How many attendees are certified in EFM?

A. Yes 47% 53%
B. No

Those who answered yes, which organization?

A. NCC 49%
B. PQF
C. Other 51%
**Background**

Intrapartum FHR monitoring is the most common obstetric practice in the US, impacting some 4 million mothers and fetuses annually.

---

**Current Limitations**

- Outcome measure not related to FHR monitoring patterns
- Lack of standardized interpretation of FHR patterns
  - Leads to poor interobserver and intraobserver consistency
- Disagreement re: algorithms for intervention for specific FHR patterns
- Inability to demonstrate the reliability, validity and ability to FHR monitoring to allow for timely obstetrical intervention

---

**FHR monitoring consists of three components:**

- **Intrapartum FHR Monitoring**
  - Definition
  - Interpretation
  - Management
  - What do I call it? What does it mean? What do I do about it?

---

**CLINICAL OPINION**

Electronic fetal heart rate monitoring: Research guidelines for interpretation

National Institutes 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...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
Education was required

- Intrapartum FHR monitoring may not be a failed technology (e.g. EKG does not prevent death from myocardial infarction)
- Three areas of likely benefit:
  - Introduction coincided with virtual elimination of intrapartum fetal death
  - At least as effective as intensive intermittent auscultation, only alternative that has been studied in prospective trials; not practical option
  - While not reliable **predictive** test, it is an exceptional **screening** test for absence of fetal acidemia when normal

Most FHR abnormalities do not result in fetal acidosis


EFM Value: Cochrane Review

- 13 clinical trials (n=37,000), 2 of high quality
  - No prospective “non monitoring” studies
  - Most are dated and have design flaws
- Continuous EFM compared to intermittent auscultation—fewer neonatal seizures; more Cesareans and operative vaginal deliveries

<table>
<thead>
<tr>
<th></th>
<th>N (trials)</th>
<th>RR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perinatal Death</td>
<td>33,513 (11)</td>
<td>0.86</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>1.75</td>
<td>0.84-3.63</td>
</tr>
<tr>
<td>Cesarean Delivery</td>
<td>18,861 (11)</td>
<td>1.63</td>
<td>1.29-2.07</td>
</tr>
<tr>
<td>Operative VD</td>
<td>18,615 (10)</td>
<td>1.15</td>
<td>1.01-1.33</td>
</tr>
</tbody>
</table>

Alfirevic et al. Cochrane 2013 (2); CD006066

Continuous Intrapartum Fetal Heart Rate Monitoring

- **OUR REALITY**
  - No reduction in cerebral palsy
  - Dramatic increase in cesarean delivery
    - c. 1975, EFM prevalence 66% with a ~10% cesarean rate

US Preventive Task Force Grade: D

- No evidence of benefit but essentially no intrapartum deaths occur.
Joint Commission
Sentinel Event Alert: Issue 30 – July 2004

- Identified “poor communication of abnormal FHR patterns” as leading risk factor for preventable perinatal injury
- Recommended standardized terminology to communicate both normal and abnormal fetal heart rate tracings
- JACHO further recommended that healthcare organizations develop clear guidelines for interpretation and management of FHR patterns

Adverse Outcome Index Indicators

<table>
<thead>
<tr>
<th>Indicator</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 NICU &gt; 2500 g and for &gt; 24 h</td>
</tr>
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Results of HCA Safety Program

Does standardization improve reliability?

A two-year quality improvement initiative to standardize the methods by which obstetric team members interpret, communicate, document and manage fetal heart rate tracings

Nearly 400 representatives from 90 of New York’s 140 hospitals

Pre-test 6/7-09 Post-test 6/7-09 6 months later 18 months later

49% 85% 80% 84%

Interobserver Reliability of Fetal Heart Rate Pattern Interpretation Using NICHD Definitions

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
- .41 – .60 Moderate
- .61 – .80 Substantial
- .81 – 1.0 Excellent

Substantial to Excellent agreement on all components

Issues of Proficiency in EFM
MCIC Vermont, Inc. Board Meeting, March 2006

- All MCIC insured & non-MCIC insured physicians involved with fetal assessment, inc. EFM will be required to sit for the NCC EFM certification exam by June 30, 2006 and to be certified by December 31, 2006;
- Resident physicians are to be certified by end of 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;
- All new hires and new medical staff members shall be required to sit for the EFM exam within 12 months of 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?

EFM Interpretation Proficiency History
MCIC Ob Leadership Committee Meeting, March 2008

- Reaffirmed original commitment for “one time” National Certification Corporation (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.
- 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.
- Each hospital has adopted one or more programs for ongoing validation of EFM competency.

EFM Interpretation Proficiency History
MCIC Vermont, Inc. Board Meeting, June 2012

- Approved 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.

The personal/professional implications
- A 2015 survey published in the *Mayo Clinic Proceedings* found that 54% of physicians reported at least one burnout symptom: loss of enthusiasm for work, feelings of cynicism and/or low sense of personal accomplishment
- And, it's gotten worse: When compared with 2011, rates of burnout among physicians were higher (54.4% vs 45.5%; P< .001) in 2014 and satisfaction with work-life balance was lower (40.9% vs 48.5%; P< .001)

Shanafelt TD. Mayo Clin Proc. 2015;90(12):1600-1613
Personal/professional implications

- A 2014 Physicians Foundation’s report:
  - 81% surveyed described themselves as either overextended or at full capacity;
  - 44% planned to cut back on patients seen, retire, work part-time, close their practice to new patients or seek non-clinical jobs;
  - 29% said they would not choose medicine if they could do over their choice of careers.

Perinatal Quality Foundation (PQF)

The Mission of PQF is to improve the quality of obstetrical medical services by providing state of the art educational programs and evidence-based statistically valid monitoring systems to evaluate current practices and facilitate the transition of emerging technologies into clinical care.

PQF EFM Credentialing History, 2011

- Convened group of experts in FHR monitoring to discuss issues of need for EFM credentialing
- Concluded that evidence of credentialing was coming and there was a need for 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
### 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

### The Examination Process
- Separate exams for physicians/CNM and nurses based upon different roles and responsibilities in management of patients
- 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 three years with institutional specific control
- The test results will not be made public, are available within 48 hours and will be sent to the examinee if they are the source of payment
- Repeat examination for initial failure is free
- Department chairs, hospital administrators, nursing leaders, or insurance company officers may receive results if they so elect and are responsible for payment of the examination fee

### Credentialing: Conclusion
- The FMC task force believes establishing a standard for defining and interpreting EFM tracings is critically important for every Labor and Delivery unit
- Each institution will decide if and how they will do this
- If the process chosen includes a credentialing exam, the PQF examination provides a private, readily available, objective and statistically sound measure of knowledge and judgment related to optimal use of FHR monitoring in modern Labor and Delivery units
Fetal Pulse Oximetry

- Reduction of >50% in cesarean deliveries performed for NR FHRT in study group (4.5% vs. 10.2%; P = .007).
- However, no net difference in overall cesarean rates (n = 147 [29%] vs. 130 [26%]; P = .49) because of more dystocia in study group.
- Signal capture failures
- Limited market penetration


Fetal Pulse Oximetry and Cesarean Delivery

- n=5341 women at term
- Open-label, RCT designed to assess safety and efficacy
- Parallel assessment model
- 36+ weeks’ GA with cervical dilatation 2 to 6 cm
- Primary outcome: Any of 5-minute Apgar ≤4, UA blood pH value ≤7.0, seizures, intubation in delivery room, stillbirth, neonatal death, or admission to the NICU for ≥48 hr. Hypoxic–ischemic encephalopathy was diagnosed if the UA blood pH was ≤7.0, seizure occurred during newborn period, and evidence of multiorgan dysfunction


Fetal Pulse Oximetry and Cesarean Delivery

<table>
<thead>
<tr>
<th></th>
<th>Open arm n=2629</th>
<th>Masked arm n=2712</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cesarean</td>
<td>26.3%</td>
<td>27.5%</td>
</tr>
<tr>
<td>Operative vaginal delivery</td>
<td>14.5%</td>
<td>14.7%</td>
</tr>
<tr>
<td>NR FHR</td>
<td>7.1%</td>
<td>7.9%</td>
</tr>
<tr>
<td>5-min Apgar &lt;7</td>
<td>2.9%</td>
<td>3.2%</td>
</tr>
<tr>
<td>5-min Apgar &lt;3</td>
<td>0.1%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Neonatal seizure</td>
<td>0.1%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Hypoxic ischemic encephalopathy</td>
<td>0</td>
<td>0.04%</td>
</tr>
<tr>
<td>Neonatal death</td>
<td>0</td>
<td>0.04%</td>
</tr>
</tbody>
</table>

Fetal Pulse Oximetry and Cesarean Delivery

Sensitivity, specificity, PPV and NPV of NR FHR patterns for low oxygen saturation (<30% for at least 2 consecutive min) were 86.7%, 19.5%, 34.6%, and 74.9%, respectively.

Interestingly, 34.6% of NR FHR patterns, but also 25.1% of normal patterns, were associated with low oxygen saturation.


Combined analysis

FHR identifies normality

ST grades deviation from normality

Guidelines indicates situations when there are reasons to intervene

A Randomized Trial of Intrapartum Fetal ECG ST-Segment Analysis

N=11,108

Open-label, RCT designed to assess safety and efficacy

– Parallel assessment model

36+ weeks’ GA with cervical dilatation 2 to 7 cm

Primary composite outcome = intrapartum fetal death, neonatal death, Apgar score ≤3 at 5 minutes, neonatal seizure, UA pH ≤7.05 with base deficit ≥12 mmol/L, intubation for ventilation at delivery, or neonatal encephalopathy

A Randomized Trial of Intrapartum Fetal ECG ST-Segment Analysis

- Primary outcome: 52 fetuses or neonates of women in open group (0.9%) and 40 fetuses or neonates of women in masked group (0.7%) (RR1.31; 95% CI 0.87 to 1.98; P = 0.20).
  - Only frequency of 5-minute Apgar score of ≤3 differed significantly between neonates of women in open group and in masked group (0.3% vs. 0.1%, P = 0.02).
- No significant between-group differences in rate of cesareans (16.9% and 16.2%, respectively; P = 0.30) or any operative delivery (22.8% and 22.0%, respectively; P = 0.31).
- Adverse events were rare.

Assessment of an e-learning training program for cardiotocography analysis: a multicentre randomized study

- Mean scores at first test were similar (32 out of 50)
- After e-learning, results were higher in "training" than in "no-training" group (37.1±5.5 vs. 32.6±5.7, p=0.003).
- Doctors had higher results than midwives in first test (34.9±5.9 vs. 32.4±4.3; p=0.005), but not in second test in training group (37.7±6.7 vs. 36.8±4.8; p=0.64).
- CONCLUSION: Training using an e-learning program improves performance of obstetric staff. Logging-in from any place at any time may favor use of an e-learning program in maternity staff.

The Future

- Intrapartum fetal monitoring is here to stay in some format
- Except for automated alerts and fECG analysis, we are using yesterday’s technology
- Credentialing for FHR interpretation will be requirements for practice
- To get to the next level, to prevent preventable poor outcomes and to avoid unnecessary interventions, we will need to leverage our technology, better educate our clinicians, and recruit innovative companies that are willing to venture capital and time

INFANT TRIAL: INTELLIGENT SYSTEM SUPPORT DECISION MAKING IN LABOR MANAGEMENT USING CTG

- Sponsored by MHS
- Objectives: 1) To determine whether intelligent decision-support can improve interpretation of CTG and thereby improve labor management for women requiring continuous EFM
  - A) Identify more clinically significant heart rate abnormalities
  - B) Result in more prompt and timely action on clinically significant heart rate abnormalities
  - C) Result in fewer “poor neonatal outcomes”
  - D) Change incidence of operative interventions

Acknowledgments

Michael Nageotte, MD (Chair)
Magella Medical Group/Long Beach Memorial/UC Irvine

Jean Spitz, MPH, RDMS
Perinatal Quality Foundation

Richard Berkowitz, MD
Columbia University Medical Center

Marin O’Keefe, RN
Perinatal Quality Foundation

Mary D’Alton, MD
Columbia University Medical Center

Gregory Toland
Perinatal Quality Foundation

Richard Depp, MD

James Goldberg, MD
San Francisco Perinatal Associates

Daniel O’Keefe, MD
Society of Maternal Fetal Medicine

Brocklehurst P. MC Pregnancy Childbirth. 2016; 16:10