KEEPING LABOR SAFE
Fetal Monitoring (EFM): Understanding “Reality” to protect Mother and Baby in labor

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Time to change our thinking

Keeping Labor Safe (KLS, LLC) Mission Statement
Make labor safe for mother, fetus, and health care providers by providing an unbiased and consistent method of evaluation of the birthing process based on sound pathophysiological principles so that prompt therapy can prevent harm.

Unfortunately, this body of work [EFM research] 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 technology.”

DISCLOSURE
KLS/MIE has patents on process described
EPIDEMIOLOGY NOT THEOLOGY

“EFM cannot produce sensitivities for acidemia >50% concluding something else is needed”

WHAT IS THE PURPOSE OF EFM?

KEEP 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. 2nd stage continue for hours]

RESCUE FROM THE “EDGE?”

THE PROBLEM - Cerebral Palsy

- In 2003, ACOG published a Monograph on “Neonatal Encephalopathy and Cerebral Palsy” (NEACP).

- 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.

RELYING SOLELY ON FHR INTERPRETATION, PER SE, IS AS EFFECTIVE AS THE MAGINOT LINE

- A stat CS for a baby with Apgar’s 9/9 and pH 7.1 is 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.
ESSENTIAL CRITERIA to conclude NE related to “an acute intrapartum event (must meet all four)"

- Metabolic acidosis (cord arterial blood) at delivery (pH < 7.00 and base deficit ≥ 12 mmol/L)
- Early onset of neonatal encephalopathy in infants born at 34 or more weeks of gestation
- Cerebral Palsy of the spastic quadriplegic or dyskinetic type
- Exclusion of “trauma, coagulation disorders, infectious conditions, or genetic disorders etc.”

NEONATAL ENCEPHALOPATHY AND CEREBRAL PALSY
DEFINING THE PATHOGENESIS AND PATHOPHYSIOLOGY
AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS
AMERICAN ACADEMY OF PEDIATRICS
JANUARY 2003

ACOG ATTEMPTS TO EVALUATE EFM AND CP

ACOG CATEGORY SYSTEM (2009)

- **CAT SYSTEM**
  - I. absolutely fine – no risk
  - III impending damage
    - Deliver now
  - II 80% of cases
    - With elements of concern but by itself not sufficient to warrant intervention
      - Statistical and programmatic nightmare

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 “New” 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

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

Unaffected

Spina bifida

Anencephaly

Cat III

UK Collaborative AFP Study, 1977

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

Unaffected

Spina bifida

Anencephaly

Cat II

UK Collaborative AFP Study, 1977

EFM/CAT misses the BIG picture!

Lacks Cumulative Time Effect

1ST ROUND

15TH ROUND

Re-engineering the interpretation of electronic fetal monitoring to identify reversible risk for cerebral palsy: a case control series

Mark I. Evans, MD, David W. Britt, PhD, Shara M. Evans, MD, and Barry S. Schiffin, MD

The Journal of Maternal-Fetal & Neonatal Medicine, 2011

Original Article

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

Robert D. Eden, MD, Mark I. Evans, MD, and Barry S. Schiffin, MD

Taylor & Francis Group
**Fetal Reserve Index (FRI)**

- Fetal Heart Rate (FHR)
- FHR Baseline variability
- FHR Accelerations
- FHR Decelerations
- Uterine activity (increased)
- Maternal risk factors
- Obstetrical risk factors (including labor)
- Fetal risk factors (separate from EFM)

Each category scores 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%

**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
- 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)
- Postdate Pregnancy (41 weeks)

**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 SCREENING CRITERIA

- Fetal Heart Rate (FHR)
  - >160 bpm
  - <110 bpm
- FHR Variability:
  - <5 bpm
  - >25 bpm
  - Sinusoidal
  - Nodal rhythm
- FHR Accelerations:
  - <10 bpm in labor
  - Overshoots, not shoulders
- FHR Decelerations:
  - Lates or variables with slow return to baseline
  - Prolonged (>2 mins)
- Excessive Uterine Activity (EXUA)
  - >4 UC’s 10-minutes or >8 UC’s in a 20-minute window

CREASED 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

FRI LABOR ANALYSIS

Standard of Care / Causation

Score assessed each interval

EFM and UA are dynamic:
  - Can go normal to abnormal – back and forth

Maternal, fetal, and obstetrical:
  - Only normal to abnormal
**REPRESENTATIVE CP CASES**

• CP Cases tend to go “RED” early in labor

• CP Cases have hours of RED zone before damage occurs

**REACHING THE “RED ZONE”**

• 20-25% of laboring patients get there.

• A call for immediate attention (Time out).

• Does not automatically mean immediate delivery required:
  - Senior obstetrical evaluation
  - Intrauterine Resuscitation
  - Attempt vaginal delivery

**Intrauterine Resuscitation (IR):**
1. Stop Oxytocin infusion (Terbutaline)
2. Oxygen By mask
3. IV fluid administration
4. Maternal Position Change

**TOLERANCE TO CONTINUING STRESS IN LABOR**

FRI: GREEN/YELLOW

FRI: RED

**BASE EXCESS AND PH BY LAST FRI SCORE**
**LABOR TRENDs by BASE EXCESS (Grouped by last FRI)**

- BE trend for Normal FRI cases
- BE trend for Abnormal cases

**Legend**

<table>
<thead>
<tr>
<th>BE Stage</th>
<th>Mean BE mM/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-13</td>
</tr>
<tr>
<td>2</td>
<td>-12</td>
</tr>
<tr>
<td>at Birth</td>
<td>-11</td>
</tr>
</tbody>
</table>

**COMPARISON OF METHODS FOR IDENTIFYING CEREBRAL PALSY (60)**

<table>
<thead>
<tr>
<th>[60 CP/360 CONTROLS]</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>
</tr>
</tbody>
</table>

*Postnatal data  ** Prenatal data

**FRI AND OUTCOME**

<table>
<thead>
<tr>
<th></th>
<th>CP CASES</th>
<th>RED CONTROLS</th>
<th>G/Y CONTROLS</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>60</td>
<td>86</td>
<td>274</td>
</tr>
<tr>
<td>APGAR 1</td>
<td>7.03</td>
<td>7.2</td>
<td>8.1</td>
</tr>
<tr>
<td>APGAR 5</td>
<td>4.9</td>
<td>8.7</td>
<td>8.9</td>
</tr>
<tr>
<td>PH</td>
<td>1.0</td>
<td>7.21</td>
<td>7.24</td>
</tr>
<tr>
<td>RED HOURS TOTAL</td>
<td>5.35</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>MEAN % LOWEST FRI</td>
<td>10</td>
<td>15</td>
<td>48</td>
</tr>
</tbody>
</table>

**EVERY CP BABY WAS IN RED ZONE >2 HOURS**

**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><strong>ROUTINE MGMT. (N)</strong></td>
<td>104</td>
<td>17.3%</td>
<td>34</td>
<td>80</td>
<td>31.3%</td>
</tr>
<tr>
<td>%</td>
<td>26%</td>
<td>8.5%</td>
<td>20%</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td><strong>FRI MGMT (N)</strong></td>
<td>113</td>
<td>4.0%</td>
<td>13</td>
<td>188</td>
<td>6.9%</td>
</tr>
<tr>
<td>%</td>
<td>28.2%</td>
<td>3.3%</td>
<td>47%</td>
<td>6.9%</td>
<td></td>
</tr>
<tr>
<td>X² P VALUE</td>
<td>.474</td>
<td>.000</td>
<td>.002</td>
<td>.043</td>
<td>.001</td>
</tr>
</tbody>
</table>
MANAGEMENT IN THE RED ZONE

Entering Red Zone starts a “shot clock” to:
1. Start IR
2. Call Obstetrician
3. Evaluate EFM
4. Implement a game plan (IR or delivery)
5. resolve within 20 minutes or triggers 30 min rule to deliver.

All CP cases were in the Red Zone for more than 2 hours.

LEARNING FROM OUR PAST

FETAL MONITORING DEAD SEA SCROLLS
Barry Schifrin’s garage x 45 years

THE INCHON INDEX
Intrapartum, Neonatal COMBINED Homeostatic Opportunity for Neurologic Integrity
CONNECTING BEFORE AND AFTER BIRTH

LEARNING FROM OUR PAST

BIBLICAL DEAD SEA SCROLLS
Judean Desert x 2000 years

THE INCHON INDEX

DEAD SEA SCROLL PROJECT
IN HONOR OF ED HON

Professor Edward Hon (1917-2006)
TRANSITION FROM FETUS TO NEONATE

EFM: MISSING THE 4th QUARTER

The focus on the prenatal period is like watching a football game.

Your team is ahead at the end of the 3rd quarter, which you think is the whole game, so you go to bed –

Only to discover that your team lost in the 4th quarter that you didn’t know existed.

DEAD SEA SCROLL PROJECT

• 475 Studies directed by Dr. Ed Hon between 1969-1975 - Sat unanalyzed x 45 years.
• Several hundred high risk cases with ROM continuously and intensely monitored through delivery and for 1 hour postpartum.
• Multiple fetal scalp samples with any concerns (e.g. decelerations)
• Cord blood and umbilical artery bloods at 4, 8, 16, 32, & 64 minutes.
• Continuous NHR for 1 hour

Initially Evaluated 275 cases (1971-73) using FRI and created a new metric for postnatal status up to 1hr.

For postnatal categories, we used the “last FRI” score which tended to be the lowest, so we combined Green & Yellow into one group.

Then we divided the Reds into “high” (Ruby) and “low” (Crimson)

We graphed each of the 3 subgroups over the first hour of neonatal life

We then created a new combined prenatally and postnatal metric:

The INCHON index [last FRI, cord blood BE and pO2] to predict risk of metabolic acidosis at 30 minutes.

INCHON: LOW RISK CASE
What happens to the Neonatal HR Rate in the 1st hour after delivery? Can it decipher timing/etiology of Birth Injury?

85% OF NEONATES HAVE TACHYCARDIA: CORRELATES WITH FRI SCORE
NHR RECOVERY CORRELATES WITH FRI SCORE
KAPLAN – MEIER

What happens to the neonatal pH in the 1st hour after delivery?

What happens to the Neonatal Base Excess in the 1st hour after delivery?
**BASE EXCESS WORSENS BEFORE IMPROVING**

Mean Postnatal Base Excess scores by Time After Birth Categorized by Fetal Reserve Index Risk

- The recovery equation assumes going straight from NY to Miami.
- In fact, plane stopped in DTW on way down so path is all wrong, goes backwards, and includes period of vulnerability not previously recognized.

**POSTPARTUM BASE EXCESS RECOVERY:**

the equation doesn’t follow the physiology

**BE RECOVERY TIME CORRELATES WITH FRI SCORE**

![Graph showing correlation between BE recovery time and FRI score]

**KEEPING LABOR SAFE**

1st step

- FRI clearly has better performance metrics than CAT
  - Identify CP
  - Earlier identification
  - Reduce CS and EOD

2nd step

- How do we “prove” that the performance comes from better prediction of the normal and abnormal physiology?
**EARLY PREDICTION OF NEONATAL COURSE BY BASE EXCESS**

Detection of lowest 25% of Base Excess at 32 minutes post partum.

**INCHON > FRI > CAT**

Detection of lowest 25% of Base Excess at 32 minutes post partum.

**NEONATAL RESPONSE TO ACIDOSIS RISK FOR HIE**

- **Stabilization**
- **Brain cooling**

- FRI predicts early response of neonate
- INCHON clarifies neonatal status by 30 minutes.
- BOTH permit earlier pediatric determination for therapy than currently.
**CONSEQUENCES OF SIGNIFICANT STRESS OF BIRTH**

**INCHON**: GREEN/YELLOW

**INCHON**: RED

---

**A HALF CENTURY (50 years) OF THE BIRTHING PROCESS MISUNDERSTANDING PATHOPHYSIOLOGY**

- pH and BE get worse before they get better after birth!
- 85% of Neonates have significant tachycardia, decreased variability and Non-reactivity immediately after birth
- 25% of Neonates exhibit a CAT III tracing shortly after birth
- 34% of cases have BE ≤-12 mMol/L ("threshold of CP risk")
- The significant period for metabolic acidemia occurs AFTER birth
- CAT system based on NON-PATHOPHYSIOLOGICAL principles.
- The FRI correlates with BE and pH (will improve with more data and weighting of risk factors)

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**"INCHON" PAPER 10/10/2019**

Original Article

Combined prenatal and postnatal prediction of early neonatal compromise risk


*Fetal Medicine Foundation of America, Mt. Sinai School of Medicine, New York, NY, USA; **Comprehensive Genetics, PLLC, Mt. Sinai School of Medicine, New York, NY, USA; 3Department of Obstetrics and Gynecology, Mt. Sinai School of Medicine, New York, NY, USA; 4Department of Maternal and Child Health, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA
Rescue

Time to Intervene?

Yellow Zone  Red Zone

CAT III

5 uc / 9 minutes – Onset of pushing

\[ \text{IR} = \text{IR} \]

- Improves prediction of HIE
- Promotes safety not rescue
- Identifies need for early IR
- Assesses standard of care
- Assesses causation of injury

EFM MUST BE A “LAB” TEST

Which comes first?

Decreased Fetal Reserve or Birth Trauma

= IR ?
INJURED BEFORE OR DURING LABOR?

Case: 30 y. o. G3 P2002 at 28+ wks
Admitted with Decreased FM, Hx IUFD, Prev c/s, Obesity
BPP 4/8 (+FBM, Normal AFV) with decreased FHR variability, NR, and late decelerations
14 hours later a FHR bradycardia occurred and an emergency c/section was performed. 1235 gm fetus delivered with a true knot in cord
Apgars 0/0/4  pH 6.89  BE -25.2
Severe HIE

CONTRIBUTORY NEGLIGENCE?

A PREVENTABLE CASE OF CEREBRAL PALSY?
35 y.o. G1P0 at 40 3/7 wks IOL, Morbid Obesity, AROM/Meconium

1ST DAY
2ND DAY
3RD DAY

INJURED ON ADMISSION
INJURED IN SECOND STAGE

A NEW “GOLD STANDARD”
• Survival was the Old metric
• Non-Emergent and Safe Vaginal Delivery with Intact Neurologic survival must become the New metric

Analogy:
Just landing on Omaha Beach was not the true measure of success; it was getting off the Beach alive and creating a Beachhead!!!
**Case: 21 y.o. G4 P3003 at 40 3/7 wks**

S/S of oligo abruptio, macrosomia on Pitocin 6 hrs prior to delivery despite EXUA

Abnormal variability, NR, lateste, and EXUA 4-5 cms/-2 station

All 4 EFM variables abnormal after 3 hours of Red Zone at 5cms/-2 station

CAT III 1 hour prior to C/S without evaluation of 4th Cardinal movement of labor at 0 station

Apgars: 3/5  pH: 6.89  BE: -21.0

**Case: 33 y.o G3 P1021 39 2/7 wks - IOL**

Sh. Stature, obesity, and EXUA for hours resulting in tachycardia, decreased variability, NR, lateste, EXUA after epidural (? IV Hydration)

4 hour 2nd stage of labor with abnormal EFM without descent of 2 cm/hr for multipara

Fetal injury evident after 4 hours of labor IN THE Red Zone, then CAT III

Total Red Zone > 5 hrs

Forceps delivery → Shoulder Dystocia

No cord gas, HIE, Seizures
Case: 25 y.o G1P0 at 40 5/7 wks

Sh. Stature (5'0''), Obese, Pre-E admitted in labor with normal tracing.

Off the monitor at 6-7 cms for almost 2 hours, then at 8-9 cms, AROM with thick meconium with decreased variability, NR, Lates.

Became C/C 1.5 hours later in the Red Zone then began pushing causing bradycardia, nodal rhythm, NR, and EXUA, and no Terbutaline given.

Kiwi vacuum attempted for 7 minutes at +1 station before Stat c/s ordered. Tight nuchal cord noted at delivery of 3640 gms baby

Apgars: 2/5/6  pH 6.629  BE: -18.1
Severe HIE despite head cooling.

The KEEP LABOR SAFE (KLS) System

KLS “box” takes EMR & EFM Inputs and calculates KLS algorithms (FRI and INCHON scores) in real time

NEXT STEPS

• Building database of abnormal and problem cases
• Computerization of algorithms
• EMR database studies
  • Late 2019 and 2020
• Go “live” studies
  • 2020

FETAL RESERVE INDEX SUMMARY

• Category system metrics fail all statistical principles of screening:
  • Poor sensitivity, specificity, positive and negative predictive values.
  • Current methods work “well” in true expert hands, but 98% of labors are managed by others – much too subjective interpretation.

• The contextualization of EFM with contractions, and medical, obstetrical, and fetal risk factors provides a better assessment of fetal reserve & status.

• Our first 8 papers show improved performance for both CP (retrospective analysis) and the ability to reduce emergency deliveries without adverse outcomes (prospective).

• With computerization of the KLS system (in progress) and weighting of variables, performance should improve further.

• Fetuses are steadily using up their “reserve” in the 2nd stage
  • Decreasing Fetal Reserve (BE) blunted by IR.
  • Should not “power through” concerning EFM tracings by upping Pitocin.
  • Should turn Pitocin down to give fetus a chance to recover.
INCHON SUMMARY

• Neonatal physiologic parameters at birth usually WORSEN before IMPROVING.

• The degree of neonatal decompensation (increased NHR, decreased pH and BE) directly correlates with the FRI before delivery.

• By adding postnatal data, the INCHON Index significantly improves the prediction of persistent metabolic acidosis and risk of neurologic injury.

• Earlier recognition of increased risk may permit more expeditious and aggressive treatment of fetuses and neonates.

• Direct, continuous intrapartum monitoring should be continued into the neonatal period for as long as risk persists to guide neuroprotective interventions.