The Case for Electronic Fetal Monitoring Credentialing

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Conflict of Interest Statement

• Previous Board Member of the Perinatal Quality Foundation

• Member of the Fetal Monitoring Credentialing Task Force

• I received no financial compensation for any of these positions.
Intrapartum FHR monitoring is the most common obstetric practice in the US, impacting some 4 million mothers and fetuses annually.
EFM Value: Cochrane Review

• 12 clinical trials (n=37,000), 2 of high quality
  - No prospective “non monitoring” studies
  - Most are dated and have problems with design

• Continuous EFM compared to intermittent auscultation—fewer neonatal seizures; more C-sections and operative vaginal deliveries

<table>
<thead>
<tr>
<th></th>
<th>N (trials)</th>
<th>RR</th>
<th>95% CI</th>
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<tbody>
<tr>
<td>Perinatal Death</td>
<td>33,513 (11)</td>
<td>0.85</td>
<td>0.59-1.23</td>
</tr>
<tr>
<td>Neonatal Seizures</td>
<td>32,386 (9)</td>
<td>0.50</td>
<td>0.31-0.80</td>
</tr>
<tr>
<td>Cerebral Palsy</td>
<td>13,252 (2)</td>
<td>1.74</td>
<td>0.97-3.11</td>
</tr>
<tr>
<td>Cesarean Delivery</td>
<td>18,761 (10)</td>
<td>1.66</td>
<td>1.30-2.13</td>
</tr>
<tr>
<td>Operative VD</td>
<td>18,151 (9)</td>
<td>1.16</td>
<td>1.01-1.32</td>
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</table>

Alfirevic et al. Cochrane 2006 (3) #CD006066
Continuous Intrapartum Fetal Heart Rate Monitoring

- No reduction in cerebral palsy
- Dramatic increase in cesarean delivery

**US Preventive Task Force Grade: D**

- No evidence of benefit but essentially no intrapartum deaths occur.
- Evidence of harm? Issues of response, communication and management.
Joint Commission
Sentinel Event Alert: Issue 30 - July 21, 2004

- Identified “poor communication of abnormal FHR patterns” as a leading risk factor for preventable perinatal injury

- Recommended that hospitals educate nurses, residents, nurse midwives, and physicians to use *standardized terminology* to communicate both normal and abnormal fetal heart rate tracings

- The commission further recommended that healthcare organizations develop clear guidelines for *interpretation and management* of FHR patterns...
Electronic fetal heart rate monitoring: Research guidelines for interpretation

National Institute of Child Health and Human Development Research Planning Workshop

The purpose of the National Institutes of Health research planning workshops is to assess the research status of clinically important areas. This article reports on a workshop whose meetings were held between May 1995 and November 1996 in Bethesda, Maryland, and Chicago, Illinois. Its specific purpose was to develop standardized and unambiguous definitions for fetal heart rate tracings. The recommendations for interpreting fetal heart rate patterns are being published here and simultaneously by the Journal of Obstetric, Gynecologic, and Neonatal Nursing. (Am J Obstet Gynecol 1997; 177:1385-90).

Clearly an area of challenge and for many practitioners, a big secret...
Intrapartum FHR monitoring may not be a failed technology (EKG does not prevent death from myocardial infarction)

Three areas of likely benefit:

- Its introduction coincided with the virtual elimination of intrapartum fetal death
- It is at least as effective as intensive intermittent auscultation, the only alternative that has been studied in prospective trials (not practical option)
- While not a reliable **predictive** test, it is an exceptional **screening** test for absence of fetal acidemia when it is normal
The 2008 National Institute of Child Health and Human Development Workshop Report on Electronic Fetal Monitoring

Update on Definitions, Interpretation, and Research Guidelines

George A. Macones, MD, Gary D. V. Hankins, MD, Catherine Y. Spong, MD, John Hauth, MD, and Thomas Moore, MD

Obstet Gynecol 2008;112:661-6

Number 106, July 2009

ACOG PRACTICE BULLETIN

CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN–GYNECOLOGISTS
NUMBER 106, JULY 2009
Replaces Practice Bulletin Number 70, December 2005

Intrapartum Fetal Heart Rate Monitoring: Nomenclature, Interpretation, and General Management Principles

Number 116, July 2010
(Reaffirmed 2015)

Management of Intrapartum Fetal Heart Rate Tracings
• Baseline rate: 110-160 bpm
• Baseline variability: moderate
• Late or variable decelerations: absent
• Early decelerations: present or absent
• Accelerations: present or absent
CATEGORY II

- All FHR tracings not categorized as Category I or Category III and represent an appreciable fraction of those encountered in clinical care
- Bradycardia with variability; BL tachycardia
- Minimal baseline variability
- Absent variability/no recurrent decelerations
- Marked baseline variability
- Absence of induced/spontaneous accelerations
CATEGORY II

- Recurrent variable decelerations accompanied by minimal or moderate variability
- Prolonged deceleration more than 2 minutes but less than 10 minutes
- Recurrent late decelerations but with moderate baseline variability
- Variable decelerations with other characteristics such as slow return, overshoots or “shoulders”
CATEGORY III

- Absent baseline FHR variability and any:
  -- recurrent late decelerations
  -- recurrent variable decelerations
  -- bradycardia

- Sinusoidal pattern
Assessment of intrapartum FHR tracing

Category I
- Routine management

Category II*
- Evaluation and surveillance
  - FHR accelerations or moderate FHR variability
    - Continue surveillance + Intrauterine resuscitative measures†
  - Absent FHR accelerations and Absent/minimal FHR variability
    - Intrauterine resuscitative measures†
    - If not improved or FHR tracing progresses to Category III, consider delivery‡

Category III
- Prepare for delivery + Intrauterine resuscitative measures†
  - If not improved, consider prompt delivery‡

* Given the wide variation of FHR tracings in Category II, this algorithm is not meant to represent assessment and management of all potential FHR tracings, but to provide an action template for common clinical situations.
† See Table 2 for list of various intrauterine resuscitative measures
‡ Timing and mode of delivery based on feasibility and maternal-fetal status

Necessity of Examination

• No objective evidence that EFM monitoring was being used optimally in any of the obstetrical services in the network of institutions insured by MCIC

• Chart reviews by MCIC
  – Clear evidence of differing terminology, interpretation and management by different providers when faced with similar EFM tracings
Issues of Proficiency in EFM

- March 2005 MCIC Vermont, Inc., Board of Directors Meeting:

  1) All MCIC insured and non-MCIC insured physicians involved with fetal assessment, including electronic fetal monitoring (EFM), will be required to sit for the NCC EFM certification exam by June 30, 2006 and to be certified by December 31, 2006;

  2) Resident physicians are to be certified by the completion of their PGY 1 year; provided, however, that if they do not pass the exam, they are to be directly supervised for fetal assessment issues until certified;

  3) All new hires and new medical staff members shall be required to sit for the EFM exam within 12 months of his/her start date and to be certified within 18 months of such start date.
Resistance to MCIC Decision

- **ABOG** actually provides certification in OB/GYN
- Existing programs already provide degrees of training in EFM for physicians and nurses
- Physicians and nurses have interpreted EFM for years “and never have had a problem”
- Although widely used for patients laboring in hospitals, EFM is actually of unproven value
- Who wants to take another examination, what do you do with the results and who pays for it?

March 2008 MCIC OB Leadership Committee Meeting:

1) Reaffirmed original commitment for “one time” NCC EFM certification exam for all clinicians caring for women in labor. All hospitals reported compliance. All new staff will take the NCC exam within first year.

2) All OB physicians & nurses at each hospital need to participate in one ongoing EFM education program (for example, PeriFACTS, Advanced Practice Strategies) or maintain NCC certification.

3) Each hospital has adopted one or more programs for ongoing validation of EFM competency.
Safety Program Adverse Outcome Index

Yale-New Haven Hospital, New Haven, CT (YNHH) quarterly obstetric (OB) Adverse Outcome Index (AOI).

## Adverse Outcome Index Indicators

<table>
<thead>
<tr>
<th>Indicators</th>
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<tbody>
<tr>
<td>Blood transfusion</td>
</tr>
<tr>
<td>Maternal death</td>
</tr>
<tr>
<td>Maternal ICU admission</td>
</tr>
<tr>
<td>Maternal return to OR or labor and delivery</td>
</tr>
<tr>
<td>Uterine rupture</td>
</tr>
<tr>
<td>Third- or fourth-degree laceration</td>
</tr>
<tr>
<td>Apgar score &lt;7 at 5 min</td>
</tr>
<tr>
<td>Fetal traumatic birth injury</td>
</tr>
<tr>
<td>Intrapartum or neonatal death &gt; 2500 g</td>
</tr>
<tr>
<td>Unexpected admission to neonatal ICU &gt; 2500 g and for &gt; 24 h</td>
</tr>
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</table>

Results of HCA Safety Program

Frequency Trends-Hospital Corporation of America
Reported Claims Per 10,000 Births
Accident Year

Perinatal Quality Foundation (PQF)

Mission

to improve the quality of Obstetrical services by providing

- state of the art educational programs
- evidence-based monitoring systems to evaluate current practices

To facilitate the transition of emerging technologies into clinical care
PQF Commitments

- To be inclusive
- To provide credible and evidence based education and recommendations to Obstetrical providers
- To encourage consensus decision processes with input from multiple specialties and interests
- To focus on service, education and quality patient care
- To facilitate the introduction of new technology into clinical practice when appropriate
- To support accountable quality care
The PQF EFM Credentialing History

• 2011 – Convened group of experts in fetal heart rate monitoring to discuss issues of need for EFM credentialing

• Concluded that evidence of credentialing was coming and there was a need for a different type of establishing EFM credentialing

• Existing examinations were suboptimal:
  − Focus was only on factual information
  − Same questions for nurses and physicians
  − No ability to assess appropriate response to changing “real world” clinical situations in L&D
The Need for Exam

• The task force suspected that at least a portion of the conflicting evidence regarding EFM resulted from:
  
  – Continued ad hoc interpretation and terminology (despite guidelines from NICHD and ACOG)

  – Lack of standardization for appropriate interpretation and intervention, particularly for common Category II patterns

• Many case reviews provided anecdotal evidence of preventable outcomes
PQF Development of Exam

• Created task force for EFM *credentialing*
• Goal was identified to create a test that would optimally demonstrate both *knowledge* and *judgment* of fetal heart rate monitoring using definitions established by national consensus
• Separate credentialing test for obstetrical nurses and physicians/CNM caring for patients
• Utilize a new form of testing appropriate to the dynamism of labor and delivery
SCT: Script Concordance Theory

- Clinicians mobilize networks of organized knowledge, called "scripts", to process information and progress toward solutions to changing clinical problems.

- Scripts are made up of realistic links between illnesses, clinical information/features and management options.

- Principle of SCT is that the multiple judgments made in the clinical reasoning process can be probed and their concordance with those of a panel of reference experts measured.

- Simulates authentic conditions of medical practice, in which courses of action or lines of thinking about specific clinical problems are presented.

- Reflects respondent’s interpretation of clinical data and response to changing clinical scenarios.
The use of the Likert scale is used in Script Concordance Theory to measure judgment. It reflects the ability to capture variable degrees of opinion rather than the simple "yes/no" answers as in the typical knowledge type questions. A 5-point scale is utilized to capture this variability.
**Using SCT: An Everyday Example**

<table>
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<td>Based on that, your initial decision is that you won’t need an umbrella.</td>
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<td><strong>New information:</strong></td>
<td>But then you open your front door and see heavy, dark clouds.</td>
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<td><strong>Question:</strong></td>
<td>How does seeing the clouds impact your initial decision to leave your umbrella at home?</td>
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<td><strong>Scale for response:</strong></td>
<td>Your initial decision is:</td>
</tr>
<tr>
<td></td>
<td>• completely validated</td>
</tr>
<tr>
<td></td>
<td>• possibly validated</td>
</tr>
<tr>
<td></td>
<td>• not affected at all</td>
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**Scale for response:**
- Your initial decision is:
  - completely validated
  - possibly validated
  - not affected at all
  - possibly invalidated
  - completely invalidated

- In SCT questions, more than one answer is acceptable with weighed value.
- In this example, most meteorologists (experts) answered “possibly invalidated”.
- Fewer experts answered “completely invalidated.”
- The answers to judgment questions (SCT) are given a weighted score, based on the distribution of how the expert panel answered the same question.
SCT: Script Concordance Theory

• Introduced by Charlin in 1998
• Researched, mainly in Canada
  – University of Montreal
  – McGill University
• Script Concordance Test: A Tool to Assess the Reflective Clinician, Charlin et al, 2000
• Assessment of Intraoperative Judgment During Gynecologic Surgery Using a Script Concordance Test, Park et al, 2010, AJOG
Goal of SCT Questions

• To provide a direct approach for testing the organization of clinical knowledge

• To assess contextual reasoning and decision making in an evolving clinical setting

• Does not measure specific knowledge or memory

• The very nature of FHR monitoring in the laboring patient makes it ideally suited for evaluation by this type of assessment tool
Creating the Test

• Separate panels of experts in nursing, midwifery, general obstetrics and MFM

• Generated a combined total of 120 KT and SCT questions for each separate exam

• Questions sent in an online examination format to 20 national obstetrical nursing experts and 20 obstetrical physician experts

• Final questions for each examination were selected based on a significant degree of concordance between experts and some 70 different Beta testers for each examination
Development of SCT Questions

• There is never one agreed upon “correct” answer to an SCT
• There are at least 2 and usually 3 answers that are clearly incorrect
• If everyone agreed on one correct answer the question would be knowledge based
• During evaluation of the examination a potential test questions were eliminated if
  - all experts agreed on a single answer
  or
  - 4 or more different answers were given
Case Example of SCT Question

- A clinical scenario is presented where an initial management decision has been made.
- A new piece of information is added...

The candidate must then decide how this new information impacts their management decision.
Case Example 1

A 25-year-old G1P0 patient presents at 41 weeks in spontaneous labor. Ruptured membranes are confirmed and the initial cervical exam is 3/+1/100%/vertex/intact. The initial FHR tracing is shown below:

Your management plan is ...

Continue FHR monitoring and expectantly manage

... and then you learn the following additional information:

It is 2 hrs later and you review the FHR tracing shown below and note that the cervix remains 3/+1/100%/vtx

How does this additional information affect your thinking about the plan of expectant management?
Answering the SCT Question

The candidate will be informed that there is more then one correct answer to the SCT questions and will be asked to use their best judgment in selecting the answer most consistent with their clinical judgement of the presented information.

- Strongly invalidates
- Could invalidate
- No Impact
- Could support
- Strongly supports
Grading the SCT Question

• Generally, full credit is given to the answer most frequently chosen by the experts
• Partial credit proportional to the percentage of experts choosing the answer is given for other “correct” choice(s)

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<tbody>
<tr>
<td>1</td>
<td>Strongly invalidates</td>
<td>0% credit</td>
</tr>
<tr>
<td>2</td>
<td>Could invalidate</td>
<td>0% credit</td>
</tr>
<tr>
<td>3</td>
<td>No Impact</td>
<td>100% credit</td>
</tr>
<tr>
<td>4</td>
<td>Could support</td>
<td>50% credit</td>
</tr>
<tr>
<td>5</td>
<td>Strongly supports</td>
<td>20% credit</td>
</tr>
</tbody>
</table>

Answer number 3 was chosen by 16 of 24 experts
Answer number 4 was chosen by 6 of 24 experts
Answer number 5 was chosen by 2 of 24 experts

Grading the Examination

• Use of SCT questions will allow PQF to provide separate scores on knowledge and judgment

• We anticipate differences between experienced clinicians (physicians, nurses and midwives) and residents/inexperienced clinicians

• Measuring both elements will provide basis for further education, experience or training

Grading the Examination

• The knowledge based questions and script concordant questions are independently graded with five unique learning objectives

• Knowledge questions are scored with either full credit or no credit

• A single pass or fail mark will be given for the examination; in addition,

• Results in each learning objective are included with the final score to identify the specific areas of strength and weakness

The Examination Process

- Separate exams for physicians/CNM and nurses based upon different roles and responsibilities in management of patients
- Midwives will take the physician exam
- Online secure examination on any computer with 90 consecutive minutes of allotted time
- PQF has not specified any preparatory materials yet many such resources exist
- Test available to institutions and individuals; results supplied to payor of examination fee

Credentialing Duration

- Candidate will be credentialed for a period of 3 years
- The test results will not be made public and will always be sent to the examinee
- Repeat examination for initial failure is free
- Department chairs,
  - Hospital CEOs,
  - Insurance company safety officers
  also receive results if they are responsible for the examination fee

June 2012 MCIC Vermont, Inc., Board of Directors Meeting:

Approved the recommendation of the Patient Safety Subcommittee, that demonstration of skill in EFM interpretation by initial certification and ongoing education become a credentialing or competency requirement for all obstetrical clinicians involved with fetal assessment at MCIC insured hospitals.

March 2013 OB Clinical Leadership Meeting:

- All shareholders have taken formal actions:
  - To implement educational programs with tests of competency and;
  - To document proficiency as a condition of credentialing and competency evaluation.
Algorithm for management of category II fetal heart rate tracings

Moderate variability or accelerations
- Yes
- No

Significant decels with ≥50% of contractions for 1 hr*
- Yes
- No
  - Latent Phase
    - Normal labor progress
    - No
    - Yes
      - Cesarean
      - Observe

  - Active Phase

Significant decels with ≥50% of contractions for 30 mins*
- Yes
- No
  - Second Stage
    - Normal progress
    - No
    - Yes
      - Cesarean
      - Observe
  - Persistent pattern
    - Yes
    - No
      - Cesarean or OVD

* That have not resolved with appropriate conservative corrective measures, which may include supplemental oxygen, maternal position changes, intravenous fluid administration, correction of hypotension, reduction or discontinuation of uterine stimulation, administration of uterine relaxant, amnioinfusion, and/or changes in second stage breathing or pushing techniques.

OVD = Operative Vaginal Delivery

Free Downloadable App

http://cat2.perigen.com/cat2/
In the decade since the 2003 “Green Book” was first published, considerable advances have been made in our knowledge and understanding of NE and long-term neurodevelopmental outcome.
Process for 2014 Report

• Dr. Richard Waldman’s presidential initiative
• Task Force convened in 2010
• Met 4 times over span of 3 years
• 88 international consultants
• Task Force identified clinicians and scientists from multiple disciplines
• Reviewed and edited draft manuscripts and deliberated to achieve consensus
Major Changes Since 2003 Report

• Classification of EFM patterns

• MRI studies conflict with epidemiological data

• Landmark introduction of hypothermia for neonatal treatment

• New chapters on neuroimaging, patient safety, placental pathology, neonatal interventions, and fetal physiology

• Significantly expanded document
Comprehensive Evaluation of NE

- Maternal medical history
- Obstetric antecedents
- Intrapartum factors
- Placental pathology
- Newborn course
  - Labs
  - EEG
  - Neuroimaging

Ob and Neonatal Checklist examples provided in the publication appendix.
Comprehensive Evaluation of NE

- Case Definition
- Neonatal Signs Consistent with an Acute Peripartum or Intrapartum Event
- Type & Timing of Contributing Factors
- Developmental Outcome Is Spastic Quadriplegia or Dyskinetic Cerebral Palsy

- Was there a sentinel event?
- What was interpretation of fetal heart rate strips?
- Timing and finding of neuroimaging?
- Other contributing events
Type and Timing of Contributing Factors Consistent with an Acute Peripartum or Intrapartum Event

• A sentinel hypoxic or ischemic event occurring immediately before or during labor and delivery

- Uterine rupture
- Placental abruption
- Umbilical cord prolapse
- Amniotic fluid embolus
- Maternal cardiac arrest
Fetal heart rate monitor patterns consistent with an acute peripartum or intrapartum event

- A category 1 or category 2 FHR tracing associated with
  - Apgar scores ≥7 at 5 minutes
  - Normal arterial cord gases [+/- 1 standard deviation (SD)]

is not consistent with an acute hypoxic–ischemic event

- Great distinction needs to be made between
  - a patient who initially presents with an abnormal fetal heart rate pattern
  - one who presents with a normal pattern and develops an abnormal fetal heart rate pattern during labor

ACOG/AAP 2014
Fetal Heart Rate Patterns

• An FHR pattern in a fetus who presents with persistent minimal or absent variability and no accels lasting ≥ 60 minutes (even in the absence of decels) is suggestive of a previously compromised or injured fetus.

• Patient presenting with a Category I FHR pattern that converts to Category III is suggestive of intrapartum hypoxia.

• Other patterns that develop following a Category I FHR pattern that may suggest intrapartum timing of HIE:
  - tachycardia with recurrent decelerations
  - persistent minimal variability with recurrent decelerations

ACOG/AAP 2014
Credentialing Exam Stats

• Through 2015, >1000 examinees thus far
• 525 physicians (52%)
• 434 nurses (43%)
• 78 certified nurse midwives (8%)
• 24 separate institutions and health systems

ABOG now accepts the PQF EFM credentialing examination as an option for meeting one of the annual MOC Part IV requirements
The FMC task force believes establishing a standard for defining and interpreting EFM tracings is critically important for every labor and delivery unit in the country.

Each institution will decide if and how they will do this.

If the process includes a credentialing exam, it provides an objective measure of knowledge and judgment related to optimal use of EFM.
FMC Task Force Members

Mike Nageotte, MD (Chair)
Obstetrix Medical Group

Dan O’Keeffe, MD
Society for Maternal-Fetal Medicine

Richard Berkowitz, MD
Columbia University Medical Center

Marin O’Keeffe, RN
Perinatal Quality Foundation

Mary D’Alton, MD
Columbia University Medical Center

Jean Spitz, MPH, RDMS
Perinatal Quality Foundation

Richard Depp, MD

Gregory Toland
Perinatal Quality Foundation

James Goldberg, MD
San Francisco Perinatal Associates
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