Patient Safety & Fetal Heart Monitoring
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- Serves at St. Joseph's Hospital as the Chairman of the Obstetric and Gynecology department, Director of the Performance Improvement Committee and is a member of the Medical Executive Committee.
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- Director of the Children's Hospital Los Angeles – University of South California Institute for Maternal – Fetal Health, a multidisciplinary, multi-institutional center specializing in fetal and neonatal assessment and treatment
- Co-author of Fetal Monitoring and Assessment, a Multidisciplinary Approach, the first multidisciplinary textbook published on the top of fetal monitoring (7th edition, Mosby 2012) and the GE Electronic Fetal Heart Rate Monitoring online education program
- Academic interests include prenatal diagnosis and antepartum and intrapartum fetal evaluation with emphasis on fetal physiology and effective, standardized methods of training in electronic fetal heart rate monitoring
- Lectures frequently and has published numerous medical journal articles
Electronic Fetal Monitoring

• Has the potential to influence the incidence of preventable life-long brain damage or death.

• Consequently, it is a common focus for litigation.

• Costs associated with these cases account for 60% of malpractice premiums.
ACOG 2012 Professional Liability Survey
2009-2011
9,006 ob-gyn responses

- 77.3% experienced at least 1 claim in lifetime (or 2.69 claims per ob-gyn)

- From, 4,060/9,006 reported having an open or closed claim during that time
  - 63% involved obstetric care

The OB Liability Problem – You already know it
More on the Survey

• Primary allegations in claims
  – 28.8% neurologically impaired infant
  – 14.4% stillbirth or neonatal death

• 20.9% associated EFM as a primary factor applicable to their claim

• Average payment for claims
  – $982,051 for neurologically injured infant
  – $271,149 stillbirth/neonatal death
Frequency and Severity


• And, “slight rise in frequency...in contrast to the past few years in which we had noted declining, or stable frequency.” 6th annual benchmarking report on professional liability claims trends in the hospital industry. Perspectives: A Risk Management Tool for the Healthcare Industry [Zurich American Insurance Co.] 17(2):1-14, Fall 2011.


  — California, Connecticut, Florida, Maine, Michigan and Wyoming
Some of the Recent OB Awards

• CA: April 2012 (OB): Brain damage in child due to ob-gyn failing to progress birth, leading to oxygen deprivation. $74M

• MI: Oct. 2011 (OB): Injured baby during delivery: fractured clavicle and severe brain trauma. $144M, reduced to $41.6 million.

• CT: May 2011 (OB): Delay in c-section, resulting in brain damage. $58.6M

• PA: May 2012 (OB): Claimed use of antiquated equipment led to 81-min delay in baby’s delivery; baby is now quadriplegic and requires life long care. $78.5 M

Jury awards Waverly family $55 million in Hopkins malpractice case
Damages among largest malpractice awards in state history, attorneys say

Jake 26, 2012 By Yvonne Wenger and Kevin Rector, The Baltimore Sun

After hours of labor, Enso Martinez cried as his wife, Rebecca Fielding, was carried from their Waverly home on a stretcher’s route to Johns Hopkins Hospital. Fielding, who had wanted to deliver her baby at home with the help of a midwife, assured her husband that everything would be OK.

But she never expected to wait more than two hours for an emergency Caesarean section after being rushed to the hospital.
The Potential Impact

- Copycat patients (file suits to obtain similar results)
- Pl attys use to large verdicts, will impact settlement negotiations
- With a ripple effect that will include judges and jurors

And It’s Already Started...

Doctors, hospitals concerned about hefty malpractice awards

By Andrea K. Walker, The Baltimore Sun
Sat Aug 4 2012 11:47 AM

Maryland’s medical community is concerned about the potential fallout from two multimillion-dollar malpractice judgments awarded by Baltimore juries to families who blamed local hospitals where their babies were delivered for their children’s disabilities.

Doctors and hospital officials worry that juries, particularly in Baltimore City, are making decisions out of sympathy for sick patients rather than science. In the process, physicians said, these decisions may create an unrealistic benchmark for what future juries are willing to award — and lawyers are willing to seek — in such cases. Such rich awards also could drive up the cost of malpractice insurance for doctors, which likely would be passed along to patients.

Doctors and hospitals said they are bracing for a trickle-down effect of more lawsuits and rising malpractice insurance rates because of the recent judgments. They argue malpractice costs could become so burdensome that doctors decide to stop working in certain locations and specialties.
What the Plaintiff Lawyers are Doing

• Taking advantage of high award publicity
• They are organized
• They are consolidating
• Taking high value cases (i.e. neurologically-impaired infants)
• Adding JD/MDs to their litigation teams
• Taking classes on how to emotionally connect with jurors
What Plaintiff Lawyers Say About EFM...

- EFM provides “real time picture of the baby’s heart rate and the mother’s contraction pattern”

- No single piece of medical evidence standing alone should be permitted to defeat a birth injury case where the totality of circumstances point to negligent management of L&D as the cause

- When the defense points to an Apgar score, dig deeper, get the raw score, question every assumption

- Depose the delivery room nurses and get to the truth

- Never accept a single cord pH test as conclusive proof that baby’s injuries could not have come from delay in delivery

- “Always, always get the fetal monitoring strips for every case.”
  – “They often tell the story the hospital does not want you to know.”

Peer-reviewed Literature Tells US

• 747 obstetrical claims analysis (Beckman, et al.)
  
  – failure to timely detect fetal distress by nursing was the cause in more than 1/2 of the claims against nurses
  
  – failure to promptly inform the physician of fetal distress resulted in 35 serious injuries and 16 deaths
And Additional Data...

- Delayed dx of fetal distress, determined by EFM, is the #1 frequent allegation.

- Among reported obstetrical claims electronic fetal monitoring is the most common variable (ACOG).

- HCA claims analysis - allegations often involved:
  - nurses and physicians failing to properly read fetal heart monitoring strips or
  - failing to act appropriately in response to tracings.

![Diagram](image.png)
OB Consult

• OBC’s 50- OB claim study - most common allegations in fetal heart monitoring cases were:

1. Failure to monitor
2. Failure to properly interpret fetal monitoring strips
3. Failure to communicate fetal distress to an obstetrician
4. Failure to take appropriate steps and timely steps in response to fetal distress
The Good News...

You Can Change the OB Liability Equation

Understand OB Risks Baseline

Risk Mitigation

Transcending the Settings

Event Management

Event

Risk

Category system

Control of the Process

Claim

Being aggressive- using the evidence/science

Lawsuit

A Different Defense

Risk Mitigation

Mitigation

You Can Change the OB Liability Equation
ELECTRONIC FETAL HEART MONITORING

The data overwhelmingly reveals that evaluation, communication, and response to tracings are key factors in outcomes and claims.
• In 2004, JCAHO, reported that 77% of sentinel events involving perinatal death or permanent injury involved non-reassuring status of the fetus, and that inadequate fetal monitoring is a root cause in 34% of perinatal death and injury cases.

• TJC recommends educating nurses, residents, nurse midwives, and physicians on the use of standardized terminology to interpret fetal heart tracings and communicate the findings.
What the Literature/Studies Say

• Appropriate interpretation is important
  – Fetal heart monitoring is the standard of care for identification
  – **One-hour window** of patterns can predict asphyxial exposure before morbidity and decompensation¹
  – FHM is most effective by those skilled in interpretation and in a collaborative manner²
  – **Standardized nomenclature** has been recommended, but **competencies and education** are also essential³

• Malpractice largely does not cause cerebral palsy⁴

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A novel survey of provider knowledge of 1997 NICHD and 2008 ACOG and SMFM nomenclature for electronic fetal monitoring; a calling for competency based evaluations for all providers

<table>
<thead>
<tr>
<th>Definition</th>
<th>MFM (n=23)</th>
<th>Fellow (n=13)</th>
<th>Obstetrician (n=25)</th>
<th>OB/GYN Resident (n=19)</th>
<th>L&amp;D Resident (n=15)</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tachysystole</td>
<td>14 (61%)</td>
<td>10 (77%)</td>
<td>13 (52%)</td>
<td>16 (84%)</td>
<td>13 (87%)</td>
<td>0.074</td>
</tr>
<tr>
<td>Hyperstimulation</td>
<td>16 (70%)</td>
<td>12 (92%)</td>
<td>11 (44%)</td>
<td>17 (89%)</td>
<td>14 (93%)</td>
<td>0.0009</td>
</tr>
<tr>
<td>Moderate Variability</td>
<td>14 (61%)</td>
<td>12 (92%)</td>
<td>15 (60%)</td>
<td>19 (100%)</td>
<td>13 (87%)</td>
<td>0.0017</td>
</tr>
<tr>
<td>Baseline Heart Rate</td>
<td>13 (57%)</td>
<td>10 (77%)</td>
<td>13 (52%)</td>
<td>16 (84%)</td>
<td>12 (80%)</td>
<td>0.10</td>
</tr>
<tr>
<td>Episodic/Periodic Patterns</td>
<td>10 (43%)</td>
<td>8 (62%)</td>
<td>12 (48%)</td>
<td>13 (68%)</td>
<td>10 (67%)</td>
<td>0.40</td>
</tr>
<tr>
<td>Prolonged Deceleration</td>
<td>19 (83%)</td>
<td>13 (100%)</td>
<td>20 (80%)</td>
<td>17 (89%)</td>
<td>12 (80%)</td>
<td>0.47</td>
</tr>
</tbody>
</table>

MFM = maternal fetal medicine; OB/GYN = obstetrics and gynecology, L&D = labor and delivery.

*p-value form Fisher's exact test
All L&D nurses were specifically trained using standardized protocols in the reading of fetal heart rate monitor tracings.

Before beginning work, nurses complete a 4-hour classroom session in basic fetal heart rate interpretation.

Within the first year, they must then successfully complete a 2-day course in fetal heart rate monitoring.

Course includes a day of lecture materials and a day of skills demonstration and testing.

Thereafter, each nurse must document continuing education in fetal heart rate interpretation.
ALL IN STRATEGY

• Laboring women are monitored by a team of health care providers that often include residents, midwives and registered nurses.

• **All providers of care** in labor and delivery should be required to complete an education course that focuses on the up-to-date criteria for fetal heart rate description.

• Participation in the course should be required of all providers as part of retaining privileges.
University of Texas Study

Indicate that different providers may develop a uniform approach to fetal distress when they practice in the same environment and follow the available electronic fetal heart rate monitoring guidelines, overcoming the effects of different personal experiences, professional background, clinical practice, and psychological traits.

Obstetrics & Gynecology:
October 2011 - Volume 118 - Issue 4 - p 809–817
Intervention for Fetal Distress Among Obstetricians, Registered Nurses, and Residents: Similarities, Differences, and Determining Factors
Chiossi, Giuseppe MD; Costantine, Maged M. MD; Pfannstiel, Joy M. MD; Hankins, Gary D. V. MD; Saade, George R. MD; Wu, Zhao Helen PhD
ELECTRONIC FETAL HEART MONITORING

The data overwhelmingly reveals that evaluation, communication, and response to tracings are key factors in outcomes and claims.
Between 1995 and 2005, the Joint Commission (JCAHO) reviewed over 3500 sentinel events and found that communication problems were the leading root cause of preventable patient harm, including injuries and deaths.
Collaboration: Why does it matter?

Root causes in obstetric malpractice cases consistently highlight miscommunication and failure of teams to function as a team as the primary cause.

65-72% of preventable adverse outcomes are secondary to lack of collaboration and poor communication (Joint Commission).

TODAY’S HEALTHCARE IS VERY COMPLEX

• During the course of a 4 day hospital stay, a patient may interact with 50 professionals from a variety of educational backgrounds.

• Lack of critical information, misinterpretation of information, unclear orders and overlooked changes in patient status causes patient harm.

• Without team collaboration women and the unborn are at serious risk.
Formal Communication Systems

C
Current Condition | Situation
What is my major concern?

H
History | Background
What are the pertinent facts?

A
Assessment
What do I think is the problem?

T
Treatment | Recommendation
What do I recommend that we do?
“ESCALATION”

If the response by the consultant does not suggest a mutually acceptable course of action, it will be necessary to follow the chain of command or communication escalation policy in your hospital until you are satisfied that a plan in the best interest of the patient has been established. If you are not familiar with your own institutional policy, please review it.
“Escalation”

• **Tip:** Reiterate before you escalate and remember we are the patient’s advocate, responsible first and foremost for the safety of the patient.
The data overwhelmingly reveals that evaluation, communication, and response to tracings are key factors in outcomes and claims.
30 MINUTES DECISION TO INCISION FOR FETAL INTOLERANCE TO LABOR

- Obstetrical practice standard
- 25% of cases were meeting this standard.
- Using a program of continuous quality improvement, various systematic and individual barriers were identified and overcome resulting in a significant change in performance

Response

Meeting the thirty minute standard

Response

A Process Strategy: CODE C

• Streamlined communication, one call summons everyone to the operative suite
• Delineate the roles and responsibilities of all team members (SCDs, Foley, Scrub etc.)
• Anesthesiologists are part of the team
• Move the patient to the delivery room immediately
• Everyone meets in the delivery room not the labor room
• Ongoing audits to assure effectiveness
The Clinical and PL Fix

1. Clinical Strategies
   - Managing the second stage of labor
   - Thirty minute standard

2. Processes and Procedures
   - Umbilical cord blood gases
   - PI – on going review of low Apgar scores
   - Event management
   - Documentation
   - Code C

3. Electronic fetal monitoring ... enhancing skills and communication
   - NICHD Terminology
   - Pocket card
   - Education
   - Competencies
How Do you Know How Your Team is Doing?

• An objective, independent on-site safety and risk management assessment (go beyond EFM) is available

• Look for the new EFM competency dashboard...more to come...
INTRAPARTUM FETAL HEART RATE MONITORING
Definitions and Interpretation

Applying Principles of Patient Safety

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I have the following relevant financial relationship with a commercial interest:

Co-author:
“Fetal Monitoring – A Multidisciplinary Approach”
Mosby’s Pocket Guide Series
Distributed by Mosby-Elsevier

Co-author:
“Electronic Fetal Heart Rate Monitoring
Interpretation and Management”
On-line, Interactive Educational Program:
Distributed by GE Healthcare

Consulting agreement
Clinical Computer Systems, Inc
Makers of OBIX
As a medical professional, there are many things on your plate, and fetal monitoring is only one of them.

It might seem that a disproportionate amount of time and energy is dedicated to this one area of medicine.

But that is because fetal monitoring...

1. Is the most common procedure you will perform in obstetrics
2. Involves the potential for preventable lifelong brain damage
3. Represents an overwhelmingly disproportionate share of the medicolegal risk you will face throughout your career
4. Our primary goal is to optimize outcomes... a secondary goal is to minimize risks
The most effective way to optimize outcomes AND minimize medical-legal risk is to practice according to...

“Standard of Care”
“Standard of Care”

Level of care expected of a reasonable practitioner

Who makes that determination?
Optimize outcomes

Standard of care

Reasonable

Credible

Factually accurate and articulate
Start with the basics

Undertake the simple exercise of deconstructing fetal heart rate monitoring into its essential components
FHR monitoring consists of three components:

- Intrapartum FHR Monitoring
- Definition
- Interpretation
- Management
Normal baseline rate 110-160 bpm

Mean FHR rounded to increments of 5 bpm in a 10-minute window
Variability is defined as fluctuations in the baseline that are irregular in amplitude and frequency...

The fluctuations are measured from peak-to-trough in bpm.

No distinction is made between short-term (beat-to-beat) variability and long term variability because in actual practice they are visually determined as a unit.
Acceleration
Abrupt increase (onset to peak < 30 sec) from baseline

32 weeks and beyond – 15 x 15

Before 32 weeks – 10 x 10
Decelerations

Early
Late
Variable
Prolonged
Late versus variable
Why have we been taught to believe that late decelerations are “ominous” but variable decelerations are “benign”?

As early as the 1970s, elegant research demonstrated that late decelerations reflect a protective reflex response to transient fetal hypoxemia during a uterine contraction.
During a uterine contraction, decreased maternal perfusion of the placenta can cause the fetal PO2 to fall below the lower limit of normal.
Decreased fetal PO2 (hypoxemia) during a uterine contraction is detected by... chemoreceptors.
Chemoreceptors signal the brain stem
In order to shunt oxygenated blood to the vital organs of the brain, heart, adrenal glands and placenta...
Sympathetic outflow causes peripheral vasoconstriction to redistribute oxygenated blood away from the extremities, gut and kidneys.

Peripheral vasoconstriction causes the blood pressure to rise.

Rising blood pressure is detected by baroreceptors.
Baroreceptors signal the brain stem
Parasympathetic (vagal) outflow slows the FHR to reduce cardiac output and lower blood pressure.
Variable Deceleration
Occlusion of the umbilical cord causes the blood pressure to... RISE
Rising blood pressure is detected by baroreceptors.
Baroreceptors signal the brain stem.
Parasympathetic (vagal) outflow slows the FHR to reduce cardiac output and lower blood pressure.
Late decelerations and variable decelerations are protective autonomic reflex responses.

Neither is inherently “ominous”

Neither is inherently “benign”
The 2008 NICHD Workshop Report on Electronic Fetal Monitoring

A very brief update
New “Three-Tier” Fetal Heart Rate Classification System

Category I – “Normal”

Category II – “Indeterminate”

Category III – “Abnormal”
New “Three-Tier” Fetal Heart Rate Classification System

Category I – “Normal”

Baseline rate: 110-160 bpm
Variability: Moderate
Decelerations: No late, variable or prolonged

Obstet Gynecol 2008;112:661-6
New “Three-Tier” Fetal Heart Rate Classification System

Category III – “Abnormal”

1. Absent variability with recurrent late decelerations
2. Absent variability with recurrent variable decelerations
3. Absent variability with bradycardia for at least 10 min
4. Sinusoidal pattern for at least 20 min

Obstet Gynecol 2008;112:661-6
Category II?
Everything Else
Factual Accuracy

Definitions:

• Baseline
• Variability
• Accelerations
• Decelerations
• Changes or trends over time
• “CATEGORY”
Interpretation
In the next few minutes, 40 years of research in intrapartum FHR interpretation will be distilled into 3 central principles that are evidence based, reflect consensus in the literature and most importantly are simple, practical and teachable.
Intrapartum FHR monitoring is intended to assess *fetal oxygenation*.
Fetal oxygenation involves the transfer of oxygen from the environment to the fetus...
And the subsequent fetal physiologic response if oxygen transfer is interrupted...
What does the fetal heart rate tracing reveal about this pathway?
What information does the FHR tracing provide regarding oxygen transfer?
Interruption of the oxygen pathway by compression of the umbilical cord can result in a variable deceleration.
Interruption of the oxygen pathway at the level of the uterus or placenta can result in a late deceleration.
Interruption of the oxygen pathway at any point can result in a prolonged deceleration.
ALL clinically significant FHR decelerations (late, variable, prolonged) HAVE EXACTLY THE SAME TRIGGER...

Interruption of the oxygen pathway at one or more points
Principle #1
Variable, late or prolonged decelerations signal interruption of the oxygen pathway at one or more points.
What information can the FHR tracing provide regarding the fetal response to interruption of the oxygen pathway?
The 2008 NICHD consensus statement identified two fetal heart rate characteristics that reliably predict the absence of fetal metabolic acidemia at the time they are observed.
Principle #2
Moderate variability or accelerations reliably predict the absence of fetal metabolic acidemia at the time they are observed.
What is the physiologic significance of excluding metabolic acidemia?
Metabolic acidemia is an essential prerequisite to intrapartum hypoxic neurologic injury (pH < 7, BD ≥ 12 mmol/L)
Fetal Heart Rate Interpretation

**Principle #1**
Variable, late or prolonged decelerations signal interruption of the oxygen pathway at one or more points

**Principle #2**
Moderate variability and/or accelerations reliably exclude fetal metabolic acidemia at the time they are observed

**Principle #3**
Excluding metabolic acidemia excludes intrapartum fetal hypoxic neurologic injury
Is this simple enough to be taught and retained?

In 2009, the Los Angeles County Department of Health mandated FHR competency testing (OVMC, HUCLA, LAC+USC)

After a series of training sessions on standard NICHD FHR definitions, NICHD categories and 3 simplified principles of interpretation, a formal written test was administered to all care providers at all levels
A two-year quality improvement initiative to standardize the methods by which obstetric team members interpret, communicate, document and manage fetal heart rate tracings.

400 representatives from 90 of New York’s 140 hospitals.
Pre and post-test mean percent correct responses

- Pre-test 6/7-09: 49%
- Post-test 6/7-09: 85%
- Post-test 12-09: 80%
- Post-test 12-10: 84%
Reviewers demonstrated agreement on:

- Baseline rate: 0.97
- Moderate variability: 0.80
- Accelerations: 0.62
- Decelerations: 0.63
- Category: 0.68
- Exclude fetal metabolic acidemia: 0.82

Kappa value Agreement

- < 0.40  Poor
- 0.41 – 0.60  Moderate
- 0.61 – 0.80  Substantial
- 0.81 – 1.0  Excellent

Substantial to Excellent agreement on all components

Factual Accuracy

Standard Definitions

We have achieved consensus in the United States on the terminology used to describe the five components of a FHR tracing.

Standard interpretation

Three central concepts of FHR interpretation are evidence-based and reflect consensus in the literature.
Ability to Articulate

Standardized management is the next challenge
A unique understanding of clinical and professional obstetric liability risk through evidence-based evaluation and experience

www.ob-consult.com

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