated roll out, conflicting publications, very variable education and subjective interpretation have lead to chaos on L & D and in court.
- Clearly individual case successes, but overall many unnecessary stat deliveries for normal babies as “saves” of possible poor outcomes.
WHAT IS THE PURPOSE OF EFM?

KEEP THE BABY OUT OF TROUBLE?
• Is EFM “Diagnostic” for damage or “Screening” for increased risk of damage?
• “How close to the edge of the cliff do we go before turning back?” (e.g. suggestions to let 2nd stage continue for hours)
• A stat CS for a baby with Apgar’s 9/9 and pH 7.1 is both a clinical success, but also a screening “false positive” failure.
• A stat CS for a baby with Apgar’s 2/3 and pH 6.9 because of a category III tracing is a “screening success” but a clinical failure

RESCUE FROM THE “EDGE?”

CONFUSION AS TO WHAT MONITORING IS SUPPOSED TO DO AND HOW TO DEFINE “SUCCESS”

• Public policy question: how many false positives do we accept per damaged baby saved?
• Individual care question: How many cases do we delay “stat” deliveries to keep CS rate down in face of concerning data?
• What is the legal exposure when things go wrong in either direction?
RELYING UPON FHR INTERPRETATION, PER SE, IS AS EFFECTIVE AS THE MAGINOT LINE

• EFM as currently practiced ignores major pieces of information that impact the ability of the fetus to withstand the stresses of labor.
• EFM interpretation is very subjective with clearly legitimate experts often disagreeing vociferously.
• Need a quantifiable, reproducible method that can be used safely even by under-trained providers.

ACOG LEADERSHIP

• ACOG
  – champion of women’s health care
  – also “union for Ob Gyn’s”
  – Fundamentally incompatible roles
• Worries too much about:
  (?hazy) borderline between lousy care and malpractice –
• Not enough about:
  getting advanced care into routine practice - “vague guidelines” (Clark)
• Some (Much) of this in our control
• Some (Much) requires broad consensus
  – Don’t hold your breath
PROPOSAL TO ACOG 1999

• Need to sift science from fiction
• Standardize the evaluation of compromised babies
• Create consensus across specialties

THE PROBLEM - cerebral palsy

• In 2003 with the endorsement of multiple organizations, and in an effort to sort out science from conjecture, ACOG published a Monograph on “Neonatal Encephalopathy and Cerebral Palsy” (NEACP). (MIE was an author)
• The Monograph categorized which CP cases could be attributable to labor and delivery (L & D) events. ACOG states that in most cases CP not related to L & D.
• ESSENTIAL CRITERIA to conclude NE related to “an acute intrapartum event (must meet all four)

• Evidence of a metabolic acidosis in fetal umbilical cord arterial blood obtained at delivery (pH <7.00 and base deficit ≥12mmol/L)
• Early onset of severe or moderate neonatal encephalopathy in infants born at 34 or more weeks of gestation
• Cerebral Palsy of the spastic quadriplegic or dyskinetic type
• Exclusion of other identifiable etiologies such as trauma, coagulation disorders, infectious conditions, or genetic disorders”

• Criteria that collectively suggest an intrapartum timing (within close proximity to labor and delivery (e.g. 0 – 48 hours) but are nonspecific as to axphyxial insults

• A sentinel (signal) hypoxic event occurring immediately before or during labor
• A sudden and sustained fetal bradycardia or the absence of fetal heart rate variability in the presence of persistent, late, or variable decelerations, usually after a hypoxic sentinel event when the pattern was previously normal.
• Apgar scores of 0 – 3 beyond 5 minutes
• Onset of multisystem involvement within 72 hours of birth
• Early imaging study showing evidence of acute nonfocal cerebral abnormality”
Models of Neuronal injury:

Requires a period of insufficient delivery of O2 and substrates (e.g. lactate) such that neurons cannot maintain homeostasis.

**Hypoxia - Ischemic model**
- O2 availability reduced but perfusion maintained.
- Use anaerobic metabolism to provide high energy metabolites
- Rapidly uses up glucose as metabolic acidosis develops
- Reduce energy consumption
- With progressive acidosis – impaired cardiac output
  diminished blood flow – cerebral ischemia

**Mechanical Ischemic model**
- With impaired blood flow both O2 and substrates are less available.
- Injury evolves more rapidly, less metabolic acidosis – If ischemia related to mechanical forces acting on the head, there is no diminution in cardiac output to the heart
- Only brain affected – minimal systemic acidosis.

- Levene and Chervenak, *Fetal and Neonatal Neurology and Neurosurgery*, page 479

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**NEONATAL ENCEPHALOPATHY AND CEREBRAL PALSY**

**DEFINING THE PATHOGENESIS AND PATHOPHYSIOLOGY**

**AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS**

**AMERICAN ACADEMY OF PEDIATRICS**

**Unintended consequence:**
- Since labor was believed to have a low likelihood to cause damage, cutbacks to staffing of L & D have been commonly seen.
- There has also been a downgrading of number and training of personnel taking care of laboring patients.
ACOG ATTEMPTS TO EVALUATE EFM AND CP

ACOG CATEGORY SYSTEM (2009)

• 3 categories
  1. absolutely fine – no risk
  2. 80% of cases
    • With elements of concern but by itself not sufficient to warrant intervention
    • Statistical and programmatic nightmare
  3. impending damage
    • Deliver now

BOTH ACOG APPROACHES ARE INADEQUATE

• ACOG actually now admits quality of interpretation of EFM is inadequate with too many mistakes.
• The truth is:
  • Inadequate training with poor quality control
  • Too much inter-operator variability
  • Even true experts have vast disagreements on individual cases
• ACOG proposes further training and certification program
• Pediatricians now recognize that adverse affects can be seen without meeting all ACOG criteria (SARNAT staging)
  • Makes ACOG system have even worse statistical performance
"CLEAR DISTINCTIONS" ARE NOT ALWAYS "CLEAR"

FETAL ALCOHOL SYNDROME
For every child with full blown FAS, there are about 4-10 x as many with “fetal alcohol effects”

Fragile X Syndrome
Full blown syndrome has >200 repeats with MR in almost all males and half of females. >125 produces learning disabilities and variable phenotype

HYPOXIC ENCEPHALOPATHY

SARNAT STAGING
(Where is the cut-off point for DX?)

<table>
<thead>
<tr>
<th>Grade I</th>
<th>Grade II</th>
<th>Grade III</th>
</tr>
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<tbody>
<tr>
<td>Mild</td>
<td>Moderate</td>
<td>Severe</td>
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</table>

<table>
<thead>
<tr>
<th>Alertness</th>
<th>Hyper alert</th>
<th>Lethargy</th>
<th>Coma</th>
</tr>
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<tbody>
<tr>
<td>Muscle tone</td>
<td>Normal or increased</td>
<td>Hypotonic</td>
<td>Flaccid</td>
</tr>
<tr>
<td>Seizures</td>
<td>None</td>
<td>Frequent</td>
<td>Uncommon</td>
</tr>
<tr>
<td>Pupils</td>
<td>Dilated, reactive</td>
<td>Small, reactive</td>
<td>Variable, fixed</td>
</tr>
<tr>
<td>Respiration</td>
<td>Regular</td>
<td>Periodic</td>
<td>Apnea</td>
</tr>
<tr>
<td>Duration</td>
<td>&lt; 24 Hours</td>
<td>2 - 14 Days</td>
<td>Weeks</td>
</tr>
</tbody>
</table>

IMPLICATIONS OF INCOMPLETE SEPARATION

- Statistical performance metrics (sensitivity, specificity, PPV< NPV) require orthogonal groups (non-overlapping)
- Blows large hole in ACOG insistence of “firewall” between those cases of CP that meet criteria vs. those that “don’t.”
- Ditto for FHR and acidosis
- Paradoxically, may explain those cases of CP that don’t meet ACOG criteria
PREVENTION OF CEREBRAL PALSY

• The ACOG monograph interpretation can only available postnatally and therefore is useless as a labor management tool.

• ACOG developed a “Category” system in 2008 in which “Category III” is considered high risk and immediately actionable. However, most babies with CP never get to a Category III EFM, and thus it is not a good screening method.

• The “cut point” to reach Category III is too far to the right on the distribution curve of patients. Thus, those who do reach Category III have a very high positive predictive value for neurologic compromise.

• There are also far too many false negatives rendering the sensitivity of Category III poor and of limited value in preventing problems.

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Unaffected

Spina bifida

Anencephaly

ACOG CATEGORY III: TOO FAR TO THE RIGHT – SAME AS USING AFP OF 4 MOM FOR NTDs

AFP (MoM)
ACOG CATEGORY II: TOO FAR TO THE LEFT – 80% OF PATIENTS “AT RISK”

Unaffected

Spina bifida

Anencephaly

ACOG CATEGORY SYSTEM

• CATEGORY I
  • Baseline rate: 110-160 BPM,
  • Baseline FHR variability: moderate
  • Late or variable decelerations: absent
  • Early decelerations: present or absent
  • Accelerations: present or absent

• CATEGORY II
  • Includes all FHR tracings not Category I or Category III. May represent an appreciable fraction of those encountered in clinical care. Examples of Cat II FHR tracings include any of the following:
    • Baseline rate
      • Bradycardia not accompanied by absent baseline variability
      • Tachycardia
    • Baseline FHR variability
      • Minimal baseline variability
      • Absent baseline variability with no recurrent decelerations
      • Marked baseline variability
    • Accelerations
      • Absence of induced accelerations after fetal stimulation

ACOG CATEGORY SYSTEM

• Periodic or episodic decelerations
  • Recurrent late decelerations > 2 minutes but <10 minutes
  • Recurrent late decelerations with moderate baseline variability
  • Variable decelerations with other characteristics such as slow return to baseline, overshoots, or "shoulder"

• CATEGORY III
  • Absent baseline FHR variability and any of the following
    • Recurrent late decelerations
    • Recurrent variable decelerations
    • Bradycardia
    • Sinusoidal pattern

As a medical community, we seem to know less than we thought we did 30 years ago regarding the utility of this ubiquitous technology.
Category IIA

Category IIB

Algorithm for management of category II fetal heart rate tracings

Moderate variability or accelerations

Yes

No

Significant desynchronizations with ≥50% of contractions for 1 hour

Yes

No

Significant desynchronizations with ≥50% of contractions for 30 minutes

Yes

No

Late labor

Active phase

Second stage

Normal labor progress

Normal progress


Observe

Cesarean or CVD

Observe

Cesarean or CVD

Manage per algorithm

Several Variants of Aramaic

Modern: introduced by Ataturk in 1928

Illiteracy drops from 90% to 30% in 15 years

Göktürk script (8TH – 10TH CENTURY)

Modern: introduced by Ataturk in 1928

Illiteracy drops from 90% to 30% in 15 years

TURKISH LANGUAGE

Göktürk script (8TH – 10TH CENTURY)

Several Variants of Aramaic

Modern: introduced by Ataturk in 1928

Illiteracy drops from 90% to 30% in 15 years

Avrupa Kitaşına Hoş Geldiniz

Welcome to Europe

Ortaköy Vapur"
OUR APPROACH – “KEEPING LABOR SAFE”

• We have re-engineered the approach to interpretation of EFM by formally incorporating 4 new factors: medical, obstetrical, and fetal factors and increased uterine activity into the interpretation that up to now only included the tracing, per se.
• We have broken down the qualitative, often ambiguous interpretation of the EFM, per se, into 4 quantifiable components. The resulting 8 components form what we have coined the “Fetal Reserve Index.”
• A completely normal FRI would receive 1 point for each of the 8 components and be scored as 100%. If 2 points were abnormal, then 6/8 would give an FRI of 75%. If 7 points were abnormal, then 1/8 = 12.5%.
• For convenience, akin to traffic lights, we divide these into normal {FRI >50%} (Green Zone), Caution { FRI ≤50% and >25%} (Yellow Zone), and Diligent {≤25%} (Red Zone)

COMPONENTS OF THE FETAL RESERVE INDEX

• Fetal Heart Rate
• Baseline variability
• Accelerations
• Decelerations
• Increased uterine activity
• Maternal risk factors
• Obstetrical risk factors (inc. labor)
• Fetal risk factors (separate from EFM)

• Each category scored as 1 if normal and 0 if not.
• Maximum 8 points = 100%
  • 6/8 = 75%
  • 1/8 = 12.5%
• Zones:
  • Green >50 to 100%
  • Yellow >25 to 50%
  • Red 0 to 25%
COMPONENTS OF THE FETAL RESERVE INDEX

• For our algorithm we used “standard” ACOG definitions of everything EXCEPT:
• We define increased uterine activity (EXUA) as being >4 contractions per ten minutes rather than >5 per 10 minutes.

MATERNAL RISK FACTORS

• Decreased cardiac output / vascular perfusion of the placenta
  • Cardiac Disease with risk of decreased cardiac output in pregnancy
  • Hypertension (Chronic and Pregnancy induced)
  • Hypotension from epidural
  • SLE, etc.
• Oxygen carrying capacity
  • Pulmonary disorders (e.g. Asthma)
  • Anemia and hemoglobinopathy
• Infection (chronic and acute)
• Chronic debilitating Disease
• Malabsorption / Poor weight gain
• Endocrine – Diabetes and hyperthyroidism
• Advanced Maternal age
• Drug abuse, addiction, and smoking
• Obesity – BMI >35
• Short stature ≤ 5’2”” (156cm)
OBSTETRICAL RISK FACTORS

• IUGR
• Macrosomia
• Oligohydramnios
• Polyhydramnios
• Bleeding and abruption
• Previous c/section
• Placental and umbilical cord anomalies
• Rupture of Membranes (PPROM, SROM, AROM)
• Dystocia (Protraction and arrest disorders of labor)
• Malpresentation

FETAL RISK FACTORS

• Abnormal Dopplers/BPP
• Genetic disorders
• Fetal arrhythmia
• Meconium passage
• Second stage of labor - labor
• Amnioinfusion
• Discontinuation of Pitocin due to fetal intolerance
• Conversion patterns (Acute prolonged tachycardia (>170 bpm)
• Ominous overshoots
• Bradycardia (<100 bpm)
• Missing important data in labor (e.g. lack of EFM in second stage)
**EFM Definitions: Fetal Heart Rate Patterns**

- **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.
**EFM Definitions: Fetal Heart Rate Patterns**

- **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
  - Prolonged decelerations
- **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
  - **Abnormal** (not recovered)
    - Prolonged overshoot
    - Recovers to higher rate
    - 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
  - 2nd stage of labor Failure to determine or establish a baseline rate immediately following deceleration x 2 is considered pathological. Assigned to Point A

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**POINT “A”**

- **THE POINT AT WHICH WE CAN NO LONGER BE CERTAIN OF THE HEALTH AND NEUROLOGIC INTEGRITY OF THE FETUS**

  Not part of scoring system
POINT “B”

• THE POINT AT WHICH WE ARE CERTAIN THE FETUS IS ALREADY DAMAGED

Not part of scoring system

Points “A” and “B”

“A” & “B” require experienced interpretation, and are NOT included in the FRI
INCREASED UTERINE ACTIVITY

- >4 Contractions within a 10 minute period averaged over a 30 minute period.
- “standard” ACOG definition requires >5 contractions per 10 minutes averaged over a 30 minute period.
- Example here: each panel 16 minutes & shows 19 contractions in 32 minutes
- Does not yet reach Point A

Our premise:
EFM misses the BIG picture

Effect of the same punch

1ST ROUND 14TH ROUND
REACHING THE “RED ZONE”

• 20-25% of controls get there.
• A call for immediate attention.
• Does not automatically mean immediate delivery required:
  – Senior obstetrical evaluation
  – Intrauterine resuscitation (stop Pit, O2, position, labor down)
  – Many cases can return to “yellow” and proceed to vaginal delivery
• Starts a “shot clock” (up to 40 min) to resolve before mandating delivery [within 30 min]
• [deliver within 70 minutes total]

In American football terms:
  – 3rd down and 5 to go
  – Not 4th down and 5.

Defending a corner kick, not a penalty kick
MANAGEMENT IN THE RED ZONE

CP cases get into Red Zone earlier and stay there longer. All CP cases were in the Red Zone for more than 2 hours. Entering Red Zone starts a “shot clock” to:

1. get senior people there
2. evaluate
3. implement a game plan (IR or delivery)
4. resolve

REPRESENTATIVE CONTROLS

• Time goes downward in 20 min intervals.
• Score assessed each interval
• EFM and IUA are dynamic:
  • Can go normal to abnormal – back and forth
• Maternal, fetal, and obstetrical:
  • Only normal to abnormal
Representative CP Cases

- Cases tend to go “RED” early in labor
- Cases have hours of RED zone before damage occurs

A Preventable Case of Cerebral Palsy
3 Day Induction

1st Day | 2nd Day | 3rd Day
STUDY DESIGN

• 60 singleton, term patients who came into labor without any evidence of compromise who were diagnosed as having cerebral palsy and who had no other apparent cause of the CP
• 360 singleton, term patients who came into labor without any evidence of compromise who had a normal prenatal, intrapartum and post-partum courses who were discharged as being normal controls.
  • 86 controls reached RED Zone
  • 274 controls had worst scores in Green or Yellow zones.
• We compared demographics, FRI scores, time, and management of those in the RED zone as determinants of outcomes using:
  • ACOG monograph
  • ACOG category system (I-III)
  • FRI

RESULTS

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>APGAR 1</th>
<th>APGAR 5</th>
<th>PH</th>
<th>RED HOURS TOTAL</th>
<th>LOWEST FRI</th>
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<tr>
<td>CP CASES</td>
<td>60</td>
<td>3.0</td>
<td>5.4</td>
<td>7.03</td>
<td>5.35</td>
<td>10</td>
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<tr>
<td>RED CONTROLS</td>
<td>86</td>
<td>7.2</td>
<td>8.7</td>
<td>7.21</td>
<td>0.98</td>
<td>15</td>
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<tr>
<td>G/Y CONTROLS</td>
<td>274</td>
<td>8.1</td>
<td>8.9</td>
<td>7.24</td>
<td>N/A</td>
<td>48</td>
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</table>

EVERY CP BABY WAS IN RED ZONE >2 HOURS
## COMPARISON OF METHODS FOR IDENTIFYING CEREBRAL PALSY

<table>
<thead>
<tr>
<th></th>
<th>ACOG MONO*</th>
<th>Category III**</th>
<th>FRI**</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SENSITIVITY</strong></td>
<td>28% [17/43]</td>
<td>45% [27/33]</td>
<td>100% (60/0)</td>
</tr>
<tr>
<td><strong>SPECIFICITY</strong></td>
<td>100% [0/360]</td>
<td>100% [0/360]</td>
<td>76% [86/274]</td>
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</table>

*Postnatal data ** Prenatal data

## WORST FRI COLOR ZONE CASES VS CONTROLS

<table>
<thead>
<tr>
<th></th>
<th>CASES</th>
<th>CONTROLS</th>
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</thead>
<tbody>
<tr>
<td>GREEN</td>
<td>6.9</td>
<td>1.2</td>
</tr>
<tr>
<td>YELLOW</td>
<td>4.5</td>
<td>1.2</td>
</tr>
<tr>
<td>RED</td>
<td>6.3</td>
<td>1.2</td>
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</table>
**pH VALUES CASES VS CONTROLS**

<table>
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<tr>
<th>pH</th>
<th>%&lt;7.0</th>
<th>% 7.0+</th>
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<tbody>
<tr>
<td>7.23</td>
<td>35%</td>
<td>65%</td>
</tr>
<tr>
<td>7.03</td>
<td>0%</td>
<td>100%</td>
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</table>

**ONTATOLOGY OF PATHOPHYSIOLOGY**

- **GREEN**
- **YELLOW**
- **RED**
- **POINT “A”**
- **POINT “B”**
- **CATEGORY III**
Injured Before or During Labor?

**Time to Intervene?**

- **Yellow Zone**
- **Red Zone**

- 5 uc / 9 minutes

- Onset of pushing

- “Rescue”

**Point A**

**Point B**

**INJURED BEFORE OR DURING LABOR?**

**Injured on Admission**

- Category 2 Tracing
- Point A

**Injured in Second Stage**

- Category 1 Tracing
- Prev Cx x 1
- Prolonged Decel

- Spontaneous Birth
- Prolonged Second Stage
- Point A

- 4290 g
- Birth: 23 (calculated - no cord gases)
- Meconium
- Severe impairment
INJURED BEFORE OR DURING LABOR?

NORMAL ON ADMISSION
INJURED DURING DELIVERY
FRI

NORMAL ON ADMISSION
INJURED DURING LABOR
FRI

2nd study: FETAL RESERVE INDEX FOR PREVENTION OF EMERGENCY OPERATIVE DELIVERIES

NORMAL CONTROLS
FETAL RESERVE INDEX FOR PREVENTION OF EMERGENCY OPERATIVE DELIVERIES

EMERGENCY OPERATIVE DELIVERIES

25% CS rate: 2/3rd were EOD's

SMFM 2018
800 control cases – all with good outcomes: FRI reduced emergency CS rate by >60%

<table>
<thead>
<tr>
<th></th>
<th>REACHED RED ZONE</th>
<th>TOTAL EMERGENCY DEL</th>
<th>EMRG CSs (ECS)</th>
<th>IR USED</th>
<th>ECS (when FRI did not improve)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EARLY (N)</td>
<td>104</td>
<td>69</td>
<td>34</td>
<td>80</td>
<td>25</td>
</tr>
<tr>
<td>EARLY %</td>
<td>26%</td>
<td>17.3%</td>
<td>8.5%</td>
<td>20%</td>
<td>31.3%</td>
</tr>
<tr>
<td>LATE (N)</td>
<td>113</td>
<td>16</td>
<td>13</td>
<td>188</td>
<td>13</td>
</tr>
<tr>
<td>LATE %</td>
<td>28.2%</td>
<td>4.0%</td>
<td>3.3%</td>
<td>47%</td>
<td>6.9%</td>
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<tr>
<td>X² P VALUE</td>
<td>.474</td>
<td>.000</td>
<td>.002</td>
<td>.043</td>
<td>.001</td>
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THE DISCONNECT IN EFM REALITY

EMF AS PRACTICED
• Not quite clear whether EFM is a screening or diagnostic test
• Very subjective interpretation
• Poor inter and intra observer variability
• Studies intermingle those cases with damage before labor vs. those with normal entry into labor.

OUR APPROACH
• EFM is clearly a screening test
• FRI has improved metrics over current system.
• End point is increased risk –
  • Is demand for immediate attention
  • Not immediate delivery
• Keep safe, not rescue

THE JOURNAL OF MATERNAL-FETAL & NEONATAL MEDICINE, 2018
Re-engineering the interpretation of electronic fetal monitoring to identify reversible risk for cerebral palsy: a case control series

Mark I. Evans, Robert D. Eden, David W. Britt, Shara M. Evans and Barry S. Schifrin

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Reengineering Electronic Fetal Monitoring Interpretation: Using the Fetal Reserve Index to Anticipate the Need for Emergent Operative Delivery

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QUANTITATIVE – NOT QUALITATIVE INTERPRETATION

IN THEORY
Interpretation cannot require the dozen wise men debating, ad nauseum, the vagaries of nuance.

IN PRACTICE
Military weapon systems designed by geniuses but must be able to be operated by high-school drop-outs.

EPIEDEMOIOLOGY NOT THEOLOGY

END THE CIVIL WAR

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Original Research

OBSTETRICS
The limits of electronic fetal heart rate monitoring in the prevention of neonatal metabolic acidemia

Steven L. Clark, MD; Emily F. Hamilton, MD; Thomas J. Garte, MD; Audra Timmins, MD; Philip A. Wantick, PhD; Samuel Smith, MD

Next steps in research
The prevention of intrapartum fetal death and the detection of a large fraction of fetuses that experience metabolic acidemia during labor represent major contributions to medicine by the technology of EFHRM. Ultimately, however, additional approaches to the detection of fetal central nervous system hypoxia during labor that does not involve fetal heart rate will be necessary to close the gap between current and desired intrapartum outcomes.
CONCLUSION: FETAL MONITORING MUST CONCEPTUALLY BECOME A “LAB” TEST

MYOCARDIAL INFARCTION
• Was principally a clinical diagnosis
• EKG improved accuracy (1909)
• Various blood tests tried with poor performance (1960s & 70s)
• CPK isoenzymes (1975) were game changer creating a “de facto” algorithm with EKG for much more accurate performance

L & D SCHIZOPHRENIA
• The FRI algorithm can provide improved statistical performance of risk assessment
• Focuses on keeping fetus safe rather than rescue
• Identifies at risk fetuses earlier in the pathophysiology
• Gives time to make a plan and get out safely before the fetus’ reserve is depleted
• First thought should be intrauterine resuscitation not stat delivery

PROGRESS TO DATE
• The FRI has much better performance in identifying CP cases that came into labor “clean” than category system
• The FRI can identify (retrospective analysis) those normal cases that required emergency deliveries much better than Category system
• Managing by FRI (prospective) can result in 65% reduction in emergency deliveries and overall lowering of Cesarean rate.
• FRI correlates with immediate neonatal physiology much better than Category designations
NEXT STEPS

• Building database of abnormal and problem cases
• Computerization underway
• EMR database studies
  • 2018 and 2019
• Go live studies
  • 2019