The availability of free fetal DNA (ffDNA) from maternal blood for noninvasive prenatal testing (NIPT) has brought about significant changes in prenatal screening. There are several companies offering NIPT testing and it is important to understand what the similarities and differences are between the various tests. The most important principle underlying all of these tests is that this is an improved screening approach and is not a diagnostic test. A small number of affected fetuses will be missed and there will be some false positive results.

There are currently four companies offering NIPT testing: Ariosa (Harmony test), Illumina (Verifi test), Natera (Panorama test), and Sequenom (Maternity21+ test).

All of the companies quote similar performance characteristics for detection of trisomies 21, 18, and 13 with reported specificities > 99% (Table 1). All of the companies also offer testing for gender and sex chromosome aneuploidies. It is difficult to assess the true sensitivity and specificity due to the small sample numbers reported by the laboratories, pooling of different disorders, or no reported data at all.

Two of the companies (Natera and Sequenom) also offer testing for a small panel of microdeletion syndromes. Unfortunately, there is no prospective data to assess the test performance for these disorders. In addition, the disorders that are included on the panels are only a small percentage of the disorders that have been prenatally detected by microarray analysis following chorionic villus sampling or amniocentesis.

Recent data also suggests that in patients with a positive combined or integrated screen (NT plus analytes) or with just an increased NT, a significant number of disorders may be missed if only NIPT screening is performed. In summary, good data exists for the improved screening performance of NIPT for detection of trisomies 21, 18, and 13 in high risk women. The data for sex chromosome aneuploidies is much less robust, and there is no prospective data for the microdeletion syndromes. Currently, the only approach that provides diagnostic testing for the greatest number of disorders is microarray testing of samples obtained by CVS or amniocentesis.

Table 1: Aneuploidy Detection Rates (from company websites)

<table>
<thead>
<tr>
<th></th>
<th>T21</th>
<th>T18</th>
<th>T13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ariosa</td>
<td>&gt;99</td>
<td>&gt;98</td>
<td>80</td>
</tr>
<tr>
<td>Illumina</td>
<td>&gt;99.9</td>
<td>97.4</td>
<td>87.5</td>
</tr>
<tr>
<td>Natera</td>
<td>&gt;99</td>
<td>&gt;99</td>
<td>&gt;99</td>
</tr>
<tr>
<td>Sequenom</td>
<td>99.1</td>
<td>&gt;99.9</td>
<td>91.7</td>
</tr>
</tbody>
</table>
The use of electronic fetal heart rate monitoring (EFM) to assess fetal well being during labor is essentially ubiquitous throughout the United States, and is virtually the only currently available tool to evaluate the fetal status during that time. The ability of this modality to accurately predict neurological outcome is questionable, but it clearly can be useful in detecting fetuses at increased risk for neonatal hypoxia and acidemia (1,2), and is almost always scrutinized in retrospect when a child is thought to have suffered neurological damage as a result of care rendered during the intrapartum period. Therefore, optimizing and standardizing the interpretation of EFM should be an essential part of efforts to improve patient safety in obstetrical care.

Recognition of the importance of the modality has led several institutions and provider networks in the country to introduce some form of credentialing in EFM interpretation for all caregivers who work in their Labor and Delivery units. This process involves either passing a freestanding EFM credentialing examination, or taking an on-line course devoted to this form of monitoring which requires correctly answering a number of questions for successful completion.

Whenever the concept of documenting competence in EFM interpretation is considered, the same objections are invariably raised. The argument most frequently made is that every obstetrical residency and nursing training program in the United States provides extensive training in EFM interpretation, and this modality is used daily in the oversight of women in labor. Many senior members of the physician and nursing staff insist that they have been interpreting FHR monitoring in exemplary fashion for years. Why then should they have to prove that they know how to optimally utilize this modality? The argument in defense of the credentialing process, however, is that while there is no objective evidence that EFM is utilized to optimal effectiveness by all members of any Labor and Delivery unit, there is general agreement that the terminology used by different caregivers to describe a particular tracing is often discrepant within any given unit. Furthermore, when the intrapartum EFM tracing of an infant who delivers with profound acidemia is reviewed, it is often found that the warning signs of that outcome have been overlooked.

The Perinatal Quality Foundation (PQF) is an independent nonprofit foundation with the mission of improving the quality of obstetrical services in the United States. In 2011, a group of nationally recognized experts in FHR monitoring was convened by the PQF to explore the advisability of creating a credentialing examination. This group concluded that growing numbers of obstetrical units through the country would want to “raise the bar” on their service and would see the wisdom of assuring that the members of their staff were at the very least speaking the same language as relates to this subject. The group also thought that the existing credentialing examination offered by the National Certification Corporation was suboptimal because it focused almost exclusively on purely factual information and the interpretation of static segments of a FHR strip, as opposed to the management of evolving clinical issues in the real world of laboring patients. Existing educational programs such as those provided by the Association of Women’s Health, Obstetric and Neonatal Nurses (AWHONN), Advanced Practice Strategies (APS), and General Electric (GE) contain testing elements within their teaching modules, but do not function as a free-standing evaluation of the examinee’s overall comprehension of the teaching material.

The group then went on to create two separate examinations, one for obstetrical nurses and the other for physicians or midwives. Both tests provide traditional “knowledge” questions relating to the current definitions of the terms that are necessary to describe EFM tracings and the interpretation of a variety of different heart rate patterns, along with a series of “judgment” (script concordance test (SCT)) questions that ask the examinee to reevaluate their management options as the tracing from a particular patient evolves over time and in association with changing clinical events. The details of the rationale underlying the use of SCT questions, an example of how these questions have
been framed, and the methodology for creating and testing the effectiveness of the examination for accomplishing its objectives has been described in a paper written by several members of the team that created the exam (3). That publication also provides details relating to use of this examination to obtain universal certification for all nursing and medical caregivers on any given Labor and Delivery Unit. Additional information about that process can be obtained from the PQF website at www.perinatalquality.org.

The leadership of PQF believes that establishing a universal standard for defining and interpreting EFM tracings is important for every labor and delivery unit in the country. It will be up to each individual institution to decide whether they will do this, and if so, how it should be done. If that process includes a credentialing examination, the creators of the exam described in this article believe that it will provide an objective measure of both knowledge and judgment relating to the optimal use of EFM.

References

WHAT IS WRONG WITH THIS IMAGE?

by
Bryann Bromley, MD

Use the nuchal translucency review criteria to identify the common errors shown in the image to the left. Turn the page to see the answers.
The Cervical Length Education & Review (CLEAR) program was developed to standardize criteria for the acquisition of cervical length in pregnancy in an effort to decrease errors. Education in the form of three lectures is provided on the CLEAR website at https://clear.perinatalquality.org/. In addition, participants can submit images for review as part of the CLEAR education. The CLEAR image review process teaches participants to critically analyze cervical images using specific criteria. The examples below demonstrate the thought process that is part of performing accurate measurements. These examples are not meant to represent passing or failing images relative to the credentialing process.

CLEAR criteria require that the cervix occupies 75% of the image and that the anterior and posterior widths of the cervix are equal. Figure 1 occupies less than 50% of the image and does not adequately show either the external os or the cervical canal at the level of the internal os. In addition, excess pressure of the transducer causes the anterior width to be slightly narrower than the posterior width. Lastly, to improve resolution, focal zones (yellow stars) should be at the level of the cervical canal.
CLEAR criteria also state that the maternal bladder should be completely empty, that the entire endocervical canal should be visible, and that calipers should be placed where the anterior and posterior walls of the cervix touch at the internal and external os. Although Figure 2 demonstrates proper focal zone placement and depth, the maternal bladder is significantly distended (yellow arrow) which obscures visualization of the internal os and results in inaccurate caliper placement. In addition, Figure 2 also demonstrates incorrect caliper placement at the external os; the caliper should instead have been placed at the ‘V’ shown by the red arrow.

Figure 3 is improved by decreasing the depth to show the cervical canal more clearly, by not placing the transducer as far into the vagina to improve visualization of the external os, and by setting the focal zones appropriately. Attention to each of the CLEAR criteria as well as appropriate setting of the focal zones will help to ensure acquisition of quality cervical length images.
Anatomic Image Quiz

The Perinatal Quality Foundation FIRST TRIMESTER IMAGE BANK on the perinatalquality.org website demonstrates the potential of first trimester ultrasound diagnosis of anatomic abnormalities, and the accompanying questions will allow you to test your diagnostic skills and knowledge.

To view the IMAGE BANK, click on the logo on the right side of the page at https://www.perinatalquality.org.

If you would like to submit images for possible inclusion in the FIRST TRIMESTER IMAGE BANK, please remove any identifying information and send the images, as well as a description of the case to Perinatal Quality Foundation, specifically Jean Spitz (jspitz@perinatalquality.org). Images sent should be of high resolution, and at this time, videos cannot be included. If you need help with de-identification, PQF staff can assist in the process.

The first trimester cases in the image bank are rotated regularly. The schedule of images for 2014 is listed below.

<table>
<thead>
<tr>
<th>Date</th>
<th>Anatomic Anomaly Focus</th>
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<tbody>
<tr>
<td>January - February 2014</td>
<td>Neural Tube</td>
</tr>
<tr>
<td>March - April 2014</td>
<td>Abdominal</td>
</tr>
<tr>
<td>May - June 2014</td>
<td>Cardiac</td>
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<td>July - August 2014</td>
<td>Skeletal</td>
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<td>September - October 2014</td>
<td>Facial</td>
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<td>November - December 2014</td>
<td>Multi-Organ Syndromes</td>
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Editor-in-Chief:
Karin M. Fuchs, MD
kmf2121@columbia.edu

Letters and Other Inquiries:
Send letters to the editor and all other inquiries to:
The Examiner
e-mail: support@perinatalquality.org
Perinatal Quality Foundation
12316 A North May Avenue #272
Oklahoma City, OK 73120

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