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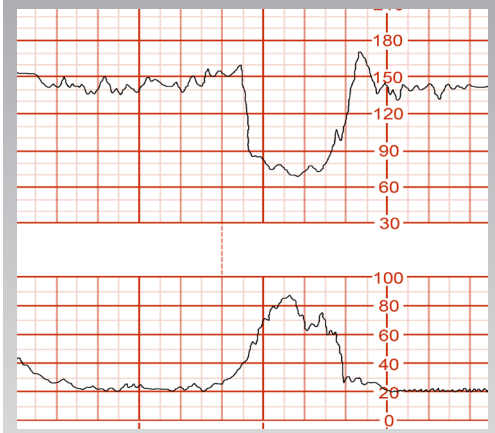

FETAL HEART RATE MONITORING: SPEAKING THE SAME LANGUAGE

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The use of continuous electronic fetal heart rate monitoring (EFM) during labor was introduced into obstetrical practice in the 1960s for complicated pregnancies. By the late 1970s it was used in around 66% of labors in the United States, and by 2002, over 84%, accounting for 3.4 million labors. [1-3] Despite the lack of evidence demonstrating an improvement in outcomes[4] and poor reproducibility between results, this universal early use without a standardized application methodology led to multiple opinions, experts, and nomenclatures. This did not allow for standardization and communication between providers when discussing FHR interpretation even within a single labor and delivery unit, let alone between institutions.

The lack of a common language for interpretation and application of fetal monitoring also hampered the ability to assess and interpret research outcomes related to FHR monitoring. Even within early randomized controlled trials, as noted later at the National Institutes of Child Health and Human Development (NICHD) workshop, "it is rarely possible to determine from most of the publications (RTCs) exactly what the authors used for definitions and quantification of the various patterns. In addition, the FHR patterns signifying jeopardy for the fetus and the need for immediate delivery are often inexactly stated, and quantitation is rarely included." [5]

In 1997, the National Institute of Child Health and Human Development (NICHD) convened a workshop with an ambitious goal to develop a universal, "standardized and rigorously, unambiguously described set of definitions that can be quantified" for fetal heart rate (FHR) patterns.[5] With creation of a common language, the hope was that further research could be developed to explore EFM in a systematic way with the goal of improving fetal outcomes, "to develop recommendations for the investigative interpretation of intrapartum FHR tracings so that the predictive value of monitoring can be assessed more meaningfully". This committee set forth, for the first time, the outline of how EFM could be discussed between providers, providing standard, clear, and precise definitions for baseline, variability, the occurrence of decelerations (episodic vs. periodic), as well as how to describe decelerations (episodic vs. periodic, type, depth, duration). From there it was hoped that research efforts could further develop a language for defining and qualifying changes in the FHR over the duration of labor in correlation with fetal and neurodevelopmental outcomes. This language of FHR interpretation and a two-tiered system was adopted by the American College of Obstetricians and Gynecologists (ACOG) in 2005.

In the ensuing years, other professional organizations and physician scientists developed interpretation systems. The Royal College of Obstetricians and

IN THIS ISSUE

Gynaecologists developed a three-tiered system (Reassuring, Non-reassuring and Abnormal), the Society of Obstetricians and Gynaecologists of Canada developed a three-tiered system (Normal, Atypical, and Abnormal), and Drs. Parer and Ikeda proposed a five-tiered system driven by variability to assess the risk of acidemia.[6] Given the advances in research and these new interpretation systems, the NICHD, along with ACOG and the Society for Maternal Fetal Medicine (SMFM) convened a second workshop in 2008 with the goal of reviewing, refining, and confirming the definitions, as well as reevaluating the interpretation system.[7] After extensive discussion based on the evidence collected using standardized terminology, the EFM tracing interpretation became a three-tiered system: Category I (Normal, no evidence of acidemia), Category II (Indeterminate, need for further assessment to determine the appropriate steps and actions), and Category III (abnormal, suggestion of acidemia). Importantly, Category II, which is typically the largest category, includes all of the tracings that are not categorized as Category I or III. Due to limited data, numerous FHR tracings are not yet classified on their risk of acidemia, thus they are classified as Category II. Category II does not necessarily imply that the tracing is a problem, just reflects the lack of evidence to categorize the risk of acidemia as absent (I) or at high risk of being present (III).

Even today with the use of the FHR categories, there is variable evidence of the ability of FHR to predict and prevent poor neurological outcomes.[4] FHR tracings correlate with the fetal acid-base status at the time of observation, but does not predict cerebral palsy. However, it does appear to allow the provider to identify some fetuses at increased risk for hypoxemia.[8,9] There is, however, a significant risk of false positive interpretation, with up to 77% of fetuses having a normal acid/base balance even in the setting of abnormal (Category III) heart rate tracings.[8] Therefore, the data cannot be interpreted in a vacuum, but instead the entire labor course and situation must be considered. It is critical to consider the evolution of the FHR tracing over time and the entire clinical picture. A category II tracing with recurrent, variable decelerations for 5-10 minutes in a multiparous patient fully at 3+ station, is probably not concerning and will likely require no intervention. However, the same Category II tracing in a patient who is nulliparous, closed, and being induced for postdates probably requires at the least an evaluation, position change, and consideration of medication/dosing alteration. Similarly, a Category III tracing without variability and with repetitive late decelerations, most strongly predicts hypoxemia and might be an indication for prompt evaluation and possibly even expeditious delivery in a term, uncomplicated patient in labor; however, the same tracing in a preterm patient with diabetic ketoacidosis should instead prompt correction of the maternal metabolic state and avoidance of delivery for the health of both mother and fetus.

Now that a universal language has been established to discuss FHR, systems and education regarding how and when to intervene can be developed. It is not enough to describe the FHR, and to factually state the presence of changes within the tracing. Providers should be trained to interpret and define the FHR tracing within these standardized categories. From there strategies for intervention that are consistent and evidence based must be developed. Our testing and training strategies must evolve to develop factual knowledge, and the ability to correctly describe the FHR tracings, to interpret and develop interventions (or non-interventions) within the events, findings, and labor course. The ACOG Practice Bulletins provide further guidance on interpretation and management of intrapartum FHR tracings.[10,11]

The maternal population has become increasingly high risk, and morbidity and mortality related to pregnancy is rising. Clinicians must be mindful of the sequential risks of many interventions, especially cesarean, prescribed to those with abnormal EFM.[12] EFM has been associated with an increased use of operative vaginal delivery and cesarean,[10] and therefore, clinicians need to interpret EFM tracings with caution using the best evidence available. Despite a rising cesarean delivery rate, cerebral palsy rates have not changed. Interventions need to be limited to only those women and infants that will truly benefit, and this will require evidence based, consistent and complete assessment and interpretation of the intrapartum FHR within the context of the best outcome for the maternal-fetal dyad.

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The PQF first trimester image bank is located on the perinatalquality.org website. Images of anomalies detected demonstrate the potential for early ultrasound, and the accompanying questions allow you to test your diagnostic skills and knowledge. Currently images of anomalies of the head, face, and neck are visible. Shortly the cases will change to those of multi-organ syndromes. If you would like to submit images for possible inclusion please contact Perinatal Quality Foundation staff.

Cervical Length Education and Review (CLEAR) Updates

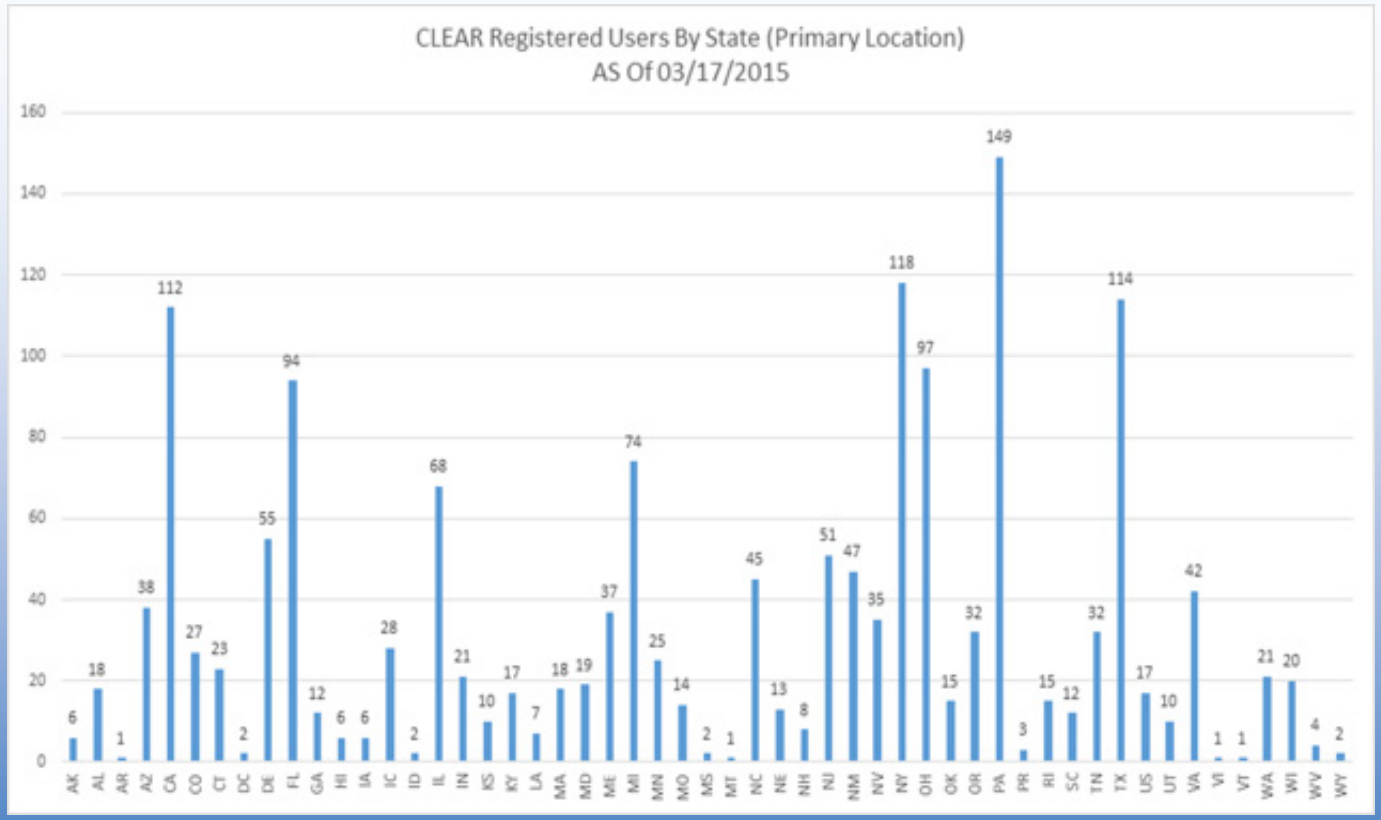
New management protocols have the potential to significantly reduce the number of pre-term births. These protocols require screening patients using cervical length measurements. Measuring the cervix correctly requires standardized sonographic techniques. If your practice is using cervical length in patient management decisions, it is important to learn and practice these techniques through modules such as the CLEAR website. Studies demonstrate that a surprisingly high percentage of incorrect images and measurements were submitted during image review even after attending a course on cervical length measurements.

Pricing Changes: The original pricing for CLEAR separated the CME module into two parts; course and examination ($75) and image review ($75). As of May 1 there will be one price for both components ($125). This provides a savings of $25 and encourages participants to complete the image review. The image review is a learning experience that provides individual critiques of cervical images. Experts who have credentialed sonographers for research studies concur that the practice and feedback provided during image review are essential for learning cervical measurement techniques.

Participants who have completed the CLEAR course and examination under the former price structure will now be able to enroll in the image review for $50.

State Programs: The Perinatal Quality Foundation Board of Directors has approved a CLEAR course and discounted enrollment for state programs that are interested in using CLEAR as part of a statewide initiative to reduce preterm births. For further details please contact Jean Spitz (jspitz@perinatalquality.org).

State by state enrollment in CLEAR is shown in the graphic below.



MAKING CERVICAL LENGTH MANAGEMENT MORE "CLEAR"

Jennifer Jury McIntosh, DO, MS
and Daniel Jackson, MD

In 2011, the PQF (Perinatal Quality Foundation) task force came together to develop the CLEAR (Cervical Length Education and Review) Program in order to standardize cervical length measurements in pregnant women. This need grew out of the accumulating data demonstrating that cervical length screening and subsequent treatment with progesterone and/or cerclage reduce the risk of recurrent preterm birth. [1-5]

With regard to management of women with a history of preterm birth and/or a short cervix, much has changed in the past decade. We now have a better understanding of the predictive value of cervical length and have both medical and surgical therapy to offer women at risk of preterm birth. Over the past three years, further accumulation of evidence led the American Congress of Obstetrics and Gynecology (ACOG) to publish practice bulletins [6, 7] to guide clinical care in the setting of a short cervix with or without a prior preterm birth. Although many practitioners routinely utilize guidelines such as these in clinical practice and although protocolized medicine has been shown to improve patient safety [8], many women fall outside of these algorithms and clinicians are often still faced with conundrums in clinical care.

The PQF Education Committee has developed an additional CLEAR lecture specifically aimed at some of the more confusing aspects of cervical length screening and preterm birth prevention including intricacies of cervical length measurements, individualizing type/route of progesterone therapy and cerclage placement based on indication and clinical scenario. Our goal is to empower obstetricians and to provide guidance for the management of both routine and more unique cases. Stay tuned for this lecture which should appear on the CLEAR website later this year!

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CLEAR
Cervical Length Education & Review

CLEAR.perinatalquality.org

**2.5 hours AMA category 1 CME
or 3 hours SDMS CME
for sonographers**

HIGHLIGHTS FROM SMFM, the PREGNANCY MEETING

The Society for Maternal Fetal Medicine held its 35th Annual Meeting in San Diego, California in early February. The abstracts highlighted below were selected from the hundreds presented given their relevance to the Perinatal Quality Foundation's programs including NTQR, CLEAR, and FMC.

Cell free DNA analysis vs sequential screening as primary testing considering all fetal chromosomal abnormalities.
Mary Norton et al.
AJOG. 2015 Jan;212(1):S2
This oral plenary presented the results of a study comparing sequential screening and cell free DNA (cfDNA) for detection of all fetal chromosomal abnormalities. Using a cohort of over 450 thousand women in the California Prenatal Screening Program between Aug 2009 and Dec 2012, the authors found that cfDNA provides lower detection rates as a primary screening test for all chromosomal abnormalities than sequential screening. Specifically, among the 2575 women with a fetal chromosomal abnormality, 73% were detectable with cfDNA whereas 81.6% were detectable with sequential screening (FPR 4.11%).

Chromosomal abnormalities detected in patients with failure to obtain test results using non-invasive prenatal testing
Turocy J, et al.
AJOG. 2015 Jan;212(1):S45
This presentation presented NIPT results performed on over 4000 women who underwent NIPT as per ACOG's guidelines. They found that 2.3% of subjects initially receiving 'no result' and – of those being redrawn – over 40% again received 'no result'; in total, 1.5% of subjects "had no final result on either one or two blood draws". Furthermore, the rate of chromosomal abnormalities in patients with 'no result' (13.8%) was higher than in the overall cohort (2.4%). The authors recommend that these results be considered when "choosing the type of follow up for these cases".

Utility of first trimester ultrasound in the setting of NIPT incorporation into practice: a retrospective pilot review.
Rashmi Rao et al.
AJOG. 2015 Jan;212(1):S198
This poster presented data from a one month pilot retrospective study of all first trimester screening (FTS) patients seen at a single referral institution over a one month period to identify the utility beyond aneuploidy screening. Among 134 cases, the authors noted 12 (8.9%) gynecologic abnormalities 5 (3.7%) placental findings, and 8 fetal abnormalities (5.9%), of which 2 had negative or non-reportable cell free DNA screening. Based on these findings, the authors concluded that first trimester ultrasound continues to "provide valuable clinical information about fetal and maternal anatomy that cannot be detected on NIPT alone".

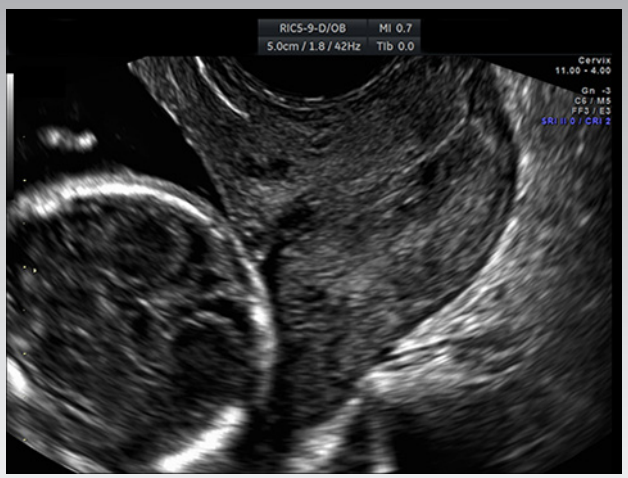
Fetal ECG analysis of the ST segment as an adjunct to intrapartum fetal heart rate monitoring: a randomized clinical trial.
George Saade for the Eunice Kennedy Shriver NICHD MFMU
AJOG. 2015 Jan;212(1):S2
This oral plenary presented the results of the recent large RCT investigating the role of fetal ECG analysis of the ST segment using the STAN FHR monitor (Neoventa Medical). The primary outcome was a composite of either intrapartum fetal or neonatal death, Apgar < 3 at 5 minutes, neonatal seizure, cord artery pH < 7.05 with base deficit > 12, intubation for ventilation at delivery, and neonatal encephalopathy. Among over 11000 cases at > 36 weeks' gestation, no difference in primary outcome or decrease in operative delivery was noted between those subjects randomized to routine FHR monitoring and those in the unmasked arm who were provided with additional information from STAN in the setting of uncertain FHR patterns.

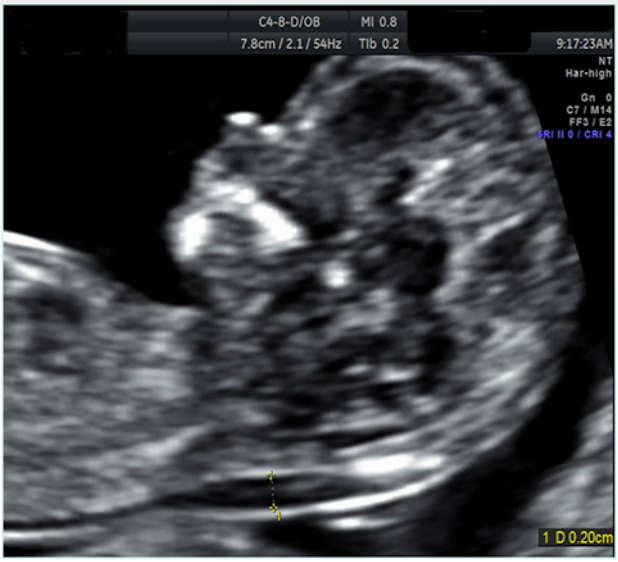
Transabdominal cervical length as a predictor of preterm birth
Naday Schwartz et al.
AJOG. 2015 Jan;212(1):S335
In this poster, the authors present data exploring whether risk of preterm birth at < 37 weeks is associated with transabdominal cervical length (TACL). Using retrospective data from over 3000 subjects undergoing transabdominal and transvaginal cervical length measurement between January 2012 and October 2013, the authors demonstrated that transabdominal cervical length below the 5th, 10th or 25th percentile was not associated with preterm delivery at < 37 weeks. The authors concluded that "while TACL assessment is predictive of a short" transvaginal cervical length, "short TACL does not appear to be associated with preterm birth risk".

Cost-effectiveness of transvaginal ultrasound cervical length screening in singletons without prior preterm birth: an update.
Maureen Hamel el al.
AJOG. 2015 Jan;212(1):S90-91.
This poster presentation showed results of a cost-effectiveness study evaluating universal transvaginal ultrasound cervical length (CL) screening at 18-24 weeks in low risk women. Assuming that the findings of a CL < 2.0 cm would prompt initiation of vaginal progesterone therapy which in turn would reduce the rate of preterm birth at < 34 weeks by 39%, the authors calculated that a program of universal transvaginal CL screening would save $2,325,457 for every 100,000 women screened.

Cervical length distribution for nulliparous women at 16 to 22 weeks.
Maged Constantine for the Eunice Kennedy Shriver NICHD MFMU
AJOG. 2015 Jan;212(1):S70
In this poster presentation, authors presented the distribution of transvaginal cervical lengths in nulliparous women by gestational age and race/ethnicity. Using data obtained on over 12 thousand women, the authors noted that – when compared to women of other races / ethnicities - cervical lengths in Black women were shorter overall, decreased more with gestational age, and showed increased rates of funneling and debris. The authors hypothesized that these findings "may partly explain the racial dispartity in preterm brith rate in the United States".

The rate of sonographic cervical shortening and the risk for spontaneous preterm delivery in twins.
Leslie Moroz et al.
AJOG. 2015 Jan;212(1):S106
In this poster, authors presented data to address whether the rate of transvaginal cervical length (TVCL) screening in twins is associated with the risk of preterm delivery before 34 weeks. Including 91 women who had an initial TVCL at 18 weeks, a repeat TVCL at < 28 weeks, and known delivery data, the authors found that shortening was associated with an increased risk of preterm delivery at < 34 weeks in twin gestations regardless of the initial cervical length measurement. Specifically, for both women with TVCL < 2.5 cm and > 2.5 cm, there was an 8% increase in the risk of delivery < 34 weeks for every 1 mm of shortening.





ALARA ALERT

For all nuchal translucency, cervical length**, and second and third trimester obstetrical studies …

- Set your output display to thermal index bone (TIB) and verify that it is displayed on your images. Do not use thermal index soft tissue (TIS) after 10 weeks gestation.
- Keep your TIB output level below 0.7 (or even better below 0.5).
- Minimize dwell time —— particularly on the fetal head and spine
- Remember ALARA —— Keep fetal energy exposure **A**s **L**ow **A**s **R**easonably **A**chievable

** The cervix is soft tissue but because the fetal head may be in the image, because TIB is the more conservative value, and because TIB is the default setting during 2nd and 3rd trimester exams, the PQF recommends TIB during cervical length studies.

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