KEEPING LABOR SAFE

Fetal Monitoring (EFM): Understanding "Reality" to protect Mother and Baby in labor

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DISCLOSURE

KLS/MIE has patents on process described

(12) United States Patent
Evans

(10) Patent No.: US 9,131,860 B2
(45) Date of Patent: Sep. 15, 2015

(54) IDENTIFYING THE LEVEL OF FETAL RISK DURING LABOR

(76) Inventor: Mark Evans, Fort Lee, NJ (US)

FOREIGN PATENT DOCUMENTS

EP 0784270 8/1990
EP 1945116 8/2205
(Continued)

URKUNDE — CERTIFICATE — CERTIFICAT

Europäisches Patent — European patent — Brevet européen

2389104

Evans, Mark

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.

OBSTETRICS

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

Steven L. Clark, MD; Michael P. Nageotte, MD; Thomas J. Garite, MD; Roger K. Freeman, MD; David A. Miller, MD; Kathleen R. Simpson, RN, PhD; Michael A. Belfort, MD, PhD; Gary A. Dildy, MD; Julian T. Parer, MD; Richard L. Berkowitz, MD; Mary D'Alton, MD; Dwight J. Rouse, MD; Larry C. Gilstrap, MD; Anthony M. Vintzileos, MD; J. Peter van Dorsten, MD; Frank H. Boehm, MD; Lisa A. Miller, CNM, JD; Gary D. V. Hankins, MD

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

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

"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."

EPIDEMIOLOGY NOT THEOLOGY

END THE CIVIL WAR

Gray Journal 2017

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. Garite, MD; Audra Timmins, MD; Philip A. Warrick, PhD; Samuel Smith, MD

"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]

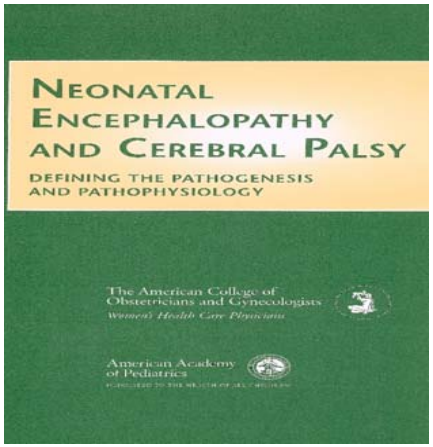
RESCUE FROM THE "EDGE?"

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 !**

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.**



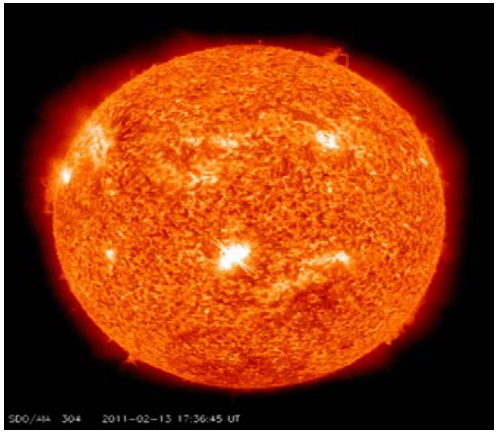
NEONATAL ENCEPHALOPATHY AND CEREBRAL PALSY

DEFINING THE PATHOGENESIS AND PATHOPHYSIOLOGY
AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS
AMERICAN ACADEMY OF PEDIATRICS
JANUARY 2003

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 ≥12mmol/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,"**

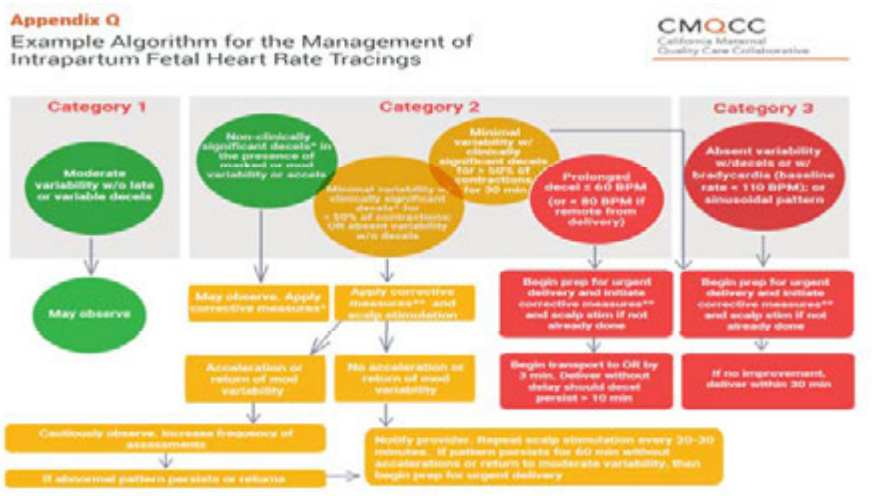
ACOG ATTEMPTS TO EVALUATE EFM AND CP



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**

CATEGORY SYSTEM SCHIZOPHRENIA



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**


THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

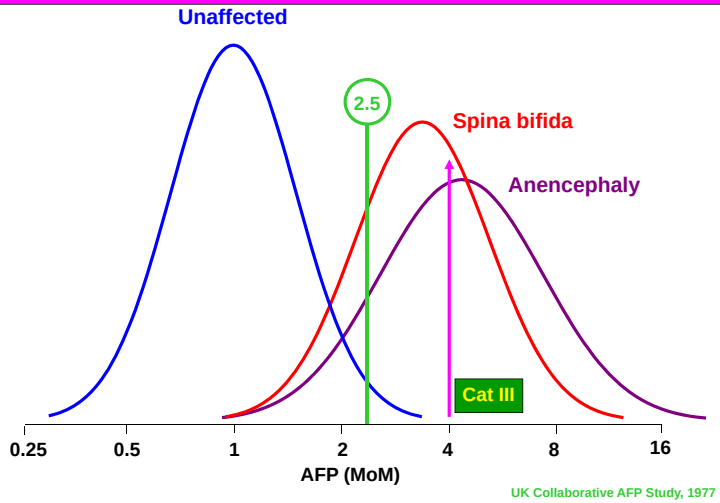
PRACTICE BULLETIN

CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN–GYNECOLOGISTS

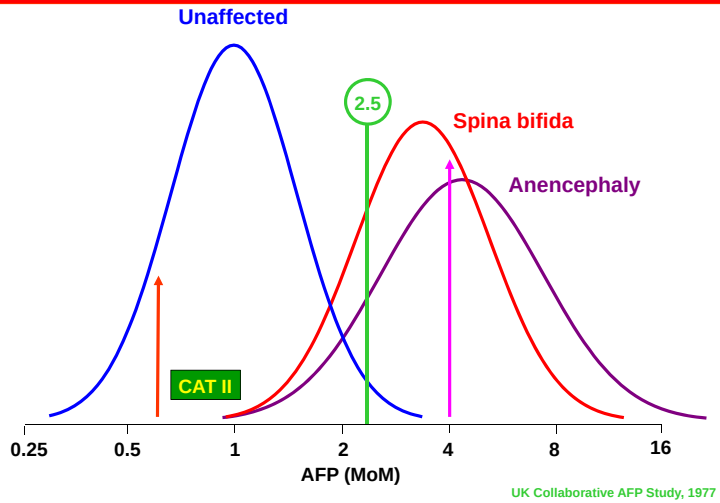
Number 116, November 2010

Management of Intrapartum Fetal Heart Rate Tracings

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



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



EFM/CAT misses the BIG picture !

Lacks Cummulative Time Effect

1ST ROUND

15TH ROUND

Fetal Diagnosis and Therapy

Fetal Diagn Ther
DOI: 10.1159/000475927

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The "Fetal Reserve Index": Re-Engineering the Interpretation and Responses to Fetal Heart Rate Patterns

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Taylor & Francis
Taylor & Francis Group

ORIGINAL ARTICLE

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

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Original Article

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

Reproductive Sciences
1–17
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Robert D. Eden, MD[1], Mark I. Evans, MD[1,2,3], Shara M. Evans, MSC, MPH[1], and Barry S. Schifrin, MD[1]

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)

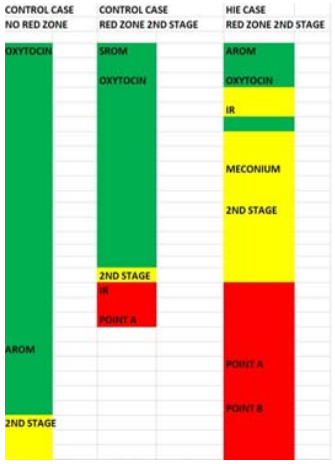
Each category scores 1 if normal and 0 if not.

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

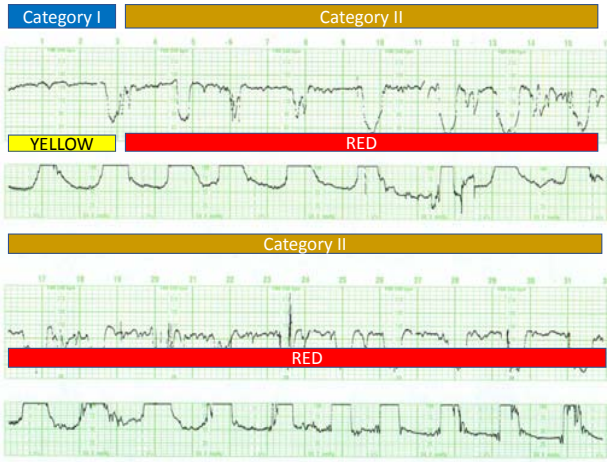
- Abnormal Dopplers/BPP
- Genetic disorders
- Fetal arrhythmia
- Meconium passage
- Second stage of labor - labor
- Amnioinfusion
- Discontinuation of Pitocin due to fetal intolerance
- Conversion patterns (Acute prolonged tachycardia (>170 bpm)
- Ominous overshoots
- Bradycardia (<100 bpm)
- Missing 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

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

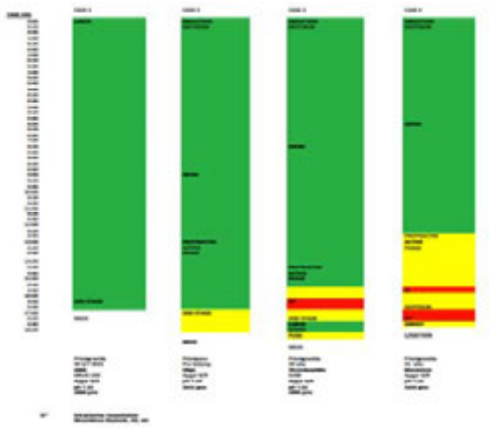


FRI LABOR ANALYSIS
Standard of Care / Causation

DURATION		Y R R	PITOCIN							TOTAL		
TIME	MATERNAL	OBSTETRIC/	FETAL		FHR	VAR	ACCELS	DECELS	EXUA	SCORE	UC/10	FRI
0:00	TEEN	SROM		1	1	DECREASE		1	1	5	2	0.625
0:10	TEEN	SROM		1	1	DECREASE		1	1	5	2	0.625
0:20	TEEN	SROM		1	1	DECREASE		V-LATE	1	4	2	0.5
0:30	TEEN	SROM		1	1	DECREASE		1	1	5	2	0.625
0:40	TEEN	SROM		1	1	DECREASE		1	1	5	4	0.625
0:50	TEEN	SROM		1	1	DECREASE		1	1	5	2	0.625
1:00	TEEN	SROM		1	1	DECREASE		1	1	5	4	0.625
0:10	TEEN	SROM		1	1	DECREASE		1	1	5	2	0.625
0:20	TEEN	SROM		1	1	DECREASE		1	1	5	2	0.625
0:30	TEEN	SROM		1	1	DECREASE		1	1	5	2	0.625
0:40	TEEN	SROM		1	1	DECREASE		1	1	5	2	0.625
0:50	TEEN	SROM		1	1	DECREASE		1	1	5	3	0.625
2:00	TEEN	SROM		1	1	DECREASE		1	1	5	4	0.625
0:10	TEEN	SROM		1	1	DECREASE		1	1	5	3	0.625
0:20	TEEN	SROM		1	1	DECREASE		1	1	5	4	0.625
0:30	TEEN	SROM		1	1	DECREASE	ABSENT	V-PROL	1	3	3	0.375
0:40	TEEN	SROM		1	1	DECREASE		V-LATE	1	4	3	0.5
0:50	TEEN	SROM		1	1	DECREASE	ABSENT		1	4	3	0.5
3:00	TEEN	SROM		1	1	DECREASE		V-LATE	1	4	4	0.5
0:10	TEEN	SROM		1	1	DECREASE		1	1	5	3	0.625
0:20	TEEN	SROM		1	1	DECREASE		V-LATE	1	4	2	0.5
0:30	TEEN	SROM		1	1	DECREASE	ABSENT	V-LATE	1	3	4	0.375
0:40	TEEN	SROM		1	1	DECREASE		1	1	5	3	0.625
0:50	TEEN	SROM		1	1	DECREASE		1	1	5	3	0.625
4:00	TEEN	SROM		1	1	DECREASE	ABSENT		1	4	3	0.5
0:10	TEEN	SROM		1	1	DECREASE	ABSENT	V-LATE	1	3	4	0.375
0:20	TEEN	SROM		1	1	DECREASE	ABSENT	V-LATE	1	3	3	0.375
0:30	TEEN	SROM		1	1	DECREASE		1	1	5	4	0.625
0:40	TEEN	SROM		1	1	DECREASE	ABSENT		1	4	4	0.5
0:50	TEEN	SROM		1	1	DECREASE	ABSENT		1	4	3	0.5
5:00	TEEN	SROM		1	1	DECREASE	ABSENT	V-LATE	1	3	4	0.375
0:10	TEEN	SROM		1	1	DECREASE	ABSENT	V-LATE	1	3	4	0.375
0:20	TEEN	SROM	2ND		1	DECREASE		V-LATE	EXUA	2	5	0.25
0:30	TEEN	SROM	2ND		1	DECREASE	ABSENT	V-LATE	EXUA	1	5	0.125
0:40	TEEN	SROM	IR		1	DECREASE	ABSENT	V-LATE	1	2	4	0.25
0:50	TEEN	SROM	IR		1	DECREASE		V-LATE	EXUA	2	5	0.25
6:00	TEEN	SROM	IR		1	DECREASE		V-LATE	1	3	4	0.375
0:10	TEEN	SROM	IR		1	DECREASE	ABSENT	V-LATE	1	2	4	0.25
0:20	TEEN	SROM	IR		1	DECREASE	ABSENT	V-LATE	1	2	4	0.25
0:30	TEEN	SROM	IR		1	DECREASE	ABSENT	1	1	3	4	0.375
0:40	TEEN	SROM	IR		1	DECREASE	ABSENT	1	1	3	3	0.375
0:50	TEEN	SROM	IR		1	DECREASE	1	1	1	4	?	0.5

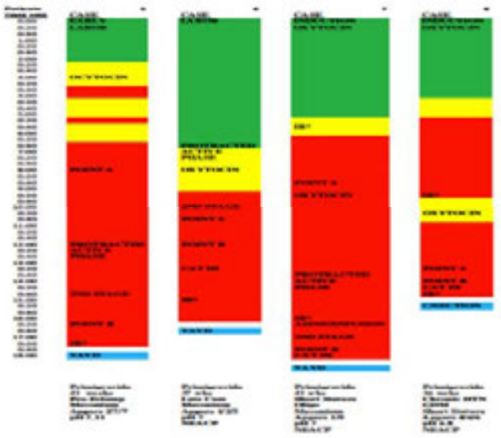
REPRESENTATIVE CONTROLS

- Time (downward) 20 min intervals.
- 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



TOLERANCE TO CONTINUING STRESS IN LABOR

FRI: GREEN/YELLOW

FRI: RED

REACHING THE "RED ZONE"

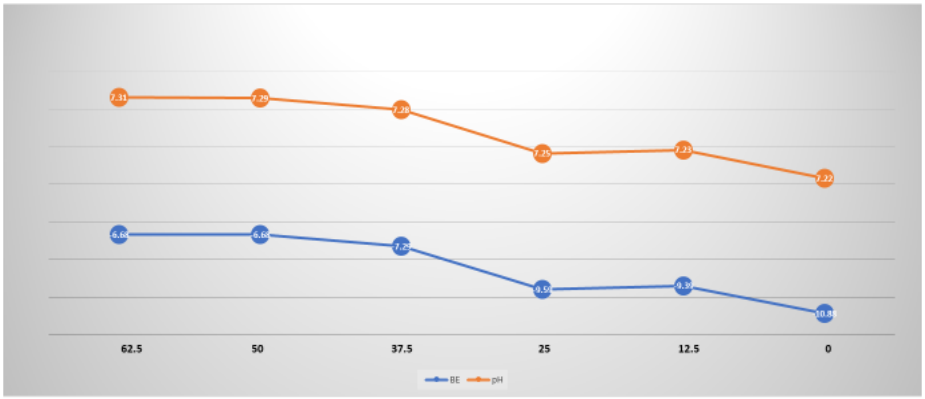
- 20-25% of laboring patients get there.
- A call for immediate attention (Time out).
- Does <u>not</u> automatically mean immediate delivery required:
  - Senior obstetrical evaluation
  - Intrauterine Resuscitation
  - Attempt vaginal delivery

- 3rd down and 4
- <u>Not</u> 4th down and 4.

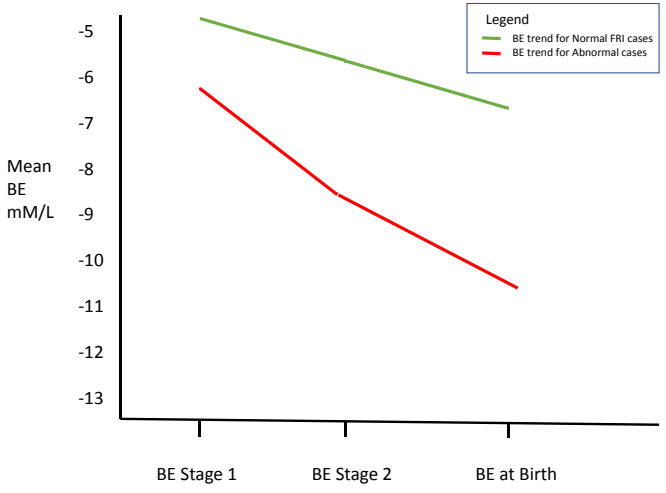
<u>Intrauterine Resuscitation (IR):</u>

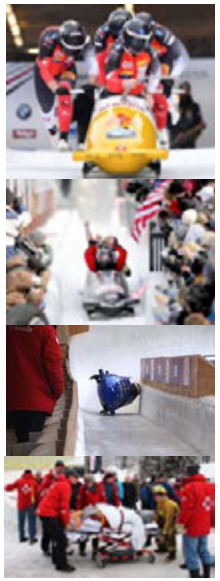
1. Stop Oxytocin infusion (Terbutaline)
2. Oxygen By mask
3. IV fluid administration
4. Maternal Position Change

BASE EXCESS AND PH BY LAST FRI SCORE



LABOR TRENDS by BASE EXCESS (Grouped by last FRI)





COMPARISON OF METHODS FOR IDENTIFYING CEREBRAL PALSY (60)

[60 CP/360 CONTROLS]	ACOG MONO*	Category III**	FRI**
SENSITIVITY	28% [17/43]	45% [27/33]	100% (60/0]
SPECIFICITY	100% [0/360]	100% [0/360]	76% [86/274]

*Postnatal data ** Prenatal data

FRI AND OUTCOME

	N	APGAR 1	APGAR 5	PH	RED HOURS TOTAL	MEAN % LOWEST FRI
CP CASES	60	3.0	5.4	7.03	5.35	10
RED CONTROLS	86	7.2	8.7	7.21	0.98	15
G/Y CONTROLS	274	8.1	8.9	7.24	N/A	48

EVERY CP BABY WAS IN RED ZONE >2 HOURS

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

	REACHED RED ZONE	TOTAL EMERGENCY DEL	EMRG CSs (ECS)	IR USED	ECS (when FRI did not improve)
ROUTINE MGMT. (N)	104	69	34	80	25
%	26%	17.3%	8.5%	20%	31.3%
FRI MGMT (N)	113	16	13	188	13
%	28.2%	4.0%	3.3%	47%	6.9%
X^2 P VALUE	.474	.000	.002	.043	.001

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

BIBLICAL DEAD SEA SCROLLS

Judean Desert x 2000 years

LEARNING FROM OUR PAST

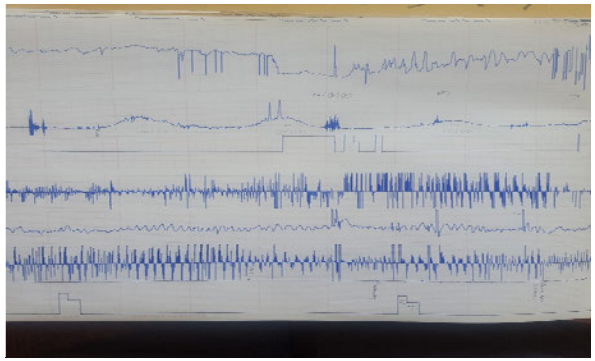
FETAL MONITORING DEAD SEA SCROLLS

Barry Schifrin's garage x 45 years

THE INCHON INDEX

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

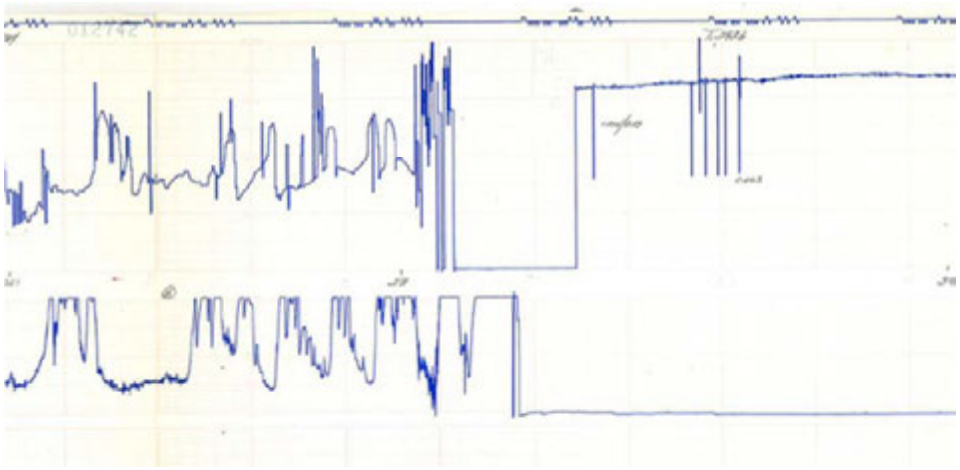
DEAD SEA SCROLL PROJECT



IN HONOR OF ED HON

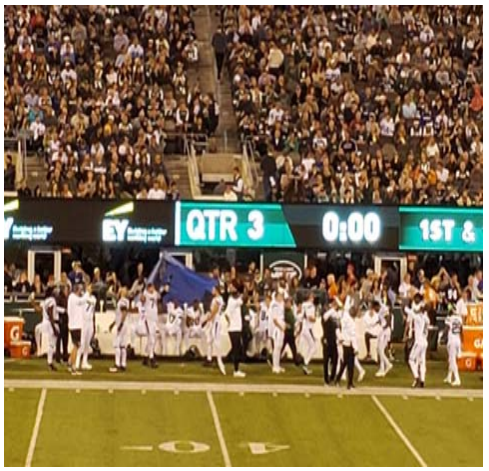
Professor Edward Hon (1917-2006)

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.

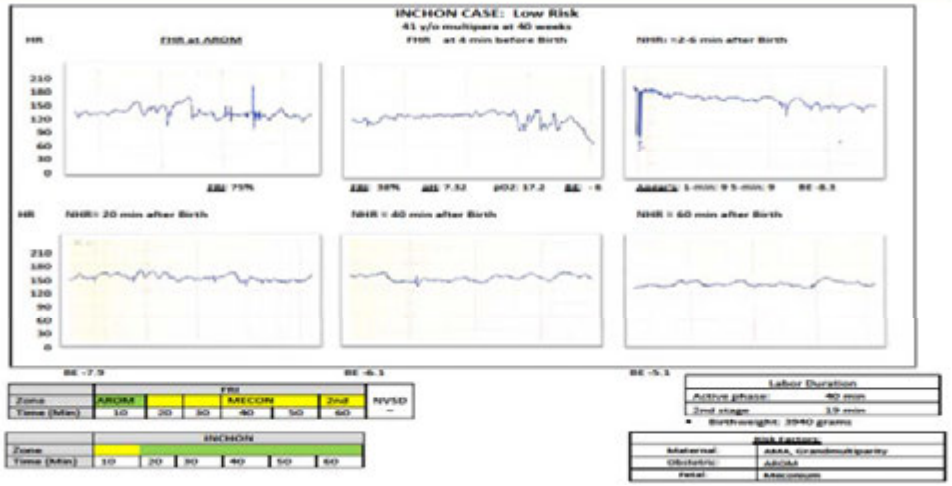


DEAD SEA SCROLL PROJECT

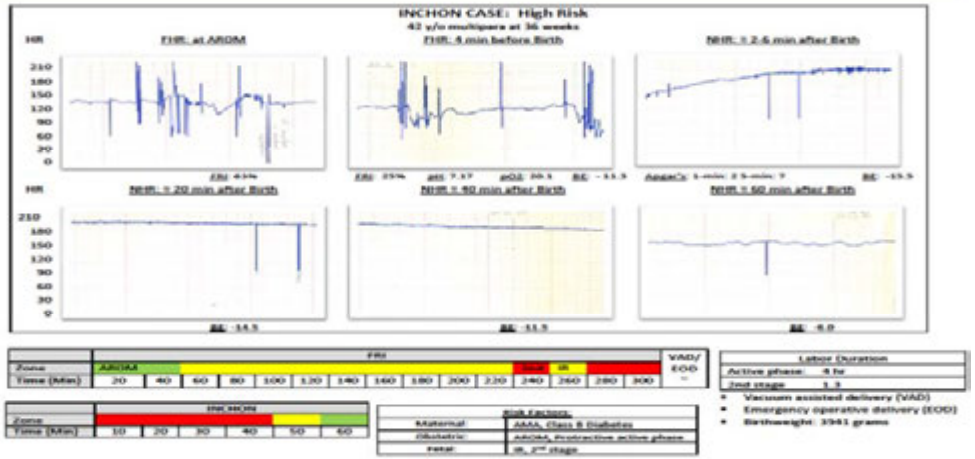
- 475 Studies directed by Dr. Ed Hon between 1969-1975 - Sat unanalyzed x 45 years.
- Several hundred high risk cases with ROM continuously and intensely monitored through delivery and for 1 hour postpartum.
- Multiple fetal scalp samples with any concerns (e.g. decelerations)
- Cord blood and umbilical 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

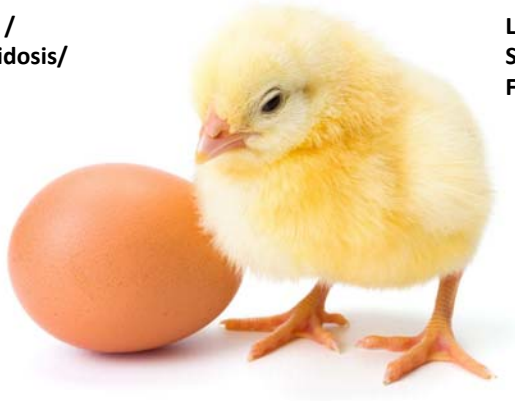


INCHON: HIGH RISK CASE



BIRTH TRAUMA ?

Fetal Distress / Metabolic Acidosis/ HIE

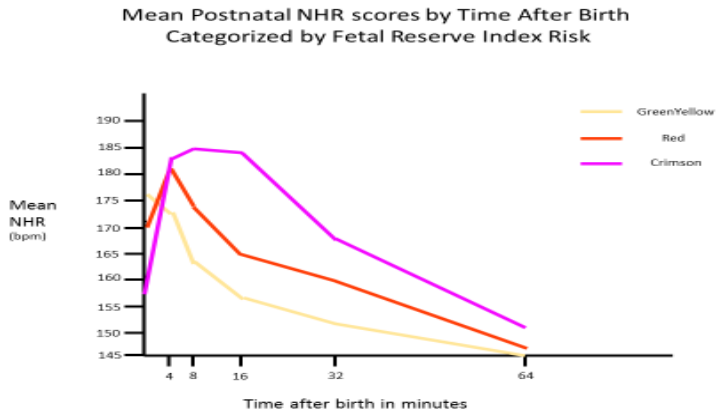


Labor Dystocia/ Shoulder Dystocia / Erb's Forcep / Vacuum injury

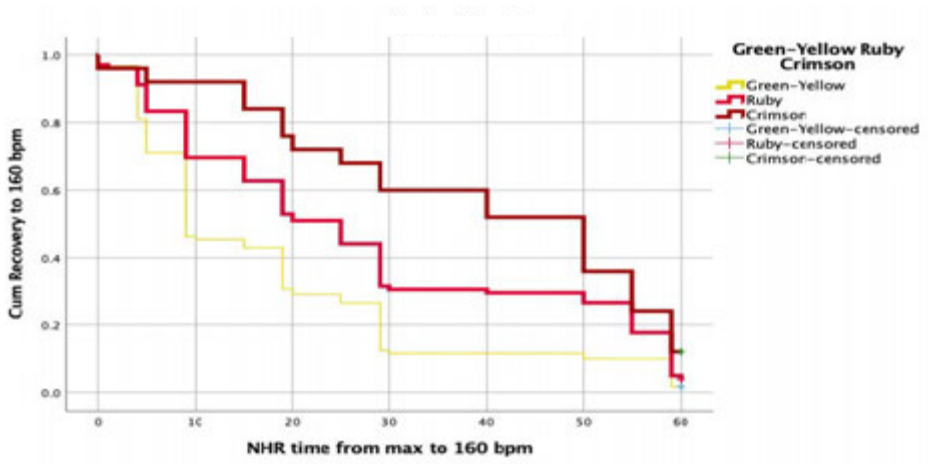
What happens to the Neonatal HR Rate in the 1st hour after delivery?

Can it decipher timing / etiology of Birth Injury?

85% OF NEONATES HAVE TACHYCARDIA: CORRELATES WITH FRI SCORE

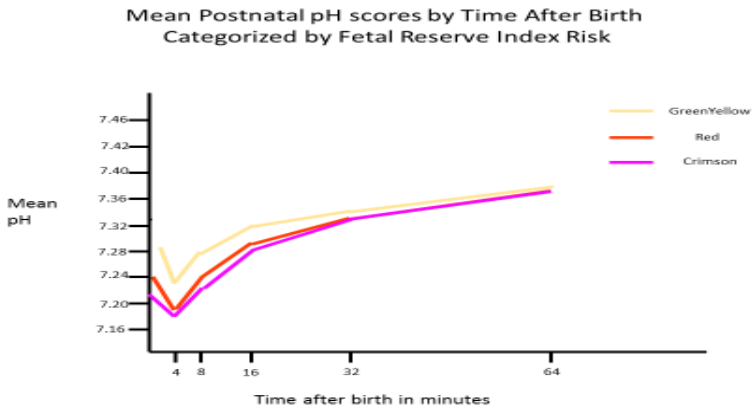


NHR RECOVERY CORRELATES WITH FRI SCORE KAPLAN – MEIER



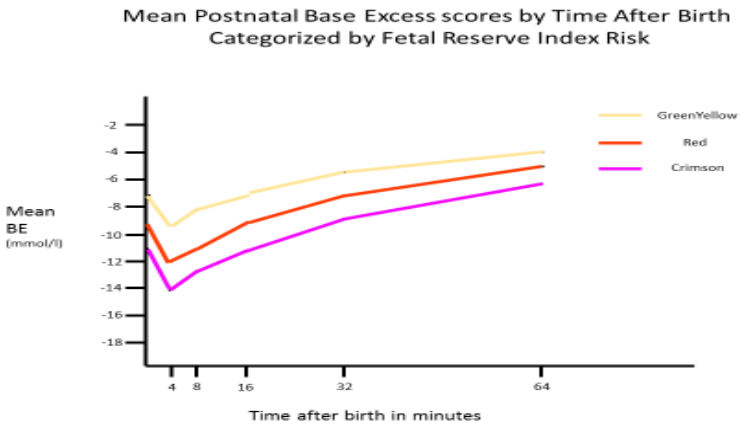
What happens to the neonatal pH in the 1st hour after delivery?

pH WORSENS BEFORE IMPROVING

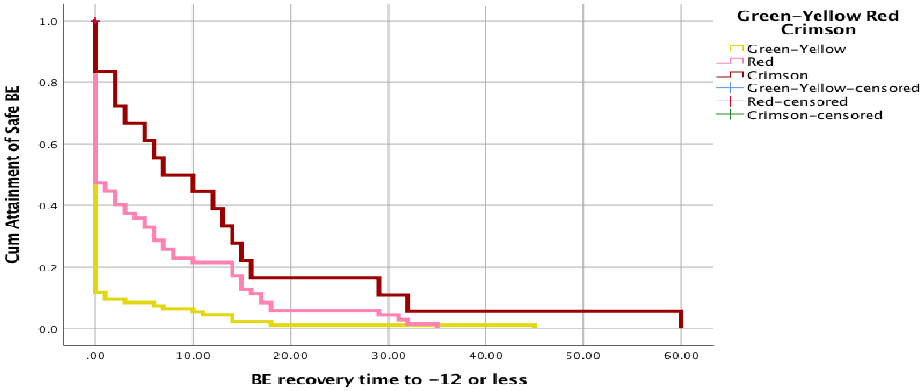


What happens to the Neonatal Base Excess in the 1st hour after delivery?

BASE EXCESS WORSENS BEFORE IMPROVING



BE RECOVERY TIME CORRELATES WITH FRI SCORE



POSTPARTUM BASE EXCESS RECOVERY:
the equation doesn't follow the physiology

- 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.

KEEPING LABOR SAFE

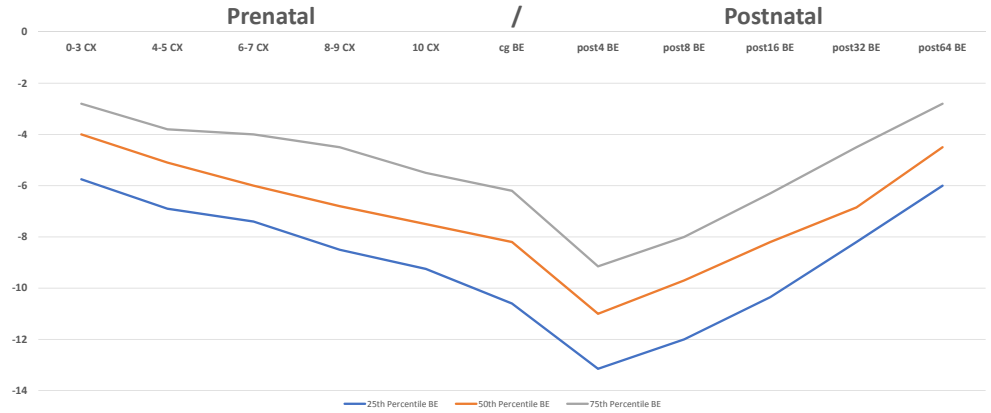
1st step

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

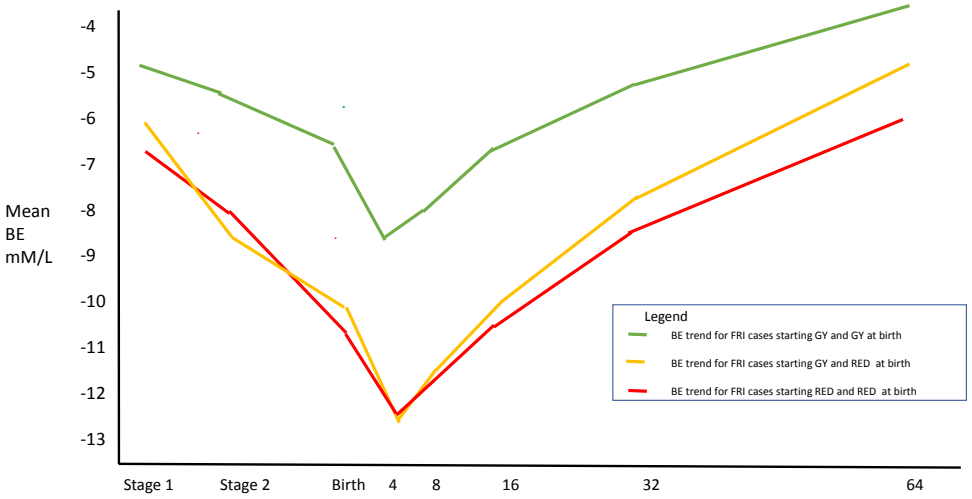
2nd step

- How do we "prove" that the performance comes from better prediction of the normal and abnormal physiology?

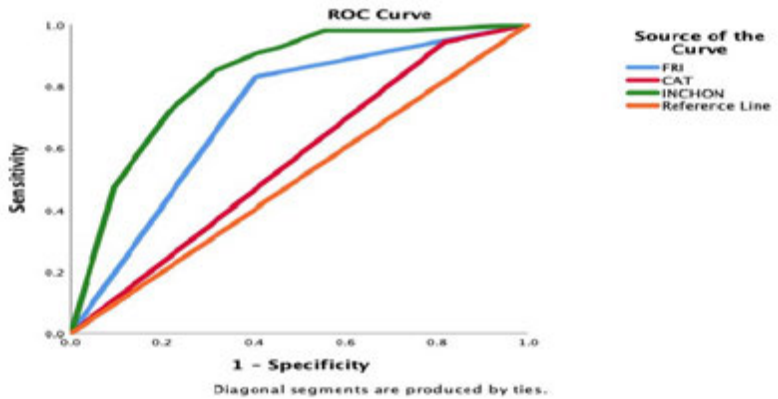
EARLY PREDICTION OF NEONATAL COURSE BY BASE EXCESS



Base Excess trend for Combined 1HR/Last FRI Risk Groups



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) MISUNDERSTANDING OF THE BIRTHING PROCESS 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)

"INCHON" PAPER 10/10/2019

THE JOURNAL OF MATERNAL-FETAL & NEONATAL MEDICINE
https://doi.org/10.1080/14767058.2019.1676714

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ORIGINAL ARTICLE

Combined prenatal and postnatal prediction of early neonatal compromise risk

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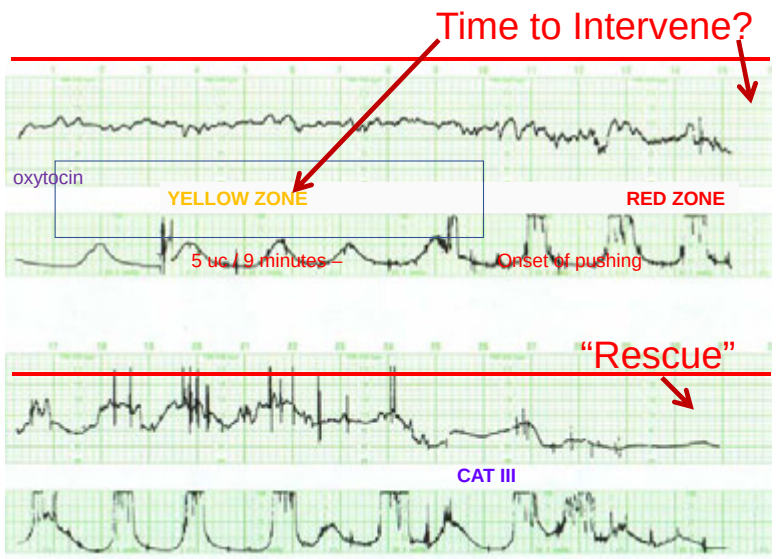

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= IR ?

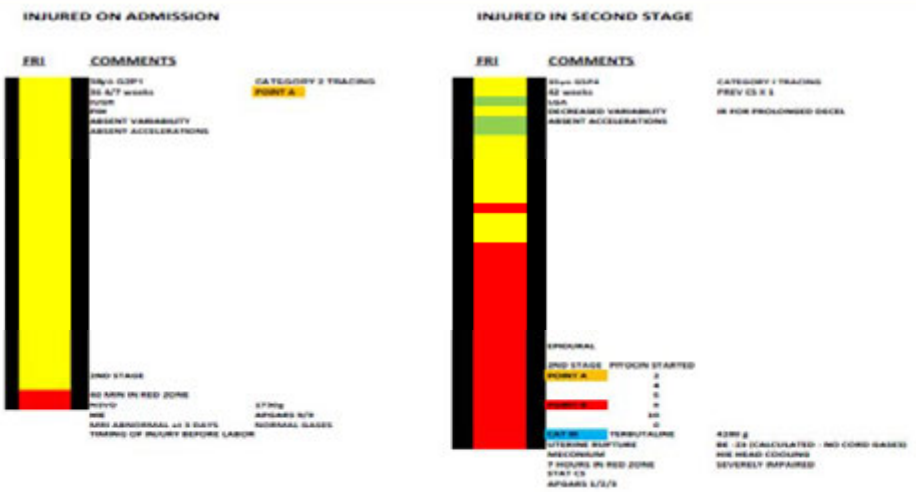
EFM MUST BE A "LAB" TEST

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

WHICH COMES FIRST ?

Decreased Fetal Reserve or Birth Trauma

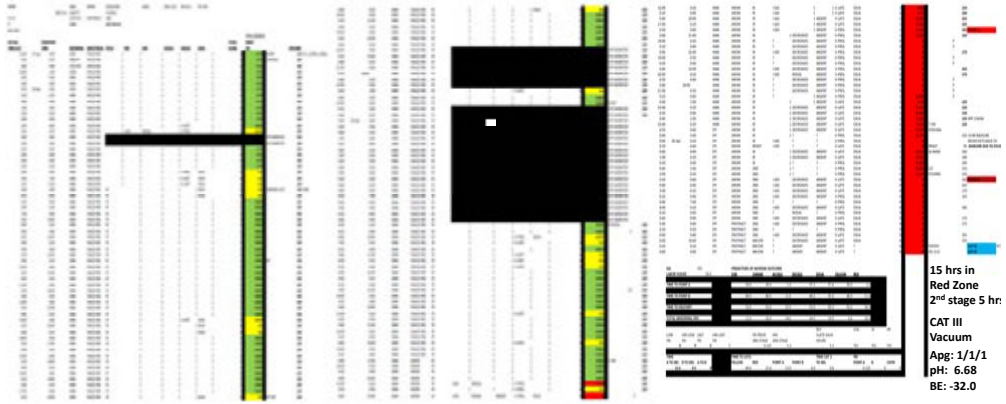
INJURED BEFORE OR DURING LABOR ?



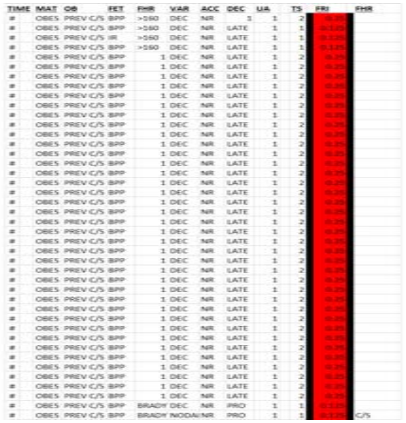
A PREVENTABLE CASE OF CEREBRAL PALSY ?

35 y.o. G1P0 at 40 3/7 wks IOL, Morbid Obesity, AROM/Meconium

1ST DAY | 2ND DAY | 3RD DAY



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 ?

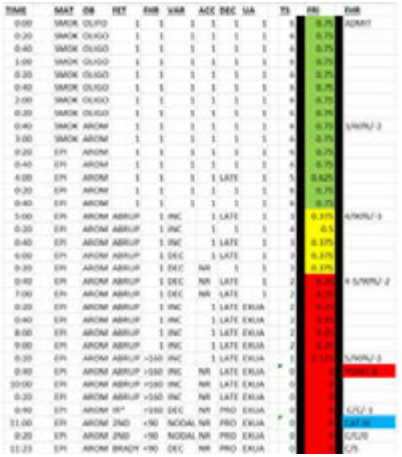
A NEW "GOLD STANDARD"

- 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 abruption, macrosomia on Pitocin 6 hrs prior to delivery despite EXUA

Abnormal variability, NR, lates, 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

TIME	MAT	OB	FET	FHR	VAR	ACC	DEC	UA	TS	FRI	CX
0:00	CHRN	1		1	1	1	1	1	7	0.875	IOL
0:20	OBESI	1		1	1	1	1	1	7	0.875	
0:40	CHRN	1		1	1	1	1	1	7	0.875	
1:00	CHRN	1		1	1	1	1	1	7	0.875	
0:20	CHRN	1		1	1	1	1	1	7	0.875	
0:40	CHRN	1		1	1	1	1	1	7	0.875	
2:00	CHRN	1		1	1	1	1	1	7	0.875	
0:20	CHRN	1		1	1	1	1	1	7	0.875	
0:40	CHRN	1		1	1	1	1	1	7	0.875	
3:00	CHRN	1		1	>160	1	1	1	EXUA	5	0.625
0:20	CHRN	1		1	>160	1	1	1	EXUA	5	0.625
0:40	CHRN	1		1	1	1	1	1	EXUA	6	0.75
4:00	CHRN	1		1	1	1	1	1	EXUA	6	0.75
0:20	EPIDL	1		1	1	1	1	LATE	EXUA	5	0.625
0:40	EPIDL	1		1	>160	DEC	NR	1	EXUA	3	0.375
5:00	EPIDL	1	IR		1	1	1	LATE	EXUA	4	0.5
0:20	EPIDL	1	IR		1	DEC	NR	LATE	EXUA	2	0.25
0:40	EPIDL	1	IR		1	DEC	NR	LATE	EXUA	2	0.25
6:00	EPIDL	AROM	IR		1	DEC	NR	PRO	EXUA	1	0.125
0:20	EPIDL	AROM	IR		>160	DEC	NR	1	EXUA	1	0.125
0:40	EPIDL	AROM	2ND		>160	DEC	NR	LATE	EXUA	0	0
7:00	EPIDL	AROM	2ND		>160	DEC	NR	LATE	EXUA	0	0
0:20	EPIDL	AROM	2ND/IR		>160	DEC	NR	LATE	EXUA	0	0
0:40	EPIDL	AROM	2ND/IR		>160	DEC	NR	LATE	EXUA	0	0
8:00	EPIDL	AROM	2ND/IR		>160	DEC	NR	LATE	EXUA	0	0
9:00	EPIDL	AROM	2ND/IR		>160	DEC	NR	LATE	EXUA	0	0
0:20	EPIDL	AROM	2ND/IR		>160	DEC	NR	PRO	EXUA	0	0
0:40	EPIDL	AROM	2ND/IR		>160	DEC	NR	LATE	EXUA	0	0
10:00	EPIDL	PROTR	2ND/IR		>160	DEC	NR	LATE	EXUA	0	0
0:20	EPIDL	PROTR	2ND/IR		>160	DEC	NR	PRO	EXUA	0	0
0:40	EPIDL	PROTR	2ND/IR		>160	DEC	NR	PRO	EXUA	0	0

Sh. Stature, obesity, and EXUA for hours resulting in tachycardia, decreased variability, NR, lates, 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

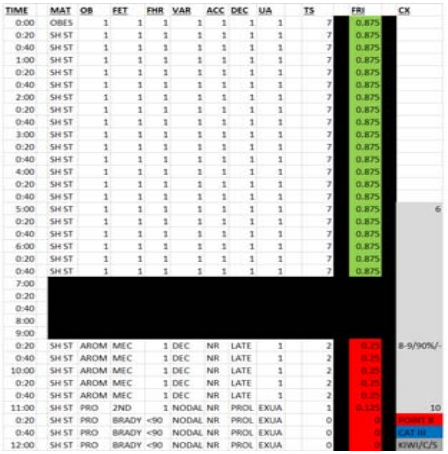
Total Red Zone > 5 hrs

Forcep delivery → Shoulder Dystocia

No cord gas, HIE, Seizures

FORCEPS INJURY/SHOULDER DYSTOCIA OR LABOR ?

Case: 25 y.o G_1P_0 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

EMR

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

EFM

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.